

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 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, 2015

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

(State or other jurisdiction of incorporation or organization)

68-0683755

(I.R.S. Employer Identification Number)

First Floor, Minerva House, Simonscourt Road, Ballsbridge, Dublin 4, Ireland

(Address of Principal Executive Offices)

Not Applicable

(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  
Ordinary shares, nominal value \$0.0001 per share

Name of each exchange on which registered  
The NASDAQ Global Market, The Toronto Stock Exchange

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 Sections 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 and posted on its corporate website, if any, every interactive data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act

Large Accelerated Filer  Accelerated Filer  Non-accelerated filer  Smaller reporting company

(Do not check if a smaller reporting company)

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

The aggregate market value of the voting common equity held by non-affiliates as of June 30, 2015 was 16,572,203,055 based on a closing sale price of \$79.65 per share as reported on the NASDAQ Global Select Market on June 30, 2015. Shares of the registrant's ordinary shares held by each officer and director and each beneficial owner of 10% or more 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 registrant's classes of ordinary shares as of February 19, 2016: 222,202,695

**Documents Incorporated by Reference**

Portions of the registrant's proxy statement to be filed with the SEC pursuant to Regulation 14A in connection with the registrant's 2016 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 SEC not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2015.

**ENDO INTERNATIONAL PLC**  
**INDEX TO FORM 10-K**  
**FOR THE YEAR ENDED DECEMBER 31, 2015**

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## 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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the 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 “Risk Factors”, supplement, 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

Endo International plc is an Ireland-domiciled, global specialty pharmaceutical company focused on branded and generic pharmaceuticals. We aim to be the premier partner to healthcare professionals and payment providers, delivering an innovative suite of branded and generic 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 Health Solutions Inc. (EHSI) and its consolidated subsidiaries prior to February 28, 2014 and Endo International plc and its consolidated subsidiaries thereafter.

The Company's focus is on U.S. Branded Pharmaceuticals, U.S. Generic Pharmaceuticals and International Pharmaceuticals and we target areas where we can build and maintain a leadership position. Endo uses a differentiated operating model based on a lean, nimble and decentralized structure, the rational allocation of capital, an emphasis on de-risked research and development and our ability to be better owners of assets than others. This operating model and the execution of our corporate strategy are enabling Endo to achieve sustainable growth and create shareholder value.

We regularly evaluate and, where appropriate, execute on opportunities to expand through the acquisition of products and companies in areas that will serve patients and customers and that we believe will offer above average growth characteristics and attractive margins. In particular, we look to continue to enhance our product lines by acquiring or licensing rights to additional products and regularly evaluate selective acquisition and license opportunities.

In November 2010, we acquired Generics International (US Parent), Inc. (formerly doing business as Qualitest Pharmaceuticals (Qualitest)), a leading U.S.-based privately held generics company. Qualitest provided high-quality generic pharmaceuticals. The Company's U.S. Generic Pharmaceuticals segment, which includes the legacy Qualitest business along with the acquisitions of Par Pharmaceutical Companies, Inc. (Par) in September 2015, Boca Pharmacal LLC (Boca) in February 2014 and DAVA Pharmaceuticals, Inc. (DAVA) in August 2014, is the fourth largest U.S. generics company based on market share. The product portfolio includes tablets, capsules, powders, injectables, liquids, nasal sprays, ophthalmics and patches.

In June 2011, we acquired American Medical Systems Holdings, Inc. (AMS), a provider of devices and therapies for treating male and female pelvic health conditions. On February 24, 2015, Endo's board of directors approved a plan to sell the Company's AMS business, which comprised the entirety of our former Devices segment. The AMS business was comprised of the Men's Health and Prostate Health business as well as the Women's Health Business (now doing business as Astora). On August 3, 2015, the Company sold the Men's Health and Prostate Health business to Boston Scientific Corporation for \$1.65 billion, with \$1.6 billion paid in upfront cash and \$50.0 million in cash contingent on Boston Scientific achieving certain product revenue milestones.

In addition to selling the Men's Health and Prostate Health business, as of December 31, 2015 and continuing into 2016, the Company was actively pursuing a sale of the Astora business with the Company in active negotiations with multiple buyers.

The operating results of AMS are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented.

On February 24, 2016, the Company's Board of Directors decided to wind down Astora business operations in order to begin bringing finality to the Company's mesh-related product liability. The Company is now actively conducting a wind down process and working to efficiently transition physicians to alternative products. The Company will cease business operations for Astora by March 31, 2016. The majority of the remaining assets and liabilities of the AMS business, which are related to the Astora business, are classified as held for sale in the Consolidated Balance Sheets as of December 31, 2015. Certain of AMS's assets and liabilities, primarily with respect to its product liability accrual related to vaginal mesh cases, the related Qualified Settlement Funds and certain intangible and fixed assets, are not classified as held for sale based on management's current expectation that these assets and liabilities will remain with the Company. Depreciation and amortization expense are not recorded on assets held for sale. Upon wind down of the Astora business, the Company will have entirely exited its AMS business.

On October 31, 2013, Endo International plc was incorporated in Ireland as a private limited company and re-registered effective February 18, 2014 as a public limited company. Endo International plc was established for the purpose of facilitating the business combination between EHSI and Paladin Labs Inc. (Paladin). On February 28, 2014 (the Paladin Acquisition Date), the Company, through a Canadian subsidiary, acquired all of the shares of Paladin and a U.S. subsidiary of the Company merged with and into EHSI, with EHSI surviving the merger. As a result of these transactions, the former shareholders of EHSI and Paladin became the shareholders of Endo International plc and both EHSI and Paladin became our indirect wholly-owned subsidiaries.

Paladin is a specialty pharmaceutical company focused on acquiring and in-licensing innovative pharmaceutical products for the Canadian and world markets. Paladin's key products serve growing therapeutic areas, including attention deficit hyperactivity disorder (ADHD), women's health and oncology. Through the acquisition of Paladin, we acquired the Litha Healthcare Group Limited (Litha) in South Africa

On February 28, 2014, we announced the commencement of reporting our diversified businesses in four key segments, U.S. Branded Pharmaceuticals, U.S. Generic Pharmaceuticals, Devices and International Pharmaceuticals. Our operation of the International Pharmaceuticals business commenced following the Paladin acquisition. As a result of the sale of the Men's Health and Prostate Health components of the AMS business to Boston Scientific Corporation and the plan to sell the Astora business, the three remaining reportable business segments in which we now operate are U.S. Branded Pharmaceuticals, U.S. Generic Pharmaceuticals and International Pharmaceuticals. The operating results of our HealthTronics and AMS businesses are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations. The revenue associated with our HealthTronics and AMS businesses totaled \$305.3 million, \$510.9 million and \$699.4 million in 2015, 2014 and 2013, respectively. In January 2014, the Company entered into a definitive agreement to sell our HealthTronics business and the sale was completed on February 3, 2014. Our segments are further discussed in Note 6. Segment Results in the Consolidated Financial Statements included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules" and in Part II, Item 7. of this report "Management's Discussion and Analysis of Financial Condition and Results of Operations" under the caption "Business Segment Results Review".

On January 29, 2015, we acquired Auxilium Pharmaceuticals, Inc. (Auxilium), a fully integrated specialty biopharmaceutical company with a focus on developing and commercializing innovative products for specific patients' needs. Auxilium, with a broad range of first- and second-line products across multiple indications, is an emerging leader in the men's healthcare sector and strategically focuses its product portfolio and pipeline in orthopedics, dermatology and other therapeutic areas.

On September 25, 2015, we acquired Par Pharmaceutical Holdings, Inc., which develops, licenses, manufactures, markets and distributes innovative and cost-effective pharmaceuticals that help improve patient quality of life. Immediately following the closing, Par Pharmaceutical Holdings, Inc. changed its name to Par Pharmaceutical Companies, Inc. (Par). Par focuses on high-barrier-to-entry products that are difficult to formulate, difficult to manufacture or face complex legal and regulatory challenges. Par has operated in two business segments, (i) Par Pharmaceutical, which includes generic products marketed under Par Pharmaceutical and sterile products marketed under Par Sterile Products, LLC; and (ii) Par Specialty Pharmaceuticals, which markets three branded products, Nascobal® Nasal Spray, Megace® ES and Cortisporin®-TC Otic Suspension.

We have a portfolio of branded pharmaceuticals offered by our U.S. Branded Pharmaceuticals segment that includes established brand names such as Lidoderm®, OPANA® ER, Voltaren® Gel, Percocet®, BELBUCA™, Fortesta® Gel, Testim®, Aveed®, Supprelin® LA, and XIAXFLEX®, among others. Our branded pharmaceuticals comprised approximately 39%, 41% and 66% of our total revenues in 2015, 2014 and 2013, respectively, with 4%, 7% and 28% of our total revenues coming from Lidoderm® in 2015, 2014 and 2013, respectively. Our non-branded U.S. Generic Pharmaceuticals portfolio, which accounted for 51%, 48% and 34% of total revenues in 2015, 2014 and 2013, respectively, currently consists of a differentiated product portfolio including tablets, capsules, powders, injectables, liquids, nasal sprays, ophthalmics and patches. The International Pharmaceuticals segment, which accounted for 10% and 11% of total revenues in 2015 and 2014, respectively, includes a variety of specialty pharmaceutical products for the Canadian, Latin American, South African and world markets, which we acquired in the Paladin acquisition and in the Grupo Farmacéutico Somar, Sociedad Anónima Promotora de Inversión de Capital Variable (Somar) acquisition in July 2014. Paladin's key products serve growing therapeutic areas, including ADHD, pain, women's health and oncology. Somar develops, manufactures and markets high-quality generic, branded generic and over-the-counter products across key market segments including dermatology and anti-infectives. Across all of our businesses, we generated total revenues of \$3.27 billion, \$2.38 billion and \$2.12 billion in 2015, 2014 and 2013, respectively.

The ordinary shares of Endo International plc are traded on The NASDAQ Global Market under the ticker symbol ENDP and on the Toronto Stock Exchange under the ticker symbol ENL. References throughout to "ordinary shares" refer to EHSI's common shares, 350,000,000 authorized, par value \$0.01 per share, prior to the consummation of the transactions and to Endo International plc's ordinary shares, 1,000,000,000 authorized, par value \$0.0001 per share, subsequent to the consummation of the transactions. In addition, on February 11, 2014 the Company issued 4,000,000 euro deferred shares of \$0.01 each at par.

Our global headquarters are located at Minerva House, Simmons Court 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).

## Our Strategy

Our strategy is focused on continuing our progress in becoming a leading global specialty pharmaceutical company. 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 strong market position, while maintaining a streamlined cost structure throughout each of our businesses. Specific areas of management's focus include:

- U.S. Branded Pharmaceuticals: Accelerating performance of organic growth drivers, increasing profitability from our mature brands and investing in key pipeline development opportunities.
- U.S. Generic Pharmaceuticals: Capitalizing on encouraging demand trends for a differentiated product portfolio and focusing on developing or acquiring high barrier to entry products, including first to file or first to market opportunities that are difficult to formulate, difficult to manufacture or face complex legal and regulatory challenges. We believe the acquisition and integration of Par will enhance and expand our existing generics platform, adding scale and diversity in products, capabilities and R&D infrastructure.
- International Pharmaceuticals: Investing in high growth business segments with durable revenue streams and where physicians play a significant role in choosing the course of therapy.

We remain committed to strategic R&D across each business unit with a particular focus on assets with inherently lower risk profiles and clearly defined regulatory pathways. We also seek to identify incremental development growth opportunities through acquisitions and product licensing.

In addition to a focus on organic growth drivers, we are also actively pursuing accretive acquisitions that offer long-term revenue growth, margin expansion through synergies and the ability to maintain a flexible capital structure. Since 2013, we have completed a number of acquisitions. See Note 5. Acquisitions in the Consolidated Financial Statements included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules" and Part II, Item 7. of this report "Management's Discussion and Analysis of Financial Condition and Results of Operations" for further discussion.

## Our Competitive Strengths

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

**Continuing proactive diversification of our business to become a leading global specialty pharmaceutical company.** In light of the evolving healthcare industry, we have executed a number of corporate acquisitions to diversify our business and become a leading global specialty pharmaceutical company that includes both branded and generic prescription drugs. We regularly 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 above average growth characteristics and attractive margins. In particular, we look to continue to enhance our product lines by acquiring or licensing rights to additional products and regularly evaluating selective acquisition and license opportunities. Such acquisitions or licenses may be effected through the purchase of assets, joint ventures and licenses or by acquiring other companies.

As a result of a series of strategic actions combined with strategic investments in our core business, we have redefined our position in the healthcare marketplace and successfully diversified our revenue base. Our acquisitions of Paladin, Auxilium and Par have also contributed to our diversification. Our acquisition of Auxilium enhanced our branded pharmaceutical research and development pipeline. The acquisition of Par created critical mass and added scale in our generics business while enhancing and expanding our capabilities in Paragraph IV products, complex dosage forms and research and development. These strategic acquisitions have also enabled us to expand our international presence. In 2015, 2014 and 2013, 9.5%, 11.4% and 0.0%, respectively, of our total revenues were from sources outside the U.S.

**Focus on our generics business differentiated products.** We develop high-barrier-to-entry generic products, including first-to-file or first-to-market opportunities that are difficult to formulate, difficult to 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 commodity generic products. Our business model continues to focus on being the lowest-cost producer of products in categories with high barriers to entry and lower levels of competition by leveraging operational efficiency. Our U.S. Generic Pharmaceuticals segment is focused in categories where there are fewer challenges from low-cost operators.

Through our acquisition of Par, we have strategically expanded our technology, manufacturing, handling and development capabilities to a diversified array of dosage forms. We believe our comprehensive suite of technology, manufacturing and development capabilities 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. We plan to optimize our generic products

pipeline and portfolio as part of a strategic assessment of our generic business. We will retain only those marketed products that deliver acceptable returns on investment, thereby leveraging our existing platform to drive operational efficiency.

**Established portfolio of branded products.** We have assembled a portfolio of branded prescription products offered by our U.S. Branded Pharmaceuticals segment to treat and manage pain and conditions in urology, urologic oncology, endocrinology and orthopedics. Our branded products include: Lidoderm<sup>®</sup>, OPANA<sup>®</sup> ER, Voltaren<sup>®</sup> Gel, Percocet<sup>®</sup>, BELBUCA<sup>™</sup>, Fortesta<sup>®</sup> Gel, Testim<sup>®</sup>, Aveed<sup>®</sup>, Supprelin<sup>®</sup> LA, XIAFLEX<sup>®</sup> for the treatment of Peyronie's disease and XIAFLEX<sup>®</sup> for Dupuytren's contracture, among others. For a more detailed description of each of our products, see "Products Overview."

**Research and development expertise.** Our research and development efforts are focused on the development of a balanced, diversified portfolio of innovative and clinically differentiated products. The acquisition of Auxilium added multiple, strategically-aligned programs to our branded pharmaceutical research and development pipeline with the addition of XIAFLEX<sup>®</sup>. Through our Par and Qualitest businesses, we seek out and develop high-barrier-to-entry generic products, including first-to-file or first-to-market opportunities. We remain committed to research and development across each business unit with a particular focus on assets with inherently lower risk profiles and clearly defined regulatory pathways. Our current research and development pipeline consists of products in various stages of development. In the United States, the U.S. Generic Pharmaceuticals segment has over 250 products in our pipeline, which include approximately 130 Abbreviated New Drug Applications (ANDA) pending with the FDA, including 38 potential first-to-file and first-to-market opportunities. In addition, we have submitted applications for regulatory approval of various products in our international markets. For a more detailed description of our development pipeline, see "Select Products in Development."

At December 31, 2015, our research and development and regulatory affairs staff consisted of 597 employees, based primarily in Huntsville, Alabama, Chestnut Ridge, New York, Chennai, India, at our global headquarters in Dublin, Ireland and at our U.S. headquarters in Malvern, Pennsylvania. Our research and development expenses were \$102.2 million, \$112.7 million and \$97.5 million in 2015, 2014 and 2013, respectively, including upfront and milestone payments of \$9.2 million, \$37.9 million and \$11.4 million, respectively.

**Targeted sales and marketing infrastructure.** We market our products directly to physicians through a dedicated and contracted sales force of over 1,200 individuals, the majority of which are in the United States. We market our products to primary care physicians and specialty physicians, including those specializing in pain management, orthopedics, neurology, rheumatology, surgery, anesthesiology, urology and pediatric endocrinology. Our sales force also targets retail pharmacies and other healthcare professionals. We distribute our products principally through independent wholesale distributors, but we also sell directly to retailers, clinics, government agencies, doctors, independent retail and specialty pharmacies and independent specialty distributors. Revenue related to independent specialty pharmacies during the year ended December 31, 2015 was approximately 3% of the Company's overall 2015 revenue. Our marketing policy is designed to provide that products and relevant, appropriate medical information are immediately available to physicians, pharmacies, hospitals, public and private payers, and appropriate healthcare professionals. 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.

**Cash flow from operations.** We have historically generated significant cash flow from operations due to a unique combination of strong brand equity and attractive margins. While we expect our core business to continue to generate significant cash flow from operations, these cash flows have been adversely impacted and may continue to be adversely impacted by certain payments related to mesh legal settlements and other items. For the year ended December 31, 2015, we generated \$62.0 million of cash from operations. Significant non-core or infrequent pre-tax cash outlays made during 2015 include \$699.3 million of previously accrued mesh-related product liability and other litigation matters payments; \$78.4 million related to unused commitment fees paid associated primarily with financing for the Par acquisition; \$73.7 million of cash paid related to restructuring initiatives; \$31.5 million related to redemption fees paid in connection with debt retirements and \$191.2 million of transaction costs and certain integration costs. Partially offsetting these cash outlays were U.S. Federal tax refunds received of \$155.8 million.

We expect to continue to maintain sufficient liquidity to give us flexibility to make strategic investments in our business and to service our liabilities. As of December 31, 2015, we had \$276.2 million of cash and cash equivalents and marketable securities and up to approximately \$773.0 million of availability under the revolving credit facilities. In addition, at December 31, 2015, our restricted cash and cash equivalents includes \$579.0 million held in Qualified Settlement Funds for mesh product liability settlement agreements, which is expected to be paid to qualified claimants within the next twelve months.

**Experienced and dedicated management team.** Our senior management team has a proven track record of building businesses, including through licensing and acquisitions. Their expertise has contributed to identifying, consummating and integrating such acquisitions. Since February 2013, members of our management team have led the consummation of over ten acquisitions.

## Our Areas of Focus

### Branded Pharmaceutical Products Markets

#### Pain Management Market

Endo has a number of key treatment offerings within the Pain Management Market. Our treatment offerings currently are in two key areas: Chronic Pain, which includes the launch of BELBUCA™ and other products, including OPANA® ER and Percocet®, in the opioid analgesics segment and Lidoderm®, which is marketed for the relief of pain associated with post-herpetic neuralgia; and Osteoarthritis (OA) Pain which is focused on Voltaren® Gel.

The total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled \$38.2 billion in 2015. This represents an approximate 11% compounded annual growth rate since 2011. Our primary area of focus within this market is analgesics. In 2015, analgesics were the third most prescribed medication in the U.S. with 288 million prescriptions written for this classification. The analgesic non-narcotic and anti-arthritis markets had over 166 million prescriptions written in 2015, representing approximately 42% of the U.S. prescription pain management market. Opioid analgesics are a segment that comprised approximately 88% of the total analgesic prescriptions for 2015 and represented about 58% of the overall U.S. prescription pain management market. Total U.S. sales for the opioid analgesic segment were approximately \$9.1 billion in 2015, representing a compounded annual growth rate of approximately 1% since 2011. The U.S. sales for the analgesic non-narcotic and anti-arthritis markets were approximately \$29.2 billion with a compound annual growth rate of approximately 16% since 2011.

#### Specialty Pharmaceuticals Market

Endo also commercializes a number of products within the market served by specialty distributors and specialty pharmacies, and in which healthcare practitioners (HCPs) can purchase and bill payors directly (the buy and bill market). Our treatment offerings currently are in two distinct areas: Urology, which focuses mainly on XIAFLEX® for the treatment of Peyronie's disease; and in Orthopedics/Pediatric Endocrinology, focusing on XIAFLEX® for Dupuytren's contracture and Supprelin® LA for Central Precocious Puberty (CPP).

*Peyronie's Disease (PD)*—PD is a condition that involves the development of collagen plaque, or scar tissue, on the shaft of the penis. The scar tissue, known as a Peyronie's plaque, may harden and reduce flexibility, which may cause bending or arching of the penis during erection. PD can result in varying degrees of penile curvature deformity and disease bother, which encompasses concern about erection appearance, erection pain and the impact of PD on intercourse and on frequency of intercourse. PD is a disease with an initial inflammatory component. This inflammatory phase is poorly understood with a somewhat variable disease course and spontaneous resolution occurring in an estimated 20% of cases. After approximately 12 months of disease, the disease is reported to often develop into a more chronic, stable phase. The incidence of PD is estimated between 3% and 9% of the population; however the disease is believed to be underdiagnosed and undertreated.

*Dupuytren's contracture (DC)*—DC is a progressive condition that limits hand function, diminishes quality of life, and may ultimately disable the hand through the inability to move or straighten one's finger or fingers. It is caused by an abnormal buildup of collagen. In people with DC, this collagen builds up over time and can thicken into a rope-like cord in the palm that contracts the finger. DC is a genetic condition and the incidence of DC is estimated to be between 3% and 9% of the population among adult Caucasians. DC is more common in men than in women, and increases in incidence with age.

*Central Precocious Puberty (CPP)*—Precocious puberty is defined as the onset of developmental signs of sexual maturation earlier than would be expected based on population norms. This is typically delineated as puberty onset before eight years in girls and nine years in boys. In its most common form, central precocious puberty (CPP), sexual maturation proceeds from a premature activation of the hypothalamic-pituitary-gonadal (HPG) axis. The HPG axis is active during infancy, dormant during childhood, and reactivated at the onset of puberty.

The epidemiology of CPP is somewhat nebulous, with a commonly cited prevalence range of one in 5,000 to one in 10,000 children. CPP is known to occur more frequently in girls than in boys and has different predominant causes for each sex. Idiopathic CPP, without an identifiable predisposing condition, accounts for the majority of cases of precocious puberty in girls, but is less frequent in boys. Central nervous system findings such as tumors and congenital malformations are more frequently observed in boys who present with central precocious puberty. It is estimated that two thirds of precocious puberty cases in boys are due to neurological abnormalities. The likelihood of an organic cause for CPP is greater in patients who present at younger ages.

#### Urology Market

Endo has a number of key treatment offerings within the urology markets, specifically the men's health sector with testosterone replacement therapies (TRT).

In the U.S. alone, the prevalence of hypogonadism is approximately 8% of men above 50 years of age, however, only approximately 9% of those affected are currently being treated. By 2025, there will be approximately 6.5 million American men 30-80 years of age who are diagnosed with androgen deficiency. Hypogonadism, or low testosterone, is under diagnosed and under treated.



Factors contributing to this include a lack of screening for low testosterone and the perceived risk of prostate cancer associated with current treatment strategies. In the U.S., TRT sales were approximately \$1.9 billion in 2015. For TRT, our treatment offerings include the long-acting products Avedo<sup>®</sup>, which was launched in March 2014 and TESTOPEL<sup>®</sup>. In addition, our TRT treatment offerings include our gel products such as Fortesta<sup>®</sup> Gel and the authorized generic of Fortesta<sup>®</sup> Gel, which launched in September 2014, and Testim<sup>®</sup>.

#### **Generic Pharmaceuticals Market**

Our U.S. Generic Pharmaceuticals segment consists of a differentiated product portfolio including high-barrier-to-entry products, first-to-file or first-to-market opportunities that are difficult to formulate, difficult to manufacture or face complex legal and regulatory challenges. The product offerings of this segment include products in the pain management, urology, Central Nervous System (CNS) disorders, immunosuppression, oncology, women's health and cardiovascular disease markets, among others. Additionally, in May 2014, we launched an authorized generic lidocaine patch 5% (referred to as Lidoderm<sup>®</sup> authorized generic).

#### **International Pharmaceuticals Market**

Our International Pharmaceuticals segment includes a variety of specialty pharmaceutical products for the Canadian, Latin American, South African and world markets, which we acquired in the Paladin acquisition in February 2014, the Somar acquisition in July 2014 and the Aspen Holdings acquisition in October 2015.

#### **Medical Device Markets**

Through our Astora business, we offer a broad array of medical devices that deliver innovative medical technology solutions to physicians treating female incontinence and pelvic floor repair.

*Female incontinence*—We estimate over 500 million women worldwide suffer from urinary or fecal incontinence. These diseases can lead to debilitating medical and social problems, ranging from embarrassment to anxiety and depression. There are three types of urinary incontinence: stress, urge, and mixed incontinence (a combination of stress and urge). Our current products in the market treat stress incontinence, which generally results from a weakening of the tissue surrounding the bladder and urethra which can be a result of pregnancy, childbirth and aging. Urge incontinence is more complex and currently not as well understood. Pads and diapers are often used to contain and absorb leaks, and may be acceptable for controlling mild incontinence. Drug therapy and electrical nerve stimulation are currently used to treat urge incontinence. We currently market the Monarc<sup>™</sup> subfascial hammock as an option for patients with this condition.

*Pelvic floor repair*—Pregnancy, labor, and childbirth are some of the primary causes of pelvic floor prolapse and other pelvic floor disorders. Prolapse and other pelvic floor defects may be treated with a variety of open, laparoscopic, and transvaginal surgeries. Procedures to repair pelvic floor prolapse in women have historically been performed through the use of suture and graft materials designed for other surgical applications. Astora offers less invasive solutions for pelvic floor repair, including the Elevate<sup>™</sup> transvaginal pelvic floor repair system.

The operating results of Astora are reported as Discontinued Operations, net of tax in the consolidated statements of operations for all periods presented.

## Products Overview

### U.S. Branded Pharmaceuticals

The following table displays the U.S. product revenues to external customers in our U.S. Branded Pharmaceuticals for the years ended December 31 (in thousands):

	2015	2014	2013
<b>Pain Management:</b>			
Lidoderm®	\$ 125,269	\$ 157,491	\$ 602,998
OPANA® ER	175,772	197,789	227,878
Percocet®	135,822	122,355	105,814
Voltaren® Gel	207,161	179,816	170,841
	<u>\$ 644,024</u>	<u>\$ 657,451</u>	<u>\$ 1,107,531</u>
<b>Specialty Pharmaceuticals:</b>			
Supprelin® LA	\$ 70,099	\$ 66,710	\$ 58,334
XIAFLEX®	158,115	—	—
	<u>\$ 228,214</u>	<u>\$ 66,710</u>	<u>\$ 58,334</u>
<b>Urology:</b>			
Fortesta® Gel, including Authorized Generic	\$ 52,827	\$ 58,661	\$ 65,860
Testim®, including Authorized Generic	40,763	—	—
	<u>\$ 93,590</u>	<u>\$ 58,661</u>	<u>\$ 65,860</u>
<b>Branded Other Revenues</b>			
Actavis Royalty	—	51,328	62,765
<b>Total U.S. Branded Pharmaceuticals</b>	<u><u>\$ 1,284,607</u></u>	<u><u>\$ 969,437</u></u>	<u><u>\$ 1,394,015</u></u>

#### Pain Management

**Lidoderm®.** Lidoderm® was launched in September 1999. A topical patch product containing lidocaine, Lidoderm® was the first U.S. Food & Drug Administration (FDA) approved product for the relief of the 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). In May 2012, we entered into a settlement and license agreement with Allergan, plc (Allergan), formerly known as Watson Pharmaceuticals, Inc. (Watson) and Actavis plc (Actavis), which allowed Allergan to launch its lidocaine patch 5%, a generic version of Lidoderm® on September 15, 2013. In May 2014, the Company's U.S. Generic Pharmaceuticals segment launched its authorized generic of Lidoderm®. In August 2015 Mylan launched a generic version of Lidoderm®.

**OPANA® ER.** OPANA® ER is 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. OPANA® ER represents the first drug in which oxymorphone is available in an oral, extended-release formulation and is available in 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg and 40 mg tablets. In December 2011, the FDA approved a new formulation of OPANA® ER with INTAC® technology. This formulation of OPANA® ER with INTAC® technology has the same dosage strengths, color and packaging and similar tablet size as original OPANA® ER. Endo transitioned to this formulation in March 2012 upon successfully accelerating its production. Launches of competing generic versions of the non-crush-resistant formulation OPANA® ER, which began in early 2013, adversely affected our results of operations. However, in August 2015 the U.S. District Court issued a ruling upholding two of the Company's patents covering OPANA® ER. As a result, it is expected that the generic version of non-crush resistant OPANA® ER currently sold by Allergan will be removed from the market and additional approved but not yet marketed generic versions of the product developed by other generic companies will not be launched in the near term.

**Percocet®.** Launched in 1976, Percocet® is approved for the treatment of moderate-to-moderately severe pain.

**Voltaren® Gel.** On March 4, 2008, the Company entered into the 2008 Voltaren® Gel Agreement, which was a license and supply agreement with and among Novartis AG and Novartis Consumer Health, Inc. to obtain the exclusive U.S. marketing rights for the prescription medicine Voltaren® Gel. On December 11, 2015, Endo, Novartis AG and Sandoz entered into the 2015 Voltaren® Gel Agreement) effectively renewing Endo's exclusive U.S. marketing and license rights to commercialize Voltaren® Gel through June 30, 2023. Voltaren® Gel received regulatory approval in October 2007 from the FDA, becoming the first topical prescription treatment for the relief of joint pain of osteoarthritis in the knees, ankles, feet, elbows, wrists, and hands and became the first new product approved in the U.S. for osteoarthritis since 2001. It was the first prescription topical osteoarthritis treatment to have proven its effectiveness in

both the knees and joints of the hands through clinical trials. Voltaren® Gel delivers effective pain relief with a favorable safety profile as its systemic absorption is 94% less than the comparable oral diclofenac treatment. It is now the most prescribed FDA-approved topical NSAID for the relief of osteoarthritis pain.

#### *Specialty Pharmaceuticals*

**Supprelin® LA.** Supprelin® LA was launched in the U.S. in June 2007. Supprelin® LA 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. CPP is the early onset of puberty in young children resulting in the development of secondary sex characteristics and, if left untreated, can result in diminished adult height attainment. The development of these secondary sex characteristics is due to an increase in the secretion of sex hormones, the cause of which is unknown. We market Supprelin® LA in the U.S. through a specialty sales force primarily to pediatric endocrinologists.

**XIAFLEX®.** XIAFLEX® was launched in 2010 for the treatment of adult patients with Dupuytren's Contracture (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 Peyronie's Disease (PD) with a collagen plaque and a penile curvature deformity of thirty degrees or greater at the start of therapy. XIAFLEX® was launched in the U.S. for PD in January 2014 and is the first and only FDA-approved non-surgical treatment for PD.

#### *Urology*

**Fortesta® Gel and Fortesta® Gel Authorized Generic.** Fortesta® Gel is a patented two percent (2%) testosterone transdermal gel and is a treatment for men suffering from hypogonadism, also known as low testosterone (Low-T). The precision-metered dose delivery system can be accurately customized and adjusted to meet individual patient needs with the appropriate dose. In August 2009, we entered into a License and Supply Agreement (the ProStrakan Agreement) with Strakan International Limited, a subsidiary of ProStrakan Group plc (ProStrakan), for the exclusive right to commercialize Fortesta® Gel in the U.S. Fortesta® Gel was approved by the FDA in December 2010. We launched Fortesta® Gel in the first quarter of 2011. During the third quarter of 2014, Endo announced that it had introduced the first and only generic 2% topical testosterone gel, an authorized generic of Fortesta® Gel.

**Testim® and Testim® Authorized Generic.** Testim® is a topical gel indicated for TRT in conditions associated with a deficiency or absence of endogenous testosterone.

#### *Actavis Royalty*

**Actavis Royalty.** Royalty income from Actavis, under the terms of the Watson Settlement Agreement, based on Actavis' gross profit generated on sales of its generic version of Lidoderm®, which commenced on September 16, 2013 and ceased in May 2014, upon our launch of the Lidoderm® authorized generic.

#### *Branded Other*

Branded Other Revenues in the table above include but are not limited to the following products:

**Frova®.** Frova® is indicated for the acute treatment of migraine headaches in adults.

**Valstar®.** Valstar® is a sterile solution for intravesical instillation of valrubicin, a chemotherapeutic anthracycline derivative. Valstar® is indicated for intravesical therapy of bacillus Calmette-Guerin (BCG)-refractory carcinoma *in situ* (CIS) of the urinary bladder in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality.

**Vantas®.** Vantas® is a soft, flexible 12-month hydrogel implant based on our hydrogel polymer technology that delivers histrelin acetate, a GnRH agonist, and is indicated for the palliative treatment of advanced prostate cancer.

**Sumavel® DosePro®.** Sumavel® DosePro® is indicated for adults for the acute treatment of migraine, with or without aura, and the acute treatment of cluster headache. Sumavel® DosePro® is a needle-free injection that comes in two doses (4 mg and 6 mg) and is delivered subcutaneously to patients.

**Aveed®.** Aveed® is a novel, long-acting testosterone undecanoate for injection for the treatment of Low-T. Aveed® is dosed only five times per year after the first month of therapy. In a clinical trial, nearly all men who received Aveed® maintained average testosterone levels within the normal range for 10 full weeks after the third injection. Aveed® was approved by the FDA and launched in March 2014.

**TESTOPEL®.** TESTOPEL® is a unique, long-acting implantable pellet indicated for TRT in conditions associated with a deficiency or absence of endogenous testosterone.

**BELBUCA™.** BELBUCA™ was approved by the FDA in October 2015, 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. BELBUCA™ became commercially available in the U.S. during February 2016.

### U.S. Generic Pharmaceuticals

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. 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. Generic drugs are the same as branded products in dosage form, safety, efficacy, route of administration, quality, performance characteristics and intended use, but they are sold generally at prices below those of the corresponding branded products. Generic drugs provide a cost-effective alternative for consumers, while maintaining the same high quality, efficacy, safety profile, purity and stability of the branded product. An ANDA is required to be filed and approved by the FDA in order to manufacture a generic drug for sale in the United States. We sell generic products primarily in the United States across multiple therapeutic categories.

We have a generics portfolio across an extensive range of dosage forms and delivery systems, including immediate and extended release oral solids (tablets, orally disintegrating tablets, capsules and powders), injectables, liquids, nasal sprays, ophthalmics (which are sterile pharmaceutical preparations administered for ocular conditions) and transdermal patches (which are medicated adhesive patches designed to deliver the drug through the skin).

We have development, manufacturing and distribution capabilities in the rapidly growing U.S. market for sterile drug products, such as injectable products, ophthalmics, and sterile vial and hormonal handling capabilities. These capabilities afford us a broader and more diversified product portfolio and a greater selection of targets for potential development. We target products with limited competition for reasons such as manufacturing complexity or the market size, which make our sterile products a key growth driver of our generics portfolio and complementary to our other generic product offerings.

Authorized generics are generic versions of branded drugs licensed by brand drug companies under a NDA and marketed as generics. Authorized generics do not face any 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. The sale of authorized generics adversely impacts the market share of a generic product that has been granted 180 days of marketing exclusivity. 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, Bristol-Myers Squibb, and Merck & Co in the recent past.

### International Pharmaceuticals

Our International Pharmaceuticals segment includes a variety of specialty pharmaceutical products for the Canadian, Mexican, South African and world markets.

Paladin, based in Canada, has a portfolio of products serving growing therapeutic areas, including ADHD, pain, women's health and oncology.

Somar, based in Mexico, develops, manufactures and markets high-quality generic, branded generic and over-the-counter products across key market segments including dermatology and anti-infectives.

Litha, based in South Africa, is a diversified healthcare group providing services, products and solutions to public and private hospitals, pharmacies, general and specialist practitioners, as well as government healthcare programs. On October 1, 2015, the Company acquired a broad portfolio of branded and generic injectable and established products focused on pain, anti-infectives, cardiovascular and other specialty therapeutics areas from a subsidiary of Aspen Holdings and from GlaxoSmithKline plc (the Aspen Holdings acquisition).

### Devices

The following table displays the significant components of our former Devices segment revenues to external customers for the years ended December 31 (in thousands):

	2015	2014	2013
Men's Health and BPH Therapy	\$ 215,086	\$ 395,231	\$ 383,128
Astora Women's Health	90,170	101,274	109,098
Total Devices	<u>\$ 305,256</u>	<u>\$ 496,505</u>	<u>\$ 492,226</u>

The operating results of AMS are reported as Discontinued operations, net of tax in the consolidated statements of operations for all periods presented.

Following is information about select on-market products in the Women's Health component in the table above:

**Monarc<sup>TM</sup> Subfascial Hammock.** The Monarc<sup>TM</sup> subfascial hammock is our leading device to treat female stress urinary incontinence, which generally results from a weakening of the tissue surrounding the bladder and urethra which can be a result of pregnancy, childbirth and aging. It incorporates unique helical needles to place a self-fixating, sub-fascial hammock through the obturator foramen.

**Elevate™ Anterior and Posterior Pelvic Floor Repair System.** Our former Devices segment offers the Elevate™ transvaginal pelvic floor repair system, for the treatment of pelvic organ prolapse, which may be caused by pregnancy, labor, and childbirth. Using an anatomically designed needle and self-fixating tips, Elevate™ allows for safe, simple and precise mesh placement through a single vaginal incision, avoiding an external incision.

## **Select Products in Development**

### ***U.S. Branded Pharmaceuticals***

XIAFLEX® (collagenase clostridium histolyticum or CCH) is currently approved and marketed in the U.S. for the treatment of both Dupuytren's Contracture and Peyronie's Disease (two separate indications). We are progressing development programs in several other indications which are ongoing, including cellulite, Dupuytren's Nodules, Adhesive Capsulitis and canine lipomas, and have recently opted into two additional new indications, Plantar Fibromatosis and Lateral Hip Fat, which we are planning to initiate Investigational New Drug Applications (INDs) in 2016 pending discussions with the FDA. We are progressing the cellulite development program into Phase 2b following meetings held with the FDA in December 2014 and a subsequent follow-up meeting in December 2015, with the Phase 2b study anticipated to begin enrolling subjects in the first quarter of 2016. We are planning to progress the Dupuytren's Nodules program following a meeting with the FDA in January 2016. In addition, we will be receiving written comments from FDA on its proposed Adhesive Capsulitis program by March 11, 2016. The Company has opted in to the development of CCH in canine lipomas.

### ***U.S. Generic Pharmaceuticals***

Our primary approach to generic pharmaceuticals product development is to target high-barrier-to-entry generic products, including first-to-file or first-to-market opportunities. A first-to-file product refers to an ANDA that is the first ANDA filed containing a Paragraph IV patent challenge to the corresponding branded product, which offers the opportunity for 180 days of generic marketing exclusivity if we are successful in litigating the patent challenge and receive final FDA approval of the product. 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. Our potential first-to-file and first-to-market opportunities account for approximately a third of our pipeline of ANDAs. We expect that these potential first-to-file and first-to-market opportunities will result in product launches that are either exclusive or have two or fewer competitors, which we believe leads to more sustainable market share and profitability for our product portfolio.

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 equivalents. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date. The time required to obtain FDA approval of ANDAs is on average currently approximately 40 months after initial filing.

As of December 31, 2015, we had over 250 products in our pipeline, which included approximately 130 ANDAs pending with the FDA representing \$37.0 billion of combined annual sales for the corresponding branded products in 2015, including 38 potential first-to-file and first-to-market opportunities. We conduct our research and development activities in our New York and India facilities to concentrate internal generic research and development effort on completing generic products currently in development that are expected to yield future product launches into markets with limited projected competition.

Planned 2016 product launches include ezetimibe tablets (generic version of Zetia®), which is a first-to-file product with an associated brand value of approximately \$2.0 billion, quetiapine ER tablets (generic version of Seroquel® XR), which is a first-to-file product with an associated brand value of approximately \$1.0 billion, and rosuvastatin tablets (generic version of Crestor®) with an associated brand value of approximately \$6.0 billion.

### ***International Pharmaceuticals***

We have submitted applications for regulatory approval of various products in our international markets, including RLX030 (serelaxin). RLX030 is a novel treatment for acute heart failure. Phase II and III studies suggested RLX030 helped patients with acute heart failure live longer. A second ongoing Phase III study follows a request from Canadian regulators for more evidence of the therapy's efficacy, with results expected by 2017.

## **Competition**

### ***Branded Pharmaceuticals***

The branded pharmaceutical industry is highly competitive. Our products compete with products manufactured by many other companies in highly competitive markets throughout the U.S. and internationally through our Paladin, Somar and Litha businesses. Our competitors vary depending upon therapeutic and product categories. Competitors include many of the major brand name and generic manufacturers of pharmaceuticals. In the market for branded pharmaceuticals, our competitors, including Abbott Laboratories (Abbott), Allergan plc (Allergan), Purdue Pharma, L.P. (Purdue), Jazz Pharmaceuticals plc (Jazz), Shire plc (Shire), Horizon Pharma

plc (Horizon), and Mallinckrodt plc (Mallinckrodt), among others, vary depending on product category, dosage strength and drug-delivery systems.

We compete principally through our acquisition and in-licensing strategies and targeted product development. The competitive landscape in the acquisition and in-licensing of pharmaceutical products has intensified in recent years as there has been a reduction in the number of compounds available and an increase in the number of companies and the collective resources 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.

The competitive environment of the branded product business requires us to continually seek out technological innovations and to market our products effectively. However, some of our current branded products not only face competition from other brands, but also from generic versions. Generic versions are generally significantly less expensive than branded versions, and, where available, may be required in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies. If competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products can be subject to progressive price reductions or decreased volume of sales, or both. Most new products that we introduce must compete with other products already on the market or products that are later developed by competitors. Manufacturers of generic pharmaceuticals typically invest far less in research and development 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. To successfully compete for business with 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.

We are aware of certain competitive activities involving OPANA<sup>®</sup> ER and other products. For a description of these competitive activities, including the litigation related to Paragraph IV Certification Notices, see Note 14. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

### **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. In the market for generic pharmaceuticals, our competitors, including Teva Pharmaceutical Industries (Teva), Mylan, Inc. (Mylan), and Impax Laboratories, Inc. (Impax), vary depending on product category and dosage strength.

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, regulatory or legal challenges or difficulty in raw material sourcing. By specializing in high barrier to entry products, we endeavor to market more profitable and longer-lived products relative to commodity generic products. 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 expectations; and the breadth of our existing generic product portfolio offering.

We make a significant amount of our sales to a relatively small number of drug wholesalers and retail drug chains. These customers represent an essential part of the distribution chain of our pharmaceutical products. Drug wholesalers and retail drug chains have undergone, and are continuing to undergo, significant consolidation. This consolidation resulted in these groups gaining additional purchasing leverage and consequently increasing the product pricing pressures facing 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, enable those groups to demand larger price discounts on our products. For example, there has been a recent trend of large wholesalers and retailer customers forming partnerships, such as the alliance between Walgreens and AmerisourceBergen Corporation, the alliance between Rite Aid and McKesson Drug Company and the alliance between CVS and Cardinal Health. As a result of this consolidation among wholesale distributors as well as the growth of large retail drug store chains, a small number of large wholesale distributors control a significant share of the market. This has resulted in our customers gaining more purchasing power. Consequently, there is heightened competition among generic drug producers for the business of this smaller and more selective customer base.

Newly introduced generic products with limited or no other generic competition typically garner higher prices. At the expiration of the exclusivity period, other generic distributors may enter the market, resulting in a significant price decline for the drug. Consequently, the maintenance of profitable operations in generic pharmaceuticals depends, in part, on our ability to select, develop and launch new generic products in a timely and cost efficient manner and to maintain efficient, high quality manufacturing capabilities.

## Seasonality

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

## Major Customers

We primarily sell our branded pharmaceuticals and generics directly to a limited number of large pharmacy chains and through a limited number of wholesale drug distributors who, in turn, supply products to pharmacies, hospitals, governmental agencies and physicians. Total revenues from customers that accounted for 10% or more of our total consolidated revenues during the years ended December 31 are as follows:

	2015	2014	2013
Cardinal Health, Inc.	21%	21%	26%
McKesson Corporation	31%	31%	32%
AmerisourceBergen Corporation	23%	16%	19%

Revenues from these customers are included within our U.S. Branded Pharmaceuticals, U.S. Generic Pharmaceuticals and International Pharmaceuticals segments.

As a result of consolidation among wholesale distributors as well as rapid 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 drug stores and small 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.

Revenue related to independent specialty pharmacies during the year ended December 31, 2015 was approximately 3% of the Company's overall 2015 revenue.

## Patents, Trademarks, Licenses and Proprietary Property

As of February 19, 2016, we held approximately: 352 U.S. issued patents, 190 U.S. patent applications pending, 856 foreign issued patents, and 510 foreign patent applications pending. In addition, as of February 19, 2016, we have licenses for approximately 81 U.S. issued patents, 56 U.S. patent applications pending, 334 foreign issued patents and 139 foreign patent applications pending. The following table sets forth information as of February 19, 2016 regarding patents relating to each of our most significant products:

Patent No.	Patent Expiration*	Relevant Product	Ownership	Jurisdiction Where Granted
7,276,250	February 4, 2023	OPANA <sup>®</sup> ER	Owned	USA
8,075,872	November 20, 2023	OPANA <sup>®</sup> ER	Exclusive License	USA
8,114,383	October 10, 2024	OPANA <sup>®</sup> ER	Exclusive License	USA
8,192,722	September 15, 2025	OPANA <sup>®</sup> ER	Exclusive License	USA
8,309,060	November 20, 2023	OPANA <sup>®</sup> ER	Exclusive License	USA
8,309,122	February 4, 2023	OPANA <sup>®</sup> ER	Owned	USA
8,329,216	February 4, 2023	OPANA <sup>®</sup> ER	Owned	USA
8,808,737	June 21, 2027	OPANA <sup>®</sup> ER	Owned	USA
8,871,779	November 22, 2029	OPANA <sup>®</sup> ER	Exclusive License	USA
7,718,640	March 14, 2027	Aveed <sup>®</sup>	Exclusive License	USA
8,338,395	February 27, 2026	Aveed <sup>®</sup>	Exclusive License	USA
5,957,886	March 8, 2016	Sumavel <sup>®</sup> DosePro <sup>®</sup>	Exclusive License	USA
6,135,979	March 21, 2017	Sumavel <sup>®</sup> DosePro <sup>®</sup>	Exclusive License	USA
6,251,091	December 9, 2016	Sumavel <sup>®</sup> DosePro <sup>®</sup>	Exclusive License	USA
6,280,410	March 27, 2017	Sumavel <sup>®</sup> DosePro <sup>®</sup>	Exclusive License	USA
6,554,818	March 27, 2017	Sumavel <sup>®</sup> DosePro <sup>®</sup>	Exclusive License	USA
7,776,007	November 22, 2026	Sumavel <sup>®</sup> DosePro <sup>®</sup>	Exclusive License	USA
7,901,385	July 31, 2026	Sumavel <sup>®</sup> DosePro <sup>®</sup>	Exclusive License	USA
8,118,771	August 10, 2023	Sumavel <sup>®</sup> DosePro <sup>®</sup>	Exclusive License	USA
8,241,243	August 10, 2023	Sumavel <sup>®</sup> DosePro <sup>®</sup>	Exclusive License	USA

Patent No.	Patent Expiration*	Relevant Product	Ownership	Jurisdiction Where Granted
8,241,244	November 21, 2022	Sumavel® DosePro®	Exclusive License	USA
8,267,903	March 18, 2023	Sumavel® DosePro®	Exclusive License	USA
8,287,489	December 6, 2024	Sumavel® DosePro®	Exclusive License	USA
8,343,130	October 18, 2022	Sumavel® DosePro®	Exclusive License	USA
8,491,524	November 21, 2022	Sumavel® DosePro®	Exclusive License	USA
8,663,158	November 21, 2022	Sumavel® DosePro®	Exclusive License	USA
8,715,259	March 18, 2023	Sumavel® DosePro®	Exclusive License	USA
8,734,384	June 8, 2032	Sumavel® DosePro®	Exclusive License	USA
RE39,941	August 24, 2019	Xiaflex®	Exclusive License	USA
6,022,539	June 3, 2019	Xiaflex®	Exclusive License	USA
7,811,560	July 12, 2028	Xiaflex®	Owned; Exclusive License	USA
7,070,556	November 9, 2023	Monarc™	Owned	USA
7,347,812	March 17, 2026	Monarc™	Owned	USA
7,988,615	June 3, 2026	Monarc™	Owned	USA
7,357,773	January 5, 2026	Monarc™	Owned	USA
6,911,003	January 23, 2023	Monarc™	Owned	USA
5,800,832	October 18, 2016	BELBUCA™	Exclusive License	USA
6,159,498	October 18, 2016	BELBUCA™	Exclusive License	USA
7,579,019	January 22, 2020	BELBUCA™	Exclusive License	USA
8,147,866	July 23, 2027	BELBUCA™	Exclusive License	USA
7,229,636	August 1, 2024	Nascobal®	Owned	USA
7,404,489	March 12, 2024	Nascobal®	Owned	USA
7,879,349	August 1, 2024	Nascobal®	Owned	USA
8,003,353	August 1, 2024	Nascobal®	Owned	USA
8,940,714	February 26, 2024	Nascobal®	Owned	USA

\* Our exclusive license agreements extend to or beyond the patent expiration dates.

The effect of these issued patents is that they provide us with patent protection for the claims covered by the patents. 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 U.S. Patent and Trademark Office 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 and know-how and all of our intellectual property are important to our business. All of our brand products and certain generic products, such as Endocet® and Endodan® 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 "Exhibits, Financial Statement Schedules". 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 to determine the scope and validity of the proprietary rights of others. Litigation is costly and time-consuming, and there can be no assurance that our litigation expenses will not be significant in the future or that we will prevail in any such litigation. See Note 14. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

## **Governmental Regulation**

### ***United States Food and Drug Administration and Drug Enforcement Agency***

In the United States, the development, testing, manufacture, holding, packaging, labeling, distribution, marketing, and sales of our products and our ongoing product development activities are 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, manufacture, packaging, labeling, storage, record keeping, approval, advertising, promotion, sale and distribution of pharmaceutical products. Noncompliance with applicable requirements can result in fines, recall or seizure of products, total or partial suspension of production and/or distribution, injunctions, refusal of the government to enter into supply contracts or to approve NDAs, ANDAs and Biologics License Applications (BLAs), civil penalties and criminal prosecution.

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 (GLP) regulations;
- Submission to the FDA of an Investigational New Drug (IND) 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 (IRB) 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 (GCPs) to establish the safety and efficacy of the proposed drug product for each intended use;
- Submission of an NDA or BLA to the FDA;
- 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 (CMC) section of the NDA or BLA to require that 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 I generally involves testing the product for safety, adverse effects, dosage, tolerance, absorption, distribution, metabolism, excretion and other elements of clinical pharmacology.
- Phase II 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 III trials are undertaken in an expanded patient population at typically 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 efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND.

Data from preclinical testing and clinical trials are submitted to the FDA in an NDA or BLA for marketing approval and to foreign government health authorities in a marketing authorization application, consistent with each health authority's specific regulatory requirements. 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 and medical device industry is heavily regulated, which creates uncertainty about our ability to bring new products to market and imposes substantial compliance costs on our business," for further discussion on FDA approval. As a condition of approval, the FDA or foreign regulatory authorities may require further studies, including Phase IV post-marketing studies or post-marketing data reporting. Results of post-marketing programs may limit or expand the further marketing of the products.

For some drugs, the FDA may require a Risk Evaluation and Mitigation Strategy (REMS), which could include medication guides, physician communication plans, or other elements to make certain safe use. In February 2009, the FDA sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a REMS designed to reduce risks

and improve the safe use of certain opioid drug products. Three products sold by Endo were included in the list of affected opioid drugs: OPANA® ER, morphine sulfate ER and oxycodone ER. In 2011, the FDA sent another letter requiring that the manufacturers of these drugs develop and submit to the FDA a post-market REMS plan. The FDA approved a class-wide extended-release/long-acting REMS in July 2012. The goal of this REMS is to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse and abuse of extended-release or long-acting opioid analgesics while maintaining patient access to pain medications. The REMS includes a Medication Guide, Elements to Assure Safe Use and annual REMS Assessment Reports. See Item 1A. Risk Factors - “The pharmaceutical and medical device industry is heavily regulated, which creates uncertainty about our ability to bring new products to market and imposes substantial compliance costs on our business”, for further discussion. In recent years, the FDA has taken steps to reduce the maximum strength of acetaminophen in prescription combination drug products to help reduce or prevent the risk of liver injury from an unintentional overdose of acetaminophen. Among the Company’s products impacted by the FDA’s actions were three branded combination drug pain relief products: Percocet®, Endocet® and Zydone®; and the generic combination drug pain relief products: butalbital/acetaminophen/caffeine, hydrocodone/acetaminophen and oxycodone/acetaminophen.

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 the same, 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 may continue to affect pharmaceutical firms’ ability to file ANDAs via the suitability petition route. 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, and thus block ANDAs from being approved on the patent expiration date.

Certain of our products are or in the future could be 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, in 2010, Congress enacted the Biologics Price Competition and Innovation Act of 2009 (BPCIA), as part of the Healthcare Reform Law, which amended the PHSA to create an abbreviated licensure pathway for products deemed to be biosimilar to or interchangeable with FDA-licensed reference biological products. Under the BPCIA, following the expiration of a 12-year reference exclusivity period, 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 of the product. 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 reference exclusivity period for our BLA-licensed biologics expires, FDA may approve under section 351(k) of the PHSA another company’s BLA for a biosimilar or interchangeable version of our product. Although licensure of a biosimilar or interchangeable under section 351(k) is generally expected to require less than the full complement of product-specific preclinical and clinical data required for innovator products licensed under section 351(a), FDA has considerable discretion over the kind and amount of scientific evidence required to demonstrate biosimilarity and interchangeability, and the agency has yet to issue regulations setting forth specific criteria for licensure of biosimilar or interchangeable products. Consequently, many questions remain about FDA’s interpretation of the BPCIA licensure framework, as well as about the potential commercial impact of biosimilar and interchangeable biologics licensed under section 351(k) of the PHSA.

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 to certain opioid products. As a result, the FDA does not have as extensive safety databases on these products as on 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.

We cannot determine what effect changes in the FDA’s laws or regulations, when and if promulgated, or changes in the FDA’s legal or regulatory interpretations or requirements, 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 record keeping. Such changes could have a material adverse effect on our business, financial condition, results of operations and cash flows. See Item 1A. Risk Factors - “The pharmaceutical and medical device industry is heavily regulated, which creates uncertainty about our ability to bring new products to market and imposes substantial compliance costs on our business”, for further discussion. In September 2013, the FDA announced class-wide safety labeling changes and new post-market study requirements for all extended-release and long-acting (ER/LA) opioids. Among other things, the updated indication states that because of the risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death, these drugs should be reserved for use in patients for whom alternative treatment options are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain; ER/LA opioid analgesics are not indicated for as-needed pain relief. The FDA is also requiring drug companies that make these products to conduct further studies and clinical trials to further assess the known serious risks of misuse, abuse, increased sensitivity to pain (hyperalgesia), addiction, overdose, and death. It is not presently known what impact, if any, these changes to the indications for use or results from the post-marketing studies may have on our business, financial position, results of operations and cash flows.

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 a Section 505(b)(2) NDA, the type of NDA that may rely upon the data in the application for which the patents are listed, or an ANDA to secure approval of a generic version of this first, or listed drug, must make a certification in respect to listed patents. The FDA may not approve such an application for the drug until expiration of the listed patents unless (1) 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 (2) 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: 30 months after submission; entry of an appellate court judgment holding the patent invalid, unenforceable or not infringed; such time as the court may order; or the patent expires.

One of the key motivators for challenging patents is the 180-day market exclusivity period vis-à-vis other generic applicants granted to the developer of a generic version of a product that is the first to have its application 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 prevails in litigation with the manufacturer of the branded product over the applicable patent(s). 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. In addition, the holder of the NDA for the listed drug may be entitled to certain non-patent exclusivity during which the FDA cannot approve an application for a competing generic product or 505(b)(2) NDA product.

Numerous governmental authorities, principally the FDA and comparable foreign regulatory agencies, regulate the development, clinical testing, design, manufacturing, packaging, labeling, storage, installation, marketing, distribution and servicing of our medical devices. In the U.S., under the FDCA, medical devices, such as those manufactured by AMS are classified into Class I, II, or III depending on the degree of risk associated with each medical device and the extent of control needed to provide for safety and effectiveness. Generally, Class I includes devices with the least risk and Class III includes those with the greatest risk and that are subject to the most extensive controls. Class I medical devices are subject to the FDA’s general controls, which include compliance with the applicable portions of the FDA’s Quality System regulations, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA’s general controls and may also be subject to other special controls as deemed necessary by the FDA to provide for the safety and effectiveness of the device. Class III medical devices are subject to the FDA’s general controls, special controls, and premarket approval prior to marketing. Uncleared or unapproved medical devices generally cannot be shipped within the U.S. unless they meet a specific regulatory exemption, such as shipments for clinical testing purposes which comply with the FDA Investigational Device Exemption (IDE) regulations.

Medical devices can be marketed as Class I, II and III. If a device is classified as Class I or II, and if it is not otherwise exempt, its manufacturer will have to undertake the premarket notification process in order to obtain marketing clearance, also referred to as the “510(k) process.” When a 510(k) is required, the manufacturer must submit to the FDA a premarket notification demonstrating that the device is substantially equivalent to either a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or to another commercially available, similar device which was subsequently cleared through the 510(k) process.

Class III devices are approved through a Premarket Approval Application (PMA), under which the applicant must submit data from adequate and well-controlled clinical trials to the FDA that demonstrate the safety and effectiveness of the device for its intended use(s). All of our marketed devices have been approved or cleared for marketing pursuant to a PMA or the 510(k) process. The FDA also has authority under the FDCA to require a manufacturer to conduct post-market surveillance of a Class II or Class III device. Further, pursuant to the March 2010 healthcare reform law, a medical device tax went into effect January 1, 2013, for devices listed

with the FDA. See Item 1A. Risk Factors - “The pharmaceutical and medical device industry is heavily regulated, which creates uncertainty about our ability to bring new products to market and imposes substantial compliance costs on our business”, for further discussion.

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 and medical devices conform to cGMPs. The cGMP regulations the FDA enforces are comprehensive and cover all aspects of manufacturing operations. The cGMP regulations for devices, called the Quality System Regulation, are also comprehensive and cover all aspects of device manufacture, from pre-production design requirements and validation to installation and servicing, insofar as they bear upon the safe and effective use of the device and whether the device otherwise meets the requirements of the FDCA. 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 the drug also ordinarily undergo a pre-approval inspection. Failure of any facility to pass a pre-approval inspection will result in delayed approval and would have a material adverse effect on our business, results of operations, financial condition and cash flows.

The FDA also conducts periodic inspections of drug and device 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 cause us to modify 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 that could adversely affect our business, results of operations, financial condition and cash flows. 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 record keeping requirements administered by the Drug Enforcement Agency (DEA). The DEA regulates controlled substances as Schedule I, II, III, IV or V substances, with Schedule I and II substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in some of our current products and products in development, including oxycodone, oxymorphone, buprenorphine, morphine, fentanyl and hydrocodone, 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. Since October 2014, hydrocodone combination products have been rescheduled by the DEA as Schedule II, which imposes additional access restrictions of these products and could ultimately impact our sales.

The DEA limits the availability of the active ingredients used in many of our current products and products in development, as well as the production of these products, and 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 current products and products in development, 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”, for further discussion on DEA regulations. 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 and accounting mechanisms required by the DEA to prevent loss and diversion of controlled substances. Failure to maintain compliance can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and cash flows. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could eventuate 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 Medicaid, Medicare, TRICARE and other government healthcare programs 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 sales of their products to certain price ceilings. In addition to the cost-containment measures described in Item 1A. Risk Factors, a final rule promulgated and reissued by the U.S. Department of Defense (DOD) in October 2010 subject drug sales to retail pharmacies under the TRICARE Retail Pharmacy Program to certain price ceilings. Specifically, under the final rule, manufacturers are required, among other things, to pay refunds for prescriptions filled beginning on January 28, 2008 and extending to future periods based on the applicable ceiling price limits. Beginning in the first quarter of 2017, a provision in the Bipartisan Budget Act of 2015 will also require drug manufacturers to pay additional rebates to State Medicaid programs if the prices of their non-innovator drugs rise at a rate faster than inflation.

The federal and/or state governments may continue to enact measures in the future aimed at containing or reducing payment levels for prescription pharmaceuticals paid for in whole or in part with government funds. We cannot predict the nature of this or other such measures or their impact on our profitability and cash flows. These efforts could, however, 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", for further discussion on Medicare and Medicaid reimbursements.

In addition, in March 2010, President Obama signed into law healthcare reform legislation (Healthcare Reform Law) that has and will continue to make major changes to the healthcare system. One such change is the requirement that 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 fee (the fee is \$3 billion in 2016, and set to increase in subsequent years) based on the dollar value of its branded prescription drug sales to specified federal programs. The implementation of the Healthcare Reform Law has and will continue to result in a transformation of the delivery and payment for healthcare services in the U.S.

### **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(b)) 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. 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. In addition, the recently enacted Healthcare Reform Law, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b. Pursuant to the statutory amendment, a person or entity no longer needs to 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. Moreover, 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", for further discussion on the Anti-Kickback Statute.

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 allow a private individual to bring civil actions on behalf of the federal government and to share in any monetary

recovery. Finally, 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 required reporting requirements under these laws could subject manufacturers and others to substantial civil money penalties.

### **International Regulations**

Our growing international operations have increased our interaction with regulatory authorities in other countries and made the Company subject to laws and regulations that differ from those under which the Company operates in the United States. In most cases, these regulatory agencies evaluate and monitor the safety, efficacy and quality of pharmaceutical products and devices, govern the approval of clinical trials and product registrations, and regulate pricing and reimbursement. Many of these markets have differing product preferences and requirements, and operate in an environment of government-mandated, cost-containment programs, including price controls. Several 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 countries must be obtained prior to marketing the product in those countries. The approval process may be more or less rigorous from country to country, and the time required for approval may be longer or shorter than that required in the United States.

### **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 complete description of our significant manufacturing, supply and other service agreements, see Note 14. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

### **Acquisitions, License and Collaboration Agreements**

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 or through company acquisitions. 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 full discussion, 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 "Exhibits, Financial Statement Schedules".

### **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 frequently 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 19, 2016, we have 6,406 employees, of which 592 are engaged in research and development and regulatory work, 1,033 in sales and marketing, 2,916 in manufacturing, 928 in quality assurance and 937 in general and administrative capacities. Our employees are generally not represented by unions, with the exception of certain production personnel in our Rochester, Michigan and Mexican manufacturing facilities. We believe that our relations with our employees are good.

**Executive Officers of the Registrant**

The following table sets forth information as of February 29, 2016 regarding each of our current executive officers:

<b>Name</b>	<b>Age</b>	<b>Position and Offices</b>
Rajiv De Silva	49	President and Chief Executive Officer and Director
Suketu P. Upadhyay	46	Executive Vice President, Chief Financial Officer
Susan Hall, Ph.D.	56	Executive Vice President, Chief Scientific Officer & Global Head of R&D & Quality
Matthew J. Maletta	44	Executive Vice President, Chief Legal Officer
Brian Lortie	55	President of U.S. Branded Pharmaceuticals
Paul V. Campanelli	53	President, Par Pharmaceutical

**Biographies**

Our executive officers are briefly described below:

**RAJIV DE SILVA**, 49, is President, Chief Executive Officer and a Director of Endo. Prior to joining Endo in March 2013, Mr. De Silva served as the President of Valeant Pharmaceuticals International, Inc. from October 2010 to January 2013 and served as its Chief Operating Officer, Specialty Pharmaceuticals from January 2009 until January 2013. He was responsible for all specialty pharmaceutical operations, including sales and marketing, research and development, manufacturing and business development. He has broad international experience, having managed businesses in the United States, Europe, Canada, Latin America, Asia, South Africa and Australia/New Zealand. Prior to joining Valeant, Mr. De Silva held various leadership positions with Novartis. He served as President of Novartis Vaccines USA and Head, Vaccines of the Americas at Novartis. During this time, he played a key leadership role at Novartis' Vaccines & Diagnostics Division. Mr. De Silva also served as President of Novartis Pharmaceuticals Canada. He originally joined Novartis as Global Head of Strategic Planning for Novartis Pharma AG in Basel, Switzerland. Prior to his time at Novartis, Mr. De Silva was a Principal at McKinsey & Company and served as a member of the leadership group of its Pharmaceuticals and Medical Products Practice. Mr. De Silva was a Director of AMAG Pharmaceuticals, Inc. and is currently a Member of the Board of Trustees at Kent Place School in Summit, NJ. He holds a Bachelor of Science in Engineering, Honors from Princeton University, and a Master of Science from Stanford University and a Master of Business Administration with Distinction from the Wharton School at the University of Pennsylvania.

**SUKETU UPADHYAY**, 46, is Executive Vice President and Chief Financial Officer, joined Endo in September 2013. Prior to joining Endo, Mr. Upadhyay served as Interim Chief Financial Officer as well as Senior Vice President of Finance, Corporate Controller, and Principal Accounting Officer of Becton Dickinson (BD). Prior to his role as the company's Interim Chief Financial Officer and Corporate Controller, Mr. Upadhyay was the Senior Vice President of Global Financial Planning and Analysis and also held the role of Vice President and Chief Financial Officer of BD's international business. Prior to his tenure at BD, Mr. Upadhyay held a number of leadership roles across AstraZeneca and Johnson & Johnson. These roles included the Global Head of R&D Finance, Head of Commercial Finance, Plant Controller, and Director of Business Development Finance. His experience spans over 20 years in the health care industry in financial roles of increasing responsibility covering all major areas of a fully integrated life sciences business. In addition, his experience covers businesses of varying size and scale and at different points of maturity. Mr. Upadhyay spent the early part of his career in public accounting with KPMG, and earned his CPA designation in 1996 and his CMA designation in 2002. He received a Bachelor of Science in Finance from Albright College and received a Master of Business Administration from The Fuqua School of Business at Duke University.

**SUSAN HALL**, Ph.D., 56, was appointed as Executive Vice President, Chief Scientific Officer and Global Head of Research & Development and Quality in March 2014. Dr. Hall is based in Dublin, Ireland at Endo's global corporate headquarters. Prior to joining Endo, Dr. Hall served as Senior Vice President and Global Head of Research and Development at Valeant Pharmaceuticals International, Inc. In this position, she led the company's product pipeline and life cycle management activities and also had responsibility for quality compliance. In addition, Dr. Hall has also held various leadership roles in research & development at GlaxoSmithKline including clinical pharmacology, project management, medical affairs, and regulatory affairs. Dr. Hall holds a B.S. degree in pharmacology from the University of Leeds (U.K.) and a Ph.D. in Pharmacokinetics from the Department of Pharmacy, University of Manchester (U.K.).

**MATTHEW J. MALETTA**, 44, 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.

BRIAN LORTIE, 55, is President, U.S. Branded Pharmaceuticals. In this role he leads the fully integrated Endo U.S. Pharmaceuticals business with responsibility for all strategic, commercial, and operational functions including sales and marketing, strategy and portfolio development, commercial operations, managed markets, supply chain, and quality. He joined Endo in 2009 from GlaxoSmithKline, having served in a number of executive roles in the U.S. and internationally, including Vice President, External Ventures; Vice President of Marketing, U.S.; Vice President and Global Head, HPV Vaccine Franchise; and Managing Director/General Manager, Ireland. Mr. Lortie holds a Bachelor of Arts degree with honors in Biology and Psychology from Boston University and studied at the Villanova University Graduate School of Business.

PAUL V. CAMPANELLI, 53, was appointed President, Par Pharmaceutical, effective September 28, 2015. In this role, he leads Endo's fully integrated U.S. Generics business. Prior to joining Endo, Mr. Campanelli served as Chief Executive Officer of Par Pharmaceutical Companies, Inc. following the company's September 2012 acquisition by TPG. Under his leadership, the company significantly increased total revenue, acquired Michigan-based JHP Pharmaceuticals, established a business office in London to serve as Par's entry point into the European generics market and most recently completed its acquisition of an active pharmaceutical ingredients (API) facility located in Chennai, India. Prior to the TPG acquisition, Mr. Campanelli served as chief operating officer and president of Par Pharmaceutical, Inc., the company's generics division, from 2011 to 2012. Earlier in his tenure at Par, Mr. Campanelli held roles of increasing responsibility, including Senior Vice President, Business Development & Licensing; Executive Vice President and President of Par Pharmaceutical, Inc.; and was named a Corporate Officer by Par's board of directors. He also served on the board of directors of Sky Growth Holdings Corporation. Prior to joining Par, Mr. Campanelli served as vice president, Business Development at Dr. Reddy's Laboratories Ltd. where he was employed from 1992-2001. He earned his Bachelor of Science degree from Springfield College.

We have employment agreements with each of our executive officers.

#### **Available Information**

Our internet address is <http://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 may also read and copy any materials we file with the SEC at the SEC's Public Reference Room that is located at 100 F Street, N.E., Room 1580, NW, Washington, DC 20549. Information about the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330 or 1-202-551-8090. You can also access our filings through the SEC's internet site: [www.sec.gov](http://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](http://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 our branded and generic pharmaceutical business and our medical devices business. In addition to product development, safety, efficacy, commercialization, marketing and promotion, other competitive factors include product quality and price, reputation, service and access to scientific and technical information. Many of our competitors, including Abbott, Allergan, Purdue, Jazz, Shire, Horizon, Mallinckrodt, Teva, Mylan, and Impax, among others, may have greater resources than we do. It is possible that our competitors may make greater research and development investments and that their new products may make our products or technologies uncompetitive or obsolete. 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. Generic 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 substituted by pharmacies for branded versions by law. The entrance of generic competition to our branded products generally reduces our market share and adversely affects our profitability and cash flows. Generic competition with our branded products has had and will continue to have a material adverse effect on the net sales and profitability of our branded products.

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. 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.



**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 U.S. Food and Drug Administration (FDA) can approve an Abbreviated New Drug Application (ANDA) for a generic bioequivalent version of a previously approved drug, without requiring the ANDA applicant to undertake the full clinical testing necessary to obtain approval to market a new drug. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its generic product 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<sup>®</sup>, both the original and crush-resistant formulations of OPANA<sup>®</sup> ER, Fortesta<sup>®</sup> Gel, Aveed<sup>®</sup> and Megace ES<sup>®</sup>. 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<sup>®</sup> and Megace ES<sup>®</sup>, we no longer have patent protection in the markets where we sell these products. Our revenues from Lidoderm<sup>®</sup> have been negatively affected by Actavis's (now Allergan) September 2013 launch and Mylan's August 2015 launch of their lidocaine patch 5%, generic versions of Lidoderm<sup>®</sup>, and we anticipate that these revenues could decrease further should one or more additional generic versions launch. With respect to OPANA<sup>®</sup> ER, Fortesta<sup>®</sup> Gel, Aveed<sup>®</sup> 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 could significantly decrease our revenues and could have a material adverse effect on our business, results of operations, financial condition and cash flows as well as our share price. For a complete description of the related legal proceedings, see Note 14. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules". As a result, 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.

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

The Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act provide for a period of 180 days of marketing exclusivity for a generic version of a previously approved drug for any applicant that is first-to-file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to the corresponding brand-name drug (commonly referred to as a "Paragraph IV certification"). A large portion of our revenues for our U.S. Generic Pharmaceuticals segment have been derived from the sales of generic drugs during such 180-day marketing exclusivity period permitted under the Hatch-Waxman Act and from the sale of other generic products for which there otherwise is limited competition. ANDAs that contain Paragraph IV certifications challenging patents, however, 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 (described further below). 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 the 180-day marketing exclusivity.

The future profitability of our U.S. Generic Pharmaceutical segment 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 the 180-day marketing period as permitted by the Hatch-Waxman Act. Our ability to timely bring our products to market is dependent upon, among other things, the timing of regulatory approval of our products, which to a large extent is outside of our control, as well as the timing of competing products. 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 to enter into contractual relationships with other parties that have obtained marketing exclusivity. 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 or our development partners are unable to continue to timely and effectively file ANDAs with the FDA 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 may be the subject of product liability claims or product recalls, and we may be unable to obtain or maintain insurance adequate to cover potential liabilities.**

Our business exposes us to significant potential liability risk associated with the testing, manufacturing, marketing and sale of our products. We have been in the past, and continue to be, subject to various product liability cases. In addition to direct expenditures for damages, settlement and defense costs, there is a possibility of adverse publicity, loss of revenues and disruption of business as a result of product liability claims. Some plaintiffs have received substantial damage awards in some jurisdictions against pharmaceutical and/or medical device companies based upon claims for injuries allegedly caused by the use of their products. 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. Thus, we could expect that any significant product liability litigation or mass tort in which we are a defendant will have a larger number of plaintiffs than such actions have seen historically because of the increasing use of wide-spread and media-varied advertising. In addition, it may be necessary for us to voluntarily or mandatorily recall or withdraw products that do not meet approved specifications or which subsequent data demonstrate may be unsafe or ineffective or which has been widely misused. Any such recall or withdraw could result in adverse publicity, costs connected to the recall and loss of revenue. We cannot confirm to you that a product liability claim or series of claims brought against us would not have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our pharmaceutical and medical device products may cause, or may appear to cause, serious adverse side effects or potentially dangerous drug interactions if misused, improperly prescribed, improperly implanted or subject to faulty surgical technique. For example, we and/or certain of our subsidiaries, 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. We and certain plaintiffs' attorneys representing mesh-related product liability claimants have entered into various Master Settlement Agreements (MSAs) regarding settling up to approximately 49,000 filed and unfiled mesh claims handled or controlled by the participating attorneys. These MSAs, which were executed at various times since June 2013, were entered into solely by way of compromise and settlement and are not in any way an admission of liability or fault by us and/or any of our subsidiaries. As of December 31, 2015, our product liability accrual for vaginal mesh cases totaled \$2.09 billion for all known pending and estimated future claims related to vaginal mesh cases. We may be subject to additional liabilities arising out of these cases, and are responsible for the cost of managing these cases.

We cannot confirm to you that we will be able to obtain or maintain product liability insurance in the future on acceptable terms or with adequate coverage against potential liabilities or the cost of a recall if any claim is brought against us, regardless of the success or failure of the claim. For example, we 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. The failure to generate sufficient cash flow or to obtain other financing could affect our ability to pay the amounts due under these liabilities not covered by insurance. See Note 14. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules" for further discussion of our product liability cases.

**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 the technologies, processes and products we are currently developing, have developed and may develop in the future. 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. We cannot confirm to you that patent applications we submit and have submitted will result in patents being issued. If an invention qualifies as a joint invention, the joint inventor may have rights in the invention and we cannot confirm to you that the joint inventor will protect the intellectual property rights to the joint invention. We cannot confirm to you that a third party will not infringe upon, design around or develop uses not covered by any patent issued or licensed to us or that these patents will 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 U.S. Patent and Trademark Office (PTO), by analogous foreign offices or in legal proceedings. Upon the expiration or loss of necessary intellectual property protection for a product, others may manufacture and distribute our patented products, which will result in a loss of a significant portion of our sales of that product.

We cannot confirm to you as to the degree of protection any patents will afford, including whether the protection obtained will be of sufficient breadth and degree to protect our commercial interests in all the countries where we conduct business. Furthermore, we cannot confirm to you that our products will not infringe the patents or other intellectual property rights held by third parties. If we infringe 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. 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.

**Agreements between branded pharmaceutical companies and generic pharmaceutical companies are facing increased government scrutiny 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, our U.S. Generic Pharmaceuticals segment is 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 (the FTC) and the Antitrust Division of the Department of Justice (DOJ) for review. The FTC has publicly stated that, in its view, these settlement agreements may violate the 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 a particular settlement agreement, and there is a risk that the FTC may commence an action against us alleging violation of the antitrust laws. For example, we received a Civil Investigation Demand (CID) from the FTC requesting documents and information concerning our settlement agreements with Watson (now Allergan) and Impax relating to OPANA<sup>®</sup> ER patent litigation and our settlement agreement with Watson relating to the Lidoderm<sup>®</sup> patent litigation, as well as information concerning the marketing and sales of OPANA<sup>®</sup> ER and Lidoderm<sup>®</sup>. Any adverse outcome of these investigations could have a significant adverse effect on our business, financial condition and results of operations. See Note 14. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules" for further discussion of FTC investigations.

In addition, some members of 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. We are subject to multiple lawsuits purporting to be class actions brought by direct and indirect payers alleging that our settlement agreement with Watson regarding the Lidoderm<sup>®</sup> patent litigation was unlawful and in violation of federal antitrust laws, as well as 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, 2015 and 2014, goodwill and other intangibles comprised approximately 78% and 48%, respectively, of our total assets. Goodwill and other intangible assets are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually. The procedures and assumptions used in our goodwill and indefinite-lived intangible assets impairment testing, and the results of our 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 captions "CRITICAL ACCOUNTING ESTIMATES" and "RESULTS OF OPERATIONS".

Events giving rise to impairment of goodwill or other intangible assets are an inherent risk in the pharmaceutical and medical device industries 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 an impairment 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, 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 and devices. 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 the 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 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.

Sanctions for violating these laws include criminal penalties and civil sanctions and possible exclusion from federal 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 or that such a challenge would not have a material adverse effect on our business or results of operations.

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. Although the FDA does not regulate a physician's choice of medications, treatments or product uses, the FDCA and FDA regulations and guidance significantly restrict the ability of pharmaceutical and medical device companies to communicate with patients, physicians, and other third-parties about unapproved or uncleared product uses. FDA, FTC, the HHS-OIG, the DOJ and various state Attorneys General actively enforce state and federal prohibitions on the promotion of unapproved uses, as well as prohibitions against promotional practices deemed false or misleading. 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 endeavored to establish and implement 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 drugs and devices. Nonetheless, the FDA, FTC, HHS-OIG, the DOJ and/or the state Attorneys General, and *qui tam* relators 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, we entered into a Deferred Prosecution Agreement (DPA) with the U.S. Department of Justice and a Corporate Integrity Agreement (CIA) with the U.S. Department of Health and Human Services to resolve allegations regarding the promotion of Lidoderm®. In March 2013, our subsidiary, Par, entered into a CIA and a Plea Agreement with the U.S. Department of Justice to resolve allegations regarding the promotion of Megace ES®. Those agreements place certain obligations on us related to the marketing of our branded 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 DPA, the Plea Agreement, and/or the CIA, 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 health care programs.

**The pharmaceutical and medical device 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 and medical device 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 clinical or other trials 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 of our new product candidates, we must demonstrate through preclinical studies and clinical trials that the product is safe and effective for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product. 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 could or 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 Current Good Manufacturing Practices. 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 cannot confirm to you that we will not experience delays or undesired results in these or any other of our clinical trials.

With respect to medical devices, such as those manufactured by our Astora business, before a new medical device, or a new use of, or claim for, an existing product can be marketed, it must first receive either premarket clearance under Section 510(k) of the FFDCFA, or premarket approval (PMA) from the FDA, unless an exemption applies. In the 510(k) premarket clearance process, the FDA must determine that the proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use, technology and safety and effectiveness to clear the proposed device for marketing. Clinical data is sometimes required to support a showing of substantial equivalence. The PMA pathway, which is a more rigorous and lengthy process, requires an applicant to demonstrate the safety and effectiveness of the device for its intended use based, in part, on extensive data including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Both the 510(k) and PMA processes can be expensive and lengthy and entail significant user fees in connection with FDA’s application review. In addition, the FDA has authority under the FFDCFA to require a manufacturer to conduct post-market surveillance of a Class II or Class III device. See Note 14. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report “Exhibits, Financial Statement Schedules”, for public health notifications regarding potential complications associated with transvaginal placement of surgical mesh to treat POP and SUI.

We cannot confirm to you that the FDA or foreign regulatory agencies will approve, clear for marketing or certify any products developed by us or that such approval will not 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, with respect specifically to pharmaceutical products, the submission of a New Drug Application (NDA) or ANDA 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 and is subject to uncertainty. The NDA 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. NDA 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 and medical device 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 as extensive safety databases on these products as on 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. 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 in development. 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.

The Obama administration has also released a comprehensive action plan to reduce prescription drug abuse, which may include proposed legislation to amend existing controlled substances laws to require healthcare practitioners who request Drug Enforcement Administration (DEA) registration to prescribe controlled substances to receive training on opioid prescribing practices as a condition of registration. 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, any such 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 and to make any labeling changes to address those risks. The FDA also can require companies to formulate approved Risk Evaluation and Mitigation Strategies (REMS) to confirm a drug's benefits outweigh its risks. For example, in 2011, we, along with other manufacturers of long-acting and extended-release opioid drug products, received a letter from the FDA requiring that we develop and submit to the FDA a post-market REMS plan for our OPANA<sup>®</sup> ER, morphine sulfate ER, and oxycodone ER drug products to require that training is provided to prescribers of these products, and that information is provided to prescribers that they can use in counseling patients about the risks and benefits of opioid drug use. In December 2011, the FDA approved our interim REMS for OPANA<sup>®</sup> ER, which was subsequently superseded by the class-wide extended-release/long-acting REMS approved in July 2012. The goal of this REMS is to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse and abuse of extended-release or long-acting opioid analgesics while maintaining patient access to pain medications. The REMS includes a Medication Guide, Elements to Assure Safe Use and annual REMS Assessment Reports.

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. 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 and device 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 and medical device 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 the dedication of substantial resources and requires significant expenditures. In the event an approved manufacturing facility for a particular drug or medical device 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 flow.

The FDA is authorized to perform inspections of U.S. and foreign facilities under the FFDCA. 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 of 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 cause us to modify certain activities identified during the inspection. 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, during 2015, our facilities, in multiple countries, across the full range of our business units, were subject to routine and new-product related inspections by the FDA, MHRA, HPRA and Health Canada. Some of these inspections resulted in non-critical inspection observations (including FDA Form 483 observations). We have responded to all inspection observations within the required time frame and have implemented, or are continuing to implement, the corrective action plans as agreed with the relevant regulatory agencies.

Many 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 operation, 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 current products and products in development, 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). The U.S. government has enacted DSCSA that 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 or the courts, when and if promulgated or issued, 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. These changes, or others required by the FDA or DEA could have an adverse effect on the sales of these products. 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 cannot confirm to you that we will 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 commercially exploit our products may be inhibited. We compete to acquire these assets that we require to continue to develop and broaden our product range. Our competitors may have greater resources than us and therefore be better able to complete acquisitions or may 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 are 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 of customer relationships. The difficulties of combining operations of companies include, among others:

- diversion of management’s attention to integration matters;
- difficulties in achieving anticipated cost savings, synergies, business opportunities and growth prospects from the combination of the businesses;
- difficulties in the integration of operations and systems;
- 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;
- 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 leverage, increased debt obligations as compared to equity, or dilution of ownership. We may not be able to finance acquisitions on terms satisfactory to us.

**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 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. Products we are currently developing may or may not receive the regulatory approvals or clearances necessary for us to market them. Furthermore, the development and commercialization process is time-consuming and costly, and we cannot confirm to you that any of our products, if and when developed and approved, can be successfully commercialized.

In addition, 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 of medical and technological products 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. As we continue to develop new products, 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. Also, after we submit a regulatory application, the relevant governmental health authority may require that we conduct additional studies, including, 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.

**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 (1) limiting both coverage and the level of reimbursement (including adjusting co-pays) for products approved for marketing by the FDA, (2) refusing, in some cases, to provide any coverage for uses of approved products for indications for which the FDA has not granted marketing approval and (3) requiring or encouraging, through more favorable reimbursement levels or otherwise, the substitution of generic alternatives to branded products.



In addition, significant uncertainty exists as to the reimbursement status of newly approved medical device products, which may impact whether customers purchase our products. Reimbursement rates vary depending on whether the procedure is performed in a hospital, ambulatory surgery center or physician's office. Furthermore, healthcare regulations and reimbursement for medical devices vary significantly from country to country, particularly in Europe.

**We may experience pricing pressure on the price of 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 the price of our products due to social or political pressure to lower the cost of drugs, which would reduce our revenue and future profitability. Recent events have resulted in increased public and governmental scrutiny of the cost of drugs, especially in connection with price increases following companies' acquisitions of the rights to certain drug products. In particular, U.S. federal prosecutors recently issued subpoenas to a pharmaceutical company seeking information about its drug pricing practices, among other issues, and members of the U.S. Congress have sought information from certain pharmaceutical companies relating to post-acquisition drug-price increases. Our revenue and future profitability could be negatively affected if these inquiries were to result in legislative or regulatory proposals that limit our ability to increase the prices of our products.

Pressure from social activist groups and future government regulations may also put downward pressure on the price of drugs, which could result in downward pressure on the prices of our products in the future.

**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 Centers for Medicare and Medicaid Services (CMS) on a periodic basis to allow for accurate determination of rebates owed under the Medicaid Drug Rebate Agreement, of ceiling prices under the 340B program and certain other government pricing arrangements, and of reimbursement rates for certain drugs paid under Medicare Part B. In January 2016, CMS issued a Proposed Final Rule implementing the Medicaid Drug Rebate provisions incorporated into the Healthcare Reform Law, effective April 1, 2016 in most instances. Implementation of the Final Rule will require operational adjustments by us in order to maintain compliance with applicable law. Changes included in the Final Rule revise how manufacturers are required to calculate Average Manufacturer Price (AMP) and Best Price and may affect the quarterly amounts that we owe to state Medicaid programs through the Medicaid Drug Rebate program. Also, CMS made changes with respect to how certain products are categorized for purposes of the Medicaid Drug Rebate program (i.e., single source, innovator multiple source, or non-innovator multiple source), which could affect the rebate calculation methodology, and thus the level of rebates incurred for affected products. In addition, CMS finalized its proposal to change the reimbursement metrics upon which Medicaid agencies are required 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, 2017, which will require operational adjustments and may result in additional rebate obligations. 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 Healthcare Reform Law provisions. Additional operational adjustments and financial implications may result upon CMS' finalization of "line extension" provisions.

We and other pharmaceutical companies are defendants in a number of lawsuits filed by local and state 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. In addition, a predecessor entity of Qualitest Pharmaceuticals and other pharmaceutical companies are defendants in a federal False Claims Act lawsuit brought by a *qui tam* relator alleging the submission (or the causing of the submission) of false claims for payments to be made through state Medicaid reimbursement programs for unapproved drugs or non-drugs. We intend to vigorously defend those lawsuits to which we are a party. Depending on developments in the litigation however, as with all litigation, there is a possibility that we will suffer adverse decisions or verdicts of substantial amounts, or that we will enter into monetary settlements in one or

more of these actions. Any unfavorable outcomes as a result of such litigation could have a material adverse effect on our business, financial condition, results of operations and cash flows.

There is additional uncertainty surrounding the healthcare insurance coverage mandate that went into effect in the U.S. in 2015 and continues into 2016. 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. 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, 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 and results of operations.

**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 large pharmacy chains. In turn, these wholesale drug distributors and large pharmacy 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 large pharmacy chains. We expect that consolidation of wholesale drug distributors and large pharmacy chains will increase pricing and other competitive pressures on pharmaceutical companies, including us. Total revenues from customers who accounted for 10% or more of our total revenues during the three years ended December 31 are as follows:

	2015	2014	2013
Cardinal Health, Inc.	21%	21%	26%
McKesson Corporation	31%	31%	32%
AmerisourceBergen Corporation	23%	16%	19%

Revenues from these customers are included within our U.S. Branded Pharmaceuticals, U.S. Generic Pharmaceuticals and International Pharmaceuticals segments. 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 and 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 is our sole source of Lidoderm® and Grünenthal GmbH (Grünenthal) is our sole source of our crush-resistant formulation of OPANA® ER. Because of contractual restraints and the lead-time necessary to obtain FDA approval, and possibly DEA registration, of a new manufacturer, replacement of any of these manufacturers may be expensive and time consuming and may cause interruptions in our supply of products to customers. As a result, any such delay could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Because many of our products are manufactured by third parties, we have a limited ability to control the manufacturing process or costs related to the process. Increases in the prices we pay our manufacturers, interruptions in our supply of products or lapses in quality could adversely impact our margins, profitability and cash flows. We are reliant on our third party manufacturers to maintain the facilities at which they manufacture our products in compliance with FDA, DEA, state and local regulations. If they fail to maintain compliance with FDA, DEA or other critical regulations, they could be ordered to cease manufacturing, or product may be recalled, which would have a material adverse impact on our business, results of operations, financial condition and cash flows. Additionally, if any facility that manufactures our products experiences a natural disaster, we could experience a material adverse impact on our business, results of operations, financial condition and cash flows. In addition to FDA and DEA regulation, violation of standards enforced by the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA) and their counterpart agencies at the state level could slow down or curtail operations of third party manufacturers.

In addition, we may consider entering into additional manufacturing arrangements with third party manufacturers. In each case, we will incur significant costs in obtaining the regulatory approvals and taking other necessary steps to begin commercial production by these manufacturers. If the market for the products manufactured by these third parties substantially contracts or

disappears, we will continue to be financially obligated under these contracts. Such an obligation could have a material adverse effect on our business.

**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 could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, we have entered into minimum purchase requirement contracts with some of our third party raw material suppliers. If the market for the products that utilize these raw materials substantially contracts or disappears, we will continue to be financially obligated under these contracts and meeting such obligations could have a material adverse effect on our business.

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 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 and medical devices (including many components of such 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 and medical device manufacturing facilities must continually expend significant time, money and effort in production, record-keeping and quality assurance and control (and design control for medical devices) 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 manufacturing facilities to possible legal or regulatory action, including shutdown, which may adversely affect our ability to supply the product. Were we not able to manufacture products at our 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, Auxilium's Horsham and Rye facilities and the facilities of the manufacturer that Auxilium is in the process of qualifying as an alternate manufacturer for XIAFLEX® (such manufacturer, the "Proposed Alternate Manufacturer" and such facility, the "Proposed Alternate Facility") are subject to such regulatory requirements and oversight. If Auxilium or the Proposed Alternate Manufacturer fail to comply with cGMP requirements, Auxilium may not be permitted to sell its products or may be limited in the jurisdictions in which it is permitted to sell them. Further, if an inspection by regulatory authorities indicates that there are deficiencies including non-compliance with regulatory requirements, Auxilium could be required to take remedial actions, stop production or close our Horsham and/or Rye facilities or the Proposed Alternate Facility, which would disrupt the manufacturing processes, limit the supplies of XIAFLEX® and TESTOPEL® 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 XIAFLEX® or TESTOPEL® in clinical trials, refusal of the government to allow distribution of XIAFLEX® or TESTOPEL® within the U.S. or other jurisdictions, criminal prosecution and 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.

**The DEA limits the availability of the active ingredients used in many of our current products and products in development, 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

current products and products in development, including oxycodone, oxymorphone, buprenorphine, morphine, fentanyl, and hydrocodone, are listed by the DEA as Schedule II or III substances under the Controlled Substances Act of 1970. 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 current products and products in development 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. 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 cannot confirm to you that we will succeed in retaining personnel or their services under existing agreements. There is intense competition for qualified personnel in the areas of our activities, and we cannot confirm to you that we will be able 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 your investment in our securities could decline in value.**

The market prices for securities of pharmaceutical companies in general have been highly volatile and may continue to be highly volatile in the future. For example, in 2015, our ordinary shares traded between \$96.58 and \$46.66 per share on the NASDAQ Global Select Market. 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 or medical device 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;
- competitors announcing technological innovations or new commercial products;
- introduction of generic 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;
- 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 in the U.S. relating to the development, sale or pricing of pharmaceuticals or medical devices;
- a determination by a regulatory agency that we are engaging or have engaged in inappropriate sales or marketing activities, including promoting the "off-label" use 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
- economic and other external factors, including market speculation or disasters and other crises.

**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. 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. Cyber-attacks could include the deployment of harmful malware, viruses, worms 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.

**The regulatory approval process outside the U.S. varies depending on foreign regulatory requirements, and failure to obtain regulatory approval in foreign jurisdictions would prevent 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 products outside of the U.S. Approval of a product by the regulatory authorities of foreign countries must be obtained 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. The non-U.S. regulatory approval process includes all of the risks associated with obtaining FDA approval set forth 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 the FDA. If we fail to comply with these 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.

**Our Astora subsidiary could be adversely affected by special risks and requirements related to its medical products manufacturing business.**

Our Astora subsidiary is subject to various risks and requirements associated with being a medical equipment manufacturer, which could have adverse effects. These include the following:

- the need to comply with applicable FDA and foreign regulations relating to cGMP and medical device approval, clearance or certification requirements, and with state licensing requirements;
- the need for special non-governmental certifications and registrations regarding product safety, product quality and manufacturing procedures in order to market products in the European Union, i.e. EN ISO certifications;
- the fact that in some foreign countries, medical device sales are strongly determined by the reimbursement policies of statutory and private health insurance companies, i.e., if insurance companies decline reimbursement for Astora's products, sales may be adversely affected;
- potential and actual product liability claims for any defective or allegedly defective goods that are 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 affect directly our business. This includes federal and state laws and regulations in the United States as well as in Europe and other markets. There has also been increased enforcement activity in the United States particularly related to data security breaches. A violation of these laws or regulations could subject us to penalties, fines 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.

**The expanding nature of our business in global markets exposes us to risks associated with adapting to emerging markets and taking advantage of growth opportunities.**

The globalization of our business, including in Mexico, South Africa and Canada, may expose us to increased risks associated with conducting business in emerging markets. Any difficulties in adapting to emerging markets could impair our ability to take advantage of growth opportunities in these regions and a decline in the growth of emerging markets could negatively affect our business, results of operations or financial condition.

The expansion of our activities in emerging markets may further expose us to more volatile economic conditions and political instability. We also face competition from companies that are already well established in these markets. Our inability to adequately respond to the unique characteristics of these markets, particularly with respect to their regulatory frameworks, the difficulties in recruiting qualified personnel, potential exchange controls, weaker intellectual property protection, higher crime levels and corruption and fraud, could have a material adverse effect on our business.

Our policies and procedures, which are designed to help us, our employees and agents comply with various laws and regulations regarding corrupt practices and anti-bribery, cannot guarantee protection against liability for actions taken by businesses in which we invest. Failure to comply with domestic or international laws could result in various adverse consequences, including possible delay in the approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, or the imposition of criminal or civil sanctions, including substantial monetary penalties.

In addition, differences in banking systems and business cultures could have an adverse effect on the efficiency of internal controls over financial reporting matters. Given the significant learning curve to fully understand the emerging markets' business, operating environment and the quality of controls in place, we may not be able to adequately assess the efficiency of internal controls over financial reporting or the effects of the laws and requirements of the local business jurisdictions.

Many jurisdictions require specific permits or business licenses, particularly if the business is considered foreign. These requirements may affect our ability to carry out our business operations in emerging markets.

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

In 2015, 9.5% of our total revenues were from sources 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 diplomatic and trade relationships, and political or economic instability in the countries where we do business, could affect payment terms and our ability to collect foreign receivables. We have little influence over these factors and changes could have a material adverse impact on our business. In addition, foreign sales are influenced by fluctuations in currency exchange rates, primarily the Canadian dollar, Euro, South African rand, Mexican peso, British pound, Australian dollar, and Swedish krona.

**The risks of selling and shipping products and of purchasing components and products internationally may adversely impact our revenues, results of operations and financial condition.**

The sale and shipping of our products and services across international borders is subject to extensive U.S. and foreign governmental trade regulations, such as various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act, export control laws, customs and import laws, and anti-boycott laws. Our failure to comply with applicable laws and regulations could result in 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. 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 sell products are, to some degree, subject to political, economic and/or social instability. Our international sales operations expose us and our representatives, agents and distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- the imposition of additional U.S. and foreign 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 the company does 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;
- imposition of restrictions on the activities of foreign agents, representatives and distributors;
- foreign tax authorities imposing significant fines, penalties and additional taxes;
- pricing pressure that we may experience internationally;
- 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 several foreign countries.

We cannot provide assurance that one or more of these factors will not harm our business. Additionally, we are experiencing fluidity in regulatory and pricing trends as a result of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010. Any material decrease in our international sales would adversely impact our results of operations and financial condition.

**We have 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. 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, 2015, we have total debt of approximately \$8.74 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 credit facility, which are at variable rates of interest;
- require us to use a substantial portion of our cash flow from 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, 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.

**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 and our lenders could terminate all commitments to extend further credit. 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. We cannot confirm to you that our assets or cash flow would be sufficient to fully repay borrowings under our outstanding debt instruments if the obligations thereunder were accelerated upon an event of default. For a description of our indebtedness, see Note 13. Debt in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

**The IRS may not agree with the conclusion that we should be treated as a foreign corporation for U.S. federal income tax purposes following the Paladin transaction.**

Although we are incorporated in Ireland, the U.S. Internal Revenue Service (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 Internal Revenue Code (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 foreign corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 provides an exception pursuant to which a foreign 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 foreign corporation for U.S. federal income tax purposes if the former shareholders of EHSI owned (within the meaning of Section 7874) less than 80% (by both vote and value) of our shares by reason of holding shares in us (the ownership test) immediately after the Paladin transaction. The former EHSI shareholders owned less than 80% (by both vote and value) of the shares in us after the Paladin merger by reason of our ownership of shares. As a result, under current law, we are expected to be treated as a foreign corporation for U.S. federal income tax purposes. There is limited guidance regarding the application of Section 7874 of the Code, 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 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 of the Code and the regulations promulgated thereunder should not apply in such a manner so as to cause us 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 United States. That portion of our earnings is taxed at the more favorable rates applicable to the activities undertaken by our subsidiaries outside of the United States. 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 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. For example, our transfer pricing has been the subject of IRS audits, and may be the subject of future audits by the IRS or other tax authorities, and we may be subject to tax assessments or the reallocation of income among our subsidiaries. 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 to U.S. and non-U.S. tax laws could materially adversely affect us.**

Under current law, we are expected to be treated as a foreign corporation for U.S. federal income tax purposes. However, changes to the rules in Section 7874 of the Code or regulations promulgated thereunder or other guidance issued by the Treasury or the IRS could adversely affect our status as a foreign corporation for U.S. federal income tax purposes, and any such changes could have prospective or retroactive application to us, 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 domestic corporation for U.S. federal income tax purposes, including with retroactive effect. In addition, recent U.S. legislative proposals would expand the scope of U.S. corporate tax residence and limit deductibility of interest payments made by our U.S. subsidiaries to related non-U.S. subsidiaries. If such a change in law were enacted, it could have a material adverse effect on our financial statements.

In addition, the U.S. Congress, the Organization for Economic Co-operation and Development, 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 legislative proposals that, if enacted, would substantially change the U.S. federal income tax system as it relates to 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 could increase our effective tax rate, negatively affecting our results of operations and have a material adverse effect on our financial statements.

**Section 7874 limits us and our U.S. affiliates' ability to utilize the U.S. tax attributes to offset certain U.S. taxable income, if any, generated by certain specified transactions for a period of time following the Paladin transaction.**

Following the acquisition of a U.S. corporation by a foreign corporation, Section 7874 can limit the ability of the acquired U.S. corporation and its U.S. affiliates to utilize U.S. tax attributes such as net operating losses to offset U.S. taxable income resulting from certain transactions. Based on the guidance available, this limitation will preclude us or our U.S. affiliates from utilizing U.S. tax attributes to offset taxable income, if any, resulting from certain specified taxable transactions.



**We may not be able to successfully maintain our low tax rates, 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 United States, Canada, Mexico, India, Bermuda, the United Kingdom, Luxembourg, and South Africa. The IRS and other taxing authorities may challenge intercompany arrangements. Responding to or defending such a challenge could be expensive, consume time and other resources, and divert management's attention. We cannot predict whether taxing authorities will conduct an audit challenging its tax positions, the cost involved in responding to and defending any such audit and resulting litigation, or the outcome. If we are unsuccessful, 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, 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 statements, results of operations and growth prospects.

**Our recently acquired subsidiary was not previously subject to the compliance obligations of the Sarbanes-Oxley Act of 2002, and we may not be able to timely and effectively implement controls and procedures over their operations as required under the Sarbanes-Oxley Act of 2002.**

Our recently acquired subsidiary, Par, was not previously subject to the information and reporting requirements of the Exchange Act and other federal securities laws, and the compliance obligations of the Sarbanes-Oxley Act of 2002. We must timely and effectively implement the internal controls necessary to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which requires annual management assessments of the effectiveness of internal controls over financial reporting and an integrated report by our independent registered public accounting firm addressing these assessments. We intend to take appropriate measures to establish or implement an internal control environment across our Par subsidiary, aimed at successfully adopting the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. However, it is possible that we may experience delays in implementing or be unable to implement the required internal financial reporting controls and procedures, which could result in enforcement actions, the assessment of penalties and civil suits, failure to meet reporting obligations and other material and adverse events that could have a negative effect on the market price for Endo ordinary shares.

**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 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 (e.g., 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 brand company 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 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 our subsidiary, Auxilium, leased its facilities in Horsham, Pennsylvania in order to have direct control over the manufacturing of the active ingredient of XIAFLEX<sup>®</sup>, we have limited experience in manufacturing XIAFLEX<sup>®</sup> or any other biologic product. Biologics such as XIAFLEX<sup>®</sup> require processing steps that are highly complex and generally more difficult than those required for most chemical pharmaceuticals. In addition, TESTOPEL<sup>®</sup> is manufactured using a unique, proprietary process. If our manufacturing processes at the Rye, New York facility or Horsham facility are disrupted, it may be difficult to find alternate manufacturing sites. We may encounter difficulties with the manufacture of the active ingredient of XIAFLEX<sup>®</sup> or TESTOPEL<sup>®</sup>, which could delay, disrupt or halt our manufacture of XIAFLEX<sup>®</sup> and TESTOPEL<sup>®</sup>, respectively, require write-offs which may affect our financial results, result in product recalls or product liability claims or otherwise materially affect our results of operations.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

Our significant properties at December 31, 2015 are as follows:

Location	Purpose	Approximate Square Footage	Ownership	Lease Term End Date
<b>Corporate Properties:</b>				
Dublin, Ireland	Global Corporate Headquarters	10,000	Leased	August 2024
Malvern, Pennsylvania	U.S. Corporate Headquarters	300,000	Leased(1)	December 2024
Chadds Ford, Pennsylvania	Former Corporate Headquarters	49,000	Leased(2)	March 2018
Chesterbrook, Pennsylvania	Administration	75,000	Leased	December 2023
<b>U.S. Branded Pharmaceuticals Segment Properties:</b>				
Cranbury, New Jersey	Manufacturing	33,000	Leased	February 2018
Rye, New York	Manufacturing	20,000	Leased	March 2018
Horsham, Pennsylvania	Administration/Research & Development	40,000	Leased	July 2022
Horsham, Pennsylvania	Manufacturing	50,000	Leased	February 2024
<b>U.S. Generic Pharmaceuticals Segment Properties:</b>				
Cranbury, New Jersey	Research & Development	21,000	Leased	February 2018
Huntsville, Alabama	Generic Pharmaceuticals Administration	24,000	Leased	July 2019
Huntsville, Alabama	Generic Pharmaceuticals Distribution	280,000	Owned	N/A
Huntsville, Alabama	Distribution/Manufacturing/Laboratories	180,000	Owned	N/A
Huntsville, Alabama	Distribution/Manufacturing/Laboratories	320,000	Owned	N/A
Huntsville, Alabama	Distribution	37,000	Leased	September 2016
Charlotte, North Carolina	Distribution/Manufacturing/Laboratories	88,000	Owned	N/A
Charlotte, North Carolina	Distribution/Manufacturing/Laboratories	56,000	Leased	June 2018
Charlotte, North Carolina	Distribution	50,000	Leased	May 2021
Chestnut Ridge, New York	Administration/Research & Development	62,000	Leased	December 2024
Irvine, California	Research & Development	27,000	Leased	August 2018
Irvine, California	Manufacturing/Distribution	41,000	Leased	March 2021
Irvine, California	Administration/Manufacturing/Quality Assurance	41,000	Leased	March 2021
Chestnut Ridge, New York	Administration/Distribution	135,000	Owned	N/A
Montebello, New York	Distribution	190,000	Leased	January 2024
Chestnut Ridge, New York	Administration/Manufacturing	120,000	Owned	N/A
Chestnut Ridge, New York	Administration/Quality Assurance	40,000	Owned	N/A
Chennai, India	Administration/Manufacturing/Research & Development	95,000	Owned	N/A
Rochester, Michigan	Administration/Manufacturing/Research & Development	320,000	Owned	N/A
<b>Former Devices Segment Properties:</b>				
Westmeath, Ireland	Manufacturing	34,000	Leased (3)	January 2031
Eden Prairie, Minnesota	Astora Headquarters	33,000	Leased	January 2021
<b>International Pharmaceuticals Segment Properties:</b>				
Montreal, Canada	Paladin Headquarters	26,000	Leased	December 2018
Mexico City, Mexico	Somar Headquarters	74,000	Leased	September 2019
Mexico City, Mexico	Somar Manufacturing	340,000	Owned	N/A
Mexico City, Mexico	Somar Manufacturing	51,000	Owned	N/A
Mexico City, Mexico	Somar Manufacturing	22,000	Owned	N/A
Mexico City, Mexico	Somar Manufacturing	46,000	Leased	September 2019
Johannesburg, South Africa	Litha Administration/Distribution	34,000	Leased	September 2023

(1) Beginning January, 2015, approximately 60,000 square feet of this property has been subleased.

(2) In connection with the relocation of our headquarters to Malvern, Pennsylvania, we exited these properties in early 2013.

(3) Initial lease term ends January, 2021.

**Item 3.    *Legal Proceedings***

The disclosures under Note 14. Commitments and Contingencies of the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules" 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 Global Select Market under the symbol "ENDP" and on the Toronto Stock Exchange (TSX) under the symbol "ENL". The following table sets forth the quarterly high and low share price information for the periods indicated. The prices shown represent quotations between dealers, without adjustment for retail markups, markdowns or commissions, and may not represent actual transactions.

	Endo Ordinary Shares			
	NASDAQ (US\$)		TSX (Cdn\$)	
	High	Low	High	Low
Year Ended December 31, 2015				
1st Quarter	\$ 93.03	\$ 70.62	\$ 117.45	\$ 84.16
2nd Quarter	\$ 96.58	\$ 78.19	\$ 119.00	\$ 97.01
3rd Quarter	\$ 88.54	\$ 59.81	\$ 114.31	\$ 79.53
4th Quarter	\$ 72.85	\$ 46.66	\$ 87.50	\$ 62.00
Year Ended December 31, 2014				
1st Quarter (1)	\$ 82.16	\$ 63.65	\$ 90.00	\$ 70.85
2nd Quarter	\$ 75.69	\$ 53.62	\$ 81.25	\$ 59.50
3rd Quarter	\$ 71.49	\$ 61.13	\$ 77.79	\$ 66.00
4th Quarter	\$ 75.20	\$ 57.14	\$ 86.90	\$ 65.24

(1) 1st Quarter 2014 excludes January 1, 2014 through February 28, 2014 for TSX.

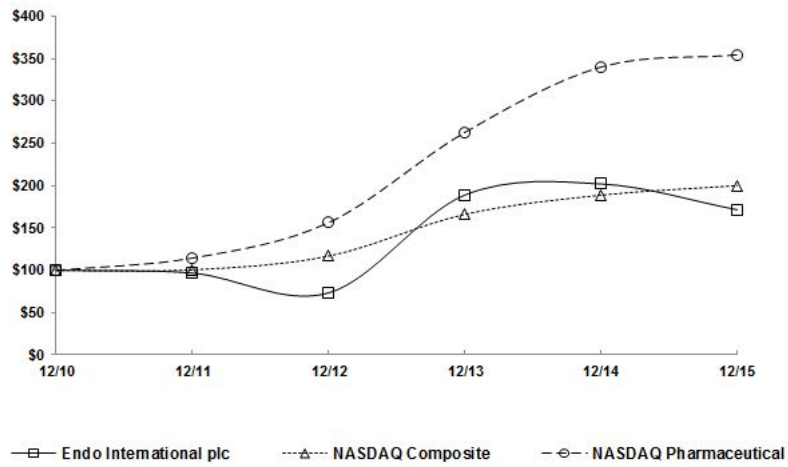
*Holders.* As of February 19, 2016, we estimate that there were approximately 171 record holders of our ordinary shares.

*Dividends.* We have never declared or paid any cash dividends on our ordinary shares and we currently have no plans to declare a dividend. Subject to limitations imposed by Irish law and the various agreements and indentures governing our indebtedness, we are permitted 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 Stock Market Index (U.S.) and (ii) the NASDAQ Pharmaceutical Index, commencing on December 31, 2010 and ending December 31, 2015. The graph assumes \$100 invested on December 31, 2010 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.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***

Among Endo International plc, the NASDAQ Composite Index and the NASDAQ Pharmaceutical Index



\*\$100 invested on 12/31/10 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

	December 31,					
	2010	2011	2012	2013	2014	2015
Endo International plc	\$ 100.00	\$ 96.70	\$ 73.45	\$ 188.91	\$ 201.96	\$ 171.44
NASDAQ Composite Index	\$ 100.00	\$ 100.53	\$ 116.92	\$ 166.19	\$ 188.78	\$ 199.55
NASDAQ Pharmaceutical Index	\$ 100.00	\$ 114.48	\$ 156.39	\$ 263.04	\$ 340.07	\$ 354.40

*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 months ended December 31, 2015.

*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, 2015:

Period	Total Number of Shares Purchased (1)	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, 2015 to October 31, 2015	—	—	—	\$ 2,500,000,000
November 1, 2015 to November 31, 2015	4,361,957	\$ 57.31	4,361,957	\$ 2,250,000,000
December 1, 2015 to December 31, 2015	—	—	—	\$ 2,250,000,000
Three months ended December 31, 2015	<u>4,361,957</u>		<u>4,361,957</u>	

- (1) On April 28, 2015, our Board of Directors resolved to approve a share buyback program (the 2015 Share Buyback Program), authorizing the Company to redeem in the aggregate up to \$2.5 billion of its outstanding ordinary shares. In accordance with Irish Law and the Company's Articles of Association, all ordinary shares redeemed shall be cancelled upon redemption. Redemptions under this program may be made from time to time in open market or negotiated transactions or otherwise, as determined by the Transactions Committee of the Board of Directors. This program does not obligate the Company to redeem any particular amount of ordinary shares. Future redemptions, if any, will depend on factors such as levels of cash generation from operations, cash requirements for investment in the Registrant's business, repayment of future debt, if any, the then current share price, market conditions, legal limitations and other factors. The 2015 Share Buyback Program may be suspended, modified or discontinued at any time. On November 6, 2015, the Company announced that it would enter into a program to repurchase up to \$250.0 million of its ordinary shares under the 2015 Share Buyback Program. During November 2015, the Company repurchased 4.4 million ordinary shares totaling \$250.0 million, not including related fees.

**Item 6. Selected Financial Data**

The consolidated financial data presented below have 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. Certain prior period amounts have been reclassified to conform to the current year presentation. See Note 2. Summary of Significant Accounting Policies and below for further discussion on reclassifications to conform to the current presentation.

	Year Ended December 31,				
	2015	2014	2013	2012	2011
(dollars in thousands, except per share data)					
<b>Consolidated Statement of Operations Data:</b>					
Total revenues	\$ 3,268,718	\$ 2,380,683	\$ 2,124,681	\$ 2,311,249	\$ 2,224,621
Operating (loss) income from continuing operations	(933,475)	326,482	517,225	177,360	468,690
(Loss) income from continuing operations before income tax	(1,437,864)	99,875	385,366	(12,049)	310,147
(Loss) income from continuing operations	(300,399)	61,608	241,624	(50,871)	197,365
Discontinued operations, net of tax	(1,194,926)	(779,792)	(874,038)	(637,150)	44,700
Consolidated net (loss) income	(1,495,325)	(718,184)	(632,414)	(688,021)	242,065
Less: Net (loss) income attributable to noncontrolling interests	(283)	3,135	52,925	52,316	54,452
Net (loss) income attributable to Endo International plc	<u>\$ (1,495,042)</u>	<u>\$ (721,319)</u>	<u>\$ (685,339)</u>	<u>\$ (740,337)</u>	<u>\$ 187,613</u>
<b>Basic and Diluted net (loss) income per share attributable to Endo International plc:</b>					
Continuing operations—basic	\$ (1.52)	\$ 0.42	\$ 2.13	\$ (0.44)	\$ 1.69
Discontinued operations—basic	(6.07)	(5.33)	(8.18)	(5.96)	(0.08)
Basic	<u>\$ (7.59)</u>	<u>\$ (4.91)</u>	<u>\$ (6.05)</u>	<u>\$ (6.40)</u>	<u>\$ 1.61</u>
Continuing operations—diluted	\$ (1.52)	\$ 0.40	\$ 2.02	\$ (0.44)	\$ 1.63
Discontinued operations—diluted	(6.07)	(5.00)	(7.74)	(5.96)	(0.08)
Diluted	<u>\$ (7.59)</u>	<u>\$ (4.60)</u>	<u>\$ (5.72)</u>	<u>\$ (6.40)</u>	<u>\$ 1.55</u>
Shares used to compute net (loss) income per share attributable to Endo International plc—Basic	197,100	146,896	113,295	115,719	116,706
Shares used to compute net (loss) income per share attributable to Endo International plc—Diluted	197,100	156,730	119,829	115,719	121,178
Cash dividends declared per share	\$ —	\$ —	\$ —	\$ —	\$ —

	As of and for the Year Ended December 31,				
	2015	2014	2013	2012	2011
	(dollars in thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 272,348	\$ 405,696	\$ 526,597	\$ 529,689	\$ 526,644
Total assets	19,350,336	10,824,169	6,510,810	6,510,694	7,215,763
Long-term debt, less current portion, net	8,251,657	4,100,627	3,262,798	2,977,166	3,344,770
Other long-term obligations, including capitalized leases	1,656,391	1,149,353	910,552	588,803	553,299
Total Endo International plc shareholders' equity	5,968,030	2,374,757	526,018	1,072,856	1,977,690
Noncontrolling interests	(54)	33,456	59,198	60,350	61,901
Total shareholders' equity	\$ 5,967,976	\$ 2,408,213	\$ 585,216	\$ 1,133,206	\$ 2,039,591
<b>Other Financial Data:</b>					
Net cash provided by operating activities	\$ 62,026	\$ 337,776	\$ 298,517	\$ 733,879	\$ 702,115
Net cash used in investing activities	\$ (6,244,770)	\$ (771,853)	\$ (883,639)	\$ (88,467)	\$ (2,374,092)
Net cash provided by (used in) financing activities	\$ 6,055,467	\$ 302,857	\$ 579,525	\$ (645,547)	\$ 1,752,681

The comparability of the forgoing information is impacted by certain charges for asset impairments and certain litigation-related and other matters during 2015, 2014, 2013 and 2012, portions of which are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations, and a number of significant acquisitions that have occurred since 2011, along with the debt incurred to finance these acquisitions. These business combinations have had a significant impact on the Company's financial statements in their respective years of acquisition and in subsequent years. This impact results from the consideration transferred by the Company for the acquisition, the initial and subsequent purchase accounting for the underlying acquisition and the post-acquisition consolidation of the acquired entity's assets, liabilities and results of operations.

Through the date of its sale in February 2014, the assets and liabilities of the HealthTronics business are classified as held for sale in the Consolidated Balance Sheets for all periods presented. On August 3, 2015, the Company sold the Men's Health and Prostate Health business to Boston Scientific. In addition, as of December 31, 2015 and continuing into 2016, the Company was actively pursuing a sale of the Astora business with the Company in active negotiations with multiple potential buyers. The assets and liabilities of the entire AMS business are classified as held for sale in the Consolidated Balance Sheets for all periods presented. The operating results of the HealthTronics and the entire AMS 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. Divestitures in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

The Company adopted ASU 2015-03 and 2015-15 on December 31, 2015. As of December 31, 2015, 2014, 2013, 2012 and 2011 the Company had \$138.4 million, \$85.4 million, \$61.0 million, \$57.9 million and \$76.8 million of net deferred financing costs that were reclassified from Other assets to a reduction in the carrying amount of Long-term debt, less current portion, net in the Consolidated Balance Sheets.

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 at 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 1 of this Report.

In prior periods, our Consolidated Financial Statements present the accounts of Endo Health Solutions Inc. and all of its subsidiaries (EHSI). Endo International plc was incorporated in Ireland on October 31, 2013 as a private limited company and re-registered effective February 18, 2014 as a public limited company. It was established for the purpose of facilitating the business combination between EHSI and Paladin Labs Inc. (Paladin). On February 28, 2014, it became the successor registrant of EHSI and Paladin in connection with the consummation of certain transactions further described elsewhere in our Consolidated Financial Statements included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules". In addition, on February 28, 2014, the shares of Endo International plc began trading on the NASDAQ under the symbol "ENDP," the same symbol under which EHSI's shares previously traded, as well as on the Toronto Stock Exchange under the symbol "ENL". References throughout to "ordinary shares" refer to EHSI's common shares, 350,000,000 authorized, par value \$0.01 per share, prior to the consummation of the transactions and to Endo International plc's ordinary shares, 1,000,000,000 authorized, par value 0.0001 per share, subsequent to the consummation of the transactions. In addition, on February 11, 2014 the Company issued 4,000,000 euro deferred shares of \$0.01 each at par.

References throughout to "Endo", the "Company", "we", "our" or "us" refer to financial information and transactions of Endo Health Solutions Inc. and its consolidated subsidiaries prior to February 28, 2014 and Endo International plc and its consolidated subsidiaries thereafter.

The majority of the assets and liabilities of the American Medical Systems Holdings, Inc. (AMS) business, previously known as the Devices segment, are classified as held for sale in the Consolidated Balance Sheets. Certain of AMS's assets and liabilities, primarily with respect to its product liability accrual for all known pending and estimated future claims related to vaginal mesh cases, the related Qualified Settlement Funds and certain intangible and fixed assets, are not classified as held for sale based on management's current expectation that these assets and liabilities will remain with the Company. The operating results of this business are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented.

Until it was sold on February 3, 2014, the assets and liabilities of the HealthTronics business, previously known as the HealthTronics segment, were classified as held for sale in the Consolidated Balance Sheets. The operating results of this business are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented.

### EXECUTIVE SUMMARY

Endo is an Ireland-domiciled, global specialty pharmaceutical company focused on branded and generic pharmaceuticals. We aim to be the premier partner to healthcare professionals and payment providers, delivering an innovative suite of branded and generic drugs to meet patients' needs.

We regularly evaluate and, where appropriate, execute on opportunities to expand through the acquisition of products and companies in areas that will serve patients and customers and that we believe will offer above average growth characteristics and attractive margins. In particular, we look to continue to enhance our product lines by acquiring or licensing rights to additional products and regularly evaluate selective acquisition and license opportunities. In addition, we remain committed to strategic R&D across each business unit with a particular focus on assets with inherently lower risk profiles and clearly defined regulatory pathways.

The following significant events and transactions occurred during 2015 and through the date of the filing of this Annual Report on Form 10-K as discussed in further detail in the Strategy, Results of Operations and Liquidity sections of Management's Discussion and Analysis:

- On January 27, 2015, certain of the Company's subsidiaries issued \$1.20 billion in aggregate principal amount of 6.00% senior notes due 2025.
- On January 29, 2015, the Company acquired Auxilium Pharmaceuticals, Inc. (Auxilium), a fully integrated specialty biopharmaceutical company with a focus on developing and commercializing innovative products for specific patient's needs, for equity and cash consideration of \$2.6 billion.
- On January 29, 2015, in connection with the consummation of the merger, Endo and Auxilium entered into an agreement relating to Auxilium's \$350.0 million of 1.50% convertible senior notes due 2018 (the Auxilium Notes), pursuant to which Endo became a co-obligor of Auxilium's obligations under the Auxilium Notes. From the closing of the acquisition on January 29, 2015, during the first quarter of 2015, holders of the Auxilium Notes converted substantially all of the Auxilium Notes.
- In February 2015, the Company acquired substantially all of Litha Healthcare Group Limited's (Litha's) remaining outstanding ordinary share capital that it did not own for consideration of approximately \$40 million.
- In April 2015, the Company settled all of the remaining outstanding 1.75% Convertible Senior Subordinated Notes Due 2015

(the Convertible Notes) with a remaining aggregate principal amount of \$98.7 million, paid related accrued interest and settled the remaining amount of the associated call options. In June 2015, the Company settled the remaining amount of the associated warrants.

- In June 2015, the Company issued 27,627,628 ordinary shares at \$83.25 per share for a total of \$2,300.0 million, before fees, in order to finance a portion of the acquisition of Par Pharmaceuticals Holdings, Inc. (Par).
- In July 2015, the Company issued \$1.64 billion in aggregate principal amount of 6.00% senior notes due 2023 (the 2023 Notes). The 2023 Notes were issued in a private offering for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended.
- In July 2015, the Company's wholly-owned subsidiaries, Endo Finance LLC and Endo Finco Inc., redeemed all \$481.9 million aggregate principal amount outstanding of their 7.00% Senior Notes due 2019 (2019 Endo Finance Notes) and the Company's wholly-owned subsidiary, EHSI, redeemed all \$18.0 million aggregate principal amount outstanding of its 7.00% Senior Notes due 2019 (2019 EHSI Notes). The aggregate redemption price included a redemption fee of \$17.5 million, or 3.5% of the aggregate principal amount of the 2019 Endo Finance Notes and the 2019 EHSI Notes, plus accrued and unpaid interest to, but not including, the redemption date.
- On August 3, 2015, the Company completed the sale of the Men's Health and Prostate Health components of its AMS business to Boston Scientific Corporation for \$1.60 billion in upfront cash.
- On September 25, 2015, the Company acquired Par for total consideration of \$8.14 billion, including the assumption of Par debt. Par is a specialty pharmaceutical company that develops, licenses, manufactures, markets and distributes innovative and cost-effective pharmaceuticals that help improve patient quality of life. Par focuses on high-barrier-to-entry products that are difficult to formulate, difficult to manufacture or face complex legal and regulatory challenges.
- On September 25, 2015, the Company increased its revolving capacity to an aggregate principal amount of \$1,000 million pursuant to the incremental revolving facility. In addition, the Company incurred an incremental term loan B facility in an aggregate principal amount of \$2,800 million and repaid in full the amount outstanding under its then existing term loan B facility.
- On October 1, 2015, the Company acquired a broad portfolio of branded and generic injectable and established products focused on pain, anti-infectives, cardiovascular and other specialty therapeutics areas from a subsidiary of Aspen Holdings and from GlaxoSmithKline plc (GSK) for total consideration of \$135.6 million (the Aspen Holdings acquisition).
- On October 23, 2015 the FDA approved BELBUCA™ (buprenorphine HCl) Buccal Film for the management of severe pain. BELBUCA™ became commercially available in the U.S. during February 2016.
- On November 6, 2015, the Company announced that it would enter into a program to repurchase up to \$250 million of its ordinary shares under the 2015 Share Buyback Program. During November 2015, the Company repurchased 4.4 million ordinary shares.
- In November 2015, the Company's wholly-owned subsidiaries, Endo Finance LLC and Endo Finco Inc., redeemed all \$393.0 million aggregate principal amount outstanding of their 7.00% Senior Notes due 2020 (2020 Endo Finance Notes) and the Company's wholly-owned subsidiary, EHSI, redeemed all \$7.0 million aggregate principal amount outstanding of its 7.00% Senior Notes due 2020 (2020 EHSI Notes). The aggregate redemption price included a redemption fee of \$14.0 million, or 3.5% of the aggregate principal amount of the 2020 Endo Finance Notes and the 2020 EHSI Notes, plus accrued and unpaid interest to, but not including, the redemption date.
- On December 11, 2015, Endo, Novartis AG and Sandoz entered into the 2015 Voltaren® Gel Agreement) effectively renewing Endo's exclusive U.S. marketing and license rights to commercialize Voltaren® Gel through June 30, 2023.

**Highlights**

The following table is a summary of our financial highlights for the three years ended December 31 (in thousands, except per share):

	2015	2014	2013
Total revenues	\$ 3,268,718	\$ 2,380,683	\$ 2,124,681
Total operating costs and expenses	\$ 4,202,193	\$ 2,054,201	\$ 1,607,456
(Loss) income from continuing operations before income tax	\$ (1,437,864)	\$ 99,875	\$ 385,366
Income tax	\$ (1,137,465)	\$ 38,267	\$ 143,742
Discontinued operations, net of tax	\$ (1,194,926)	\$ (779,792)	\$ (874,038)
Net loss attributable to Endo International plc	\$ (1,495,042)	\$ (721,319)	\$ (685,339)
Net loss per share attributable to Endo International plc ordinary shareholders—Basic:			
Continuing operations	\$ (1.52)	\$ 0.42	\$ 2.13
Discontinued operations	(6.07)	(5.33)	(8.18)
Basic	\$ (7.59)	\$ (4.91)	\$ (6.05)
Net loss per share attributable to Endo International plc ordinary shareholders—Diluted:			
Continuing operations	\$ (1.52)	\$ 0.40	\$ 2.02
Discontinued operations	(6.07)	(5.00)	(7.74)
Diluted	\$ (7.59)	\$ (4.60)	\$ (5.72)
Cash, cash equivalents and marketable securities	\$ 276,237	\$ 408,017	\$ 529,576

**Business Environment**

The Company conducts its business within the pharmaceutical industry within both the branded and generic pharmaceutical markets. The pharmaceutical industry is highly competitive and subject to comprehensive government regulations. Many factors may significantly affect the Company's sales of its products, including, but not limited to, efficacy, safety, price and cost-effectiveness, marketing effectiveness, product labeling, quality control and quality assurance at our and our third-party manufacturing operations and research and development of new products. To compete successfully for business in the healthcare industry, the Company must demonstrate that its products offer medical benefits as well as cost advantages. Currently, most of the Company's products compete with other products already on the market in the same therapeutic category, and are subject to potential competition from new products that competitors may introduce in the future.

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. 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. Generic drugs are the same as branded products in dosage form, safety, efficacy, route of administration, quality, performance characteristics and intended use, but they are sold generally at prices below those of the corresponding branded products. Generic drugs provide a cost-effective alternative for consumers, while maintaining the same high quality, efficacy, safety profile, purity and stability of the branded product. An ANDA is required to be filed and approved by the FDA in order to manufacture a generic drug for sale in the United States. We sell generic products primarily in the United States across multiple therapeutic categories.

We have a generics portfolio across an extensive range of dosage forms and delivery systems, including immediate and extended release oral solids (tablets, orally disintegrating tablets, capsules and powders), injectables, liquids, nasal sprays, ophthalmics (which are sterile pharmaceutical preparations administered for ocular conditions) and transdermal patches (which are medicated adhesive patches designed to deliver the drug through the skin).

We have development, manufacturing and distribution capabilities in the rapidly growing U.S. market for sterile drug products, such as injectable products, ophthalmics, and sterile vial and hormonal handling capabilities. These capabilities afford us a broader and more diversified product portfolio and a greater selection of targets for potential development. We target products with limited competition for reasons such as manufacturing complexity or the market size, which make our sterile products a key growth driver of our generics portfolio and complementary to our other generic product offerings.

Authorized generics are generic versions of branded drugs licensed by brand drug companies under a NDA and marketed as generics. Authorized generics do not face any 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. The sale of authorized generics adversely impacts the market share of a generic product that has been granted 180 days of marketing exclusivity. 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, Bristol-Myers Squibb, and Merck & Co in the recent past.

The healthcare industry is subject to various limitations on coverage and reimbursement that have and will continue to have an impact on the Company's sales. The U.S. Congress and some state legislatures have considered a number of proposals and have enacted laws that could result in major changes in the current healthcare system, either nationally or at the state level, and there is an increasing focus on the pricing of pharmaceutical products in particular. Driven in part by budget concerns, Medicaid access and reimbursement restrictions have been implemented in some states and proposed in many others. In addition, the Medicare Prescription Drug Improvement and Modernization Act provides outpatient prescription drug coverage to senior citizens in the U.S. This legislation has had a modest favorable impact on the Company as a result of an increase in the number of seniors with drug coverage. At the same time, there continues to be a potential negative impact on the U.S. pharmaceutical business that could result from continuing pricing pressures or new price controls.

The growth of Managed Care Organizations (MCOs) in the U.S. has increased competition in the healthcare industry. MCOs seek to reduce healthcare expenditures for participants by making volume purchases and entering into long-term contracts to negotiate discounts with various pharmaceutical providers. Because of the market potential created by the large pool of participants, marketing prescription drugs to MCOs has become an important part of the Company's strategy. Companies compete for inclusion in MCO formularies and the Company generally has been successful in having its major products included. The Company believes that developments in the managed care industry, including continued consolidation, have had and will continue to have downward pressure on prices.

Changes in the behavior and spending patterns of purchasers of healthcare products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing healthcare insurance coverage, may impact the Company's business.

Pharmaceutical production processes are complex, highly regulated and vary widely from product to product. In addition to the pharmaceutical manufacturing operations of the Company's subsidiaries, the Company contracts with various third-party manufacturers and suppliers to provide it with raw materials used in its products and finished goods. These contracts include agreements with Novartis Consumer Health, Inc., Novartis AG and Sandoz, Inc. (collectively, Novartis), Teikoku Seiyaku Co., Ltd., Noramco, Inc., Grünenthal GmbH, Sharp Corporation and Jubilant HollisterStier Laboratories LLC. Shifting or adding manufacturing capacity can be a lengthy process that could require significant expenditures and regulatory approvals. If for any reason the Company is unable to continue its internal manufacturing operations or obtain sufficient quantities of any of the finished goods or raw materials or components required for its products, it could have an adverse effect on the Company's business, financial condition, results of operations and cash flows.

## **CRITICAL ACCOUNTING ESTIMATES**

To understand our financial statements, it is important to understand our critical accounting estimates. The preparation of our financial statements in conformity with accounting principles generally accepted in the U.S. requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in the determination of revenue recognition and sales deductions for estimated chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and allowances. Significant estimates and assumptions are also required when determining the fair value of financial instruments, the valuation of long-lived assets, income taxes, contingencies and stock-based compensation. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption made by us, there may also be other estimates or assumptions that are reasonable. Although we believe that our estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made. Actual results may differ significantly from our estimates.

We consider an accounting estimate to be critical if: (1) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (2) 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**

#### *Pharmaceutical Products*

Our net pharmaceutical product sales consist of revenues from sales of our pharmaceutical products, less estimates for chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and allowances as well as fees for services. We recognize revenue for product sales when title and risk of loss has passed to the customer, which is typically upon delivery to the customer, when estimated provisions for revenue reserves are reasonably determinable, and when collectability is reasonably confirmed. Revenue from the launch of a new or significantly unique product, for which we are unable to develop the requisite historical data on which to base estimates of returns and allowances due to the uniqueness of the therapeutic area or delivery

technology as compared to other products in our portfolio and in the industry, may be deferred until such time that an estimate can be determined and all of the conditions above are met and when the product has achieved market acceptance, which is typically based on dispensed prescription data and other information obtained prior to and during the period following launch.

Decisions made by wholesaler customers and large retail chain customers regarding the levels of inventory they hold (and thus the amount of product they purchase from us) can materially affect the level of our sales in any particular period and thus may not correlate to the number of prescriptions written for our products based on external third-party data. We believe that speculative buying of product, particularly in anticipation of possible price increases, has been the historic practice of many pharmaceutical wholesalers. In recent years, our wholesaler customers, as well as others in the industry, began modifying their business models from arrangements where they derive profits from price arbitrage, to arrangements where they charge a fee for their services. Accordingly, we have entered into distribution service agreements (DSAs) with certain of our significant wholesaler customers. These agreements obligate the wholesalers to provide us with specific services, including the provision of periodic retail demand information and current inventory levels for our branded products held at their warehouse locations; additionally, under these DSAs, the wholesalers have agreed to manage the variability of their purchases and inventory levels within specified limits based on product demand.

We receive information from certain of our wholesaler customers about the levels of inventory they held for our branded and generic products. Based on this information, which we have not independently verified, we believe that total pharmaceutical inventory held at these wholesalers is within normal levels at December 31, 2015. We also estimate inventory levels at other wholesalers based on buying patterns and believe these levels to be within normal ranges. In addition, we evaluate market conditions for products primarily through the analysis of wholesaler and other third party sell-through and market research data, as well as internally-generated information.

#### *Other*

Product royalties received from third party collaboration partners and licensees of our products and patents are recorded as part of Total revenues. Royalties are recognized as earned in accordance with the contract terms when royalties from third parties can be reasonably estimated and collectability is reasonably confirmed. If royalties cannot be reasonably estimated or collectability of a royalty amount is not reasonably confirmed, royalties are recognized as revenue when the cash is received.

Milestone payments earned by the Company under out-license agreements are recorded in Total revenues. Revenue from these milestone payments is recognized as revenue ratably from the point in which the milestone is achieved over the remaining performance period. See Note 11. License and Collaboration Agreements in the Consolidated Financial Statements for specific agreement details.

### Sales deductions

When we recognize revenue from the sale of our products, we simultaneously record an adjustment to revenue for estimated chargebacks, rebates, sales incentives and allowances, certain royalties, DSA fees, returns and allowances. These provisions, as described in greater detail below, are estimated based on historical experience, estimated future trends, estimated customer inventory levels, current contract sales terms with our wholesale and indirect customers and other competitive factors. If the assumptions we used to calculate these adjustments 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 and assets and liabilities held for sale, for our product sales provisions for the three years ended December 31 (in thousands):

	Returns and Allowances	Rebates	Chargebacks	Other Sales Deductions	Total
Balance, January 1, 2013	\$ 83,800	\$ 327,184	\$ 61,302	\$ 17,780	\$ 490,066
Current year provision	71,486	1,036,770	775,109	50,557	1,933,922
Prior year provision	(5,072)	(11,152)	—	—	(16,224)
Payments or credits	(45,515)	(1,016,718)	(718,397)	(55,440)	(1,836,070)
Balance, December 31, 2013	\$ 104,699	\$ 336,084	\$ 118,014	\$ 12,897	\$ 571,694
Additions related to acquisitions	13,512	985	234	653	15,384
Current year provision	104,768	1,260,210	1,227,102	42,789	2,634,869
Prior year provision	(5,531)	3,000	(320)	—	(2,851)
Payments or credits	(42,508)	(1,102,917)	(1,127,628)	(30,959)	(2,304,012)
Balance, December 31, 2014	\$ 174,940	\$ 497,362	\$ 217,402	\$ 25,380	\$ 915,084
Additions related to acquisitions	129,281	184,290	117,236	27,970	458,777
Current year provision	146,615	1,604,062	2,272,896	148,090	4,171,663
Prior year provision	4,070	(12,604)	(7,011)	—	(15,545)
Payments or credits	(97,974)	(1,449,953)	(2,221,307)	(154,638)	(3,923,872)
Balance, December 31, 2015	\$ 356,932	\$ 823,157	\$ 379,216	\$ 46,802	\$ 1,606,107

#### Returns and Allowances

Our provision for returns and allowances consists of our estimates of future product returns, pricing adjustments and delivery errors. Consistent with industry practice, we maintain a return policy that allows our customers to return product within a specified period of time both prior and subsequent to the product's expiration date. Our return policy generally allows customers to receive credit for expired products within six months prior to expiration and within one year after expiration. 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
- 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 the 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 if the increase may be 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. Other-than-temporary increases in inventory levels, however, may be an indication that future product returns could be higher than originally anticipated and, accordingly, we may need to adjust our estimate 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, 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 extend the shelf life of our products, which could result in a period of higher returns related to older product with the shorter shelf life;
- introduction of new product or generic competition;
- increasing price competition from generic competitors; and
- recent 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*

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. We estimate rebates, sales incentives and other allowances based upon the terms of the contracts with our customers, historical experience, estimated inventory levels of our customers and estimated future trends. Our rebate programs can generally be categorized into the following four types:

- direct rebates;
- indirect rebates;
- managed care rebates; and
- Medicaid and Medicare Part D rebates.

Direct rebates are generally rebates paid to direct purchasing customers based on a percentage applied to a direct customer's purchases from us, including DSA fees paid to wholesalers under our DSA's, 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. In estimating our provisions for these types of rebates, we consider relevant statutes with respect to governmental pricing programs and contractual sales terms with managed-care providers and group purchasing organizations. Starting in 2011, as a result of the implementation of certain provisions of the Healthcare Reform Law, we are required to provide a 50% 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 estimate an accrual for Managed Care, Medicaid, Medicare Part D and Coverage Gap rebates as a reduction of revenue at the time product sales are recorded. These rebate reserves are estimated based upon the historical utilization levels, historical payment experience, historical relationship to revenues, estimated future trends, and include an estimate of outstanding claims for end-customer sales that occurred but for which the related claim has not been billed and an estimate for future claims that will be made when inventory in the distribution channel is sold through to plan participants. 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.

We participate in state government-managed Medicaid programs, as well as certain other qualifying federal and state government programs whereby discounts and rebates are provided to participating government entities. Medicaid rebates are amounts owed based upon contractual agreements or legal requirements with public sector (Medicaid) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. Medicaid reserves are based on expected payments, which are driven by patient usage, contract performance, as well as 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. Medicaid pricing programs involve particularly difficult interpretations of statutes and regulatory guidance, which are complex and thus our estimates could differ from actual experience.

We continually update these factors based on new contractual or statutory requirements and significant changes in sales trends that may impact the percentage of our products subject to rebates.

### *Chargebacks*

The provision for chargebacks is one of the most significant and the most complex estimates used in the recognition of our revenue. We market and sell products directly to wholesalers, distributors, warehousing pharmacy chains, and other direct purchasing groups. We also market products indirectly to independent pharmacies, non-warehousing chains, managed care organizations, and group purchasing organizations, collectively referred to as indirect customers. We enter into agreements with some indirect customers to establish contract pricing for certain products. These indirect customers then independently select a wholesaler from which to purchase the products at these contracted prices. Alternatively, we may pre-authorize wholesalers to offer specified contract pricing to other indirect customers, including government entities. 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. 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 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*

Long-lived assets, including property, plant and equipment, licenses, developed technology, trade names and patents are assessed for impairment whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Recoverability of assets 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 value of the asset exceeds its undiscounted future cash flows and the carrying value is not considered recoverable, impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value, generally based on a discounted future cash flow method, independent appraisals or preliminary 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 amortizable intangibles, any recognized impairment loss could have a material adverse impact on our financial position and results of operations.

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 reviews of long-lived assets during the three years ended December 31, 2015 resulted in certain asset impairment charges, which are described below under the caption "RESULTS OF OPERATIONS".

*License Rights* - The cost of licenses are either expensed immediately or, if capitalized, are stated at cost, less accumulated amortization and are amortized using the straight-line method over their estimated useful lives ranging from 3 to 15 years, with a weighted average useful life of approximately 10 years. We determine amortization periods for licenses based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental and regulatory issues, and contractual terms. Significant changes to any of these factors may result in a reduction in the useful life of the license and an acceleration of related amortization expense, which could cause our operating income and net income to decrease. The value of these licenses is subject to continuing scientific, medical and marketplace uncertainty.

*Trade Names* - Acquired trade names are recorded at fair value upon acquisition and, if deemed to have definite lives, are amortized using the straight-line method over their estimated useful lives of approximately 12 years. We determine amortization



periods for trade names based on our assessment of various factors impacting estimated useful lives and cash flows from the acquired assets. Such factors include the strength of the trade name and our plans regarding the future use of the trade name. 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 and net income to decrease.

*Developed Technology* - Acquired developed technology is recorded at fair value upon acquisition and is amortized using the economic benefit model or the straight-line method, over the estimated useful life ranging from 3 to 20 years for our intangibles relating to continuing operations, with a weighted average useful life of approximately 12 years. We determine amortization periods and method of amortization for developed technology based on our assessment of various factors impacting estimated useful lives and timing and extent of estimated cash flows of the acquired assets. Such factors include the strength of the intellectual property protection of the product and various other competitive and regulatory issues, and contractual terms. 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. The value of these assets is subject to continuing scientific, medical and marketplace uncertainty.

#### **Goodwill and indefinite-lived intangible assets**

As of December 31, 2015 and 2014, excluding amounts classified as Assets held for sale in our Consolidated Balance Sheets, goodwill and other intangibles comprised approximately 78% and 48%, respectively, of our total assets.

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 1<sup>st</sup>. The goodwill test consists of a Step I analysis that requires a comparison between the respective reporting unit's fair value and carrying amount. A Step II analysis would be required if the fair value of the reporting unit is lower than its carrying amount. If the fair value of the reporting unit exceeds its carrying amount, an impairment does not exist and no further analysis is required. The indefinite-lived intangible asset impairment test consists of a one-step analysis that compares the fair value of the intangible asset with its carrying amount. If the carrying amount of an intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. For the purpose of the October 1, 2015 annual goodwill impairment test, the Company had five operating segments and reporting units; (1) Branded, (2) Generics, (3) Paladin Canada, (4) Litha and (5) Somar. During the fourth quarter of 2015, the Company combined certain resources within the Branded business and management realigned how they review the segment's performance. As a result, we determined that our Pain and UEO reporting units should be combined into one Branded reporting unit for purposes of testing goodwill as of October 1, 2015. In addition to testing the Pain and UEO reporting units separately for goodwill impairment as of October 1, 2015, the Company also tested the combined Branded reporting unit for impairment.

We estimated the fair value of our reporting units through an income approach using a discounted cash flow model, or, where appropriate, a market approach, or a combination thereof. Our discounted cash flow models are highly reliant on various assumptions, including estimates of future cash flows (including long-term growth rates), discount rate, and expectations about variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. Where an income approach was utilized, the discount rates applied to the estimated cash flows for our October 1, 2015 annual goodwill and indefinite-lived intangible assets impairment test ranged from 9.0% to 16.0%, 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.

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 unit's fair values over the market capitalization) or an implied control discount (the excess sum of total invested capital over the sum of the reporting unit's 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.

During 2015 the Company recorded certain pre-tax, non-cash impairment charges relating to our former UEO and Paladin Canada reporting units. For a complete description of these impairment charges, refer to Note 10. Goodwill and Other Intangibles.

The excess of fair value over carrying amount (Step I cushion) for our reporting units, other than those impaired as discussed above, as of October 1, 2015 ranged from approximately 19% to 93% of carrying amount. An increase of 50 basis points to our assumed discount rates used in testing any of these reporting units would not have changed the results of our Step I analyses.

Our annual review of goodwill and indefinite-lived intangible assets during the three years ended December 31, 2015 resulted in certain asset impairment charges, which are described below under the caption "RESULTS OF OPERATIONS".

### **Acquisition-related in-process research and development**

Acquired businesses 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. Amounts allocated to acquired in-process research and development (IPR&D) are recorded to the balance sheet at the date of acquisition based on their relative fair values. The judgments made in determining the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact our results of operations.

There are several methods that can be used to determine the fair value of assets acquired and liabilities assumed. For intangible assets, including IPR&D, we typically use the income method. This method starts with our forecast of all of the expected future net cash flows. 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. Some of the more significant estimates and assumptions inherent in the income method or other methods include: the amount and timing of projected future cash flows; the amount and timing of projected costs to develop the IPR&D into commercially viable products; the discount rate selected to measure the risks inherent in the future cash flows; and the assessment of the asset's life cycle and the competitive trends impacting the asset, including consideration of any technical, legal, regulatory, or economic barriers to entry, as well as expected changes in standards of practice for indications addressed by the asset.

Determining the useful life of an intangible asset also requires judgment, as different types of intangible assets will have different useful lives. Acquired IPR&D is designated as an indefinite-lived intangible asset until the associated research and development activities are completed or abandoned.

### **Income taxes**

Our income tax expense, deferred tax assets and liabilities, 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 United States and numerous other foreign jurisdictions. Significant judgments and estimates are required in determining the consolidated income tax expense for financial statement purposes. Deferred income taxes arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements, which will result in taxable or deductible amounts in the future. In assessing the realizability of deferred tax assets, we consider future taxable income by tax jurisdiction and tax planning strategies. 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 adjusted for the results of discontinued operations and incorporate assumptions about the amount of future earnings within a specific jurisdiction's pretax operating income adjusted for material changes in business operations. The assumptions about future taxable income require significant judgment and are consistent with the plans and estimates we are using to manage the underlying businesses.

Changes in tax laws and tax rates could also affect recorded deferred tax assets and liabilities in the future. The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in a multitude of jurisdictions across our global operations. Accounting Standards Codification (ASC) Topic 740, Income Taxes, states that a benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits. We first record unrecognized tax benefits as liabilities in accordance with ASC 740 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 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 is available.

We consider the earnings of the majority of our subsidiaries to be indefinitely invested within their country of incorporation on the basis of estimates that future cash generation will be sufficient to meet future cash needs and our specific plans for reinvestment of those subsidiary earnings. Should we decide to repatriate earnings, we would need to adjust our income tax provision in the period we determined that the earnings will no longer be indefinitely invested outside the relevant tax jurisdiction.

### **Contingencies**

The Company is subject to various patent, product liability, 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.

The factors we consider in developing our contingent accruals for product litigation and other contingent liability items include the merits and jurisdiction of the litigation, the nature and the number of other similar current and past litigation cases, the nature of the product and the current assessment of the science subject to the litigation, and the likelihood of the conditions of settlement being met. In addition, we accrue for certain product liability claims incurred, but not filed, to the extent we can formulate a reasonable estimate of the number of such claims and their estimated costs. We estimate these expenses based primarily on our historical claims experience and data regarding product usage. As of December 31, 2015, the Company has accrued \$2.09 billion for all known probable and estimable future claims related to vaginal mesh cases. Our accrual is primarily based on Master Settlement Agreements

(MSAs) between AMS and certain plaintiffs' counsel representing mesh-related product liability claimants. AMS has agreed to settle up to approximately 49,000 filed and unfiled mesh claims handled or controlled by the participating counsel.

As previously disclosed, our estimated liability had historically included a reduction factor applied to the maximum number of potentially eligible claims resulting in a liability that was lower than the maximum payouts under the previously executed MSAs. This reduction factor was based on our estimate of likely duplicative claims and claims that would not ultimately obtain recovery under our MSAs or otherwise. During the second quarter of 2015, we adjusted the reduction factor from 21% to 18% based on the available claims processing information available to us at that time. Due to the actual number of claims processed and the lack of any meaningful reduction factor observed to date, we removed this assumption in its entirety from our estimated liability as of December 31, 2015. Eliminating the reduction factor assumption resulted in a \$401 million increase to our estimated liability and a corresponding pre-tax charge recorded in Discontinued operations, net of tax.

All MSAs are subject to a process that includes guidelines and procedures for administering the settlements and the release of funds. All MSAs have participation thresholds requiring participation by the majority of claims represented by each law firm. If certain participation thresholds are not met, then AMS will have the right to terminate the settlement with that law firm. We expect that valid claims under the MSAs will continue to be settled. However, we and our subsidiaries intend to vigorously contest pending and future claims that are invalid or in excess of the maximum claim amounts under the MSAs. We are also aware of a substantial number of additional claims or potential claims, some of which may be invalid or contested, for which we lack sufficient information to determine whether any potential liability is probable, and such claims have not been included in our estimated product liability accrual. We and our subsidiaries intend to contest these claims vigorously.

As of the date of this report, we believe that the current product liability accrual includes all known claims for which liability is probable and estimable. In order to evaluate whether a mesh claim is probable of a loss, the company must obtain and evaluate certain information pertaining to each individual claim, including but not limited to the following items; the name and social security number of the plaintiff, evidence of an AMS implant, the date of implant, the date the claim was first asserted to AMS, the date that plaintiff's counsel was retained, and most importantly, medical records establishing the injury alleged. Without access to at least this information and the opportunity to evaluate it, the Company is not in a position to determine whether a loss is probable for such claims. It is currently not possible to determine the validity or outcome of any additional or potential claims and such claims may result in additional losses that could have a material adverse effect on our business, financial condition, results of operations and cash flow. We will continue to monitor the situation, including with respect to any additional claims of which we may later become aware, and, if appropriate, make further adjustments to the product liability accrual based on new information.

During the fourth quarter of 2015, we recorded an \$834.0 million pre-tax charge to increase the estimated product liability accrual for vaginal mesh cases. The increase in our estimated liability reflects the impact of removing the reduction factor assumption described above, the execution of additional MSAs in 2016 and an increase in the number of claims probable of a loss as determined by our ongoing assessment of outstanding claims.

Contingent accruals are recorded in the Consolidated Statements of Operations when the Company determines that a loss related to a litigation matter 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.

While the Company is retaining the liability for all known pending and estimated future claims related to vaginal mesh cases related to products sold prior to the sale date, the Company is pursuing the sale of the underlying vaginal mesh products to a third party and thus the litigation expense and legal defense costs specifically attributable to the vaginal mesh cases has been included in Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented.

See Note 14. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules" for further discussion of our product liability cases.

## RESULTS OF OPERATIONS

The Company reported net loss attributable to Endo International plc in 2015 of \$1,495.0 million or \$7.59 per diluted share on total revenues of \$3,268.7 million compared with net loss attributable to Endo International plc of \$721.3 million or \$4.60 per diluted share on total revenues of \$2,380.7 million in 2014 and net loss attributable to Endo International plc of \$685.3 million or \$5.72 per diluted share on total revenues of \$2,124.7 million in 2013.

### Consolidated Results Review

#### Year Ended December 31, 2015 Compared to Year Ended December 31, 2014

**Revenues.** Revenues in 2015 increased 37% to \$3,268.7 million from 2014. This revenue increase was primarily attributable to growth in our U.S. Generic Pharmaceuticals segment and revenues related to our February 2014 acquisition of Paladin, July 2014 acquisition of Grupo Farmacéutico Somar, Sociedad Anónima Promotora de Inversión de Capital Variable (Somar), January 2015 acquisition of Auxilium and September 2015 acquisition of Par. The increases were partially offset by decreased revenues from our U.S. Branded Pharmaceuticals segment, driven mainly by decreased Lidoderm® and OPANA® ER revenues related to generic competition. A discussion of revenues by reportable segment is included below under the caption “Business Segment Results Review.”

**Gross margin, costs and expenses.** The following table sets forth costs and expenses for the years ended December 31 (dollars in thousands):

	2015		2014	
	\$	% of Revenue	\$	% of Revenue
Cost of revenues	\$ 2,075,651	64	\$ 1,231,497	52
Selling, general and administrative	741,304	23	567,986	24
Research and development	102,197	3	112,708	5
Litigation-related and other contingencies, net	37,082	1	42,084	2
Asset impairment charges	1,140,709	35	22,542	1
Acquisition-related and integration items	105,250	3	77,384	3
Total costs and expenses*	\$ 4,202,193	129	\$ 2,054,201	86

\* Percentages may not add due to rounding.

**Cost of revenues and gross margin.** Cost of revenues in 2015 increased 69% to \$2,075.7 million from 2014. This increase was primarily attributable to increased costs related to our acquisitions of Paladin, Sumavel, Somar, DAVA, Auxilium and Par. Gross margins in 2015 decreased to 36% from 48% in 2014. These decreases were primarily attributable to growth in lower margin generic pharmaceutical product sales, increased intangible asset amortization of \$342.6 million, increased inventory step-up amortization as a result of recent acquisitions of \$166.9 million and a decline in higher margin branded pharmaceutical product sales due to generic competition on certain products.

**Selling, general and administrative expenses.** Selling, general and administrative expenses in 2015 increased 31% to \$741.3 million from 2014. The increase was primarily a result of the acquisitions of Paladin, Sumavel, Somar, DAVA, Auxilium and Par, including a charge during the first quarter of 2015 related to the acceleration of Auxilium employee equity awards at closing of \$37.6 million and restructuring charges related to the Auxilium and Par acquisitions. These increases were partially offset by a \$54.3 million charge in 2014 for the reimbursement of directors’ and certain employee’s excise tax liabilities pursuant to Section 4985 of the Internal Revenue Code, which were approved by the Company’s shareholders on February 26, 2014. These liabilities resulted from the shareholder gain from the merger between Endo and Paladin.

**Research and development expenses.** Research and development (R&D) expenses in 2015 decreased 9% to \$102.2 million from 2014. The following table presents the composition of our total R&D expense for the years ended December 31 (in thousands):

	Research and Development Expense (in thousands)	
	2015	2014
U.S. Branded Pharmaceuticals portfolio	\$ 25,828	\$ 64,764
U.S. Generic Pharmaceuticals portfolio	58,418	32,060
International Pharmaceuticals portfolio	9,624	6,238
Enterprise-wide R&D costs	8,327	9,646
Total R&D expense	\$ 102,197	\$ 112,708

The decrease in U.S. Branded Pharmaceuticals expenses in 2015 was primarily attributable to \$30.0 million in milestone charges incurred during 2014 related to the achievement of certain BELBUCA™ clinical milestones and decreases in other branded pharmaceutical product expenses. We undertook initiatives in 2014 to optimize commercial spend and refocus our research and development efforts on progressing late-stage pipeline and maximizing value of marketed products. On June 2, 2014, we completed the sale of our branded pharmaceutical drug discovery platform to Asana BioSciences, LLC, an independent member of the Amneal Alliance of Companies. The sale included multiple early-stage drug discovery and development candidates in a variety of therapeutic areas, including oncology, pain and inflammation, among others. In addition, on November 4, 2014 we sold most of the assets and intellectual property of our second generation implantable drug technology to Braeburn Pharmaceuticals, excluding the existing implant platform used for our two marketed histrelin-containing products, Vantas® and Supprelin®.

As part of the Auxilium acquisition, the Company acquired Auxilium's licensed right to cover certain XIAFLEX® indications. As a result, the Company has incurred related early-stage and middle-stage development expenses for these XIAFLEX® indications.

The Company's primary U.S. Generic Pharmaceuticals R&D efforts are focused on high-barrier-to-entry generic products, including first-to-file or first-to-market opportunities that are difficult to formulate, difficult to 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 commodity generic products. In 2015 and 2014, the Company's direct R&D expense related to generics totaled \$58.4 million and \$32.1 million, respectively. The increase in expense is a result of the Par acquisition and additional investments in expanding our research and development and manufacturing capabilities.

**Litigation-related and other contingencies, net.** Charges for Litigation-related and other contingencies, net in 2015 totaled \$37.1 million, compared to \$42.1 million in 2014. These amounts mainly relate to fluctuations in charges associated with certain litigation matters. The Company's legal proceedings and other contingent matters are described in more detail in Note 14. Commitments and Contingencies of the Consolidated Financial Statements of Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

**Asset impairment charges.** Asset impairment charges in 2015 totaled \$1,140.7 million, compared to \$22.5 million in 2014. This increase primarily relates to 2015 pre-tax, non-cash impairment charges of \$673.5 million and \$85.8 million, for the UEO and Paladin Canada reporting units, respectively, representing the difference between the estimated implied fair value of the UEO and Paladin Canada reporting units' goodwill and their respective net book value. Goodwill in our UEO reporting unit, prior to the impairments, was approximately \$915 million with approximately \$815 million stemming from the Paladin and Auxilium acquisitions. We assigned the goodwill arising from the Paladin acquisition to multiple reporting units across each of our reportable segments. This assignment was based on the relative incremental benefit expected to be realized by each impacted reporting unit. The level of goodwill created by the Paladin and Auxilium acquisitions was impacted by the increase in our share price from the acquisition announcement date to the date the acquisition closed. During the year, the Company's revised expectations of certain TRT products and other elements of the UEO business due to current and expected market conditions coupled with the new investment opportunities resulting from the FDA approval of BELBUCA™ and other strategic priorities resulted in a shift in investment strategy. As a result of these factors, there was a decline in the fair value of the UEO reporting unit. Goodwill in our Paladin Canada reporting unit, prior to the impairments, was approximately \$520 million. In addition to the goodwill impairment charges, during 2015 the Company also recorded pre-tax, non-cash impairment charges of \$370.6 million on certain intangible assets primarily from our U.S. Branded Pharmaceuticals and U.S. Generic Pharmaceuticals segments.

The amounts incurred during 2014 related primarily to a charge of \$12.3 million to fully impair a license intangible asset related to OPANA® ER as well as charges of \$4.3 million to completely write off certain miscellaneous property, plant and equipment. These impairment charges were recorded because the Company determined the carrying amounts of these assets were no longer recoverable.

**Acquisition-related and integration items.** Acquisition-related and integration items in 2015 totaled \$105.3 million in expense, compared to \$77.4 million in expense in 2014. During 2015, the Company recorded \$65.6 million of income, net, resulting from the change in the fair value of certain contingent consideration. The change in contingent consideration is due to certain market conditions

impacting the commercial potential of the underlying products. This income was partially offset by an increase in overall acquisition-related and integration costs associated with our acquisition of Auxilium, which closed during the first quarter of 2015, and acquisition of Par, which closed during the third quarter of 2015.

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

	2015	2014
Interest expense	\$ 378,901	\$ 231,163
Interest income	(5,687)	(4,049)
Interest expense, net	<u>\$ 373,214</u>	<u>\$ 227,114</u>

Interest expense in 2015 totaled \$378.9 million compared to \$231.2 million in 2014. This increase was primarily attributable to an increase in our average total indebtedness to \$6.6 billion in 2015 from \$4.3 billion in 2014.

**Loss on extinguishment of debt.** Loss on extinguishment of debt totaled \$67.5 million in 2015 compared to \$31.8 million in 2014. These amounts relate to our various debt-related transactions in 2015 and 2014. See Note 13. Debt of the Consolidated Financial Statements of Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

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

	2015	2014
Net gain on sale of certain early-stage drug discovery and development assets	\$ —	\$ (5,200)
Foreign currency gain, net	(23,058)	(10,054)
Equity loss (earnings) from unconsolidated subsidiaries, net	3,217	(8,325)
Other than temporary impairment of equity investment	18,869	—
Legal settlement	(12,500)	—
Costs associated with unused financing commitments	78,352	—
Other miscellaneous	(1,189)	(8,745)
Other expense (income), net	<u>\$ 63,691</u>	<u>\$ (32,324)</u>

Fluctuations in foreign currency rates are primarily driven by our increased global presence subsequent to the acquisitions of Paladin and Somar as well as foreign currency rate movements. In 2015, the Company recognized an other than temporary impairment of our Litha joint venture investment totaling \$18.9 million, reflecting the excess carrying value of this investment over its estimated fair value. In addition, the Company incurred \$78.4 million during 2015 related to unused commitment fees primarily associated with financing for the Par acquisition.

**Income tax (benefit) expense.** In 2015, we recognized an income tax benefit of \$1,137.5 million on \$1,437.9 million of loss from continuing operations before income tax, compared to \$38.3 million of tax expense on \$99.9 million of income from continuing operations before income tax in 2014. The effective income tax rate was 79.1% in benefit on the current period loss from continuing operations before income tax in 2015, compared to an effective income tax rate of 38.3% in expense on income from continuing operations before income tax in 2014. 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 earned in those various jurisdictions. It is also impacted by discrete items that may occur in any given year, but are not consistent from year to year and may not be indicative of our on-going operations. 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:

#### 2015

- \$674.2 million net tax benefit or a 46.9% rate benefit associated with a worthless stock deduction.
- \$359.5 million net tax benefit or a 25.0% rate benefit associated with our geographical mix of earnings. No provision has been made for Irish taxes, as the majority of our undistributed foreign earnings are intended to be permanently reinvested outside of Ireland.
- \$278.3 million tax expense or 19.4% rate charge resulting from the non-deductible portion of the impaired goodwill.
- \$111.9 million tax benefit or a 7.8% rate benefit associated with the recognition of an outside basis difference.

#### 2014

- \$52.5 million net tax benefit or a 52.3% rate benefit associated with our geographical mix of earnings. No provision has been made for Irish taxes, as the majority of our undistributed foreign earnings are intended to be permanently reinvested outside of Ireland.
- \$16.3 million tax expense or a 16.4% rate charge associated with the Health Care Reform Act.

- \$15.4 million tax expense or a 15.4% rate charge associated with the excise tax incurred in connection with our business combination with Paladin.
- \$10.1 million tax expense or a 10.1% rate charge associated with U.S. state income taxes net of the U.S. federal tax benefit.
- \$5.9 million tax expense or a 5.9% rate charge associated with the non-deductible portion of our acquisition costs. These costs are related to our business combination with Paladin and our acquisition of Somar.
- \$5.5 million tax expense or a 5.4% rate charge associated with the loss of our domestic manufacturing deduction benefit pursuant to our 2014 U.S. net operating loss carryback claim.

For additional information on our income taxes, see Note 19. Income Taxes of the Consolidated Financial Statements of Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

**Discontinued operations, net of tax.** As a result of our decision to sell our AMS business, which comprises the entirety of our former Devices segment, as well as our February 2014 sale of our HealthTronics business, the operating results of these businesses are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented. The results of our discontinued operations totaled \$1,194.9 million of loss, net of tax, in 2015 compared to \$779.8 million of loss, net of tax, in 2014.

The fluctuation in Discontinued operations in 2015 compared to 2014 was mainly related to a decrease in income tax benefit of \$282.7 million, an increase in impairment charges of \$230.7 million and a decrease in income from operations due to the sale of the Men's Health and Prostate Health components. The decrease in income tax expense benefit relates to the tax impact of the underlying differences between book and tax basis of the underlying assets sold as part of the transaction. These fluctuations were partially offset by a decrease in expense associated with mesh-related product liability claimants of \$165.6 million and a gain on the sale of the Men's Health and Prostate Health components of approximately \$13.6 million in 2015.

For additional information on discontinued operations, see Note 3. Divestitures of the Consolidated Financial Statements of Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

**Net (loss) income attributable to noncontrolling interests.** The Company historically owned majority controlling interests in certain entities through HealthTronics and its subsidiaries and Paladin and its subsidiaries, including Litha. In February 2015, the Company acquired substantially all of Litha's remaining outstanding ordinary share capital that it did not own for consideration of approximately \$40 million. Additionally, prior to the sale of our HealthTronics business in February 2014, HealthTronics, Inc. owned interests in various partnerships and limited liability corporations (LLCs) where HealthTronics, Inc., as the general partner or managing member, exercised effective control. In accordance with the accounting consolidation principles, we consolidated various entities which neither we nor our subsidiaries owned 100%. Net (loss) income attributable to noncontrolling interests relates to the portion of the net income of these entities not attributable, directly or indirectly, to our ownership interests. The Company recognized \$0.3 million of loss in 2015 compared to \$3.1 million of income in 2014 as a result of the HealthTronics and Paladin transactions mentioned above.

### **2016 Outlook**

We estimate that our 2016 total revenues will be between \$4.32 billion and \$4.52 billion. This estimate is based on our expectation of growth for company revenues from our core products and the full year impact of our 2015 acquisitions, including our acquisition of Par, which closed on September 25, 2015. We consistently apply our lean operating model principles to streamline general and administrative expenses, optimize commercial spend and focus research and development efforts onto lower-risk projects and higher-return investments to Endo's current business and in the identification of value-creation from strategic acquisitions. The Company also intends to seek growth both internally and through acquisitions in order to support its objective of transforming Endo into a leading global specialty pharmaceuticals company. There can be no assurance that the Company will achieve these results.

### **Year Ended December 31, 2014 Compared to Year Ended December 31, 2013**

**Revenues.** Revenues in 2014 increased 12% to \$2,380.7 million from 2013. This revenue increase was primarily attributable to growth in our U.S. Generic Pharmaceuticals segment and revenues related to our February 2014 acquisition of Paladin and July 2014 acquisition of Somar. The increases were partially offset by decreased revenues from our U.S. Branded Pharmaceuticals segment, driven mainly by decreased Lidoderm® revenues related to generic competition. A discussion of revenues by reportable segment is included below under the caption "Business Segment Results Review."

**Gross margin, costs and expenses.** The following table sets forth costs and expenses for the years ended December 31 (dollars in thousands):

	2014		2013	
	\$	% of Revenue	\$	% of Revenue
Cost of revenues	\$ 1,231,497	52	\$ 886,603	42
Selling, general and administrative	567,986	24	574,313	27
Research and development	112,708	5	97,465	5
Litigation-related and other contingencies, net	42,084	2	9,450	—
Asset impairment charges	22,542	1	32,011	2
Acquisition-related and integration items	77,384	3	7,614	—
Total costs and expenses*	\$ 2,054,201	86	\$ 1,607,456	76

\* Percentages may not add due to rounding.

**Cost of revenues and gross margin.** Cost of revenues in 2014 increased 39% to \$1,231.5 million from 2013. This increase was primarily attributable to increased net sales, primarily in the generic pharmaceutical business. Gross margins in 2014 decreased to 48% from 58% in 2013. These decreases were primarily attributable to growth in lower margin generic pharmaceutical product sales, increased intangible amortization and inventory step-up amortization as a result of recent acquisitions and a decline in higher margin branded pharmaceutical product sales due to generic competition on certain products.

**Selling, general and administrative expenses.** Selling, general and administrative expenses in 2014 decreased 1% to \$568.0 million from 2013. The decrease in 2014 was primarily attributable to cost savings resulting from ongoing cost reduction initiatives and a decrease in severance expense related to the June 2013 restructuring initiative, partially offset by \$54.3 million in expense for the reimbursement of directors' and certain employee's excise tax liabilities pursuant to Section 4985 of the Internal Revenue Code, which were approved by the Company's shareholders on February 26, 2014. These liabilities resulted from the shareholder gain from the merger between Endo and Paladin. In addition, Selling, general and administrative expenses increased as a result of the acquisitions of Paladin, Boca, Sumavel, Somar and DAVA.

**Research and development expenses.** Research and development (R&D) expenses in 2014 increased 16% to \$112.7 million from 2013. The following table presents the composition of our total R&D expense for the years ended December 31:

	Research and Development Expense (in thousands)	
	2014	2013
U.S. Branded Pharmaceuticals portfolio	\$ 64,764	\$ 41,461
U.S. Generic Pharmaceuticals portfolio	32,060	15,530
International Pharmaceuticals portfolio	6,238	—
Enterprise-wide R&D costs	9,646	40,474
Total R&D expense	\$ 112,708	\$ 97,465

The increase in 2014 was primarily driven by \$10.0 million of milestone charges incurred during each of the first, second and fourth quarters of 2014 related to the achievement of certain BEMA<sup>®</sup> Buprenorphine HCl Buccal film clinical and regulatory milestones and an increase in expenses related to generic pharmaceutical products, partially offset by decreases to other branded pharmaceutical product expenses as we focused our efforts on a limited number of key products in development.

As part of the Company's broader strategic, operational and organizational steps announced in June 2013, U.S. Branded Pharmaceuticals R&D efforts were refocused on progressing late-stage pipeline and maximizing value of marketed products. As a result, the Company's branded pharmaceutical drug discovery platform was sold to Asana Biosciences on June 2, 2014. In addition, on November 4, 2014 we sold most of the assets and intellectual property of our second generation implantable drug technology to Braeburn Pharmaceuticals, excluding the existing implant platform used for our two marketed histrelin-containing products, Vantas<sup>®</sup> and Supprelin<sup>®</sup>.

In 2014 and 2013, the Company's direct R&D expense related to generics totaled \$32.1 million and \$15.5 million, respectively. The increase in expense was a result of the growth in the Company's investment in generic pharmaceuticals R&D.

**Litigation-related and other contingencies, net.** Charges for Litigation-related and other contingencies, net in 2014 totaled \$42.1 million, compared to \$9.5 million in 2013. These amounts mainly relate to legal proceedings and other contingent matters, which are described in more detail in Note 14. Commitments and Contingencies of the Consolidated Financial Statements of Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".



**Asset impairment charges.** There were \$22.5 million of Asset impairment charges in 2014 compared to \$32.0 million in 2013.

The amounts incurred during 2014 related primarily to a charge of \$12.3 million to fully impair a license intangible asset related to OPANA® ER as well as charges of \$4.3 million to completely write off certain miscellaneous property, plant and equipment. These impairment charges were recorded because the Company determined the carrying amounts of these assets were no longer recoverable.

The amounts incurred during 2013 related primarily to \$17.0 million and \$6.0 million of asset impairment charges related to the write off of certain Qualitest and AMS IPR&D assets, respectively.

**Acquisition-related and integration items.** Acquisition-related and integration items in 2014 totaled \$77.4 million in expense compared to \$7.6 million in expense in 2013. This increase was primarily due to costs associated with our acquisitions during 2014 and 2014 acquisition-related costs associated with our acquisition of Auxilium, which was acquired on January 29, 2015.

**Interest expense, net.** The components of Interest expense, net in 2014 and 2013 are as follows (in thousands):

	2014	2013
Interest expense	\$ 231,163	\$ 174,933
Interest income	(4,049)	(1,327)
Interest expense, net	<u>\$ 227,114</u>	<u>\$ 173,606</u>

Interest expense in 2014 totaled \$231.2 million compared to \$174.9 million in 2013. This increase was primarily due to increases in our average total indebtedness to \$4.3 billion in 2014 from \$3.2 billion in 2013.

**Loss on extinguishment of debt.** Loss on extinguishment of debt totaled \$31.8 million in 2014 compared to \$11.3 million in 2013. These amounts relate to our various debt-related transactions in 2014 and 2013. See Note 13. Debt of the Consolidated Financial Statements of Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules" for further discussion of our indebtedness and the transactions leading to these charges.

**Other income, net.** The components of Other income, net in 2014 and 2013 are as follows (in thousands):

	2014	2013
Watson litigation settlement income, net	\$ —	\$ (50,400)
Net gain on sale of certain early-stage drug discovery and development assets	(5,200)	—
Foreign currency gain, net	(10,054)	(21)
Equity loss (earnings) from unconsolidated subsidiaries, net	(8,325)	(1,482)
Other miscellaneous	(8,745)	(1,156)
Other expense (income), net	<u>\$ (32,324)</u>	<u>\$ (53,059)</u>

Fluctuations in foreign currency rates are primarily driven by our increased global presence subsequent to the acquisitions of Paladin and Somar as well as foreign currency rate movements in 2014. Royalty income from Allergan, under the terms of the Watson Settlement Agreement, based on Allergan's gross profit generated on sales of its generic version of Lidoderm®, which commenced on September 16, 2013 and ceased in May 2014, upon Endo's launch of its Lidoderm® authorized generic by the U.S. Generic Pharmaceuticals business.

**Income tax.** In 2014, we recognized income tax expense of \$38.3 million on \$99.9 million of income from continuing operations before income tax, compared to \$143.7 million of tax expense on \$385.4 million of income from continuing operations before income tax in 2013. The effective income tax rate was 38.3% in expense on the current period income from continuing operations before income tax in 2014, compared to an effective income tax rate of 37.3% in expense on income from continuing operations before income tax in 2013. The decrease in tax expense for the current period is primarily related to a decrease in income from continuing operations before income tax as compared to the comparable prior period and tax benefits from our foreign operations in the current period. For additional information on our income taxes, see Note 19. Income Taxes of the Consolidated Financial Statements of Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

**Discontinued operations, net of tax.** As a result of the Company's decision to sell our AMS business, as well as our February 2014 sale of our HealthTronics business, the operating results of these businesses are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented. The results of our discontinued operations totaled \$779.8 million of loss, net of tax, in 2014 compared to \$874.0 million of loss, net of tax, in 2013. In 2014, there was a pre-tax increase in our charges for mesh product liability of approximately \$798.6 million compared to 2013, which is described in more detail in Note 14. Commitments and Contingencies of the Consolidated Financial Statements of Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules". There were pre-tax asset impairment charges of \$648.2 million recorded in 2013 related to the HealthTronics and AMS reporting units' goodwill and other assets which did not reoccur in 2014. Additionally, taxes associated with our HealthTronics and AMS businesses changed favorably on a combined basis, primarily driven by the pre-tax impacts described above.

For additional information on discontinued operations, see Note 3. Divestitures of the Consolidated Financial Statements of Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

**Net income attributable to noncontrolling interests.** Net income attributable to noncontrolling interests totaled \$3.1 million of income in 2014 compared to \$52.9 million of income in 2013. This fluctuation from 2013 related primarily to a partial period of HealthTronics results in 2014, as the HealthTronics business was sold on February 3, 2014. This compared to a full period in 2013. Net income attributable to noncontrolling interests related to Paladin and its subsidiaries was not material to the Consolidated Financial Statements.

### **Business Segment Results Review**

As a result of the Company's first quarter 2015 announcement of its plan to sell its AMS business, the results of our former Devices segment are included in Discontinued operations, net of tax in our Consolidated Statements of Operations. The three reportable business segments in which the Company now operates are: (1) U.S. Branded Pharmaceuticals, (2) U.S. Generic Pharmaceuticals and (3) International Pharmaceuticals. These segments reflect the level at which executive management 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 (loss) from continuing operations before income tax, a financial measure not determined in accordance with U.S. GAAP, which we define as (loss) income from continuing operations before income tax before certain upfront and milestone payments to partners; acquisition-related and integration items, including transaction costs, earn-out payments or adjustments, changes in the fair value of contingent consideration and bridge financing costs; 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; excess costs that will be eliminated pursuant to integration plans; asset impairment charges; amortization of intangible assets; inventory step-up recorded as part of our acquisitions; certain non-cash interest expense; litigation-related and other contingent matters; gains or losses from early termination of debt activities; foreign currency gains or losses on intercompany financing arrangements; and certain other items that the Company believes do not reflect its core operating performance.

Certain of the corporate general and administrative 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, including interest expense. 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 costs.

We refer to adjusted income (loss) from continuing operations before income tax in making operating decisions because we believe it provides meaningful supplemental information regarding the Company's operational performance. For instance, we believe that this measure facilitates its internal comparisons to our historical operating results and comparisons to competitors' results. The Company believes this measure is useful to investors in allowing for greater transparency related to supplemental information used in our financial and operational decision-making. In addition, we have historically reported similar financial measures to our investors and believe that the inclusion of comparative numbers provides consistency in our current financial reporting. Further, we believe that adjusted income (loss) from continuing operations before income tax may be useful to investors as we are aware that certain of our significant shareholders utilize adjusted income (loss) from continuing operations before income tax to evaluate our financial performance. Finally, adjusted income (loss) from continuing operations before income tax is utilized in the calculation of adjusted diluted income per share, which is 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 (loss) from continuing operations before income tax. Other companies in our industry may define adjusted income (loss) from continuing operations before income tax differently than we do. As a result, it may be difficult to use adjusted income (loss) 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 (loss) from continuing operations before income tax should not be considered as a measure of the income generated by our business or discretionary cash available to us to invest in the growth of our business. The Company compensates for these limitations by providing reconciliations of our segment adjusted income from continuing operations before income tax to our consolidated (loss) income 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 (dollars in thousands):

	2015		2014	
	\$	% of Revenue	\$	% of Revenue
<b>Net revenues to external customers:</b>				
U.S. Branded Pharmaceuticals	\$ 1,284,607	39	\$ 969,437	41
U.S. Generic Pharmaceuticals	1,672,416	51	1,140,821	48
International Pharmaceuticals (1)	311,695	10	270,425	11
<b>Total net revenues to external customers</b>	<b>\$ 3,268,718</b>	<b>100</b>	<b>\$ 2,380,683</b>	<b>100</b>

(1) Revenues generated by our International Pharmaceuticals segment are primarily attributable to Canada, Mexico and South Africa.

*U.S. Branded Pharmaceuticals.* The following table displays the significant components of our U.S. Branded Pharmaceuticals revenues to external customers for the years ended December 31 (in thousands):

	2015	2014
<b>Pain Management:</b>		
Lidoderm®	\$ 125,269	\$ 157,491
OPANA® ER	175,772	197,789
Percocet®	135,822	122,355
Voltaren® Gel	207,161	179,816
	<b>\$ 644,024</b>	<b>\$ 657,451</b>
<b>Specialty Pharmaceuticals:</b>		
Supprelin® LA	\$ 70,099	\$ 66,710
XIAFLEX®	158,115	—
	<b>\$ 228,214</b>	<b>\$ 66,710</b>
<b>Urology:</b>		
Fortesta® Gel, including Authorized Generic	\$ 52,827	\$ 58,661
Testim®, including Authorized Generic	40,763	—
	<b>\$ 93,590</b>	<b>\$ 58,661</b>
<b>Branded Other Revenues</b>		
	318,779	135,287
Actavis Royalty	—	51,328
<b>Total U.S. Branded Pharmaceuticals</b>	<b>\$ 1,284,607</b>	<b>\$ 969,437</b>

*Pain Management*

Net sales of Lidoderm® in 2015 decreased 20% to \$125.3 million from 2014. Net sales were negatively impacted by the September 16, 2013 launch of Actavis's (now Allergan) lidocaine patch 5%, a generic form of Lidoderm®, the May 2014 launch by the Company's U.S. Generic Pharmaceuticals of its authorized generic of Lidoderm® and the August 2015 generic launch by Mylan. To the extent additional competitors are able to launch generic versions of Lidoderm®, our revenues could decline.

Net sales of OPANA® ER in 2015 decreased 11% to \$175.8 million from 2014. Net sales continue to be impacted by competing generic versions of the non-crush resistant formulation of OPANA® ER, which launched beginning in early 2013. To the extent additional competitors are able to launch generic versions of the non-crush resistant formulation OPANA® ER, our revenues could decline further. However, in August 2015 the U.S. District Court issued a ruling upholding two of the Company's patents covering OPANA® ER. As a result, it is expected that the generic version of non-crush resistant OPANA® ER currently sold by Allergan will be removed from the market and additional approved but not yet marketed generic versions of the product developed by other generic companies will not be launched in the near term.

Net sales of Percocet® in 2015 increased 11% to \$135.8 million from 2014. This increase was attributable to price increases.

Net sales of Voltaren® Gel in 2015 increased 15% to \$207.2 million from 2014. This increase was primarily attributable to volume increases resulting from increased promotional activities and price increases. Subject to FDA approval, it is possible one or more competing generic products could potentially enter the market during 2016, which could negatively impact future sales of Voltaren® Gel.

#### Specialty Pharmaceuticals

Net sales of Supprelin® LA in 2015 increased 5% to \$70.1 million from 2014. This revenue increase was primarily attributable to price increases.

Net sales of XIAFLEX® for the treatment of Peyronie's disease and Dupuytren's contracture for the period from January 29, 2015 to December 31, 2015 were \$158.1 million and were the result of the acquisition of Auxilium.

#### Urology

Net sales of Fortesta® Gel, including Authorized Generic in 2015, decreased 10% to \$52.8 million from 2014. This decrease was primarily attributable to reduced volume of branded Fortesta® Gel sales, partially offset by the launch of the authorized generic in September 2014.

Net sales of Testim®, including Authorized Generic for the period from January 29, 2015 to December 31, 2015 were \$40.8 million and were the result of the acquisition of Auxilium.

#### Branded Other

Net sales of Branded Other products in 2015 increased 136% to \$318.8 million from 2014. This increase was primarily attributable to the acquisitions of Sumavel®, Auxilium and Par which we acquired in May 2014, January 2015 and September 2015, respectively, and the launch of Aveed® in March 2014.

#### Actavis Royalty

Actavis, formerly known as Watson Pharmaceuticals, Inc. (Watson), royalty revenue decreased to zero in 2015 from 2014. This decrease was related to a decrease in royalty income from Actavis, under the terms of the Watson Settlement Agreement, based on Actavis' gross profit generated on sales of its generic version of Lidoderm®, which commenced on September 16, 2013 and ceased in May 2014, upon our launch of the Lidoderm® authorized generic.

*U.S. Generic Pharmaceuticals.* Net sales of our generic products in 2015 increased 47% to \$1,672.4 million from 2014. This increase was primarily attributable to an additional \$382.7 million of revenue due to the acquisition of Par. In addition, the Generics business benefited from new product launches, an increase in demand for generic pain products and certain sales incentives offered to customers in the fourth quarter of 2015 in anticipation of additional competitive entrants expected in early 2016. This benefit was partially offset by increased pricing pressures due to increased competition across pain and commoditized products within the legacy Qualitest business.

*International Pharmaceuticals.* Revenues from our International Pharmaceuticals segment in 2015 increased 15% to \$311.7 million from 2014 mainly as a result of a full year of revenues from Somar, which we acquired in July 2014.

**Adjusted income (loss) from continuing operations before income tax.** The following table displays our adjusted income (loss) from continuing operations before income tax by reportable segment for the years ended December 31 (in thousands):

	2015	2014
Adjusted income (loss) from continuing operations before income tax:		
U.S. Branded Pharmaceuticals	\$ 694,440	\$ 529,507
U.S. Generic Pharmaceuticals	\$ 741,767	\$ 464,029
International Pharmaceuticals	\$ 81,789	\$ 80,683
Corporate unallocated	\$ (544,456)	\$ (355,417)

During the quarter ended December 31, 2015, we realigned certain costs between our International Pharmaceuticals segment, U.S. Branded Pharmaceuticals segment and corporate unallocated costs based on how our chief operating decision maker currently reviews segment performance. As a result of this realignment, certain expenses included in our consolidated adjusted income (loss) from continuing operations before income tax for the nine months ended September 30, 2015 have been reclassified among our various segments to conform to current period presentation. The net impact of these reclassification adjustments was to increase U.S. Branded Pharmaceuticals segment and corporate unallocated costs by \$1.7 million and \$21.1 million, respectively, with an offsetting \$22.8 million decrease to International Pharmaceuticals segment costs. The realignment of these expenses did not impact periods prior to 2015.

*U.S. Branded Pharmaceuticals.* Adjusted income from continuing operations before income tax in 2015 increased 31% to \$694.4 million from 2014. This increase was primarily attributable to the acquisition of Auxilium and the resulting incremental adjusted income from continuing operations before income tax.

*U.S. Generic Pharmaceuticals.* Adjusted income from continuing operations before income tax in 2015 increased 60% to \$741.8 million from 2014. In 2015, revenues and gross margins increased primarily due to the DAVA and Par acquisitions and the resulting incremental adjusted income from continuing operations before income tax. In addition, adjusted income from continuing operations before income tax increased as a result of new product launches and an increase in demand for generic pain products.

*International Pharmaceuticals.* Adjusted income from continuing operations before income tax in 2015 increased 1% to \$81.8 million from 2014. This increase was primarily attributable to the acquisition of Somar and the resulting incremental adjusted income from continuing operations before income tax, partially offset by increased operating expenses associated with the expansion of our global operations.

*Corporate unallocated.* Corporate unallocated adjusted loss from continuing operations before income tax in 2015 increased 53% to \$544.5 million from 2014. This increase was primarily attributable to the previously discussed increase in interest expense.

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

	2015	2014
Total segment adjusted income from continuing operations before income tax:	\$ 1,517,996	\$ 1,074,219
Corporate unallocated costs (1)	(544,456)	(355,417)
Upfront and milestone payments to partners	(16,155)	(51,774)
Asset impairment charges (2)	(1,140,709)	(22,542)
Acquisition-related and integration items (3)	(105,250)	(77,384)
Separation benefits and other cost reduction initiatives (4)	(125,407)	(25,760)
Excise tax (5)	—	(54,300)
Amortization of intangible assets	(561,302)	(218,712)
Inventory step-up and certain manufacturing costs that will be eliminated pursuant to integration plans	(249,464)	(65,582)
Non-cash interest expense related to the 1.75% Convertible Senior Subordinated Notes	(1,633)	(12,192)
Loss on extinguishment of debt	(67,484)	(31,817)
Certain litigation-related charges, net (6)	(37,082)	(42,084)
Costs associated with unused financing commitments	(78,352)	—
Acceleration of Auxilium employee equity awards at closing	(37,603)	—
Charge related to the non-recoverability of certain non-trade receivables	—	(10,000)
Net gain on sale of certain early-stage drug discovery and development assets	—	5,200
Other than temporary impairment of equity investment	(18,869)	—
Foreign currency impact related to the remeasurement of intercompany debt instruments	25,121	13,153
Charge for an additional year of the branded prescription drug fee in accordance with IRS regulations issued in the third quarter of 2014	(3,079)	(24,972)
Other, net	5,864	(161)
Total consolidated (loss) income from continuing operations before income tax	\$ (1,437,864)	\$ 99,875

(1) Corporate unallocated costs include certain corporate overhead costs, interest expense, net, and certain other income and expenses.

(2) Asset impairment charges primarily related to charges to write down goodwill and intangible assets as further described in Note 10. Goodwill and Other Intangibles.

(3) Acquisition-related and integration-items include costs directly associated with the closing of certain acquisitions of \$170.9 million in 2015 compared to \$77.4 million in 2014. In 2015, these costs were net of a benefit due to changes in the fair value of contingent consideration of \$65.6 million, respectively.

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(4) Separation benefits and other cost reduction initiatives include employee separation costs of \$60.2 million, \$14.4 million and \$35.2 million in 2015, 2014 and 2013, respectively. Other amounts in 2015 primarily consist of \$41.2 million of inventory write-offs and \$13.3 million of building costs, including a \$7.9 million charge recorded upon the cease use date of our Auxilium subsidiary's former corporate headquarters. Amounts in 2014 primarily consisted of employee separation costs and changes in estimates related to certain cost reduction initiative accruals. These amounts were primarily recorded as Selling, general and administrative expense in our Consolidated Statements of Operations. See Note 4. Restructuring for discussion of our material restructuring initiatives.

(5) This amount represents charges related to the expense for the reimbursement of directors' and certain employees' excise tax liabilities pursuant to Section 4985 of the Internal Revenue Code.

(6) These amounts include charges for Litigation-related and other contingencies, net as further described in Note 14. Commitments and Contingencies.

**Revenues.** The following table displays our revenue by reportable segment for the years ended December 31 (dollars in thousands):

	2014		2013	
	\$	% of Revenue	\$	% of Revenue
Net revenues to external customers:				
U.S. Branded Pharmaceuticals	\$ 969,437	41	\$ 1,394,015	66
U.S. Generic Pharmaceuticals	1,140,821	48	730,666	34
International Pharmaceuticals (1)	270,425	11	—	—
<b>Total net revenues to external customers</b>	<b>\$ 2,380,683</b>	<b>100</b>	<b>\$ 2,124,681</b>	<b>100</b>

(1) Revenues generated by our International Pharmaceuticals segment are primarily attributable to Canada, Mexico and South Africa.

**U.S. Branded Pharmaceuticals.** The following table displays the significant components of our U.S. Branded Pharmaceuticals revenues to external customers for the years ended December 31 (in thousands):

	2014	2013
<b>Pain Management</b>		
Lidoderm®	\$ 157,491	\$ 602,998
OPANA® ER	197,789	227,878
Percocet®	122,355	105,814
Voltaren® Gel	179,816	170,841
	<u>\$ 657,451</u>	<u>\$ 1,107,531</u>
<b>Specialty Pharmaceuticals</b>		
Supprelin® LA	\$ 66,710	\$ 58,334
<b>Urology</b>		
Fortesta® Gel, including Authorized Generic	\$ 58,661	\$ 65,860
<b>Branded Other Revenues</b>	<b>135,287</b>	<b>99,525</b>
Actavis Royalty	51,328	62,765
<b>Total U.S. Branded Pharmaceuticals</b>	<b>\$ 969,437</b>	<b>\$ 1,394,015</b>

\* Percentages may not add due to rounding.

**Pain Management**

Net sales of Lidoderm® in 2014 decreased 74% to \$157.5 million from 2013. Net sales were negatively impacted by the September 16, 2013 launch of Actavis's (now Allergan) lidocaine patch 5%, a generic version of Lidoderm®. In May 2014, the Company's U.S. Generic Pharmaceuticals segment launched its authorized generic of Lidoderm®.

Net Sales of OPANA<sup>®</sup> ER in 2014 decreased 13% to \$197.8 million from 2013. Net sales were negatively impacted by competing generic versions of the non-crush-resistant formulation OPANA<sup>®</sup> ER, which launched beginning in early 2013.

Net sales of Percocet<sup>®</sup> in 2014 increased 16% to \$122.4 million from 2013. This increase was primarily attributable to price increases, partially offset by reduced volumes.

Net Sales of Voltaren<sup>®</sup> Gel in 2014 increased 5% to \$179.8 million from 2013. This increase was primarily attributable to increased volumes resulting from an increased sales and marketing emphasis on the product.

#### *Specialty Pharmaceuticals*

Net sales of Supprelin<sup>®</sup> LA in 2014 increased 14% to \$66.7 million from 2013. This revenue increase was primarily attributable to price increases.

#### *Urology*

Net sales of Fortesta<sup>®</sup> Gel, including Authorized Generic in 2014 decreased 11% to \$58.7 million from 2013. This decrease was primarily attributable to reduced volume of branded Fortesta<sup>®</sup> Gel sales, partially offset by the launch of the authorized generic in September 2014.

#### *Branded Other*

Net sales of other branded products in 2014 increased 36% to \$135.3 million from 2013. The increase in 2014 was primarily attributable to sales of Sumavel<sup>®</sup>, which was acquired in May 2014, and increased revenues from Frova<sup>®</sup>.

#### *Actavis Royalty*

Actavis royalty revenue in 2014 decreased 18% to \$51.3 million from 2013. This decrease was related to a decrease in royalty income from Actavis, under the terms of the Watson Settlement Agreement, based on Actavis' gross profit generated on sales of its generic version of Lidoderm<sup>®</sup>, which royalty commenced on September 16, 2013 and ceased in May 2014, upon our launch of the Lidoderm<sup>®</sup> authorized generic.

*U.S. Generic Pharmaceuticals.* Net sales of our generic products in 2014 increased 56% to \$1,140.8 million from 2013. This increase was primarily attributable to \$176.0 million of revenue due to the May 2014 launch of our authorized generic of Lidoderm<sup>®</sup>; \$101.8 million of revenue due to the acquisition of Boca, which we acquired in February 2014 and \$46.6 million in revenue due to the acquisition of DAVA, which we acquired in August 2014.

*International Pharmaceuticals.* Revenues from our International Pharmaceuticals segment in 2014 relate to the revenues of Paladin, which we acquired in February 2014, and Somar, which we acquired in July 2014.

**Adjusted income (loss) from continuing operations before income tax.** The following table displays our adjusted income (loss) from continuing operations before income tax by reportable segment for the years ended December 31 (in thousands):

	2014	2013
Adjusted income (loss) from continuing operations before income tax:		
U.S. Branded Pharmaceuticals	\$ 529,507	\$ 783,927
U.S. Generic Pharmaceuticals	\$ 464,029	\$ 193,643
International Pharmaceuticals	\$ 80,683	\$ —
Corporate unallocated	\$ (355,417)	\$ (315,743)

*U.S. Branded Pharmaceuticals.* Adjusted income from continuing operations before income tax in 2014 decreased 32% to \$529.5 million from 2013. This decrease was primarily attributable to decreased revenues, partially offset by cost reductions realized in connection with the June 2013 restructuring initiative and other cost reduction initiatives.

*U.S. Generic Pharmaceuticals.* Adjusted income from continuing operations before income tax in 2014 increased 140% to \$464.0 million from 2013. In 2014, revenues and gross margins increased primarily due to the Boca and DAVA acquisitions, the May 2014 launch of our authorized generic of Lidoderm<sup>®</sup> and certain pricing increases.

*International Pharmaceuticals.* Adjusted income from continuing operations before income tax from our International Pharmaceuticals segment in 2014 related to the results of Paladin, which we acquired in February 2014, and Somar, which we acquired in July 2014.

*Corporate unallocated.* Corporate unallocated adjusted loss from continuing operations before income tax in 2014 increased 13% to \$355.4 million from 2013. This increase in the loss was primarily attributable to the previously discussed increase in interest expense, partially offset by decreased operating expenses, primarily resulting from the June 2013 restructuring initiative and other cost reduction initiatives.

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

	2014	2013
Total segment adjusted income from continuing operations before income tax:	\$ 1,074,219	\$ 977,570
Corporate unallocated costs (1)	(355,417)	(315,743)
Upfront and milestone payments to partners	(51,774)	(29,703)
Asset impairment charges	(22,542)	(32,011)
Acquisition-related and integration items (2)	(77,384)	(7,614)
Separation benefits and other cost reduction initiatives (3)	(25,760)	(91,530)
Excise tax (4)	(54,300)	—
Amortization of intangible assets	(218,712)	(123,547)
Inventory step-up and certain manufacturing costs that will be eliminated pursuant to integration plans	(65,582)	—
Non-cash interest expense related to the 1.75% Convertible Senior Subordinated Notes	(12,192)	(22,742)
Loss on extinguishment of debt	(31,817)	(11,312)
Watson litigation settlement income, net	—	50,400
Certain litigation-related charges, net (5)	(42,084)	(9,450)
Charge related to the non-recoverability of certain non-trade receivables	(10,000)	—
Net gain on sale of certain early-stage drug discovery and development assets	5,200	—
Foreign currency impact related to the remeasurement of intercompany debt instruments	13,153	—
Charge for an additional year of the branded prescription drug fee in accordance with IRS regulations issued in the third quarter of 2014	(24,972)	—
Other, net	(161)	1,048
Total consolidated income from continuing operations before income tax	<u>\$ 99,875</u>	<u>\$ 385,366</u>

- (1) Corporate unallocated costs include certain corporate overhead costs, interest expense, net, and certain other income and expenses.
- (2) Acquisition-related and integration-items include costs directly associated with the closing of certain acquisitions, changes in the fair value of contingent consideration and the costs of integration activities related to both current and prior period acquisitions.
- (3) Separation benefits and other cost reduction initiatives include employee separation costs of \$14.4 million in 2014 compared to \$35.2 million in 2013. Amounts in 2014 included changes in estimates related to certain cost reduction initiative accruals. Contract termination fees of \$5.8 million in 2013 are also included in this amount. The amount of separation benefits and other cost reduction initiatives in 2013 includes an expense recorded upon the cease use date of our Chadds Ford, Pennsylvania and Westbury, New York properties in the first quarter of 2013, representing the liability for our remaining obligations under the respective lease agreements of \$7.2 million. These expenses were primarily recorded as Selling, general and administrative and Research and development expense in our Consolidated Statements of Operations. See Note 4. Restructuring of the Consolidated Financial Statements included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules" for discussion of our material restructuring initiatives.
- (4) This amount represents charges related to the expense for the reimbursement of directors' and certain employees' excise tax liabilities pursuant to Section 4985 of the Internal Revenue Code.
- (5) These amounts include charges for Litigation-related and other contingencies, net as further described in Note 14. Commitments and Contingencies.

## LIQUIDITY AND CAPITAL RESOURCES

Our principal source of liquidity is cash generated from operations. Our principal liquidity requirements are for working capital for operations, acquisitions, licenses, milestone payments, capital expenditures and debt service payments. The Company's working capital was \$0.8 million at December 31, 2015 compared to \$1,946.1 million at December 31, 2014. The decrease related to cash used to fund the Par and Auxilium acquisitions, mesh settlement charges, cash used to redeem the 7.00% Senior Notes due 2019, cash used to redeem the 7.00% Senior Notes due 2020, the reclassification of deferred tax assets from current to non-current upon the adoption of ASU 2015-17 in December 2015, cash used for share repurchases, cash used for deferred financing costs and cash used for the purchases of property, plant and equipment. This decrease was partially offset by cash received, net of fees, from the equity and debt issuances to finance the Par, Auxilium and Aspen Holdings acquisitions, working capital acquired in the Par and Auxilium acquisitions and cash from the exercise of options. Working capital at December 31, 2015 includes restricted cash and cash equivalents of \$579.0



million held in Qualified Settlement Funds for mesh product liability settlement agreements, which is expected to be paid to qualified claimants within the next twelve months. Working capital at December 31, 2014 included restricted cash and cash equivalents of \$485.2 million held in Qualified Settlement Funds for mesh product liability settlement agreements.

We have historically had broad access to financial markets that provide liquidity. Cash and cash equivalents, which primarily consisted of bank deposits, time deposits and money market accounts, totaled \$272.3 million at December 31, 2015 compared to \$405.7 million at December 31, 2014.

In 2016, we expect cash generated from operations together with our cash, cash equivalents and the revolving credit facilities to be sufficient to cover cash needs for working capital and general corporate purposes, certain contingent liabilities, payment of contractual obligations, principal and interest payments on our indebtedness, capital expenditures, ordinary share repurchases and any regulatory and/or sales milestones that may become due.

Beyond 2016, we expect cash generated from operations together with our cash, cash equivalents and the revolving credit facilities to continue to be sufficient to cover cash needs for working capital and general corporate purposes, certain contingent liabilities, payment of contractual obligations, principal and interest payments on our indebtedness, capital expenditures, ordinary share repurchases and any regulatory and/or sales milestones that may become due.

At this time, we cannot accurately predict the effect of certain developments on the rate of sales growth, such as the degree of market acceptance, patent protection and exclusivity of our products, 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 near-term product candidates. Additionally, we may not be successful in implementing, or may face unexpected changes or expenses in connection with our lean operating model and strategic direction, including the potential for opportunistic corporate development transactions. Any of the above could adversely affect our future cash flows. We may need to obtain additional funding for future transactions, to repay our outstanding indebtedness, or for our future operational needs, and we cannot be certain that funding will be available on terms acceptable to us, or at all. Any issuances of equity securities or convertible securities 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 our 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 or costs of restructuring activities.

We consider the undistributed earnings from the majority of our subsidiaries as of December 31, 2015, to be indefinitely reinvested and, accordingly, neither Irish income tax or withholding taxes have been provided thereon. As of December 31, 2015, indefinitely reinvested earnings were approximately \$915.4 million. While we have historically repatriated funds on a tax-free basis to our parent company for stock repurchases and to our Irish and Luxembourg financing companies to repay debt, we do not anticipate the need to repatriate funds to satisfy liquidity needs arising in the ordinary course of our business.

**Borrowings.** At December 31, 2015, the Company's indebtedness includes a credit agreement with combined outstanding principal borrowings of \$3,817.5 million and additional availability of approximately \$773.0 million under the revolving credit facilities.

The credit agreement contains affirmative and negative covenants that the Company believes to be usual and customary for a senior secured credit facility. The negative covenants include, among other things, limitations on capital expenditures, asset sales, mergers and acquisitions, indebtedness, liens, dividends, investments and transactions with the Company's affiliates. As of December 31, 2015, we were in compliance with all such covenants.

At December 31, 2015, the Company's indebtedness includes senior notes with aggregate principal amounts totaling \$4.7 billion. These 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%. These notes are senior unsecured obligations of the Company's subsidiaries and are issued or guaranteed on a senior unsecured basis, as applicable, by all of our significant subsidiaries (other than Astora Women's Health Technologies, Grupo Farmacéutico Somar, S.A. de C.V., Laboratoris Paladin S.A. de C.V. and Litha Healthcare Group Limited) and certain of our other subsidiaries, except for the 7.25% Senior Notes due 2022, which are issued by Endo Health Solutions Inc. and guaranteed on a senior unsecured basis by the guarantors named in the Fifth Supplemental Indenture relating to such notes (see Exhibit 4.4 to this Annual Report on Form 10-K).

The indentures governing our various senior notes contain affirmative and negative covenants that the Company believes to be usual and customary for senior unsecured credit agreements. 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 restricted payments, sell certain assets, agree to any restrictions on the ability of restricted subsidiaries to make payments to us, create certain liens, merge, consolidate, or sell substantially all of the Company's assets, or enter into certain transactions with affiliates. As of December 31, 2015, we were in compliance with all covenants.

During 2016, we expect to continue to pay down our borrowings and lower our leverage ratio.

**Credit ratings.** The Company's corporate credit ratings assigned by Moody's Investors Service and Standard & Poor's are Ba3 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, 2015 and December 31, 2014 are below (dollars in thousands):

	December 31, 2015	December 31, 2014
Total current assets	\$ 3,475,152	\$ 5,112,054
Less: total current liabilities	(3,474,312)	(3,165,976)
Working capital	<u>\$ 840</u>	<u>\$ 1,946,078</u>
Current ratio	1.0:1	1.6:1

Working capital decreased by \$1,945.2 million from December 31, 2014 to December 31, 2015. This decrease related to cash used to fund the Par, Auxilium and Aspen Holdings acquisitions, mesh settlement charges, cash used to redeem the 7.00% Senior Notes due 2019, cash used to redeem the 7.00% Senior Notes due 2020, the reclassification of deferred tax assets from current to non-current, cash used for share repurchases, cash used for deferred financing costs and cash used for the purchases of property, plant and equipment. This decrease was partially offset by cash received, net of fees, from the equity and debt issuances to finance the Par and Auxilium acquisitions, working capital acquired in the Par and Auxilium acquisitions and cash from the exercise of options.

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

	2015	2014	2013
Net cash flow (used in) provided by:			
Operating activities	\$ 62,026	\$ 337,776	\$ 298,517
Investing activities	(6,244,770)	(771,853)	(883,639)
Financing activities	6,055,467	302,857	579,525
Effect of foreign exchange rate	(7,068)	(4,037)	1,692
Net decrease in cash and cash equivalents	<u>\$ (134,345)</u>	<u>\$ (135,257)</u>	<u>\$ (3,905)</u>

**Net cash provided by operating activities.** Net cash provided by operating activities was \$62.0 million in 2015 compared to \$337.8 million provided by operating activities in 2014 and \$298.5 million provided by operating activities in 2013.

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 in the ordinary course of business.

The \$275.8 million decrease in Net cash provided by operating activities in 2015 compared to 2014 was primarily the result of the timing of cash collections and cash payments related to our operations and cash provided from the operations of our acquisitions. The \$39.3 million increase in Net cash provided by operating activities in 2014 compared to 2013 was primarily the result of the timing of cash collections and cash payments related to our operations and cash provided from the operations of our acquisitions.

The following table summarizes certain of our significant non-core or infrequent pre-tax cash outlays and cash receipts impacting net cash used in operating activities for the years ended December 31 (in thousands). The cash outlays were mainly related to mesh-related product liability payments and cash outlays as a result of significant acquisitions and the associated transaction and integration costs:

	2015	2014	2013
Mesh-related product liability and other litigation matters payments	\$ 699,347	\$ 333,763	\$ 42,982
Redemption fees paid in connection with debt retirements	31,496	—	—
Financing unused commitment fees	78,352	—	—
Severance and restructuring payments	73,655	34,652	40,132
Excise tax reimbursement	—	54,300	—
Transaction costs and certain integration charges paid in connection with acquisitions	191,195	80,639	7,614
U.S. Federal tax refunds received	(155,814)	(111,863)	—
Total	<u>\$ 918,231</u>	<u>\$ 391,491</u>	<u>\$ 90,728</u>

**Net cash used in investing activities.** Net cash used in investing activities was \$6,244.8 million in 2015 compared to \$771.9 million used in investing activities in 2014 and \$883.6 million used in investing activities in 2013.

This \$5,472.9 million increase in cash used in investing activities in 2015 compared to 2014 relates primarily to an increase in cash used for acquisitions in 2015 related primarily to the acquisitions of Par, Auxilium and Aspen Holdings of \$6,563.9 million. We also paid \$743.1 million into the Qualified Settlement Funds for mesh settlements during the year ended December 31, 2015, resulting in a cash outflow for investing activities. In addition, cash previously held in escrow of \$770.0 million was released upon the close of the Paladin transaction in February 2014, which resulted in a prior year corresponding cash inflow for investing activities. In addition, there was an increase in cash used for patent acquisition costs and license fees of \$39.0 million. These decreases were partially offset by an increase of \$1,534.3 million in proceeds from sale of business, primarily relating to the sale of the Men's Health and Prostate Health components of the AMS business, \$649.4 million of cash released from the Qualified Settlement Funds for mesh settlements, and approximately \$40 million of cash released from the escrow account associated with the acquisition of the remaining outstanding share capital of Litha during the year ended December 31, 2015. In addition, we paid \$585.2 million into the Qualified Settlement Funds for mesh settlements during the year ended December 31, 2014, resulting in a prior year cash outflow for investing activities. Payments related to our Qualified Settlement Funds are further described in Note 14. Commitments and Contingencies of the Consolidated Financial Statements of Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

This \$111.8 million decrease in cash used in investing activities in 2014 compared to 2013 relates primarily to a net change in restricted cash and cash equivalents of \$1,006.7 million. Restricted cash and cash equivalents increased in 2013 by \$770.0 million due to cash placed in escrow related to the close of the Paladin transaction in February 2014. Restricted cash decreased in 2014 by \$770.0 million upon the close of the Paladin transaction and \$99.9 million related to payments out of Qualified Settlement Funds for mesh litigation settlements. Restricted cash increased in 2014 by \$633.2 million, primarily related to cash paid into Qualified Settlement Funds for mesh settlements and cash paid into the escrow account associated with the acquisition of the remaining outstanding share capital of Litha. Additionally, there was an increase in proceeds from the sale of marketable securities in 2014 of \$87.2 million, an increase in proceeds from the sale of businesses in 2014 of \$46.4 million, primarily related to the sale of the HealthTronics business, and an increase in proceeds from notes receivable of \$32.7 million. These items were partially offset by an increase in cash used for acquisitions related to the acquisitions of Paladin, Boca, Sumavel, Somar and DAVA of \$1,082.9 million. Payments related to our Qualified Settlement Funds are further described in Note 14. Commitments and Contingencies of the Consolidated Financial Statements of Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

**Net cash provided by financing activities.** Net cash provided by financing activities was \$6,055.5 million in 2015 compared to \$302.9 million provided by financing activities in 2014 and \$579.5 million provided by financing activities in 2013.

Items contributing to the \$5,752.6 million increase in cash provided by financing activities in 2015 compared to 2014 include an increase in issuance of ordinary shares of \$2,300.0 million to finance the Par acquisition, an increase in proceeds from the issuance of notes of \$2,085.0 million, an increase in proceeds from the issuance of term loans of \$1,275.0 million, a decrease in principal payments on term loan indebtedness of \$956.8 million, a decrease in the repurchase of convertible senior subordinated notes of \$340.0 million, a decrease in payments to settle ordinary share warrants of \$284.5 million and net proceeds from draws of revolving debt of \$225.0 million, partially offset by an increase in principal payments on notes of \$899.9 million, a decrease in proceeds from the settlement of the hedge on convertible senior subordinated notes of \$356.3 million, an increase in repurchase of ordinary shares of \$250.1 million, an increase in payments related to the issuance of ordinary shares of \$62.2 million and an increase in cash buy-outs of noncontrolling interests of \$37.9 million related to the acquisition of the remaining outstanding share capital of Litha.

Items contributing to the \$276.7 million decrease in cash provided by financing activities in 2014 compared to 2013 include an increase in principal payments on term loan indebtedness of \$1,278.1 million, an increase in net cash payments of \$516.5 million to repurchase a portion of our Convertible Notes and a proportionate amount of the associated warrants and call options and an increase in cash paid for deferred financing fees of \$52.2 million, partially offset by an increase in proceeds from the issuance of term loans and senior notes of \$1,525.0 million and \$50.0 million, respectively.

**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 what is currently approved in their respective labels.

We undertook initiatives in 2014 to optimize commercial spend and refocus our research and development efforts on progressing late-stage pipeline and maximizing value of marketed products. On June 2, 2014, we completed the sale of our branded pharmaceutical drug discovery platform to Asana BioSciences, LLC, an independent member of the Amneal Alliance of Companies. The sale included multiple early-stage drug discovery and development candidates in a variety of therapeutic areas, including oncology, pain and inflammation, among others. In addition, on November 4, 2014 we sold most of the assets and intellectual property of our second generation implantable drug technology to Braeburn Pharmaceuticals, excluding the existing implant platform used for our two marketed histrelin-containing products, Vantas® and Supprelin®. As part of the Auxilium acquisition, the Company acquired Auxilium's licensed right to cover certain XIAFLEX® indications. As a result, the Company has incurred related early-stage and middle-stage development expenses for these XIAFLEX® indications.

We expect to incur research and development expenditures relative to the development and advancement of our current product pipeline and any additional product candidates we may add via license, acquisition or organically. There can be no assurance 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 current good manufacturing practices for the geographies where the products are approved, successfully marketed in a timely manner, or at all, or that we will have sufficient funds to develop or commercialize any of our products.

**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, customer service support, warehouse and distribution services. These contracts include agreements with Novartis Consumer Health, Inc., Novartis AG and Sandoz, Inc. (collectively, Novartis), Teikoku Seiyaku Co., Ltd., Noramco, Inc., Grünenthal GmbH, Sharp Corporation, UPS Supply Chain Solutions, Inc. and Jubilant HollisterStier Laboratories LLC. If, for any reason, our subsidiaries are unable to obtain sufficient quantities of any of the finished goods or raw materials or components required for their products needed to conduct their business, it could have an adverse effect on our business, financial condition, results of operations and cash flows.

**License and collaboration agreements.** Our subsidiaries have agreed to certain contingent payments in certain license, collaboration and other agreements. Payments under these agreements generally become due and payable only upon the achievement of certain developmental, regulatory, commercial and/or other milestones. Due to the fact that it is uncertain if and when these milestones will be achieved, such contingencies have not been recorded in our Consolidated Balance Sheets. In addition, under certain arrangements, we or our subsidiaries may have to make royalty payments based on a percentage of future sales of the products in the event regulatory approval for marketing is obtained. From a business perspective, we view these payments favorably as they signify that the products are moving successfully through the development phase toward commercialization.

**Acquisitions.** As part of our business strategy, we plan to 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 our 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 or costs of restructuring activities.

**Legal proceedings.** We are subject to various patent, product liability, government investigations and other legal proceedings in the ordinary course of business. Accruals are recorded when we determine that a loss related to a litigation matter is both probable and reasonably estimable. Due to the fact that legal proceedings and other contingencies are inherently unpredictable, our assessments involve significant judgments regarding future events. For additional discussion of legal proceedings, see Note 14. Commitments and Contingencies of the Consolidated Financial Statements included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

**Contractual Obligations.** The following table lists our enforceable and legally binding noncancelable obligations as of December 31, 2015.

Contractual Obligations	Payment Due by Period (in thousands)						
	Total	2016	2017	2018	2019	2020	Thereafter
Long-term debt obligations (1)	\$ 8,741,768	\$ 330,282	\$ 139,673	\$ 181,673	\$ 717,030	\$ 28,000	\$ 7,345,110
Interest expense (2)	3,020,679	416,353	412,312	408,468	393,370	388,546	1,001,630
Capital lease obligations (3)	69,556	9,950	8,114	6,951	7,051	7,242	30,248
Operating lease obligations (4)	108,995	23,103	16,292	15,201	12,471	10,624	31,304
Minimum Voltaren® royalty obligations due to Novartis (5)	22,500	22,500	—	—	—	—	—
Purchase obligations (6)	58,564	42,909	7,060	2,263	1,590	—	4,742
Mesh-related product liability settlements (7)	1,445,706	882,131	563,575	—	—	—	—
Other obligations and commitments (8)	34,811	13,481	7,215	4,892	1,223	1,000	7,000
<b>Total (9)</b>	<b>\$ 13,502,579</b>	<b>\$ 1,740,709</b>	<b>\$ 1,154,241</b>	<b>\$ 619,448</b>	<b>\$ 1,132,735</b>	<b>\$ 435,412</b>	<b>\$ 8,420,034</b>

(1) Includes minimum cash payments related to principal associated with our indebtedness. A discussion of such indebtedness is included above under the caption "Borrowings".

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- (2) Includes interest associated with our indebtedness. Since future interest rates on our variable rate borrowings are unknown, for purposes of this contractual obligations table, amounts scheduled above were calculated using the greater of (i) the respective contractual interest rate spread corresponding to our current leverage ratios or (ii) the respective contractual interest rate floor, if any.
- (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 the company headquarters in Malvern, Pennsylvania. On September 4, 2014, the Company entered into a sublease agreement to lease approximately 60,000 square feet from January 1, 2015 to December 31, 2016 increasing to 90,000 square feet from January 1, 2017 to December 31, 2024. We will receive approximately \$21.5 million in minimum rental payments over the remaining term of the sublease, which is not included in the table above.
- (4) Includes minimum cash payments related to our leased automobiles, machinery and equipment and facilities not included in capital lease obligations. Under the terms of our leases for our former headquarters' in Chadds Ford, Pennsylvania, and Auxilium's former headquarters' in Chesterbrook, Pennsylvania, we are required to continue to pay all future minimum lease payments to the landlord.
- (5) Under the terms of the 2008 Voltaren® Gel Agreement, Endo has agreed to pay royalties to Novartis on annual Net Sales of the Licensed Product, subject to certain thresholds all as defined in the 2008 Voltaren® Gel Agreement. In addition, subject to certain limitations, Endo has agreed to make certain guaranteed minimum annual royalty payments beginning in the fourth year of the 2008 Voltaren® Gel Agreement, which may be reduced under certain circumstances, including Novartis's failure to supply the Licensed Product. On December 11, 2015, Endo, Novartis AG and Sandoz entered into the 2015 Voltaren® Gel Agreement) effectively renewing Endo's exclusive U.S. marketing and license rights to commercialize Voltaren® Gel through June 30, 2023. Pursuant to the 2015 Voltaren® Gel Agreement, the former 2008 Voltaren® Gel Agreement will expire on June 30, 2016 in accordance with its terms. The 2015 Voltaren® Gel Agreement will become effective on July 1, 2016 and will be accounted for as a business combination as of the effective date.
- (6) Purchase obligations are enforceable and legally binding obligations for purchases of goods and services including minimum inventory contracts.
- (7) The amount included above represents contractual payments for mesh-related product liability settlements pursuant to existing Master Settlement Agreements (MSAs) and reflect the earliest date that a settlement payment could be due and the largest amount that could be due on that date. These matters are described in more detail in Note 14. Commitments and Contingencies of the Consolidated Financial Statements included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".
- (8) Other obligations and commitments include agreements to purchase third-party assets, products and services and other minimum royalty obligations.
- (9) Total does not include contractual obligations already included in current liabilities on our Consolidated Balance Sheet, except for current portion of long-term debt, short-term capital lease obligations, short-term royalty obligations and the current portion of the mesh-related product liability or 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. 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, 2015, 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.

As of December 31, 2015, our liability for unrecognized tax benefits amounted to \$328.9 million (including interest and penalties). 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, asset impairment 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 a business combination. 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 strategic investments, licensing arrangements, acquisitions of businesses, product rights or technologies, and strategic alliances and promotional arrangements 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

the Company's subsidiaries' product lines by acquiring new products and technologies, including international opportunities; increasing revenues and earnings through sales and marketing programs for our subsidiaries' innovative product offerings and effectively using the Company's and its subsidiaries' resources; and providing additional resources to support our generics business.

**Non-U.S. operations.** Fluctuations in foreign currency rates resulted in a net gain of \$23.1 million in 2015. This compares to a net gain of \$10.1 million in 2014 and an immaterial gain in 2013.

**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 the term loan portion and revolving credit facilities portion of our credit agreement. To the extent we utilize amounts under our term loans and revolving credit facilities, we would be exposed to additional interest rate risk. At December 31, 2015, our term loans include principal amount of floating-rate debt of \$3.8 billion and our revolving credit facilities include principal amount of floating-rate debt of \$225.0 million. Borrowings under our revolving credit facilities and our Term Loan A facility bear interest at a rate equal to an applicable margin plus London Interbank Offered Rate (LIBOR). In addition, borrowings under our Term Loan B facility bear interest at a rate equal to an applicable margin plus LIBOR, subject to a LIBOR floor of 0.75%. A hypothetical 1% increase in LIBOR over the 0.75% floor would result in \$40.4 million in incremental annual interest expense.

As of December 31, 2015 and 2014, we had no other assets or liabilities with significant interest rate sensitivity.

##### *Investment Risk*

At December 31, 2015 and 2014, we had immaterial investments in available-for-sale securities, primarily associated with equity securities of publicly traded companies. Any decline in value below our original investments will be evaluated to determine if the decline in value is considered temporary or other-than-temporary. An other-than-temporary decline in fair value would be included as a charge to earnings.

##### *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 historical 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 income in shareholders' equity. Gains and losses on foreign currency transactions and short term inter-company receivables from foreign subsidiaries are included in Other expense (income), net.

Fluctuations in foreign currency rates resulted in a net gain of \$23.1 million in 2015. This compares to a net gain of \$10.1 million in 2014 and a net gain of less than \$0.1 million in 2013.

Based on the Company's significant foreign currency denominated intercompany loans existing at December 31, 2015, we estimate that a 10% appreciation or depreciation in the underlying currencies of our foreign currency denominated intercompany loans, relative to the U.S. Dollar, would result in approximately \$4.0 million in incremental foreign currency gains or losses, respectively.

In addition, we purchase Lidoderm® in U.S. dollars from Teikoku Seiyaku Co., Ltd., a Japanese manufacturer. As part of the purchase agreement with Teikoku, there is a price adjustment feature that prevents the cash payment in U.S. dollars from falling outside of a certain pre-defined range in Japanese yen even if the spot rate is outside of that range.

##### *Inflation*

We do not believe that inflation has had a significant impact on our revenues or operations.

**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**

As previously disclosed in our Current Report on Form 8-K filed on June 13, 2014, on June 11, 2014 the Audit Committee of our Board of Directors requested Deloitte & Touche LLP to resign as the independent registered public accounting firm previously engaged as the principal accountant to audit the Company’s financial statements. This became effective on June 12, 2014, upon the engagement of PricewaterhouseCoopers. There were no disagreements or reportable events in connection with the change in accountants requiring disclosure under Item 304(b) of Regulation S-K. There were no additional changes made during fiscal year 2015.

**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, 2015. 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, 2015.

*(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 “Reports of Independent Registered Public Accounting Firm” and incorporated herein by reference.

*(d) Changes in Internal Control over Financial Reporting*

The Company acquired certain entities during the year ended December 31, 2015. As permitted by the Securities and Exchange Commission, management has elected to exclude these entities from its assessment of the effectiveness of its internal controls over financial reporting as of December 31, 2015. The Company began to integrate these acquired companies into its internal control over financial reporting structure subsequent to their respective acquisition dates and expects to complete this integration in early 2016. As such, there have been changes during the year ended December 31, 2015 associated with the establishment and continued integration of internal control over financial reporting with respect to these acquired companies.

**Item 9B. Other Information**

On February 28, 2016, we entered into a new executive employment agreement (the “Employment Agreement”) with Mr. De Silva, the Company’s President and Chief Executive Officer. The Employment Agreement generally provides for the continued employment of Mr. De Silva on substantially the same terms and conditions as his existing employment agreement, which will expire on March 18, 2016.

The Employment Agreement has a term of three years ending on March 18, 2019, unless earlier terminated. Under the Employment Agreement, Mr. De Silva is entitled to receive a base salary of \$1,155,000 (with such base salary being effective upon the expiration of his existing employment agreement and is initially eligible to receive a target annual cash bonus of 125% of his base salary in 2016.

During the term of the Employment Agreement, Mr. De Silva is also eligible to receive equity-based compensation to be awarded in the sole discretion of the Compensation Committee of the Board (the “Committee”) (at a level commensurate with his position as President and Chief Executive Officer, as compared to other senior executives of the Company), which may be subject to the achievement of certain performance targets set by the Committee. The Employment Agreement provides that 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. Mr. De Silva is also entitled to receive employee benefits, executive benefits, perquisites, reimbursement of expenses and vacation generally on the same basis as other senior executives.

The Employment Agreement also provides that on termination of Mr. De Silva’s employment by the Company without cause or by Mr. De Silva for good reason (as such terms are defined in the Employment Agreement), Mr. De Silva will be entitled to the

following amounts, subject to his execution of a release of claims: a prorated bonus for year of termination (based on actual results), severance in an amount equal to two times the sum of his base salary and target bonus, and continuation of medical and life insurance benefits for two years following termination. If such qualifying termination occurs within twenty-four months following a change in control and subject to his execution of a release, Mr. De Silva will be entitled to similar payments and benefits, except severance will be calculated using a multiple of three and his benefits will continue for three years. Payments upon termination due to death or disability include a prorated bonus for the year of termination (based on actual results), continuation of medical and life insurance benefits for Mr. De Silva and/or his dependents for two years following such termination, and, in the event of disability, 24 months of salary continuation offset by disability benefits. Mr. De Silva may reduce payments to the extent such payments would constitute “excess parachute payments” under Sections 280G and 4999 of the Internal Revenue Code. If, within ninety days following the expiration of the Employment Agreement, Mr. De Silva’s employment is terminated by the Company under circumstances that would not have constituted cause or by Mr. De Silva that would have constituted good reason, he will receive a prorated bonus for the year of termination (based on actual results), and such termination will be treated as a termination without cause or for good reason for purposes of his equity-based long-term incentive awards held by Mr. De Silva as of the date of such termination of employment.

The Employment Agreement also contains a twenty-four month non-solicitation covenant, a twenty-four month non-competition covenant, a non-disparagement covenant, a covenant providing for cooperation by Mr. De Silva in connection with any investigations and/or litigation, and a covenant not to cooperate with non-governmental third parties in certain matters against the Company. See Exhibit 10.33 to this Annual Report on Form 10-K for a complete description of the Employment Agreement.



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 2016 Annual General Meeting (2016 Proxy Statement).

**Executive Officers**

For information concerning Endo's executive officers, see Part I, Item 1. of this report "Business" under the caption "Executive Officers of the Registrant" and our 2016 Proxy Statement.

**Code of Ethics**

The information concerning our Code of Conduct is incorporated herein by reference from our 2016 Proxy Statement and can be viewed on our website, the internet address for which is <http://www.endo.com>.

**Audit Committee**

The information concerning our Audit Committee is incorporated herein by reference from our 2016 Proxy Statement.

**Audit Committee Financial Experts**

The information concerning our Audit Committee Financial Experts is incorporated herein by reference from our 2016 Proxy Statement.

**Item 11. Executive Compensation**

The information required under this Item is incorporated herein by reference from our 2016 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, 2015 regarding the Company's compensation plans, under which equity securities of Endo may be issued to employees and directors.

Plan Category	Column A	Column B	Column C
	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	4,558,977	\$ 51.48	9,288,514
Equity compensation plans not approved by security holders	—	—	—
<b>Total</b>	<b>4,558,977</b>	<b>\$ 51.48</b>	<b>9,288,514</b>

(1) Excludes shares of restricted stock units and performance share units outstanding.

In June 2015, the Company's shareholders approved the 2015 Stock Incentive Plan (the 2015 Plan). Under the 2015 Plan, 10.0 million ordinary shares, which included the transfer of 5.0 million ordinary shares available to be granted under the 2010 Stock Incentive Plan as of the date the 2015 Plan became effective, have been reserved for the grant of stock options (including incentive stock options), stock appreciation rights, restricted stock awards, performance awards and other share-based awards, which may be issued at the discretion of the Company's board of directors from time to time. Upon the 2015 Plan becoming effective, all other existing stock incentive plans were terminated. The 2015 Plan provides that stock options may be granted thereunder to non-employee consultants.

The other information required under this Item is incorporated herein by reference from our 2016 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 2016 Proxy Statement.

**Item 14. *Principal Accounting Fees and Services***

Information about the fees for 2015 and 2014 for professional services rendered by our independent registered public accounting firm is incorporated herein by reference from our 2016 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 2016 Proxy Statement.

The information required under this Item is incorporated herein by reference from our 2016 Proxy Statement.

## PART IV

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

Documents filed as part of this Annual Report on Form 10-K

1. Consolidated Financial Statements: See accompanying Index to Financial Statements.
2. Consolidated Financial Statement Schedule:

**SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS**

(in thousands)

	<b>Balance at Beginning of Period</b>	<b>Additions, Costs and Expenses</b>	<b>Deductions, Write-offs</b>	<b>Balance at End of Period</b>
<b>Allowance For Doubtful Accounts:</b>				
Year Ended December 31, 2013	\$ 5,533	\$ 1,358	\$ (1,297)	\$ 5,594
Year Ended December 31, 2014	\$ 5,594	\$ 165	\$ (1,840)	\$ 3,919
Year Ended December 31, 2015	\$ 3,919	\$ 5,073	\$ (5,212)	\$ 3,780

The amounts in the table above include amounts classified as Assets held for sale in our Consolidate Balance Sheets.

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: The information called for by this Item is incorporated by reference to the Exhibit Index of this Report.

**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)

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/s/ RAJIV DE SILVA

Name: **Rajiv De Silva**  
Title: **President and Chief Executive Officer**  
(Principal Executive Officer)

Date: February 29, 2016

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/S/ RAJIV DE SILVA</u> Rajiv De Silva	Director, President and Chief Executive Officer (Principal Executive Officer)	February 29, 2016
<u>/S/ SUKETU P. UPADHYAY</u> Suketu P. Upadhyay	Executive Vice President, Chief Financial Officer (Principal Financial Officer)	February 29, 2016
<u>/S/ DANIEL A. RUDIO</u> Daniel A. Rudio	Vice President, Controller (Principal Accounting Officer)	February 29, 2016
<u>*</u> Roger H. Kimmel	Chairman and Director	February 29, 2016
<u>*</u> Shane M. Cooke	Director	February 29, 2016
<u>*</u> Arthur J. Higgins	Director	February 29, 2016
<u>*</u> Nancy J. Hutson, Ph.D.	Director	February 29, 2016
<u>*</u> Michael Hyatt	Director	February 29, 2016
<u>*</u> William P. Montague	Director	February 29, 2016
<u>*</u> Jill D. Smith	Director	February 29, 2016
<u>*</u> William F. Spengler	Director	February 29, 2016
<u>*By: /S/ MATTHEW J. MALETTA</u> Matthew J. Maletta	Attorney-in-fact pursuant to a Power of Attorney filed with this Report as Exhibit 24	February 29, 2016

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Consolidated Statements of Shareholders’ Equity for the Years Ended December 31, 2015, 2014 and 2013	<a href="#">F-8</a>
Consolidated Statements of Cash Flows for the Years Ended December 31, 2015, 2014 and 2013	<a href="#">F-10</a>
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## 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, 2015. 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, 2015, the Company's internal control over financial reporting is effective based on those criteria.

Management has excluded Par Pharmaceutical Holdings, Inc. (Par) from its assessment of internal control over financial reporting as of December 31, 2015 since it was acquired by the Company in a purchase business combination during 2015. Par is a wholly-owned subsidiary with approximately 12% of total revenues for the year ended December 31, 2015 and approximately 22% of total assets as of December 31, 2015.

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, 2015. This report appears on page F-3.

/S/ RAJIV DE SILVA

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Rajiv De Silva  
Director, President and Chief Executive Officer  
(Principal Executive Officer)

/S/ SUKETU P. UPADHYAY

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Suketu P. Upadhyay  
Executive Vice President, Chief Financial Officer  
(Principal Financial Officer)

February 29, 2016

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of Endo International plc

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows present fairly, in all material respects, the financial position of Endo International plc and its subsidiaries at December 31, 2015 and December 31, 2014, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule of valuation and qualifying accounts appearing under Item 15.2 as of December 31, 2015 and December 31, 2014 presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control - Integrated Framework* 2013 issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements and financial statement schedule, 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 these financial statements, on the financial statement schedule and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. 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.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it classifies deferred taxes and deferred financing costs in 2015.

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.

As described in Management's Report on Internal Control over Financial Reporting, management has excluded Par Pharmaceutical Holdings, Inc. (Par) from its assessment of internal control over financial reporting as of December 31, 2015 because it was acquired by the Company in a purchase business combination during 2015. We have also excluded Par from our audit of internal control over financial reporting. Par is a wholly-owned subsidiary whose total assets and total revenues represent 22% and 12%, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2015.

/s/ PricewaterhouseCoopers LLP

Philadelphia, Pennsylvania

February 29, 2016



**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders of

Endo International plc

Dublin, Ireland

We have audited the accompanying consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows of Endo Health Solutions Inc. (now known as Endo International plc, see Note 1 to the consolidated financial statements) and subsidiaries (the "Company") for the year ended December 31, 2013. Our audit also included the consolidated financial statement schedule for the year ended December 31, 2013 listed in the Index at Item 15. These consolidated financial statements and consolidated financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the consolidated financial statements and consolidated financial statement schedule based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the results of operations and cash flows of Endo Health Solutions Inc. and subsidiaries for the year ended December 31, 2013, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such consolidated financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ DELOITTE & TOUCHE LLP

Philadelphia, Pennsylvania

February 28, 2014 (June 2, 2015 as to the effects of the discontinued operations discussed in Note 3)

**ENDO INTERNATIONAL PLC**  
**CONSOLIDATED BALANCE SHEETS**  
**DECEMBER 31, 2015 AND 2014**  
(In thousands, except share and per share data)

	December 31, 2015	December 31, 2014
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 272,348	\$ 405,696
Restricted cash and cash equivalents	585,379	530,930
Marketable securities	34	815
Accounts receivable, net of allowance of \$1,309 and \$60 at December 31, 2015 and 2014, respectively	995,077	1,118,720
Inventories, net	744,665	414,995
Prepaid expenses and other current assets	53,526	38,680
Income taxes receivable	735,901	52,326
Deferred income taxes	—	561,974
Assets held for sale (NOTE 3)	88,222	1,987,918
<b>Total current assets</b>	<b>\$ 3,475,152</b>	<b>\$ 5,112,054</b>
MARKETABLE SECURITIES	3,855	1,506
PROPERTY, PLANT AND EQUIPMENT, NET	670,574	387,052
GOODWILL	7,299,354	2,897,775
OTHER INTANGIBLES, NET	7,812,655	2,332,250
DEFERRED INCOME TAXES	9,145	4,933
OTHER ASSETS	79,601	88,599
<b>TOTAL ASSETS</b>	<b>\$ 19,350,336</b>	<b>\$ 10,824,169</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 344,267	\$ 294,001
Accrued expenses	1,151,172	1,144,325
Current portion of legal settlement accrual	1,606,726	1,443,114
Current portion of long-term debt	328,705	155,937
Income taxes payable	8,551	—
Deferred income taxes	—	22
Liabilities held for sale (NOTE 3)	34,891	128,577
<b>Total current liabilities</b>	<b>\$ 3,474,312</b>	<b>\$ 3,165,976</b>
DEFERRED INCOME TAXES	871,040	677,486
LONG-TERM DEBT, LESS CURRENT PORTION, NET	8,251,657	4,100,627
LONG-TERM LEGAL SETTLEMENT ACCRUAL, LESS CURRENT PORTION, NET	549,098	262,781
OTHER LIABILITIES	236,253	209,086
<b>COMMITMENTS AND CONTINGENCIES (NOTE 14)</b>		
<b>SHAREHOLDERS' EQUITY:</b>		
Euro deferred shares, \$0.01 par value; 4,000,000 shares authorized; 4,000,000 issued	43	48
Ordinary shares, \$0.0001 and \$0.0001 par value; 1,000,000,000 and 1,000,000,000 shares authorized; 222,124,282 and 153,912,985 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	22	15
Additional paid-in capital	8,693,385	3,093,867
Accumulated deficit	(2,341,215)	(595,085)
Accumulated other comprehensive loss	(384,205)	(124,088)
<b>Total Endo International plc shareholders' equity</b>	<b>\$ 5,968,030</b>	<b>\$ 2,374,757</b>
Noncontrolling interests	(54)	33,456
<b>Total shareholders' equity</b>	<b>\$ 5,967,976</b>	<b>\$ 2,408,213</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 19,350,336</b>	<b>\$ 10,824,169</b>

See Notes to Consolidated Financial Statements.

**ENDO INTERNATIONAL PLC**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**YEARS ENDED DECEMBER 31, 2015, 2014 AND 2013**  
(In thousands, except per share data)

	2015	2014	2013
TOTAL REVENUES	\$ 3,268,718	\$ 2,380,683	\$ 2,124,681
<b>COSTS AND EXPENSES:</b>			
Cost of revenues	2,075,651	1,231,497	886,603
Selling, general and administrative	741,304	567,986	574,313
Research and development	102,197	112,708	97,465
Litigation-related and other contingencies, net	37,082	42,084	9,450
Asset impairment charges	1,140,709	22,542	32,011
Acquisition-related and integration items	105,250	77,384	7,614
OPERATING (LOSS) INCOME FROM CONTINUING OPERATIONS	\$ (933,475)	\$ 326,482	\$ 517,225
INTEREST EXPENSE, NET	373,214	227,114	173,606
LOSS ON EXTINGUISHMENT OF DEBT	67,484	31,817	11,312
OTHER EXPENSE (INCOME), NET	63,691	(32,324)	(53,059)
(LOSS) INCOME FROM CONTINUING OPERATIONS BEFORE INCOME TAX	\$ (1,437,864)	\$ 99,875	\$ 385,366
INCOME TAX (BENEFIT) EXPENSE	(1,137,465)	38,267	143,742
(LOSS) INCOME FROM CONTINUING OPERATIONS	\$ (300,399)	\$ 61,608	\$ 241,624
DISCONTINUED OPERATIONS, NET OF TAX (NOTE 3)	(1,194,926)	(779,792)	(874,038)
CONSOLIDATED NET LOSS	\$ (1,495,325)	\$ (718,184)	\$ (632,414)
Less: Net (loss) income attributable to noncontrolling interests	(283)	3,135	52,925
NET LOSS ATTRIBUTABLE TO ENDO INTERNATIONAL PLC	\$ (1,495,042)	\$ (721,319)	\$ (685,339)
NET LOSS PER SHARE ATTRIBUTABLE TO ENDO INTERNATIONAL PLC ORDINARY SHAREHOLDERS'—BASIC:			
Continuing operations	\$ (1.52)	\$ 0.42	\$ 2.13
Discontinued operations	(6.07)	(5.33)	(8.18)
Basic	\$ (7.59)	\$ (4.91)	\$ (6.05)
NET LOSS PER SHARE ATTRIBUTABLE TO ENDO INTERNATIONAL PLC ORDINARY SHAREHOLDERS'—DILUTED:			
Continuing operations	\$ (1.52)	\$ 0.40	\$ 2.02
Discontinued operations	(6.07)	(5.00)	(7.74)
Diluted	\$ (7.59)	\$ (4.60)	\$ (5.72)
WEIGHTED AVERAGE SHARES:			
Basic	197,100	146,896	113,295
Diluted	197,100	156,730	119,829

See Notes to Consolidated Financial Statements.

**ENDO INTERNATIONAL PLC**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
**YEARS ENDED DECEMBER 31, 2015, 2014 AND 2013**  
(In thousands)

	<u>2015</u>		<u>2014</u>		<u>2013</u>	
CONSOLIDATED NET LOSS	\$ (1,495,325)		\$ (718,184)		\$ (632,414)	
<b>OTHER COMPREHENSIVE (LOSS) INCOME, NET OF TAX</b>						
Net unrealized gain (loss) on securities:						
Unrealized gain (loss) arising during the period	\$ 2,299		\$ (1,099)		\$ 775	
Less: reclassification adjustments for loss realized in net loss	—	2,299	17	(1,082)	—	775
Foreign currency translation (loss) gain:						
Foreign currency (loss) gain during period	\$ (284,722)		\$ (121,389)		\$ 714	
Less: reclassification adjustments for loss realized in net loss	25,715	(259,007)	—	(121,389)	—	714
Fair value adjustment on derivatives designated as cash flow hedges:						
Fair value adjustment on derivatives designated as cash flow hedges arising during the period	\$ —		\$ —		\$ 546	
Less: reclassification adjustments for cash flow hedges settled and included in net loss	—	—	—	—	(148)	398
OTHER COMPREHENSIVE (LOSS) INCOME	\$ (256,708)		\$ (122,471)		\$ 1,887	
CONSOLIDATED COMPREHENSIVE LOSS	\$ (1,752,033)		\$ (840,655)		\$ (630,527)	
Less: Net (loss) income attributable to noncontrolling interests	(283)		3,135		52,925	
Less: Other comprehensive loss attributable to noncontrolling interests	(495)		(3,298)		—	
COMPREHENSIVE LOSS ATTRIBUTABLE TO ENDO INTERNATIONAL PLC	<u>\$ (1,751,255)</u>		<u>\$ (840,492)</u>		<u>\$ (683,452)</u>	

See Notes to Consolidated Financial Statements.

**ENDO INTERNATIONAL PLC**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**  
**YEARS ENDED DECEMBER 31, 2015, 2014 AND 2013**  
**(In thousands, except share data)**

	Endo International plc Shareholders											
	Ordinary Shares		Euro Deferred Shares		Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Accumulated Other Compre- hensive (Loss) Income	Treasury Stock		Total Endo International plc Shareholders' Equity	Noncontrolling Interests	Total Shareholders' Equity
	Number of Shares	Amount	Number of Shares	Amount				Number of Shares	Amount			
BALANCE, JANUARY 1, 2013	140,040,882	\$ 1,400	—	\$ —	\$ 1,035,115	\$ 811,573	\$ (6,802)	(29,247,027)	\$ (768,430)	\$ 1,072,856	\$ 60,350	\$ 1,133,206
Net (loss) income	—	—	—	—	—	(685,339)	—	—	—	(685,339)	52,925	(632,414)
Other comprehensive income	—	—	—	—	—	—	1,887	—	—	1,887	—	1,887
Compensation related to share-based awards	—	—	—	—	38,998	—	—	—	—	38,998	—	38,998
Forfeiture of restricted stock awards	(12,191)	—	—	—	—	—	—	—	—	—	—	—
Exercise of options	3,836,560	39	—	—	97,090	—	—	—	—	97,129	—	97,129
Tax benefits of share awards, net	—	—	—	—	4,265	—	—	—	—	4,265	—	4,265
Ordinary shares issued	547,823	5	—	—	263	—	—	—	—	268	—	268
Tax withholding for restricted shares	—	—	—	—	(9,781)	—	—	—	—	(9,781)	—	(9,781)
Issuance of ordinary shares from treasury	—	—	—	—	—	—	—	188,346	5,310	5,310	—	5,310
Distributions to noncontrolling interests	—	—	—	—	—	—	—	—	—	—	(52,711)	(52,711)
Buy-out of noncontrolling interests, net	—	—	—	—	—	—	—	—	—	—	(1,366)	(1,366)
Other	—	—	—	—	425	—	—	—	—	425	—	425
BALANCE, DECEMBER 31, 2013	144,413,074	\$ 1,444	—	\$ —	\$ 1,166,375	\$ 126,234	\$ (4,915)	(29,058,681)	\$ (763,120)	\$ 526,018	\$ 59,198	\$ 585,216
Net (loss) income	—	—	—	—	—	(721,319)	—	—	—	(721,319)	3,135	(718,184)
Other comprehensive loss	—	—	—	—	—	—	(119,173)	—	—	(119,173)	(3,298)	(122,471)
Compensation related to share-based awards	—	—	—	—	32,671	—	—	—	—	32,671	—	32,671
Forfeiture of restricted stock awards	(3,298)	—	—	—	—	—	—	—	—	—	—	—
Exercise of options	1,528,295	4	—	—	41,388	—	—	—	—	41,392	—	41,392
Tax benefits of share awards, net	—	—	—	—	33,531	—	—	—	—	33,531	—	33,531
Ordinary shares issued	36,235,228	17	—	—	2,844,349	—	—	—	—	2,844,366	—	2,844,366
Euro deferred shares issued	—	—	4,000,000	55	—	—	—	—	—	55	—	55
Tax withholding for restricted shares	—	—	—	—	(25,081)	—	—	—	—	(25,081)	—	(25,081)
Distributions to noncontrolling interests	—	—	—	—	—	—	—	—	—	—	(5,291)	(5,291)
Buy-out of noncontrolling interests, net	—	—	—	—	—	—	—	—	—	—	(1,729)	(1,729)
Addition of Paladin noncontrolling interests due to acquisition	—	—	—	—	—	—	—	—	—	—	38,800	38,800
Removal of HealthTronics, Inc. noncontrolling interests due to disposition	—	—	—	—	—	—	—	—	—	—	(57,359)	(57,359)
Result of contribution of Endo Health Solutions Inc. to Endo International plc	(29,058,681)	(1,450)	—	—	(761,670)	—	—	29,058,681	763,120	—	—	—
Repurchase of convertible senior subordinated notes due 2015	798,367	—	—	—	(309,829)	—	—	—	—	(309,829)	—	(309,829)
Settlement of common stock warrants	—	—	—	—	(284,454)	—	—	—	—	(284,454)	—	(284,454)
Settlement of the hedge on convertible senior subordinated notes due 2015	—	—	—	—	356,265	—	—	—	—	356,265	—	356,265

## Endo International plc Shareholders

	Ordinary Shares		Euro Deferred Shares		Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Accumulated Other Comprehensive (Loss) Income	Treasury Stock		Total Endo International plc Shareholders' Equity	Noncontrolling Interests	Total Shareholders' Equity
	Number of Shares	Amount	Number of Shares	Amount				Number of Shares	Amount			
Other	—	—	—	(7)	322	—	—	—	—	315	—	315
BALANCE, DECEMBER 31, 2014	153,912,985	\$ 15	4,000,000	\$ 48	\$ 3,093,867	\$ (595,085)	\$ (124,088)	—	\$ —	\$ 2,374,757	\$ 33,456	\$ 2,408,213
Net loss	—	—	—	—	—	(1,495,042)	—	—	—	(1,495,042)	(283)	(1,495,325)
Other comprehensive loss	—	—	—	—	—	—	(256,213)	—	—	(256,213)	(495)	(256,708)
Compensation related to share-based awards	—	—	—	—	61,185	—	—	—	—	61,185	—	61,185
Exercise of options	880,885	—	—	—	27,217	—	—	—	—	27,217	—	27,217
Tax benefits of share awards, net	—	—	—	—	20,051	—	—	—	—	20,051	—	20,051
Issuance of ordinary shares related to the employee stock purchase plan	67,867	—	—	—	4,299	—	—	—	—	4,299	—	4,299
Ordinary shares issued	27,982,302	3	—	—	2,299,997	—	—	—	—	2,300,000	—	2,300,000
Equity issuance fees	—	—	—	—	(66,956)	—	—	—	—	(66,956)	—	(66,956)
Ordinary shares issued in connection with the Auxilium acquisition	18,609,835	2	—	—	1,519,318	—	—	—	—	1,519,320	—	1,519,320
Ordinary shares issued in connection with the Par acquisition	18,069,899	2	—	—	1,325,246	—	—	—	—	1,325,248	—	1,325,248
Tax withholding for restricted shares	—	—	—	—	(15,398)	—	—	—	—	(15,398)	—	(15,398)
Share repurchases	(4,361,957)	—	—	—	—	(251,088)	—	—	—	(251,088)	—	(251,088)
Buy-out of noncontrolling interests, net	—	—	—	—	(2,972)	—	(3,904)	—	—	(6,876)	(32,732)	(39,608)
Fair value of equity component of acquired Auxilium Notes	—	—	—	—	266,649	—	—	—	—	266,649	—	266,649
Conversion of Auxilium Notes	5,170,239	—	—	—	160,892	—	—	—	—	160,892	—	160,892
Settlement of common stock warrants	1,792,379	—	—	—	—	—	—	—	—	—	—	—
Other	(152)	—	—	(5)	(10)	—	—	—	—	(15)	—	(15)
BALANCE, DECEMBER 31, 2015	222,124,282	\$ 22	4,000,000	\$ 43	\$ 8,693,385	\$ (2,341,215)	\$ (384,205)	—	\$ —	\$ 5,968,030	\$ (54)	\$ 5,967,976

See Notes to Consolidated Financial Statements.

**ENDO INTERNATIONAL PLC**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**YEARS ENDED DECEMBER 31, 2015, 2014 AND 2013**  
(In thousands)

	2015	2014	2013
<b>OPERATING ACTIVITIES:</b>			
Consolidated net loss	\$ (1,495,325)	\$ (718,184)	\$ (632,414)
Adjustments to reconcile consolidated net loss to Net cash provided by operating activities:			
Depreciation and amortization	632,756	331,651	255,663
Inventory step-up	232,461	65,582	—
Share-based compensation	61,185	32,671	38,998
Amortization of debt issuance costs and discount	23,604	29,086	36,264
Provision for bad debts	5,073	165	3,495
Deferred income taxes	(447,168)	(275,123)	(155,727)
Net loss on disposal of property, plant and equipment	3,256	2,626	2,571
Change in fair value of contingent consideration	(65,640)	—	—
Loss on extinguishment of debt	67,484	31,817	11,312
Prepayment penalty on long-term debt	(31,496)	—	—
Asset impairment charges	1,390,281	22,542	680,198
Gain on sale of business and other assets	(13,550)	(8,780)	(2,665)
Changes in assets and liabilities which (used) provided cash:			
Accounts receivable	(274,994)	(341,404)	(80,195)
Inventories	29,130	42,346	(29,286)
Prepaid and other assets	18,283	51,895	(22,509)
Accounts payable	630	(96,361)	(159,532)
Accrued expenses	442,768	1,549,749	(167,107)
Other liabilities	69,926	(302,251)	487,625
Income taxes payable/receivable	(586,638)	(80,251)	31,826
Net cash provided by operating activities	\$ 62,026	\$ 337,776	\$ 298,517
<b>INVESTING ACTIVITIES:</b>			
Purchases of property, plant and equipment	(81,774)	(80,425)	(96,483)
Proceeds from sale of property, plant and equipment	—	174	1,857
Acquisitions, net of cash acquired	(7,650,404)	(1,086,510)	(3,645)
Proceeds from sale of marketable securities and investments	1,230	87,233	—
Proceeds from notes receivable	17	32,659	—
Increase in notes receivable	—	(35,400)	—
Patent acquisition costs and license fees	(43,968)	(5,000)	(12,000)
Proceeds from sale of business, net	1,588,779	54,521	8,150
Proceeds from settlement escrow	—	11,518	(11,518)
Increase in restricted cash and cash equivalents	(747,649)	(633,173)	(770,000)
Decrease in restricted cash and cash equivalents	688,999	869,936	—
Other investing activities	—	12,614	—
Net cash used in investing activities	\$ (6,244,770)	\$ (771,853)	\$ (883,639)

	2015	2014	2013
<b>FINANCING ACTIVITIES:</b>			
Proceeds from issuance of notes	2,835,000	750,000	700,000
Proceeds from issuance of term loans	2,800,000	1,525,000	—
Principal payments on notes	(899,875)	—	—
Principal payments on term loans	(473,376)	(1,430,144)	(152,032)
Proceeds from draw of revolving debt	525,000	—	—
Repayments of revolving debt	(300,000)	—	—
Principal payments on other indebtedness, net	(10,070)	(7,588)	(3,447)
Repurchase of convertible senior subordinated notes	(247,760)	(587,803)	—
Sale of AMS mandatorily redeemable preferred shares	60,000	—	—
Redemption of AMS mandatorily redeemable preferred shares	(60,000)	—	—
Payments to settle ordinary share warrants	—	(284,454)	—
Proceeds from the settlement of the hedge on convertible senior subordinated notes due 2015	—	356,265	—
Deferred financing fees	(125,111)	(62,715)	(10,475)
Payment for contingent consideration	(29,786)	—	(5,000)
Tax benefits of share awards	21,979	35,188	12,017
Payments of tax withholding for restricted shares	(15,398)	(25,081)	(9,781)
Exercise of options	27,217	41,392	97,129
Repurchase of ordinary shares	(250,088)	—	—
Issuance of ordinary shares related to the employee stock purchase plan	4,299	4,617	5,310
Issuance of ordinary shares	2,300,000	—	—
Payments related to the issuance of ordinary shares	(66,956)	(4,800)	—
Cash distributions to noncontrolling interests	—	(5,291)	(52,711)
Cash buy-out of noncontrolling interests	(39,608)	(1,729)	(1,485)
Net cash provided by financing activities	\$ 6,055,467	\$ 302,857	\$ 579,525
Effect of foreign exchange rate	(7,068)	(4,037)	1,692
NET DECREASE IN CASH AND CASH EQUIVALENTS	\$ (134,345)	\$ (135,257)	\$ (3,905)
LESS: NET DECREASE IN CASH AND CASH EQUIVALENTS OF DISCONTINUED OPERATIONS	(997)	(14,356)	(813)
NET DECREASE IN CASH AND CASH EQUIVALENTS OF CONTINUING OPERATIONS	\$ (133,348)	\$ (120,901)	\$ (3,092)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	405,696	526,597	529,689
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 272,348	\$ 405,696	\$ 526,597
<b>SUPPLEMENTAL INFORMATION:</b>			
Cash paid for interest	\$ 284,985	\$ 159,492	\$ 128,452
Cash paid for income taxes	\$ 42,700	\$ 36,356	\$ 70,160
Cash paid into Qualified Settlement Funds for mesh legal settlements	\$ 743,132	\$ 585,165	\$ 54,500
Cash paid out of Qualified Settlement Funds for mesh legal settlements	\$ 649,391	\$ 111,454	\$ 42,982
Other cash distributions for mesh legal settlements	\$ 27,380	\$ 26,709	\$ —
<b>SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>			
Purchases of property, plant and equipment financed by capital leases	\$ 4,234	\$ 4,784	\$ 497
Accrual for purchases of property, plant and equipment	\$ 4,476	\$ 11,397	\$ 8,351
Acquisition financed by ordinary shares	\$ 2,844,568	\$ 2,844,279	\$ —
Repurchase of convertible senior subordinated notes financed by ordinary shares	\$ 625,483	\$ 55,229	\$ —

See Notes to Consolidated Financial Statements.



**ENDO INTERNATIONAL PLC**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**YEARS ENDED DECEMBER 31, 2015, 2014 AND 2013**

**NOTE 1. DESCRIPTION OF BUSINESS**

The accompanying Consolidated Financial Statements of Endo International plc have been prepared in accordance with United States (U.S.) generally accepted accounting principles (GAAP). In periods prior to February 28, 2014, our Consolidated Financial Statements presented the accounts of Endo Health Solutions Inc., which was incorporated under the laws of the State of Delaware on November 18, 1997, and all of its subsidiaries (EHSI). Endo International plc was incorporated in Ireland on October 31, 2013 as a private limited company and re-registered effective February 18, 2014 as a public limited company. Endo International plc was established for the purpose of facilitating the business combination between EHSI and Paladin Labs Inc. (Paladin). On February 28, 2014, we became the successor registrant of EHSI and Paladin in connection with the consummation of certain transactions further described elsewhere in our Consolidated Financial Statements. In addition, on February 28, 2014, the shares of Endo International plc began trading on the NASDAQ under the symbol “ENDP,” the same symbol under which EHSI’s shares previously traded, and on the Toronto Stock Exchange under the symbol “ENL”. References throughout to “ordinary shares” refer to EHSI’s common shares, 350,000,000 authorized, par value \$0.01 per share, prior to the consummation of the transactions and to Endo International plc’s ordinary shares, 1,000,000,000 authorized, par value \$0.0001 per share, subsequent to the consummation of the transactions. In addition, on February 11, 2014 the Company issued 4,000,000 euro deferred shares of \$0.01 each at par.

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 EHSI and its consolidated subsidiaries prior to February 28, 2014 and Endo International plc and its consolidated subsidiaries thereafter.

Endo International plc is an Ireland-domiciled, global specialty pharmaceutical company focused on branded and generic pharmaceuticals. Our goal is to be the premier partner to healthcare professionals and payment providers, delivering an innovative suite of branded and generic drugs to meet patients’ needs.

**NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

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

The Company owns majority controlling interests in certain entities. Additionally, prior to the sale of our HealthTronics business in February 2014, HealthTronics, Inc. owned interests in various partnerships and limited liability corporations where HealthTronics, Inc., as the general partner or managing member, exercised effective control. In accordance with the accounting consolidation principles, we consolidate various entities which neither we nor our subsidiaries own 100%. For additional information relating to the sale of HealthTronics, see Note 3. Divestitures.

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

Prior to December 31, 2015, the Company had classified product sales reserves for chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and allowances as well as fees for services (collectively, revenue reserves) as accrued expenses on its consolidated balance sheet. This classification was based on the Company’s historical practices, at times, to settle these reserves in cash. In conjunction with our acquisition of Par in September 2015, we re-evaluated our planned settlement practice and determined that we will offset certain customer receivables with amounts due to the customers. As a result, we have classified \$898.8 million of revenue reserves as reductions from accounts receivable on our consolidated balance sheet as of December 31, 2015. We have treated this change on a prospective basis and will not adjust any amounts previously reported in our consolidated financial statements. Amounts related to similar reserves classified as accrued expenses on our consolidated balance sheet as of December 31, 2014 totaled \$441.5 million.

In April 2015, the FASB issued ASU No. 2015-03, “*Simplifying the Presentation of Debt Issuance Costs*” (ASU 2015-03). ASU 2015-03 requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability instead of being presented as an asset. The Company adopted ASU 2015-03 on December 31, 2015. As of December 31, 2015 and 2014, the Company had \$138.4 million and \$85.4 million of net deferred financing costs that were reclassified from Other assets to a reduction in the carrying amount of Long-term debt, less current portion, net in the Consolidated Balance Sheets.

In November 2015, the FASB issued ASU No. 2015-17, “*Balance Sheet Classification of Deferred Taxes*” (ASU 2015-17). ASU 2015-17 simplifies the presentation of deferred income taxes by requiring that all deferred income tax assets and liabilities be classified as non-current in the consolidated balance sheet. The Company adopted ASU 2015-17 on December 31, 2015 on a prospective basis. As of December 31, 2015, the Company had \$329.7 million and \$81.8 million of Deferred income tax assets and Deferred income tax liabilities, respectively, that were reclassified from current to non-current in the Consolidated Balance Sheets.

Prior periods were not retrospectively adjusted. Amounts that would have been reclassified from current to non-current on our Consolidated Balance Sheets as of December 31, 2014 if the change was applied retrospectively totaled \$562.0 million Deferred income tax assets and \$22.0 thousand Deferred income tax liabilities, respectively.

*Use of Estimates*—The preparation of our Consolidated Financial Statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the Consolidated Financial Statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in the determination of revenue recognition and sales deductions for estimated chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and allowances. Significant estimates and assumptions are also required when determining the fair value of certain financial instruments, the valuation of long-lived and indefinite-lived assets, income taxes, contingencies and share-based compensation. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. Our estimates often are based on complex judgments, probabilities and assumptions that we believe to be reasonable but that are inherently uncertain and unpredictable. For any given individual estimate or assumption made by us, there may also be other estimates or assumptions that are reasonable.

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 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 unless they are required to be treated retrospectively under the relevant accounting standard. It is possible that other professionals, applying reasonable judgment to the same facts and circumstances, could develop and support a range of alternative estimated amounts. 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.

*Customer, Product and Supplier Concentration*—We primarily sell our products directly to a limited number of large pharmacy chains and through a limited number of wholesale drug distributors who, in turn, supply products to pharmacies, hospitals, governmental agencies and physicians. Total revenues from customers who accounted for 10% or more of our total consolidated revenues during the years ended December 31 are as follows:

	2015	2014	2013
Cardinal Health, Inc.	21%	21%	26%
McKesson Corporation	31%	31%	32%
AmerisourceBergen Corporation	23%	16%	19%

Revenues from these customers are included within our U.S. Branded Pharmaceuticals, U.S. Generic Pharmaceuticals and International Pharmaceuticals segments.

Products that accounted for 10% or more of our total revenues during the years ended December 31 were as follows:

	2015	2014	2013
Lidoderm®	4%	7%	28%
OPANA® ER	5%	8%	11%

We have agreements with Novartis Consumer Health, Inc., Novartis AG, Sandoz, Inc., Teikoku Seiyaku Co., Ltd., Noramco, Inc., Grünenthal GmbH, Sharp Corporation and Jubilant HollisterStier Laboratories LLC for the manufacture and supply of a substantial portion of our existing pharmaceutical products. Additionally, we utilize UPS Supply Chain Solutions, Inc. for certain customer service support, warehouse and distribution services. See Note 14. Commitments and Contingencies for further information.

#### *Revenue Recognition*—

##### *Pharmaceutical Products*

Our net pharmaceutical product sales consist of revenues from sales of our pharmaceutical products, less estimates for chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and allowances as well as fees for services. We recognize revenue for product sales when title and risk of loss has passed to the customer, which is typically upon delivery to the customer, when estimated provisions for revenue reserves are reasonably determinable, and when collectability is reasonably confirmed. Revenue from the launch of a new or significantly unique product, for which we are unable to develop the requisite historical data on which to base estimates of returns and allowances due to the uniqueness of the therapeutic area or delivery technology as compared to other products in our portfolio and in the industry, may be deferred until such time that an estimate can be determined, all of the conditions above are met and when the product has achieved market acceptance, which is typically based on dispensed prescription data and other information obtained prior to and during the period following launch.

### *Other*

Product royalties received from third party collaboration partners and licensees of our products and patents are recorded as part of Total revenues. Royalties are recognized as earned in accordance with the contract terms when royalties from third parties can be reasonably estimated and collectability is reasonably confirmed. If royalties cannot be reasonably estimated or collectability of a royalty amount is not reasonably confirmed, royalties are recognized as revenue when the cash is received.

Milestone payments earned by the Company under out-license agreements are recorded in Total revenues. Revenue from these milestone payments is recognized as revenue ratably from the point in which the milestone is achieved over the remaining performance period. See Note 11. License and Collaboration Agreements for specific agreement details.

*Sales Deductions*—When we recognize net sales from the sale of our pharmaceutical products, we record an adjustment to revenue for estimated revenue reserves. These provisions are estimated based on historical experience, estimated future trends, estimated customer inventory levels, current contract sales terms with our wholesale and indirect customers and other competitive factors. If the assumptions we used to calculate these adjustments do not appropriately reflect future activity, our financial position, results of operations and cash flows could be materially impacted.

*Research and Development*—Expenditures for research and development are expensed as incurred. In addition to upfront and milestone payments, total R&D expenses include the costs of discovery research, preclinical development, early- and late-clinical development and drug formulation, as well as clinical trials, medical support of marketed products, 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. Upfront and milestone payments made to third parties in connection with agreements with third parties are generally expensed as incurred up to the point of regulatory approval. Payments made to third parties subsequent to regulatory approval are generally capitalized and amortized over the remaining useful life of the related product. 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, 2015, cash equivalents were deposited in financial institutions and consisted of immediately available fund balances. The Company maintains its cash deposits and cash equivalents with well-known and stable financial institutions.

*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 recorded in Restricted cash and cash equivalents in the Consolidated Balance Sheets. At December 31, 2015, restricted cash and cash equivalents totaled \$585.4 million, of which \$579.0 million is held in Qualified Settlement Funds for mesh product liability settlement agreements. The restricted cash related to Qualified Settlement Funds are for payments related to the Company's vaginal mesh liability. See Note 14. Commitments and Contingencies for further information relating to the vaginal mesh liability. At December 31, 2014, restricted cash and cash equivalents totaled \$530.9 million, of which \$485.2 million was held in Qualified Settlement Funds for mesh product liability settlement agreements, and \$40.2 million was held in an escrow account, primarily for the purpose of guaranteeing amounts required to be paid to Litha Healthcare Group Limited's (Litha) security holders in connection with acquisition of Litha's remaining outstanding issued share capital.

*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. The allowance for doubtful accounts against gross accounts receivable reflects the best estimate of probable losses inherent in the receivables portfolio determined on the basis of historical experience, specific allowances for known troubled accounts and other currently available information. 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, marketable debt securities and accounts receivable. We invest our excess cash in high-quality, liquid money market instruments maintained by major U.S. 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 77% and 76% of our gross trade accounts receivable balance represent amounts due from three customers at December 31, 2015 and 2014, respectively.

We do not expect our current or future credit risk exposures to have a significant impact on our operations. However, there can be no assurance that our business will not experience any adverse impact from credit risk in the future.

*Inventories*—Inventories consist of finished goods held for distribution, raw materials and work-in-process. Our inventories are stated at the lower of cost or market. Cost is determined by the first-in, first-out method. We write-down inventories to net realizable

value based on forecasted demand and market conditions, which may differ from actual results. 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.

*Property, plant and equipment*—Property, plant and equipment is stated at cost less accumulated depreciation. Costs incurred on assets under construction are capitalized as construction is in progress. Depreciation is computed over the estimated useful life of the related assets on a straight-line basis. Leasehold improvements and capital lease assets are depreciated on a straight-line basis over the shorter of their estimated useful lives or the terms of their respective leases. Depreciation is not recorded on assets held for sale. Gains and losses on disposals are included in Other expense (income), net in the Consolidated Statements of Operations.

Depreciation is based on the following estimated useful lives, as of December 31, 2015:

	<b>Range of Useful Lives, from:</b>		
Buildings	8 years	to	45 years
Machinery and equipment	2 years	to	20 years
Leasehold improvements	2 years	to	10 years
Computer equipment and software	2 years	to	10 years
Assets under capital lease	Shorter of useful life or lease term		
Furniture and fixtures	2 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 amortized 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.

*License Rights*—The cost of licenses are either expensed immediately or, if capitalized, are stated at cost, less accumulated amortization and are amortized using the straight-line method over their estimated useful lives ranging from 3 years to 15 years, with a weighted average useful life of approximately 10 years. We determine amortization periods for licenses based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental and regulatory issues, and contractual terms. Amortization expense is not recorded on assets held for sale.

*Customer Relationships*—Acquired customer relationships are recorded at fair value upon acquisition. All customer relationship assets relate to our AMS business and are classified as Assets held for sale in the Consolidated Balance Sheets. Amortization expense is not recorded on assets held for sale.

*Trade names*—Acquired trade names are recorded at fair value upon acquisition and, if deemed to have definite lives, are amortized using the straight-line method over their estimated useful lives of approximately 12 years. We determine amortization periods for trade names based on our assessment of various factors impacting estimated useful lives and cash flows from the acquired assets. Such factors include the strength of the trade name and our plans regarding the future use of the trade name. 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*—Acquired developed technology is recorded at fair value upon acquisition and is amortized using the economic benefit model or the straight-line method, over the estimated useful life ranging from 3 years to 20 years for our intangibles relating to continuing operations, with a weighted average useful life of approximately 12 years. We determine amortization periods and method of amortization for developed technology based on our assessment of various factors impacting estimated useful lives and timing and extent of estimated cash flows of the acquired assets. Such factors include the strength of the intellectual property protection of the product and various other competitive and regulatory issues, and contractual terms. 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. The value of these assets is subject to continuing scientific, medical and marketplace uncertainty.

*Long-Lived Asset Impairment Testing*—Long-lived assets, which include property, plant and equipment and definite-lived intangible assets, are assessed for impairment whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows generated by that asset. In the event the carrying amount of the asset exceeds the undiscounted future cash flows generated by that asset and the carrying amount is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset's carrying amount over its fair value. An impairment loss is recognized in net income in the period that the impairment occurs.

*In-Process Research and Development Assets (IPR&D)*—The fair value of IPR&D acquired in a business combination is determined based on the present value of each research project's projected cash flows using an income approach. Future cash flows are predominately based on the net income forecast of each project, consistent with historical pricing, margins and expense levels of similar products. Revenues are estimated based on relevant market size and growth factors, expected industry trends, individual project life cycles and the life of each research project's underlying patent. In determining the fair value of each research project, expected cash flows are adjusted for the technical and regulatory risk of completion.

IPR&D is initially capitalized and considered indefinite-lived intangible assets subject to annual impairment reviews. The reviews, which occur annually or more frequently upon the occurrence of certain events, requires the determination of the fair value of the respective intangible assets. 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 amortized over the expected useful lives.

*Goodwill*—Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is carried at cost. Goodwill is not amortized; rather, it is subject to a periodic assessment for impairment by applying a fair value based test. Goodwill is assessed for impairment on an annual basis, as of October 1st of each year or more frequently if events or changes in circumstances indicate that the asset might be impaired. The impairment model requires a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our reporting units using an appropriate valuation methodology. If the net book value of a reporting unit exceeds its fair value, we would then perform the second step of the impairment test which requires allocation of the reporting unit's fair value to all of its assets and liabilities using the acquisition method prescribed under authoritative guidance for business combinations. Any residual fair value is allocated to goodwill. An impairment charge is recognized only when the implied fair value of our reporting unit's goodwill is less than its carrying amount.

*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 in the Consolidated Statements of Operations. Contingent accruals are recorded with a corresponding charge to Litigation-related and other contingencies, net in the Consolidated Statements of Operations 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 assessments 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 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 contingent consideration liability is remeasured at current fair value with changes recorded in earnings. Changes in any of the inputs may result in a significantly different fair value adjustment.

*Convertible Senior Subordinated Notes*—We accounted for the issuance of our 1.75% Convertible Senior Subordinated Notes due April 2015 (the Convertible Notes) in accordance with the guidance regarding the accounting for convertible debt instruments that may be settled in cash upon conversion, which among other items, specifies that contracts issued or held by an entity that are both (1) indexed to the entities own ordinary shares and (2) classified in shareholders' equity in its statement of financial position are not

considered to be derivative financial instruments if the appropriate provisions are met. Accordingly, we recorded the Convertible Notes as debt in the Consolidated Balance Sheets.

*Convertible Notes Hedge & Warrants*—Concurrent with the issuance of the Convertible Notes we entered into privately negotiated ordinary share call options with affiliates of the initial purchasers. In addition, we sold warrants to affiliates of certain of the initial purchasers. In addition to entering into the convertible note hedge transaction and the warrant transaction, we entered into a privately negotiated, accelerated share repurchase agreement with the same counterparty, as part of our broader share repurchase program described in Note 16. Shareholders' Equity. We accounted for the call options, warrants, and accelerated share repurchase agreement in accordance with the guidance regarding the accounting derivative financial instruments indexed to, and potentially settled in, a company's own stock. The call options, warrants, and accelerated share repurchase agreement meet the requirements to be accounted for as equity instruments. The cost of the call options and the proceeds related to the sale of the warrants are included in Additional paid-in capital in the Consolidated Balance Sheets.

*Share Repurchases*—The Company accounts for the repurchase of ordinary shares at par value. Under applicable Irish law, ordinary shares repurchased are retired and not displayed separately as treasury stock. Upon retirement of the ordinary shares, the Company records the 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 and amounted to \$57.9 million, \$28.1 million and \$31.6 million for the years ended December 31, 2015, 2014 and 2013, respectively.

*Cost of Revenues*—Cost of revenues includes all costs directly related to bringing both purchased and manufactured products to their final selling destination. It includes 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. Cost of revenues also includes royalties paid or owed by Endo on certain in-licensed products, inspection costs, depreciation, amortization of intangible assets, warehousing costs, freight charges, costs to operate our equipment, and other shipping and handling activity.

*Share-Based Compensation*—Share-based compensation for employees and non-employee directors is measured at the grant date based on the estimated fair value of the award and is recognized as an expense over the requisite service period. 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.

*Foreign Currency Translation*—The Company's operations utilize the U.S. dollar (USD) or local currency as the functional currency, where applicable. The company identifies its separate and distinct foreign entities and groups the foreign entities into two categories: 1) extension of the parent (USD functional currency) and 2) self-contained (local functional currency). If a foreign entity does not align with either category, factors are evaluated and a judgment is made to determine the functional currency.

For foreign entities where the USD is the functional currency, all foreign currency-denominated asset and liability amounts are re-measured into USD at end-of-period exchange rates, except for inventories, prepaid expenses, property, plant and equipment, goodwill and other intangible assets, which are re-measured at historical rates. Foreign currency income and expenses are re-measured at average exchange rates in effect during the year, except for expenses related to balance sheet amounts re-measured at historical exchange rates. Exchange gains and losses arising from re-measurement of foreign currency-denominated monetary assets and liabilities are included in income in the period in which they occur.

For foreign entities where the local currency is the functional currency, assets and liabilities denominated in local currencies are translated into USD at end-of-period exchange rates and the resultant translation adjustments are reported, net of their related tax effects, as a component of accumulated other comprehensive income (loss) in equity. Assets and liabilities denominated in other than the local currency are re-measured into the local currency prior to translation into USD and the resultant exchange gains or losses are included in income in the period in which they occur. Income and expenses are translated into USD at average exchange rates in effect during the period.

*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 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 in accordance with Accounting Standards Codification (ASC) Topic 740, Income Taxes, 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 line in the accompanying 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 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*

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards update (ASU) No. 2014-09, “*Revenue from Contracts with Customers*” (ASU 2014-09). ASU 2014-09 represents a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled to receive in exchange for those goods or services. This ASU sets forth a new five-step revenue recognition model which replaces the prior revenue recognition guidance in its entirety and is intended to eliminate numerous industry-specific pieces of revenue recognition guidance that have historically existed. In August 2015, the FASB issued ASU No. 2015-14, “*Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*” (ASU 2015-14), which defers the effective date of ASU No. 2014-09 by one year, but permits entities to adopt one year earlier if they choose (i.e., the original effective date). As such, ASU No. 2014-09 will be effective for annual and interim reporting periods beginning after December 15, 2017. The Company currently plans to adopt this ASU on January 1, 2018. Companies may use either a full retrospective or a modified retrospective approach to adopt this ASU. The Company is currently evaluating the impact of ASU 2014-09 on the Company’s consolidated results of operations and financial position.

In April 2015, the FASB issued ASU No. 2015-03, “*Simplifying the Presentation of Debt Issuance Costs*” (ASU 2015-03). ASU 2015-03 requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability instead of being presented as an asset. Debt disclosures will include the face amount of the debt liability and the effective interest rate. In August 2015, the FASB issued ASU No. 2015-15, “*Interest - Imputation of Interest (Subtopic 835-30): Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of Credit Arrangements*” (ASU 2015-15). The amendments in ASU 2015-15 state that an entity may defer and present debt issuance costs associated with line-of-credit arrangements as an asset and subsequently amortize the deferred debt issuance costs ratably over the term of the line-of-credit arrangement, regardless of whether there are any outstanding borrowings on the line-of-credit arrangement. ASU 2015-03 and ASU 2015-15 are effective for fiscal years beginning after December 15, 2015, with early adoption permitted, and require retrospective application. The Company adopted ASU 2015-03 and 2015-15 on December 31, 2015. As of December 31, 2015 and 2014, the Company had \$138.4 million and \$85.4 million of net deferred financing costs that were reclassified from Other assets to a reduction in the carrying amount of Long-term debt, less current portion, net in the Consolidated Balance Sheets.

In April 2015, the FASB issued ASU No. 2015-05, “*Customer’s Accounting for Fees Paid in a Cloud Computing Arrangement*” (ASU 2015-05). ASU 2015-05 provides guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. The guidance will not change GAAP for a customer’s accounting for service contracts. In addition, all software licenses within the scope of Subtopic 350-40 will be accounted for consistent with other licenses of intangible assets as a result of the guidance in ASU 2015-05. ASU 2015-05 is effective for annual periods beginning after December 15, 2015 and interim periods in annual periods beginning after December 15, 2016, with early adoption permitted. Companies may use either a full retrospective approach or a prospective approach entered into or materially modified after the effective date to adopt this ASU. The Company is currently evaluating the impact of ASU 2015-05 on the Company’s consolidated results of operations and financial position.

In July 2015, the FASB issued ASU No. 2015-11, “*Simplifying the Measurement of Inventory*” (ASU 2015-11). ASU 2015-11 states that an entity should measure inventory at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. For public entities, ASU 2015-11 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The amendments in this update should be applied prospectively and early application is permitted. The Company is currently evaluating the impact of ASU 2015-11 on the Company’s consolidated results of operations and financial position.

In September 2015, the FASB issued ASU No. 2015-16, “*Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments*” (ASU 2015-16). This ASU requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined, including the cumulative effect of the change in the provisional amount as if the accounting had been completed at the acquisition date. The adjustments related to previous reporting periods since the acquisition date must be disclosed by income statement line item either on the face of the income statement or in the footnotes. For public entities, the new standard is effective for interim and annual periods beginning after December 15, 2015, with early adoption permitted. The Company adopted ASU 2015-16 on July 1, 2015. Accordingly, the Company applied the amendments in this update to the measurement period adjustments made during the six months ended December 31, 2015. See Note 5. Acquisitions for more information regarding adjustments to provisional amounts that occurred during 2015.

In November 2015, the FASB issued ASU No. 2015-17, “*Balance Sheet Classification of Deferred Taxes*” (ASU 2015-17). ASU 2015-17 simplifies the presentation of deferred income taxes by requiring that all deferred income tax assets and liabilities be classified as non-current in the consolidated balance sheet. For public entities, the new standard is effective for interim and annual periods beginning after December 15, 2016, with early adoption permitted. The ASU may be applied either prospectively to all deferred tax assets and liabilities or retrospectively to all periods presented. The Company adopted ASU 2015-17 on December 31, 2015 on a prospective basis. As of December 31, 2015, the Company had \$329.7 million and \$81.8 million of Deferred income tax assets and Deferred income tax liabilities, respectively, that were reclassified from current to non-current in the Consolidated Balance Sheets. Prior periods were not retrospectively adjusted. Amounts that would have been reclassified from current to non-current on our Consolidated Balance Sheets as of December 31, 2014 if the change was applied retrospectively totaled \$562.0 million Deferred income tax assets and \$22.0 thousand Deferred income tax liabilities, respectively.

In February 2016, the FASB issued ASU No. 2016-02, “*Leases (Topic 842)*” (ASU 2016-02). ASU 2016-02 establishes the principles to report transparent and economically neutral information about the assets and liabilities that arise from leases. This guidance results in a more faithful representation of the rights and obligations arising from operating and capital leases by requiring lessees to recognize the lease assets and lease liabilities that arise from leases in the statement of financial position and to disclose qualitative and quantitative information about lease transactions, such as information about variable lease payments and options to renew and terminate leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the impact of ASU 2016-02 on the Company’s consolidated results of operations and financial position.

### **NOTE 3. DIVESTITURES**

#### ***American Medical Systems***

On February 24, 2015, the Board of Directors approved a plan to sell the Company’s American Medical Systems Holdings, Inc. (AMS) business, which comprised the entirety of our former Devices segment. The AMS business was comprised of the Men’s Health and Prostate Health business as well as the Women’s Health business (now doing business as Astora). On August 3, 2015, the Company sold the Men’s Health and Prostate Health business to Boston Scientific Corporation (Boston Scientific) for \$1.65 billion, with \$1.60 billion paid in upfront cash and \$50.0 million in cash contingent on Boston Scientific achieving certain product revenue milestones in the Men’s Health and Prostate Health components in 2016. In addition, Boston Scientific paid \$60.0 million in exchange for 60,000 shares of American Medical Systems Holdings, Inc. Series B Non-Voting Preferred Stock (Series B Senior Preferred Stock) sold by our subsidiary Endo Pharmaceuticals Inc. (EPI). On December 11, 2015, the Company redeemed all 60,000 shares of the Series B Senior Preferred Stock from Boston Scientific Corporation for \$61.6 million, including accrued and unpaid dividends.

In addition to selling the Men’s Health and Prostate Health business, as of December 31, 2015 and continuing into 2016, the Company was actively pursuing a sale of the Astora business with the Company in active negotiations with multiple potential buyers.

The operating results of the AMS business are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented.

On February 24, 2016, the Company’s Board of Directors decided to wind down Astora business operations in order to begin bringing finality to the Company’s mesh-related product liability. The Company is now actively conducting a wind down process and working to efficiently transition physicians to alternative products. The Company will cease business operations for Astora by March 31, 2016. The majority of the remaining assets and liabilities of the AMS business, which are related to the Astora business, are classified as held for sale in the Consolidated Balance Sheets as of December 31, 2015. Certain of AMS’s assets and liabilities, primarily with respect to its product liability accrual related to vaginal mesh cases, the related Qualified Settlement Funds and certain intangible and fixed assets, are not classified as held for sale based on management’s current expectation that these assets and liabilities will remain with the Company. Depreciation and amortization expense are not recorded on assets held for sale. Upon wind down of the Astora business, the Company will have entirely exited its AMS business.



In connection with classifying AMS as held for sale, the Company was required to compare the estimated fair values of the underlying disposal groups, less the costs to sell, to the respective carrying amounts. As a result of this analysis, the Company recorded a combined asset impairment charge of \$222.8 million during the three months ended March 31, 2015, which was classified as Discontinued operations, net of tax in the Consolidated Statements of Operations. We estimated the fair value of the Men's Health and Prostate Health division based on the agreed upon purchase price with Boston Scientific. The fair value of the Astora business was estimated based on expressions of interest from third parties. Subsequently, at the time of the sale of the Men's Health and Prostate Health component in August 2015, the Company recorded a gain based on the difference between the net proceeds received and the net book value of the assets sold of approximately \$13.6 million, which included an adjustment of \$25.7 million relating to amounts transferred from foreign currency translation adjustments and included in the determination of net income for the period as a result of the sale, which decreased the gain. This amount is included in Discontinued operations, net of tax in the Consolidated Statements of Operations for the year ended December 31, 2015.

During the three months ended September 30, 2015 and December 31, 2015, the Company compared the estimated fair value of the Astora business, less the costs to sell, to its respective carrying amount. As a result of these analyses, the Company recorded total additional asset impairment charges of \$7.9 million for the year ended December 31, 2015, which were classified as Discontinued operations, net of tax in the Consolidated Statements of Operations. The fair value of the Astora business was estimated based on updated expressions of interest from third parties.

In addition, as a result of determining that the sale of the AMS disposal groups was probable as of December 31, 2015, the Company re-assessed its permanent reinvestment assertion for certain components of the AMS business and recognized a corresponding tax benefit of \$161.8 million during the year ended December 31, 2015, which was recorded as Income tax benefit (a component of income (loss) from continuing operations) in the Consolidated Statements of Operations. In addition, due to the overall differences between the book and tax basis of the underlying assets sold during the third quarter of 2015, the Company recognized a tax benefit of \$157.4 million during the year ended December 31, 2015, from Discontinued operations.

The results of our 2013 Step I analysis for the AMS reporting unit showed that the fair value of that reporting unit was lower than its carrying amount, thus requiring a Step II analysis for the reporting unit. The decline in the fair value, as well as fair value changes for other assets and liabilities in the Step II goodwill impairment test, resulted in an implied fair value of goodwill below the carrying amount of the goodwill for the reporting unit. Accordingly, we recorded combined pre-tax non-cash goodwill impairment charges within Discontinued operations, net of tax in the Consolidated Statements of Operations totaling \$481.0 million in 2013.

As a result of the 2013 Step II analysis, we also determined that the carrying amounts of certain AMS IPR&D intangible assets were impaired. This determination was based primarily on lower than initially expected revenue and profitability levels over a sustained period of time and downward revisions to management's short-term and long-term forecasts. Accordingly, we recorded pre-tax non-cash impairment charges of \$6.0 million within Discontinued operations, net of tax in the Consolidated Statements of Operations, to impair the IPR&D assets, representing the difference between the fair values and the carrying amounts.

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

	2015	2014	2013
Revenue	\$ 305,256	\$ 496,505	\$ 492,226
Litigation related and other contingencies, net	\$ 1,107,752	\$ 1,273,358	\$ 474,792
Asset impairment charges	\$ 230,703	\$ —	\$ 487,000
Gain on sale of business	\$ 13,550	\$ —	\$ —
Loss from discontinued operations before income taxes	\$ (1,352,344)	\$ (1,225,576)	\$ (944,933)
Income tax benefit	\$ (157,418)	\$ (440,107)	\$ (167,809)
Discontinued operations, net of tax	\$ (1,194,926)	\$ (785,469)	\$ (777,124)

The following table provides the components of Assets and Liabilities held for sale of AMS as of December 31, 2015 and December 31, 2014 (in thousands):

	December 31, 2015	December 31, 2014
Current assets	\$ 29,085	\$ 165,075
Property, plant and equipment	5,050	41,122
Goodwill	—	862,960
Other intangibles, net	16,287	861,174
Other assets	1,278	7,533
Assets held for sale	<u>\$ 51,700</u>	<u>\$ 1,937,864</u>
Current liabilities	\$ 14,676	\$ 53,143
Deferred taxes	—	46,538
Other liabilities	—	3,657
Liabilities held for sale	<u>\$ 14,676</u>	<u>\$ 103,338</u>

The following table provides the Depreciation and amortization and Purchases of property, plant and equipment of AMS for the years ended December 31 (in thousands):

	2015	2014	2013
Cash flows from discontinued operating activities:			
Net loss	\$ (1,194,926)	\$ (785,469)	\$ (777,124)
Depreciation and amortization	\$ 11,555	\$ 70,275	\$ 72,003
Cash flows from discontinued investing activities:			
Purchases of property, plant and equipment	\$ (2,709)	\$ (4,423)	\$ (3,517)

### HealthTronics

On December 28, 2013, the EHSI Board approved a plan to sell the HealthTronics business and the Company entered into a definitive agreement to sell the business on January 9, 2014 to Altaris Capital Partners LLC for an upfront cash payment of \$85.0 million, subject to cash and other working capital adjustments. During the three months ended March 31, 2015, we received additional cash payments of \$4.7 million from the purchaser of HealthTronics. The sale was completed on February 3, 2014.

In 2014, the Company recorded a net gain of \$3.6 million, representing the carrying amount of the assets sold less the amount of the net proceeds, including the \$4.7 million described above, which the Company became entitled to receive during the fourth quarter of 2014.

The operating results of this business are reported as Discontinued operations, net of tax, in the Consolidated Statements of Operations for the years ended December 31, 2014 and December 31, 2013.

The following table provides the operating results of Discontinued operations of HealthTronics, net of tax for the years ended December 31 (in thousands).

	2014	2013
Revenue	\$ 14,443	\$ 207,194
Income (loss) from discontinued operations before income taxes	\$ 6,434	\$ (119,690)
Income tax expense (benefit)	\$ 757	\$ (22,776)
Discontinued operations, net of tax	\$ 5,677	\$ (96,914)

There were no Assets or Liabilities held for sale relating to HealthTronics included in the Consolidated Balance Sheets as of December 31, 2015 and December 31, 2014.

**Other**

As of December 31, 2015, the Company committed to a plan to divest a component of its business that is not individually material. The Company has retrospectively classified this component's assets and liabilities as held for sale in the accompanying Consolidated Balance Sheets. Given that the component does not represent a strategic shift in the Company's business, the Company has not classified the operations of this component as discontinued.

**NOTE 4. RESTRUCTURING**

***U.S. Generic Pharmaceuticals Restructuring***

In connection with the acquisition of Par Pharmaceutical Holdings, Inc. (Par) on September 25, 2015, we implemented cost-rationalization and integration initiatives to capture operating synergies and generate cost savings across the Company. These measures included realigning the Company's U.S. Generic Pharmaceuticals segment sales, sales support, and management activities and staffing, which resulted in severance benefits to U.S. Generic Pharmaceuticals employees. The cost reduction initiatives included a reduction in headcount of approximately 6% of the U.S. Generic Pharmaceuticals workforces. Under this restructuring initiative, severance is expensed over the requisite service period, if any, while retention is being expensed ratably over the respective retention period.

As a result of the U.S. Generic Pharmaceuticals restructuring initiative, the Company incurred restructuring expenses of \$23.6 million during the year ended December 31, 2015, consisting of employee severance, retention and other benefit-related costs. The Company anticipates there will be additional pre-tax restructuring expenses of \$5.3 million related to employee severance, retention and other benefit-related costs and these actions are expected to be completed by October 31, 2016, with substantially all cash payments made by the end of 2016. In addition, the Company anticipates there will be additional pre-tax restructuring expenses of \$12.3 million related to accelerated depreciation on certain assets. These restructuring costs are allocated to the U.S. Generic Pharmaceuticals segment, and are primarily included in Selling, general and administrative in the Consolidated Statements of Operations.

The liability related to the U.S. Generic Pharmaceuticals restructuring initiative totaled \$17.9 million at December 31, 2015. At December 31, 2015, this liability is included in Accrued expenses in the Consolidated Balance Sheets. Changes to this accrual during the year ended December 31, 2015 were as follows (in thousands):

	Total
Liability balance as of January 1, 2015	\$ —
Expenses	23,591
Cash payments	(5,677)
Liability balance as of December 31, 2015	\$ 17,914

***Auxilium Restructuring***

In connection with the acquisition of Auxilium Pharmaceuticals, Inc. (Auxilium) on January 29, 2015, the Company implemented cost-rationalization and integration initiatives to capture operating synergies and generate cost savings across the Company. These measures included realigning our sales, sales support, and management activities and staffing, which included severance benefits to former Auxilium employees, in addition to the closing of duplicative facilities. The cost reduction initiatives included a reduction in headcount of approximately 40% of the former Auxilium workforce. For former Auxilium employees that have agreed to continue employment with the Company for a merger transition period, the severance payable upon completion of their retention period was expensed over their respective retention period.

As a result of the Auxilium restructuring initiative, the Company incurred restructuring expenses of \$41.9 million during the year ended December 31, 2015, consisting of \$26.7 million of employee severance, retention and other benefit-related costs. The expenses were also attributable to certain charges related to our Auxilium subsidiary's former corporate headquarters in Chesterbrook,

Pennsylvania, including \$7.0 million of asset impairment charges on certain related leasehold improvements during the first quarter of 2015, and \$7.9 million recorded upon the facility's cease use date, representing the liability for our remaining obligations under the respective lease agreement, net of estimated sublease income, during the first quarter of 2015. The Company does not anticipate there will be additional material pre-tax restructuring expenses related to this initiative. The Company anticipates that substantially all cash payments relating to this initiative will be made by the end of 2016. These restructuring costs are allocated to the U.S. Branded Pharmaceuticals segment, and are primarily included in Selling, general and administrative in the Consolidated Statements of Operations.

A summary of expenses related to the Auxilium restructuring initiatives is included below for the year ended December 31, 2015 (in thousands):

	<b>Total</b>
Employee severance, retention and other benefit-related costs	\$ 26,696
Asset impairment charges	7,000
Other restructuring costs	8,215
<b>Total</b>	<b>\$ 41,911</b>

The liability related to the Auxilium restructuring initiative totaled \$12.3 million at December 31, 2015 and is included in Accrued expenses and Other liabilities in the Consolidated Balance Sheets. Changes to this accrual during the year ended December 31, 2015 were as follows (in thousands):

	<b>Employee Severance, Retention and Other Benefit-Related Costs</b>	<b>Other Restructuring Costs</b>	<b>Total</b>
Liability balance as of January 1, 2015	\$ —	\$ —	\$ —
Expenses	26,696	8,215	34,911
Cash payments	(21,343)	(1,305)	(22,648)
Liability balance as of December 31, 2015	<u>\$ 5,353</u>	<u>\$ 6,910</u>	<u>\$ 12,263</u>

### June 2013 Restructuring Initiative

On June 4, 2013, the Board approved certain strategic, operational and organizational steps for the Company and its subsidiaries to take to refocus its operations and enhance shareholder value. These actions were the result of a comprehensive assessment of the Company's strengths and challenges, its cost structure and execution capabilities, and its most promising opportunities to drive future cash flow and earnings growth. The cost reduction initiatives included a reduction in headcount of approximately 15% worldwide, streamlining of general and administrative expenses, optimizing commercial spend and refocusing research and development efforts.

There were no restructuring expenses related to the June 2013 restructuring initiative during the year ended December 31, 2015. As a result of this initiative, the Company incurred restructuring expenses of \$2.1 million during the year ended December 31, 2014, consisting of \$1.2 million of employee severance, retention and other benefit-related costs and \$0.9 million of other costs associated with the restructuring. During the year ended December 31, 2013, the Company incurred restructuring expenses of \$56.3 million, consisting of \$41.4 million of employee severance, retention and other benefit-related costs, \$12.0 million of other costs associated with the restructuring, mainly contract termination fees and \$2.8 million of asset impairment charges. The majority of these restructuring costs, with the exception of the costs related to AMS and HealthTronics, are included in Selling, general and administrative expense in the Consolidated Statements of Operations. The operating results of AMS and HealthTronics are reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented.

A summary of expenses related to the June 2013 restructuring initiatives is included below by reportable segment and for corporate unallocated for the year ended December 31, 2013 (in thousands):

	<b>Employee Severance, Retention and Other Benefit-Related Costs</b>	<b>Asset Impairment Charges</b>	<b>Other Restructuring Costs</b>	<b>Total</b>
U.S. Branded Pharmaceuticals	\$ 22,847	\$ 2,849	\$ 8,780	\$ 34,476
U.S. Generic Pharmaceuticals	262	—	1,142	1,404
Discontinued operations (Note 3)	9,905	—	2,044	11,949
Corporate unallocated	8,421	—	—	8,421
<b>Total</b>	<u>\$ 41,435</u>	<u>\$ 2,849</u>	<u>\$ 11,966</u>	<u>\$ 56,250</u>

A summary of the liability balance related to the June 2013 restructuring initiative is included below for the years ended December 31, 2015 and December 31, 2014 (in thousands):

	Employee Severance, Retention and Other Benefit-Related Costs	Other Restructuring Costs	Total
Liability balance as of January 1, 2014	\$ 7,379	\$ 4,919	\$ 12,298
Expenses	1,224	880	2,104
Cash distributions	(7,320)	(4,453)	(11,773)
Other non-cash adjustments	—	(1,191)	(1,191)
Liability balance as of December 31, 2014	\$ 1,283	\$ 155	\$ 1,438
Cash distributions	(1,283)	(155)	(1,438)
Liability balance as of December 31, 2015	\$ —	\$ —	\$ —

## NOTE 5. ACQUISITIONS

For each of the acquisitions described below, except for Boca Pharmacal LLC (Boca), Paladin, Sumavel® DosePro® (Sumavel®), Somar Grupo Farmacéutico Somar, Sociedad Anónima Promotora de Inversión de Capital Variable (Somar), DAVA Pharmaceuticals, Inc. (DAVA), Natesto™ and Auxilium the estimated fair values of the net assets acquired below are provisional as of December 31, 2015 and are based on information that is currently available to the Company. Additional information is being gathered to finalize these provisional measurements. Accordingly, the measurement of the assets acquired and liabilities assumed may change upon finalization of the Company's valuations and completion of the purchase price allocations, all of which are expected to occur no later than one year from the respective acquisition dates.

### Paladin Labs Inc. Acquisition

On February 28, 2014 (the Paladin Acquisition Date), the Company, through a Canadian subsidiary, acquired all of the shares of Paladin and a U.S. subsidiary of the Company merged with and into EHSI, with EHSI surviving the merger. As a result of these transactions, the former shareholders of EHSI and Paladin became the shareholders of Endo, a public limited company organized under the laws of Ireland, and both EHSI and Paladin became our indirect wholly-owned subsidiaries.

Under the terms of the transaction, former Paladin shareholders received 1.6331 Endo ordinary shares, or 35.5 million shares, and C\$1.16 in cash, for total consideration of \$2.87 billion as of February 28, 2014. On the Paladin Acquisition Date, each then current EHSI shareholder received one ordinary share of Endo for each share of EHSI common stock owned upon closing. Immediately following the closing of the transaction, former EHSI shareholders owned approximately 79% of Endo, and former Paladin shareholders owned approximately 21%.

The acquisition consideration was as follows (in thousands, except for per share amounts):

Number of Paladin shares paid through the delivery of Endo International ordinary shares	20,765
Exchange ratio	1.6331
Number of ordinary shares of Endo International—as exchanged*	33,912
Endo International ordinary share price on February 28, 2014	\$ 80.00
Fair value of ordinary shares of Endo International issued to Paladin Shareholders*	\$ 2,712,956
Number of Paladin shares paid in cash	20,765
Per share cash consideration for Paladin shares (1)	\$ 1.09
Cash distribution to Paladin shareholders*	22,647
Fair value of the vested portion of Paladin stock options outstanding—1.3 million at February 28, 2014 (2)	131,323
Total acquisition consideration	\$ 2,866,926

\* Amounts do not recalculate due to rounding.

(1) Represents the cash consideration per the arrangement agreement of C\$1.16 per Paladin share translated into U.S. dollars utilizing an exchange rate of \$0.9402.

(2) Represents the fair value of vested Paladin stock option awards attributed to pre-combination services that were outstanding on the Paladin Acquisition Date and settled on a cash-less exercise basis for Endo ordinary shares.

Paladin is a specialty pharmaceutical company headquartered in Montreal, Canada, focused on acquiring and in-licensing innovative pharmaceutical products for the Canadian and world markets. Paladin's key products serve growing therapeutic areas including attention deficit hyperactivity disorder (ADHD), pain, and urology. In addition to its Canadian operations, as of the Paladin Acquisition date, Paladin owned a controlling interest in Laboratorios Paladin de Mexico S.A. in Mexico and in publicly traded Litha Healthcare Group Limited (Litha) in South Africa.

The operating results of Paladin are included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2015 and the operating results from the acquisition date of February 28, 2014 are included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2014. The Consolidated Balance Sheets as of December 31, 2015 and December 31, 2014 reflect the acquisition of Paladin, effective February 28, 2014.

Our measurement period adjustments for Paladin were complete as of February 28, 2015. In connection with the finalization of our measurement period adjustments for Paladin, we recorded a decrease to certain deferred tax assets of \$1.4 million, with a corresponding increase to goodwill. Other than these adjustments, there have been no changes to the fair values of the assets acquired and liabilities assumed at the Paladin Acquisition Date from December 31, 2014. Goodwill arising from the Paladin acquisition has been assigned to multiple reporting units across each of the Company's reportable segments based on the relative incremental benefit expected to be realized by each impacted reporting unit.

The Company recognized acquisition-related transaction costs associated with the Paladin acquisition during the year ended December 31, 2014 totaling \$27.5 million. These costs, which related primarily to bank fees, legal and accounting services, and fees for other professional services, are included in Acquisition-related and integration items in the accompanying Consolidated Statements of Operations. There were no acquisition-related transaction costs associated with the Paladin acquisition during the year ended December 31, 2015.

The amounts of Paladin Revenue and Net income attributable to Endo International plc included in the Company's Consolidated Statements of Operations from and including February 28, 2014 to December 31, 2014 are as follows (in thousands, except per share data):

Revenue	\$	224,806
Net income attributable to Endo International plc	\$	26,966
Basic net income per share	\$	0.18
Diluted net income per share	\$	0.17

The following supplemental unaudited pro forma information presents the financial results as if the acquisition of Paladin had occurred on January 1, 2014 for the year ended December 31, 2014. This supplemental pro forma information has been prepared for comparative purposes and does not purport to be indicative of what would have occurred had the acquisition been made on January 1, 2014, nor are they indicative of any future results.

	<b>Year Ended December 31, 2014</b>
<b>Unaudited pro forma consolidated results (in thousands, except per share data):</b>	
Revenue	\$ 2,423,683
Net loss attributable to Endo International plc	\$ (727,961)
Basic net loss per share	\$ (4.96)
Diluted net loss per share	\$ (4.64)

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of Paladin to reflect factually supportable adjustments that give effect to events that are directly attributable to the Paladin acquisition assuming the Paladin acquisition had occurred January 1, 2014. These adjustments mainly include adjustments to interest expense and additional intangible amortization. The adjustments to interest expense, net of tax, related to borrowings to finance the acquisition which decreased the expense by \$4.1 million for the year ended December 31, 2014. The adjustments to additional intangible amortization, net of tax, that would have been charged assuming the Company's estimated fair value of the intangible assets, increased the expense by \$2.8 million for the year ended December 31, 2014.

#### **Acquisition of Remaining Shares of Litha**

In February 2015, the Company acquired substantially all of Litha's remaining outstanding ordinary share capital that it did not own for consideration of approximately \$40 million. At December 31, 2014, the Company owned 70.3% of the issued ordinary share capital of Litha. In connection with this transaction, the Company had deposited cash into an escrow account, primarily for the purpose of guaranteeing amounts required to be paid to Litha's security holders in connection with this acquisition. The balance

in this account at December 31, 2014 of approximately \$40 million was included in Restricted cash and cash equivalents in the Consolidated Balance Sheets and was subsequently paid in February 2015.

#### ***Boca Pharmacal LLC Acquisition***

On February 3, 2014, the Company acquired Boca Pharmacal LLC for \$236.6 million in cash. Boca is a specialty generics company that focuses on niche areas, commercializing and developing products in categories that include controlled substances, semisolids and solutions.

The fair values of the net identifiable assets acquired totaled \$212.3 million, resulting in goodwill of \$24.3 million, which was assigned to our U.S. Generic Pharmaceuticals segment. The amount of net identifiable assets acquired in connection with the Boca acquisition includes \$140.9 million of intangible assets, including \$112.3 million of developed technology to be amortized over an average life of approximately 11 years and \$28.6 million of IPR&D.

The operating results of Boca are included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2015 and the operating results from the acquisition date of February 3, 2014 are included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2014. The Consolidated Balance Sheets as of December 31, 2015 and December 31, 2014 reflect the acquisition of Boca, effective February 3, 2014. Our measurement period adjustments were complete for Boca as of February 3, 2015.

Pro forma results of operations have not been presented because the effect of the Boca acquisition was not material.

#### ***Sumavel® DosePro®***

On May 19, 2014, the Company acquired the worldwide rights to Sumavel® DosePro® for subcutaneous use, a needle-free delivery system for sumatriptan, from Zogenix, Inc. The Company is accounting for this transaction as a business combination in accordance with the relevant accounting literature. The Company acquired the product for consideration of \$93.8 million, consisting of an upfront payment of \$89.7 million and contingent cash consideration with an acquisition-date fair value of \$4.1 million. See Note 7. Fair Value Measurements for further discussion of this contingent consideration. In addition, the Company provided Zogenix, Inc. with a \$7.0 million non-interest bearing loan due 2023 for working capital needs and it assumed an existing third-party royalty obligation on net sales. Sumavel® is a prescription medicine given with a needle-free delivery system to treat adults who have been diagnosed with acute migraine or cluster headaches.

The fair values of the net identifiable assets acquired totaled \$93.8 million, resulting in no goodwill. The amount of net identifiable assets acquired in connection with the Sumavel® acquisition includes \$90.0 million of developed technology intangible assets to be amortized over an average life of approximately 13 years.

The operating results of Sumavel® are included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2015 and the operating results from the acquisition date of May 19, 2014 are included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2014. The Consolidated Balance Sheets as of December 31, 2015 and December 31, 2014 reflect the acquisition of Sumavel®, effective May 19, 2014. Our measurement period adjustments were complete for Sumavel as of May 19, 2015.

Pro forma results of operations have not been presented because the effect of the Sumavel® acquisition was not material.

#### ***Grupo Farmacéutico Somar Acquisition***

On July 24, 2014, the Company acquired the representative shares of the capital stock of Grupo Farmacéutico Somar, Sociedad Anónima Promotora de Inversión de Capital Variable (Somar), a leading privately-owned specialty pharmaceuticals company based in Mexico City, for \$270.1 million in cash consideration.

The fair values of the net identifiable assets acquired totaled \$184.5 million, resulting in goodwill of \$85.6 million, which was assigned to our International Pharmaceuticals segment. The amount of net identifiable assets acquired in connection with the Somar acquisition includes \$167.9 million of intangible assets, including \$148.3 million to be amortized over an average life of approximately 12 years and \$19.6 million of IPR&D.

The operating results of Somar are included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2015 and the operating results from the acquisition date of July 24, 2014 are included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2014. The Consolidated Balance Sheets as of December 31, 2015 and December 31, 2014 reflect the acquisition of Somar, effective July 24, 2014. Our measurement period adjustments were complete for Somar as of July 24, 2015.

Pro forma results of operations have not been presented because the effect of the Somar acquisition was not material.

### ***DAVA Pharmaceuticals, Inc. Acquisition***

On August 6, 2014, the Company acquired DAVA Pharmaceuticals, Inc., a privately-held company specializing in marketed, pre-launch and pipeline generic pharmaceuticals based in Fort Lee, New Jersey, for consideration of \$590.1 million. The consideration consisted of cash consideration of \$585.0 million and contingent cash consideration with an acquisition-date fair value of \$5.1 million. See Note 7. Fair Value Measurements for further discussion of this contingent consideration. DAVA's strategically-focused generics portfolio includes 13 on-market products in a variety of therapeutic categories.

The operating results of DAVA are included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2015 and the operating results from the acquisition date of August 6, 2014 are included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2014. The Consolidated Balance Sheets as of December 31, 2015 and December 31, 2014 reflect the acquisition of DAVA, effective August 6, 2014. Our measurement period adjustments were complete for DAVA as of August 6, 2015.

Pro forma results of operations have not been presented because the effect of the DAVA acquisition was not material.

### ***Natesto™***

On December 9, 2014, the Company acquired the rights to Natesto™ (testosterone nasal gel), the first and only testosterone nasal gel for replacement therapy in adult males diagnosed with hypogonadism, from Trimel BioPharma SRL, a wholly-owned subsidiary of Trimel Pharmaceuticals Corporation (Trimel), which was subsequently acquired by Acerus Pharmaceuticals Corporation (Acerus). The Company collaborates with Trimel on all regulatory and clinical development activities regarding Natesto™. The Company is accounting for this transaction as a business combination in accordance with the relevant accounting literature. Natesto™ was approved by the U.S. Food and Drug Administration (FDA) in May 2014. On March 16, 2015, Endo announced the commercial availability of Natesto™.

The Company acquired the product for consideration of \$56.7 million, consisting of an upfront payment of \$25.0 million, prepaid inventory of \$5.0 million and contingent cash consideration with an acquisition-date fair value of \$26.7 million, including the impact of a measurement period adjustment recorded during the first quarter of 2015. See Note 7. Fair Value Measurements for further discussion of this contingent consideration.

The preliminary fair values of the net identifiable assets acquired totaled \$56.7 million, resulting in no goodwill. The amount of net identifiable assets acquired in connection with the Natesto™ acquisition includes \$51.7 million of developed technology to be amortized over 10 years. The net identifiable assets acquired in connection with the Natesto™ acquisition were fully written off during the third quarter of 2015. See Note 10. Goodwill and Other Intangibles for further discussion of this impairment.

On December 30, 2015, the Company provided written notice to Acerus that it was terminating the License, Development, and Supply Agreement by and between the Company and Acerus. The effective date of the termination is June 30, 2016.

The operating results of Natesto™ are included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2015. There are no results included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2014. The Consolidated Balance Sheets as of December 31, 2015 and December 31, 2014 reflect the acquisition of Natesto™, effective December 9, 2014. Our measurement period adjustments were complete for Natesto as of September 30, 2015.

Pro forma results of operations have not been presented because the effect of the Natesto™ acquisition was not material.

### ***Auxilium Pharmaceuticals, Inc.***

On January 29, 2015 (the Auxilium Acquisition Date), the Company acquired all of the outstanding shares of common stock of Auxilium in a transaction valued at \$2.6 billion, as enumerated in the table below.

Pursuant to the terms of the Merger Agreement, of the 55.0 million outstanding Auxilium shares eligible to make an election, 94.9% elected to receive transaction consideration equal to 0.4880 Endo ordinary shares per Auxilium share (the Stock Election Consideration), 0.4% elected to receive 100% cash, which equated to \$33.25 of cash per Auxilium share (the Cash Election Consideration) and 4.7% elected or defaulted to receive a mix of \$16.625 in cash and 0.2440 Endo ordinary shares per Auxilium share (the Standard Election Consideration). The result of the elections led to an oversubscription of the Stock Election Consideration and, in accordance with the proration method described in the Merger Agreement and proxy statement/prospectus provided to Auxilium shareholders, each Auxilium share for which an election was made to receive the Stock Election Consideration was instead entitled to receive approximately 0.3448 Endo shares and \$9.75 in cash.



The acquisition consideration was as follows (in thousands, except for per share amounts):

Number of Endo ordinary shares issued pursuant to the Merger Agreement	18,610	
Endo share price on January 29, 2015	\$ 81.64	
Fair value of Endo ordinary shares issued to Auxilium stockholders		\$ 1,519,320
Cash distribution at closing (1)		1,021,864
Settlement of pre-existing relationships		28,400
Total acquisition consideration		<u>\$ 2,569,584</u>

(1) Represents the cash paid directly to shareholders pursuant to the Merger Agreement, the fair value of Auxilium stock awards attributed to pre-combination services that were outstanding on the Auxilium Acquisition Date and settled in connection with the Auxilium acquisition, and amounts paid by Endo on behalf of Auxilium (including transactions costs incurred by Auxilium in connection with the acquisition and amounts paid to settle existing Auxilium indebtedness and related instruments).

Auxilium is a fully integrated specialty biopharmaceutical company with a focus on developing and commercializing innovative products for specific patients' needs. Auxilium, with a broad range of first- and second-line products across multiple indications, is an emerging leader in the men's healthcare sector and has strategically focused its product portfolio and pipeline in orthopedics, dermatology and other therapeutic areas.

The Company believes Auxilium is highly complementary to Endo's branded pharmaceuticals business. The Company further believes this transaction is well aligned with its growth strategy and the Company sees significant opportunities to leverage its leading presence in men's health, as well as the Company's R&D capabilities and financial resources to accelerate the growth of Auxilium's XIAFLEX® and its other products.

While the Auxilium acquisition was primarily equity based, Endo also made changes to its existing debt structure to complete the transaction, as further described in Note 13. Debt.

The operating results from the acquisition date of January 29, 2015 are included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2015. The Consolidated Balance Sheet as of December 31, 2015 reflects the acquisition of Auxilium, effective January 29, 2015.

The following table summarizes the fair values of the assets acquired and liabilities assumed at the Auxilium Acquisition Date (in thousands):

	January 29, 2015 (As initially reported)	Measurement period adjustments	January 29, 2015 (As adjusted)
Cash and cash equivalents	\$ 115,973	\$ —	\$ 115,973
Accounts receivable	75,849	—	75,849
Inventories	341,900	(44,699)	297,201
Prepaid expenses and other current assets	6,687	521	7,208
Property, plant and equipment	31,500	(5,839)	25,661
Intangible assets	2,838,000	(218,500)	2,619,500
Other assets	9,285	(953)	8,332
Total identifiable assets	<u>\$ 3,419,194</u>	<u>\$ (269,470)</u>	<u>\$ 3,149,724</u>
Accounts payable and accrued expenses	\$ 120,553	\$ 9,956	\$ 130,509
Deferred income taxes	164,379	(8,336)	156,043
Convertible debt, including equity component (1)	571,132	—	571,132
Other liabilities	171,400	48,253	219,653
Total liabilities assumed	<u>\$ 1,027,464</u>	<u>\$ 49,873</u>	<u>\$ 1,077,337</u>
Net identifiable assets acquired	<u>\$ 2,391,730</u>	<u>\$ (319,343)</u>	<u>\$ 2,072,387</u>
Goodwill	177,854	319,343	497,197
Net assets acquired	<u>\$ 2,569,584</u>	<u>\$ —</u>	<u>\$ 2,569,584</u>

(1) As further described in Note 13. Debt, this amount consists of \$304.5 million and \$266.6 million, representing the debt and equity components of the Auxilium convertible notes, respectively.

Our measurement period adjustments for Auxilium were complete as of December 31, 2015. During the three months ended September 30, 2015, the Company recorded an additional \$4.4 million loss on extinguishment of debt related to the conversion of Auxilium's convertible debt, which occurred during the first quarter of 2015. This loss on extinguishment of debt represents differences between the fair values of the repurchased debt components and their carrying values.

The valuation of the intangible assets acquired and related amortization periods are as follows:

	Valuation (in millions)	Amortization period (in years)
<b>Developed Technology:</b>		
XIAFLEX®	\$ 1,501.1	12
TESTOPEL®	584.3	15
Urology Retail	314.3	13
Other	128.9	15
Total	\$ 2,528.6	
<b>In Process Research &amp; Development (IPR&amp;D):</b>		
XIAFLEX®—Cellulite	\$ 90.9	n/a
Total	\$ 90.9	n/a
Total other intangible assets	\$ 2,619.5	n/a

The preliminary fair values of the developed technology and IPR&D assets were estimated using a discounted present value income approach. Under this method, an intangible asset's fair value is equal to the present value of the incremental after-tax cash flows (excess earnings) attributable solely to the intangible asset over its remaining useful life. To calculate fair value, the Company used cash flows discounted at rates ranging from 9% to 11%, which were considered appropriate given the inherent risks associated with each type of asset. The Company believes that the level and timing of cash flows appropriately reflect market participant assumptions.

The goodwill recognized is attributable primarily to strategic and synergistic opportunities related to existing pharmaceutical businesses, the assembled workforce of Auxilium and other factors. No material amount of the goodwill allocated to Auxilium is deductible for income tax purposes.

Deferred tax assets and liabilities are related primarily to the difference between the book basis and tax basis of identifiable intangible assets and inventory step-up.

The Company recognized acquisition-related transaction costs associated with the Auxilium acquisition during the year ended December 31, 2015 totaling \$23.1 million. These costs, which related primarily to bank fees, legal and accounting services, and fees for other professional services, are included in Acquisition-related and integration items in the accompanying Consolidated Statements of Operations.

The amounts of Auxilium Revenue and Net loss attributable to Endo International plc included in the Company's Consolidated Statements of Operations from and including January 29, 2015 to December 31, 2015 are as follows (in thousands, except per share data):

Revenue	\$ 341,520
Net loss attributable to Endo International plc (1)	\$ (469,986)
Basic & diluted net loss per share	\$ (2.38)

(1) Net loss attributable to Endo International plc does not include any portion of the goodwill impairment charges recorded during 2015 since it is not possible to distinguish the amount of the charges directly attributable to Auxilium.

The following supplemental unaudited pro forma information presents the financial results as if the acquisition of Auxilium had occurred on January 1, 2014 for the years ended December 31, 2015 and 2014. This supplemental pro forma information has been prepared for comparative purposes and does not purport to be indicative of what would have occurred had the acquisition been made on January 1, 2014, nor are they indicative of any future results.

	Year Ended December 31, 2015	Year Ended December 31, 2014
<b>Unaudited pro forma consolidated results (in thousands, except per share data):</b>		
Revenue	\$ 3,292,293	\$ 2,740,829
Net loss attributable to Endo International plc	\$ (1,513,625)	\$ (954,956)
Basic net loss per share	\$ (7.68)	\$ (6.50)
Diluted net loss per share	\$ (7.68)	\$ (6.09)

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of Auxilium to reflect factually supportable adjustments that give effect to events that are directly attributable to the Auxilium acquisition assuming the Auxilium acquisition had occurred January 1, 2014. These adjustments mainly include adjustments to interest expense and additional intangible amortization. The adjustments to interest expense, net of tax, related to borrowings to finance the acquisition increased the expense by \$1.1 million and \$22.4 million for the years ended December 31, 2015 and December 31, 2014, respectively. In addition, the adjustments include additional intangible amortization, net of tax, that would have been charged assuming the Company's estimated fair value of the intangible assets. An adjustment to the amortization expense for the years ended December 31, 2015 and December 31, 2014 increased the expense by \$6.2 million and \$69.7 million, respectively.

#### **Acquisition of Par Pharmaceutical Holdings, Inc.**

On September 25, 2015, the Company acquired Par for total consideration of \$8.14 billion, including the assumption of Par debt. The consideration included 18,069,899 ordinary shares valued at \$1.33 billion.

The acquisition consideration was as follows (in thousands, except for per share amounts):

Number of Endo ordinary shares issued pursuant to the Merger Agreement	18,070	
Endo opening share price on September 25, 2015	\$ 73.34	
Fair value of Endo ordinary shares issued to Par stockholders (1)		\$ 1,325,246
Cash distribution at closing (2)		4,405,551
Fair value of Par debt settled at closing		2,404,857
Total acquisition consideration		<u>\$ 8,135,654</u>

(1) Amounts do not recalculate due to rounding.

(2) Amount includes transaction costs incurred by Par in connection with the acquisition.

Par is a specialty pharmaceutical company that develops, licenses, manufactures, markets and distributes innovative and cost-effective pharmaceuticals that help improve patient quality of life. Par focuses on high-barrier-to-entry products that are difficult to formulate, difficult to manufacture or face complex legal and regulatory challenges. Par has operated in two business segments, (i) Par Pharmaceutical, which includes generic products marketed under Par Pharmaceutical and sterile products marketed under Par Sterile Products, LLC and (ii) Par Specialty Pharmaceuticals, which provides niche, innovative brands. As a result, we believe Par's business is highly complementary to Endo's generic pharmaceuticals business. The Company also believes this transaction provides attractive long-term pipeline opportunities and significant financial synergies.

The operating results from Par's acquisition date of September 25, 2015 are included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2015. The Consolidated Balance Sheet as of December 31, 2015 reflects the acquisition of Par, effective September 25, 2015.

The following table summarizes the fair values of the assets acquired and liabilities assumed at the Par Acquisition Date (in thousands):

	September 25, 2015 (As initially reported)	Measurement period adjustments	September 25, 2015 (As adjusted)
Cash and cash equivalents	\$ 215,612	\$ —	\$ 215,612
Accounts and other receivables	500,108	30,556	530,664
Inventories	359,000	(28,594)	330,406
Prepaid expenses and other current assets	34,582	(3,458)	31,124
Deferred income tax assets, current	6,387	8,265	14,652
Property, plant and equipment	239,983	16,310	256,293
Intangible assets	4,762,600	(1,135,600)	3,627,000
Other assets	11,421	(2,944)	8,477
Total identifiable assets	<u>\$ 6,129,693</u>	<u>\$ (1,115,465)</u>	<u>\$ 5,014,228</u>
Accounts payable and accrued expenses	\$ 548,953	\$ 2,661	\$ 551,614
Deferred income tax liabilities	1,556,111	(462,332)	1,093,779
Other liabilities	14,286	1,771	16,057
Total liabilities assumed	<u>\$ 2,119,350</u>	<u>\$ (457,900)</u>	<u>\$ 1,661,450</u>
Net identifiable assets acquired	<u>\$ 4,010,343</u>	<u>\$ (657,565)</u>	<u>\$ 3,352,778</u>
Goodwill	4,125,311	657,565	4,782,876
Net assets acquired	<u>\$ 8,135,654</u>	<u>\$ —</u>	<u>\$ 8,135,654</u>

The estimated fair value of the Par assets acquired and liabilities assumed are provisional as of December 31, 2015 and are based on information that is currently available to the Company. Additional information is being gathered to finalize these provisional measurements, particularly with respect to property, plant and equipment, intangible assets, inventory, accrued expenses, deferred income taxes and income taxes payable. Accordingly, the measurement of the Par assets acquired and liabilities assumed may change significantly upon finalization of the Company's valuations and completion of the purchase price allocation, both of which are expected to occur no later than one year from the acquisition date. During the three months ended December 31, 2015, the Company recorded an additional \$3.1 million of expense related to the amortization of inventory step-up and intangible assets, which related to the third quarter of 2015.

The valuation of the intangible assets acquired and related amortization periods are as follows:

	Valuation (in millions)	Amortization period (in years)
<b>Developed Technology:</b>		
Vasostrict™	\$ 560.9	8
Aplisol®	315.4	11
Developed - Other - Non-Partnered (Generic Non-Injectable)	246.3	7
Developed - Other - Partnered (Combined)	167.6	7
Nascobal®	120.1	9
Developed - Other - Non-Partnered (Generic Injectable)	118.5	10
Other	563.2	9
Total	\$ 2,092.0	
<b>In Process Research &amp; Development (IPR&amp;D):</b>		
IPR&D 2019 Launch	\$ 428.2	n/a
IPR&D 2018 Launch	310.9	n/a
Ezetimibe	168.2	n/a
IPR&D 2016 Launch	152.4	n/a
Neostigmine vial	134.7	n/a
Ephedrine Sulphate	130.0	n/a
Other	210.6	n/a
Total	\$ 1,535.0	n/a
Total other intangible assets	\$ 3,627.0	n/a

The preliminary fair values of the developed technology and IPR&D assets were estimated using a discounted present value income approach. Under this method, an intangible asset's fair value is equal to the present value of the incremental after-tax cash flows (excess earnings) attributable solely to the intangible asset over its remaining useful life. To calculate fair value, the Company used cash flows discounted at rates ranging from 9% to 10.5%, which were considered appropriate given the inherent risks associated with each type of asset. The Company believes that the level and timing of cash flows appropriately reflect market participant assumptions.

The goodwill recognized is attributable primarily to strategic and synergistic opportunities related to existing pharmaceutical businesses, the assembled workforce of Par and other factors. Approximately \$34.2 million of goodwill is expected to be deductible for income tax purposes.

Deferred tax assets and liabilities are related primarily to the difference between the book basis and tax basis of identifiable intangible assets and inventory step-up.

The Company recognized acquisition-related transaction costs associated with the Par acquisition during the year ended December 31, 2015 totaling \$46.3 million. These costs, which related primarily to bank fees, legal and accounting services, and fees for other professional services, are included in Acquisition-related and integration items in the accompanying Consolidated Statements of Operations.

The amounts of Par Revenue and Net loss attributable to Endo International plc included in the Company's Consolidated Statements of Operations from and including September 25, 2015 to December 31, 2015 are as follows (in thousands, except per share data):

Revenue	\$ 401,238
Net loss attributable to Endo International plc	\$ (4,348)
Basic and diluted net income per share	\$ (0.02)

The following supplemental unaudited pro forma information presents the financial results as if the acquisition of Par had occurred on January 1, 2014 for the years ended December 31, 2015 and 2014. This supplemental pro forma information has been prepared for comparative purposes and does not purport to be indicative of what would have occurred had the acquisition been made on January 1, 2014, nor are they indicative of any future results.

	Year Ended December 31, 2015	Year Ended December 31, 2014
<b>Unaudited pro forma consolidated results (in thousands, except per share data):</b>		
Revenue	\$ 4,268,110	\$ 3,689,304
Net loss attributable to Endo International plc	\$ (1,594,130)	\$ (1,023,663)
Basic net loss per share	\$ (8.09)	\$ (6.97)
Diluted net loss per share	\$ (8.09)	\$ (6.53)

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of Par to reflect factually supportable adjustments that give effect to events that are directly attributable to the Par acquisition assuming the Par acquisition had occurred January 1, 2014. These adjustments mainly include adjustments to interest expense, and additional intangible amortization. The adjustments to interest expense, net of tax, related to borrowings to finance the acquisition increased the expense by \$11.7 million and \$37.7 million for the years ended December 31, 2015 and 2014, respectively. In addition, the adjustments include additional intangible amortization, net of tax, that would have been charged assuming the Company's estimated fair value of the intangible assets. An adjustment to the amortization expense for the years ended December 31, 2015 and 2014 increased the expense by \$129.2 million and \$159.2 million, respectively.

#### **Aspen Holdings**

On October 1, 2015, the Company acquired a broad portfolio of branded and generic injectable and established products focused on pain, anti-infectives, cardiovascular and other specialty therapeutics areas from a subsidiary of Aspen Holdings, a leading publicly-traded South African company that supplies branded and generic products in more than 150 countries, and from GlaxoSmithKline plc (GSK) for total consideration of approximately \$135.6 million. The transaction is expected to expand Endo's presence in South Africa.

The fair values of the net identifiable assets acquired totaled \$129.1 million, resulting in goodwill of \$6.5 million, which was assigned to our International Pharmaceuticals segment. The amount of net identifiable assets acquired in connection with the Aspen Holdings acquisition includes \$118.4 million of intangible assets to be amortized over an average life of approximately 19 years, and inventory of \$10.7 million.

The operating results of Aspen Holdings from the acquisition date of October 1, 2015 are included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2015. There are no results included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2014. The Consolidated Balance Sheets as of December 31, 2015 reflect the acquisition of Aspen Holdings, effective October 1, 2015.

Pro forma results of operations have not been presented because the effect of the Aspen Holdings acquisition was not material.

#### **Other Acquisitions**

In addition to the business combinations disclosed above, the Company has acquired the rights to commercialize developed technology assets treated as business combinations, which were not individually material. During the year ended December 31, 2015, the Company entered into additional business combinations for total consideration of \$122.0 million, consisting of upfront payments of \$14.0 million and contingent cash consideration with acquisition-date fair values of \$108.0 million. The fair values of the net identifiable intangible assets acquired totaled \$119.8 million.

#### **NOTE 6. SEGMENT RESULTS**

The reportable business segments in which the Company operates are: (1) U.S. Branded Pharmaceuticals, (2) U.S. Generic Pharmaceuticals and (3) International Pharmaceuticals. These segments reflect the level at which executive management 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 (loss) from continuing operations before income tax, which we define as (loss) income from continuing operations before income tax before certain upfront and milestone payments to partners; acquisition-related and integration items, including transaction costs, earn-out payments or adjustments, changes in the fair value of contingent consideration and bridge financing costs; 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; excess costs that will be eliminated pursuant to integration plans; asset impairment charges; amortization of intangible assets; inventory step-up recorded as part of our acquisitions; certain non-cash interest expense; litigation-related and other contingent matters; gains or losses from early termination of debt activities; foreign currency gains or losses on intercompany financing arrangements; and certain other items that the Company believes do not reflect its core operating performance.

Certain of the corporate general and administrative 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". 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 costs.

#### **U.S. Branded Pharmaceuticals**

Our U.S. Branded Pharmaceuticals segment includes a variety of branded prescription products related to treating and managing pain as well as our urology and men's health, endocrinology and orthopedic products. The marketed products that are included in this segment include Lidoderm<sup>®</sup>, OPANA<sup>®</sup> ER, Voltaren<sup>®</sup> Gel, Percocet<sup>®</sup>, BELBUCA<sup>™</sup>, Fortesta<sup>®</sup> Gel, Testim<sup>®</sup>, Aveed<sup>®</sup>, Supprelin<sup>®</sup> LA, and XIAFLEX<sup>®</sup>, among others.

#### **U.S. Generic Pharmaceuticals**

Our U.S. Generic Pharmaceuticals segment consists of a differentiated product portfolio including high barrier to entry products, first to file or first to market opportunities, that are difficult to formulate, difficult to manufacture or face complex legal and regulatory challenges. The product offerings of this segment include products in the pain management, urology, CNS 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 for the Canadian, Mexican, South African and world markets. Paladin, based in Canada, has a portfolio of products serving growing therapeutic areas, including ADHD, pain, women's health and oncology. Somar, based in Mexico, develops, manufactures and markets high-quality generic, branded generic and over-the-counter products across key market segments including dermatology and anti-infectives. Litha, based in South Africa, is a diversified healthcare group providing services, products and solutions to public and private hospitals, pharmacies, general and specialist practitioners, as well as government healthcare programs.

The following represents selected information for the Company's reportable segments for the years ended December 31 (in thousands):

	2015	2014	2013
<b>Net revenues to external customers:</b>			
U.S. Branded Pharmaceuticals	\$ 1,284,607	\$ 969,437	\$ 1,394,015
U.S. Generic Pharmaceuticals	1,672,416	1,140,821	730,666
International Pharmaceuticals (1)	311,695	270,425	—
<b>Total net revenues to external customers</b>	<b>\$ 3,268,718</b>	<b>\$ 2,380,683</b>	<b>\$ 2,124,681</b>
<b>Adjusted income from continuing operations before income tax:</b>			
U.S. Branded Pharmaceuticals	\$ 694,440	\$ 529,507	\$ 783,927
U.S. Generic Pharmaceuticals	\$ 741,767	\$ 464,029	\$ 193,643
International Pharmaceuticals	\$ 81,789	\$ 80,683	\$ —

(1) Revenues generated by our International Pharmaceuticals segment are primarily attributable to Canada, Mexico and South Africa.

During the quarter ended December 31, 2015, we realigned certain costs between our International Pharmaceuticals segment, U.S. Branded Pharmaceuticals segment and corporate unallocated costs based on how our chief operating decision maker currently reviews segment performance. As a result of this realignment, certain expenses included in our consolidated adjusted income (loss) from continuing operations before income tax for the nine months ended September 30, 2015 have been reclassified among our various segments to conform to current period presentation. The net impact of these reclassification adjustments was to increase U.S. Branded Pharmaceuticals segment and corporate unallocated costs by \$1.7 million and \$21.1 million, respectively, with an offsetting \$22.8 million decrease to International Pharmaceuticals segment costs. The realignment of these expenses did not impact periods prior to 2015.

There were no material revenues from external customers attributed to an individual foreign country during the years ended December 31, 2015, 2014 or 2013. There were no material tangible long-lived assets in an individual foreign country as of December 31, 2015 or December 31, 2014.

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

	2015	2014	2013
Total segment adjusted income from continuing operations before income tax:	\$ 1,517,996	\$ 1,074,219	\$ 977,570
Corporate unallocated costs (1)	(544,456)	(355,417)	(315,743)
Upfront and milestone payments to partners	(16,155)	(51,774)	(29,703)
Asset impairment charges (2)	(1,140,709)	(22,542)	(32,011)
Acquisition-related and integration items (3)	(105,250)	(77,384)	(7,614)
Separation benefits and other cost reduction initiatives (4)	(125,407)	(25,760)	(91,530)
Excise tax (5)	—	(54,300)	—
Amortization of intangible assets	(561,302)	(218,712)	(123,547)
Inventory step-up and certain manufacturing costs that will be eliminated pursuant to integration plans	(249,464)	(65,582)	—
Non-cash interest expense related to the 1.75% Convertible Senior Subordinated Notes	(1,633)	(12,192)	(22,742)
Loss on extinguishment of debt	(67,484)	(31,817)	(11,312)
Watson litigation settlement income, net	—	—	50,400
Certain litigation-related charges, net (6)	(37,082)	(42,084)	(9,450)
Costs associated with unused financing commitments	(78,352)	—	—
Acceleration of Auxilium employee equity awards at closing	(37,603)	—	—
Charge related to the non-recoverability of certain non-trade receivables	—	(10,000)	—
Net gain on sale of certain early-stage drug discovery and development assets	—	5,200	—
Other than temporary impairment of equity investment	(18,869)	—	—
Foreign currency impact related to the remeasurement of intercompany debt instruments	25,121	13,153	—
Charge for an additional year of the branded prescription drug fee in accordance with IRS regulations issued in the third quarter of 2014	(3,079)	(24,972)	—
Other, net	5,864	(161)	1,048
Total consolidated (loss) income from continuing operations before income tax	<u>\$ (1,437,864)</u>	<u>\$ 99,875</u>	<u>\$ 385,366</u>

- (1) Corporate unallocated costs include certain corporate overhead costs, interest expense, net, and certain other income and expenses.
- (2) Asset impairment charges primarily related to charges to write down goodwill and intangible assets as further described in Note 10. Goodwill and Other Intangibles.
- (3) Acquisition-related and integration-items include costs directly associated with the closing of certain acquisitions of \$170.9 million, \$77.4 million and \$7.6 million in 2015, 2014 and 2013. During 2015, these costs are net of a benefit due to changes in the fair value of contingent consideration of \$65.6 million.
- (4) Separation benefits and other cost reduction initiatives include employee separation costs of \$60.2 million, \$14.4 million and \$35.2 million in 2015, 2014 and 2013, respectively. Other amounts in 2015 primarily consist of \$41.2 million of inventory write-offs and \$13.3 million of building costs, including a \$7.9 million charge recorded upon the cease use date of our Auxilium subsidiary's former corporate headquarters. Amounts in 2014 primarily consisted of employee separation costs and changes in estimates related to certain cost reduction initiative accruals. The amount of separation benefits and other cost reduction initiatives in 2013 includes an expense recorded upon the cease use date of our Chadds Ford, Pennsylvania and Westbury, New York properties in the first quarter of 2013, representing the liability for our remaining obligations under the respective lease agreements of \$7.2 million. Contract termination fees of \$5.8 million in 2013 are also included in this amount. These amounts were primarily recorded as Selling, general and administrative expense in our Consolidated Statements of Operations. See Note 4. Restructuring for discussion of our material restructuring initiatives.
- (5) This amount represents charges related to the expense for the reimbursement of directors' and certain employees' excise tax liabilities pursuant to Section 4985 of the Internal Revenue Code.



(6) These amounts include charges for Litigation-related and other contingencies, net as further described in Note 14. Commitments and Contingencies.

The following represents additional selected financial information for our reportable segments for the years ended December 31(in thousands):

	2015	2014	2013
<b>Depreciation expense:</b>			
U.S. Branded Pharmaceuticals	\$ 19,884	\$ 16,209	\$ 19,828
U.S. Generic Pharmaceuticals	29,193	16,751	13,354
International Pharmaceuticals	3,147	1,856	—
Corporate unallocated	7,674	7,849	8,354
<b>Total depreciation expense</b>	<b>\$ 59,898</b>	<b>\$ 42,665</b>	<b>\$ 41,536</b>
<b>Amortization expense:</b>			
U.S. Branded Pharmaceuticals	\$ 280,954	\$ 78,890	\$ 80,223
U.S. Generic Pharmaceuticals	223,367	95,042	43,924
International Pharmaceuticals	56,981	44,780	\$ —
<b>Total amortization expense</b>	<b>\$ 561,302</b>	<b>\$ 218,712</b>	<b>\$ 124,147</b>

Interest income and expense are considered corporate items and included in Corporate unallocated. 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, 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 are structured to maintain the fund's net asset value at \$1.00 per unit, which assists in providing adequate liquidity upon demand by the holder. Money market funds pay dividends that generally reflect short-term interest rates. Thus, only the dividend yield fluctuates. Due to their short-term maturity, the carrying amounts of non-restricted and restricted cash and cash equivalents (including money market funds), accounts receivable, accounts payable and accrued expenses approximate their fair values.

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 fair value hierarchy, as defined above. 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 the Consolidated Balance Sheets at December 31, 2015 and December 31, 2014.

At the time of purchase, we classify our marketable securities as either available-for-sale securities or trading securities, depending on our intent at that time. Available-for-sale and trading securities are carried at fair value with unrealized holding gains and losses recorded within other comprehensive income or net income, respectively. The Company reviews unrealized losses associated with available-for-sale securities to determine the classification as a "temporary" or "other-than-temporary" impairment. A temporary impairment results in an unrealized loss being recorded in other comprehensive income. An impairment that is viewed as

other-than-temporary is recognized in net income. The Company considers various factors in determining the classification, including the length of time and extent to which the fair value has been less than the Company's cost basis, the financial condition and near-term prospects of the issuer or investee, and the Company's ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value.

**Loans Receivable**

Our loans receivable at December 31, 2015 relate primarily to loans totaling \$14.1 million to our joint venture investment owned through our Litha subsidiary. The joint venture investment is further described below. The majority of this amount is secured by certain of the assets of our joint venture. The fair values of these loans were based on anticipated cash flows, which approximate the carrying amount, and were classified in Level 2 measurements in the fair value hierarchy. The Company has retrospectively classified these loans into Assets held for sale in the accompanying Consolidated Balance Sheets.

**Equity and Cost Method Investments**

As of December 31, 2015, we have various investments that we account for using the equity or cost method of accounting totaling \$15.2 million, including a joint venture investment owned through our Litha subsidiary.

During the three months ended June 30, 2015, the Company recognized an other than temporary impairment of our Litha joint venture investment totaling \$18.9 million, reflecting the excess carrying value of this investment over its estimated fair value. To estimate the fair value of this joint venture investment we relied primarily on a market approach based on the terms of the recently announced divestiture of that investment. The Company has retrospectively classified this investment into Assets held for sale in the accompanying Consolidated Balance Sheets.

With respect to our other equity or cost method investments, which are included in Other Assets in our Consolidated Balance Sheets at December 31, 2015 and December 31, 2014, the Company did not recognize any other-than-temporary impairments. We considered various factors, including the operating results of our equity method investments and the lack of an unrealized loss position on our cost method investments.

**Acquisition-Related Contingent Consideration**

Acquisition-related contingent consideration is measured at fair value on a recurring basis using unobservable inputs; hence these instruments represent Level 3 measurements within the fair value hierarchy. See Recurring Fair Value Measurements below for additional information on the fair value methodology used for the acquisition-related contingent consideration.

**Voltaren® Gel Royalties due to Novartis**

The initial fair value of the Minimum Voltaren® Gel royalties due to Novartis under the 2008 License and Supply Agreement were determined using an income approach (present value technique) taking into consideration the level and timing of expected cash flows and an assumed discount rate. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The liability is currently being accreted up to the expected minimum payments, less payments made to date. We believe the carrying amount of this minimum royalty guarantee at December 31, 2015 and December 31, 2014 represents a reasonable approximation of the price that would be paid to transfer the liability in an orderly transaction between market participants at the measurement date. Accordingly, the carrying value approximates fair value as of December 31, 2015 and December 31, 2014.

**Recurring Fair Value Measurements**

The Company's financial assets and liabilities measured at fair value on a recurring basis at December 31, 2015 and December 31, 2014 were as follows (in thousands):

	Fair Value Measurements at Reporting Date using:			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
<b>December 31, 2015</b>				
<b>Assets:</b>				
Money market funds	\$ 51,145	\$ —	\$ —	\$ 51,145
Equity securities	3,889	—	—	3,889
Total	\$ 55,034	\$ —	\$ —	\$ 55,034
<b>Liabilities:</b>				
Acquisition-related contingent consideration—short-term	\$ —	\$ —	\$ 65,265	\$ 65,265
Acquisition-related contingent consideration—long-term	—	—	78,237	78,237
Total	\$ —	\$ —	\$ 143,502	\$ 143,502

At December 31, 2015, money market funds include \$51.1 million in Qualified Settlement Funds to be disbursed to mesh-related product liability claimants. See Note 14. Commitments and Contingencies for further discussion of our product liability cases.

	Fair Value Measurements at Reporting Date using:			Total
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>December 31, 2014</b>				
<b>Assets:</b>				
Money market funds	\$ 279,327	\$ —	\$ —	\$ 279,327
Equity securities	2,321	—	—	2,321
Total	\$ 281,648	\$ —	\$ —	\$ 281,648
<b>Liabilities:</b>				
Acquisition-related contingent consideration—short-term	\$ —	\$ —	\$ 4,282	\$ 4,282
Acquisition-related contingent consideration—long-term	—	—	41,723	41,723
Total	\$ —	\$ —	\$ 46,005	\$ 46,005

At December 31, 2014, money market funds include \$124.4 million in Qualified Settlement Funds to be disbursed to mesh-related product liability claimants. See Note 14. Commitments and Contingencies for further discussion of our product liability cases.

#### Acquisition-Related Contingent Consideration

On November 30, 2010 (the Qualitest Pharmaceuticals Acquisition Date), the Company acquired Generics International (US Parent), Inc. (formerly doing business as Qualitest Pharmaceuticals), which was party to an asset purchase agreement with Teva Pharmaceutical Industries Ltd (Teva) (the Teva Agreement). Pursuant to the Teva Agreement, Qualitest Pharmaceuticals purchased certain pipeline generic products from Teva and could be obligated to pay consideration to Teva upon the achievement of certain future regulatory milestones (the Teva Contingent Consideration). The current range of the undiscounted amounts the Company could be obligated to pay in future periods under the Teva Agreement is between zero and \$2.5 million after giving effect to payments made to date. The fair value of the contractual obligation to pay the Teva Contingent Consideration was determined to be \$1.1 million at December 31, 2015 and \$5.2 million at December 31, 2014. The decrease in the balance primarily relates to first and third quarter 2015 payments of \$2.5 million each related to the achievement of certain regulatory milestones, partially offset by an increase due to certain regulatory conditions impacting the commercial potential of related products.

During the second quarter of 2014, in connection with the Company's acquisition of Sumavel<sup>®</sup>, we entered into an agreement to make contingent cash consideration payments to the former owner of Sumavel<sup>®</sup> of between zero and \$20.0 million (the Sumavel<sup>®</sup> Contingent Consideration), based on certain factors relating primarily to the financial performance of Sumavel<sup>®</sup>. At the acquisition date, we estimated the fair value of this obligation to be \$4.1 million based on a probability-weighted discounted cash flow model (income approach). Using this valuation technique, the fair value of the contractual obligation to pay the Sumavel<sup>®</sup> Contingent Consideration was determined to be approximately \$0.6 million at December 31, 2015 and \$4.7 million at December 31, 2014. The change in the balance primarily relates to certain market conditions impacting the commercial potential of the product.

In connection with our acquisition of DAVA, we agreed to make cash consideration payments of up to \$25.0 million (the DAVA Contingent Consideration) contingent on the achievement of certain sales-based milestones. At the DAVA acquisition date, we estimated the fair value of this obligation to be \$5.1 million based on a probability-weighted discounted cash flow model (income approach). Using this valuation technique, the fair value of the contractual obligation to pay the DAVA Contingent Consideration was determined to be zero at December 31, 2015 and \$5.1 million at December 31, 2014. The change in the balance relates to certain market conditions impacting the commercial potential of related products.

In connection with the acquisition of Natesto<sup>™</sup>, we entered into an agreement to make contingent cash consideration payments to the former owners of Natesto<sup>™</sup> based on certain potential clinical and commercial milestones of up to \$165.0 million as well as royalties based on a percentage of potential future sales of Natesto<sup>™</sup> (the Natesto<sup>™</sup> Contingent Consideration). As of the Natesto acquisition date, Endo estimated the fair value of this obligation to be \$31.0 million based on a probability-weighted discounted cash flow model (income approach). Using this valuation technique, the fair value of the contractual obligation to pay the Natesto<sup>™</sup> Contingent Consideration was determined to be zero at December 31, 2015 and \$31.0 million at December 31, 2014. The change in the balance primarily relates to certain market conditions impacting the commercial potential of the related product and a measurement period adjustment of \$4.3 million to reduce the obligation. On December 30, 2015, the Company provided written notice to Acerus that it was terminating the License, Development, and Supply Agreement by and between the Company and Acerus. The effective date of the termination is June 30, 2016.

On January 29, 2015, we acquired Auxilium, which is party to an agreement pursuant to which it could be obligated to make certain contingent cash consideration payments (the Actient Contingent Consideration). These payments relate primarily to potential sales-based royalties on edex<sup>®</sup> and TESTOPEL<sup>®</sup>, which Auxilium had previously acquired. As of the Auxilium acquisition date, Endo

estimated the fair value of the Actient Contingent Consideration to be \$46.8 million. The fair value was estimated based on a probability-weighted discounted cash flow model (income approach). The fair value of the Actient Contingent Consideration was determined to be \$25.5 million at December 31, 2015. The change in the balance primarily relates to certain market conditions impacting the commercial potential of the related products, 2015 payments of \$9.1 million related to sales-based royalties and a measurement period adjustment of \$3.9 million to reduce the obligation.

Auxilium is also party to an agreement with VIVUS, Inc. (VIVUS) to make contingent cash consideration payments consisting of royalties based on a percentage of net sales of STENDRA<sup>®</sup> as well as sales-based milestones of up to approximately \$260 million (the STENDRA<sup>®</sup> Contingent Consideration). On January 29, 2015, the date Endo acquired Auxilium, Endo estimated the fair value of the STENDRA<sup>®</sup> Contingent Consideration to be \$59.6 million. The fair value was estimated based on a probability-weighted discounted cash flow model (income approach). Using this valuation technique, the fair value of the STENDRA<sup>®</sup> Contingent Consideration was determined to be \$1.0 million at December 31, 2015. The change in the balance primarily relates to certain market conditions impacting the commercial potential of the related product, 2015 payments of \$0.3 million related to sales-based royalties and a measurement period adjustment of \$4.3 million to reduce the obligation. On December 30, 2015, the Company provided written notice to VIVUS that the Company was terminating the STENDRA<sup>®</sup> License Agreement effective June 30, 2016.

In connection with the acquisition of the exclusive license rights of certain products, we entered into agreements to make contingent cash consideration payments based on certain operational and commercial milestones, as well as payments based on a percentage of profits realized on the licensed products. At the acquisition date, we estimated the fair value of these obligations to be \$108.0 million based on a probability-weighted discounted cash flow models (income approach). Using this valuation technique, the fair value of the contractual obligations to pay the contingent consideration was determined to be \$115.3 million at December 31, 2015. The increase in the balance relates mainly to certain market conditions impacting the commercial potential of related products, partially offset by 2015 payments of \$23.2 million related to the achievement of certain commercial milestones and a measurement period adjustment of \$0.9 million to reduce the obligations.

The fair values of contingent consideration amounts above were estimated based on assumptions and projections relevant to revenues and a discounted cash flow model using risk-adjusted discount rates ranging from 0.5% to 25.0%. The Company assesses these assumptions on an ongoing basis as additional information impacting the assumptions is obtained.

Amounts recorded for the short-term and long-term portions of acquisition related contingent consideration are included in Accrued expenses and Other liabilities, respectively, in the Consolidated Balance Sheets.

**Fair Value Measurements Using Significant Unobservable Inputs**

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

	2015	2014
Beginning of period	\$ 46,005	\$ 4,747
Amounts acquired	214,435	40,224
Amounts settled	(37,583)	—
Transfers (in) and/or out of Level 3	—	—
Measurement period adjustments	(13,434)	—
Changes in fair value recorded in earnings	(65,640)	1,034
Effect of currency translation	(281)	—
End of period	<u>\$ 143,502</u>	<u>\$ 46,005</u>

Changes in fair value recorded in earnings related to acquisition-related contingent consideration are included in the Consolidated Statements of Operations as Acquisition-related and integration items.

The following is a summary of available-for-sale securities held by the Company at December 31, 2015 and December 31, 2014 (in thousands):

	Available-for-sale			Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	
<b>December 31, 2015</b>				
Money market funds	\$ 51,145	\$ —	\$ —	\$ 51,145
<i>Total included in cash and cash equivalents</i>	\$ 3	\$ —	\$ —	\$ 3
<i>Total included in restricted cash and cash equivalents</i>	\$ 51,142	\$ —	\$ —	\$ 51,142
Equity securities	\$ 24	\$ 10	\$ —	\$ 34
<i>Total other short-term available-for-sale securities</i>	\$ 24	\$ 10	\$ —	\$ 34
Equity securities	\$ 1,766	\$ 2,089	\$ —	\$ 3,855
<i>Long-term available-for-sale securities</i>	\$ 1,766	\$ 2,089	\$ —	\$ 3,855
<b>December 31, 2014</b>				
Money market funds	\$ 279,327	\$ —	\$ —	\$ 279,327
<i>Total included in cash and cash equivalents</i>	\$ 154,959	\$ —	\$ —	\$ 154,959
<i>Total included in restricted cash and cash equivalents</i>	\$ 124,368	\$ —	\$ —	\$ 124,368
Equity securities	\$ 805	\$ 10	\$ —	\$ 815
<i>Total other short-term available-for-sale securities</i>	\$ 805	\$ 10	\$ —	\$ 815
Equity securities	\$ 1,766	\$ —	\$ (260)	\$ 1,506
<i>Long-term available-for-sale securities</i>	\$ 1,766	\$ —	\$ (260)	\$ 1,506

#### Nonrecurring Fair Value Measurements

The Company's financial assets and liabilities measured at fair value on a nonrecurring basis during the year ended December 31, 2015 were as follows (in thousands):

	Fair Value Measurements at Reporting Date using:			Total Expense for the Year Ended December 31, 2015
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>Assets:</b>				
Auxilium leasehold improvements (Note 4)	\$ —	\$ —	\$ —	\$ (7,000)
Litha equity investment	—	—	10,469	(18,869)
Certain U.S. Branded Pharmaceuticals intangible assets (Note 10)	—	—	48,266	(175,031)
Certain U.S. Generic Pharmaceuticals intangible assets (Note 10)	—	—	38,005	(181,000)
Certain International Pharmaceuticals intangible assets (Note 10)	—	—	3,838	(14,579)
UEO reporting unit goodwill (Note 10)	—	—	240,994	(673,500)
Paladin reporting unit goodwill (Note 10)	—	—	436,919	(85,780)
Total	\$ —	\$ —	\$ 778,491	\$ (1,155,759)
<b>Liabilities:</b>				
Minimum Voltaren® Gel royalties due to Novartis	—	—	15,000	—
Total	\$ —	\$ —	\$ 15,000	\$ —

The Company's financial assets and liabilities measured at fair value on a nonrecurring basis during the year ended December 31, 2014 were as follows (in thousands):

	Fair Value Measurements at Measurement Date using:			Total Expense for the Year Ended December 31, 2014
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>Assets:</b>				
Certain U.S. Branded Pharmaceuticals intangible assets (Note 10)	\$ —	\$ —	\$ —	\$ (12,300)
Certain U.S. Generic Pharmaceuticals intangible assets (Note 10)	—	—	3,300	(5,900)
Property, plant and equipment (See Note 9)	—	—	—	(4,342)
<b>Total</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 3,300</b>	<b>\$ (22,542)</b>
<b>Liabilities:</b>				
Minimum Voltaren® Gel royalties due to Novartis	\$ —	\$ —	\$ 37,500	\$ —
<b>Total</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 37,500</b>	<b>\$ —</b>

#### NOTE 8. INVENTORIES

Inventories consist of the following at December 31, 2015 and December 31, 2014 (in thousands):

	December 31, 2015	December 31, 2014
Raw materials (1)	\$ 207,516	\$ 118,431
Work-in-process (1)	176,881	43,290
Finished goods (1)	360,268	253,274
<b>Total</b>	<b>\$ 744,665</b>	<b>\$ 414,995</b>

(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, which relates primarily to XIAFLEX® inventory, is classified as long-term inventory and is not included in the table above. At December 31, 2015, \$24.9 million of long-term inventory was included in Other assets in the Consolidated Balance Sheets.

**NOTE 9. PROPERTY, PLANT AND EQUIPMENT**

	Land and Buildings	Machinery and Equipment	Leasehold Improvements	Computer Equipment and Software	Assets under Capital Lease	Furniture and Fixtures	Assets under Construction	Total
(In thousands)								
<b>Cost:</b>								
At January 1, 2015	\$ 223,841	\$ 91,899	\$ 16,165	\$ 88,984	\$ 6,082	\$ 3,218	\$ 79,861	\$ 510,050
Additions	18,068	11,507	6,701	25,634	3,502	1,236	9,926	76,574
Additions due to acquisitions	98,969	95,848	28,091	20,633	—	16,530	23,383	283,454
Disposals/transfers/impairments/other	(335)	(13,494)	(4,857)	(21,265)	(463)	(805)	(3,351)	(44,570)
Effect of currency translation	(2,998)	(1,452)	(330)	(741)	—	(225)	(36)	(5,782)
At December 31, 2015	\$ 337,545	\$ 184,308	\$ 45,770	\$ 113,245	\$ 9,121	\$ 19,954	\$ 109,783	\$ 819,726
<b>Accumulated Depreciation:</b>								
At January 1, 2015	\$ (30,656)	\$ (36,399)	\$ (8,034)	\$ (42,043)	\$ (1,820)	\$ (1,035)	\$ (3,011)	\$ (122,998)
Additions	(13,078)	(13,499)	(8,802)	(20,135)	(2,514)	(1,870)	—	(59,898)
Disposals/transfers/impairments/other	1,045	9,070	5,856	8,861	876	582	5,119	31,409
Effect of currency translation	702	951	105	401	—	176	—	2,335
At December 31, 2015	\$ (41,987)	\$ (39,877)	\$ (10,875)	\$ (52,916)	\$ (3,458)	\$ (2,147)	\$ 2,108	\$ (149,152)
<b>Net Book Amount:</b>								
At December 31, 2015	\$ 295,558	\$ 144,431	\$ 34,895	\$ 60,329	\$ 5,663	\$ 17,807	\$ 111,891	\$ 670,574
At December 31, 2014	\$ 193,185	\$ 55,500	\$ 8,131	\$ 46,941	\$ 4,262	\$ 2,183	\$ 76,850	\$ 387,052

Depreciation expense, including expense related to assets under capital lease, was \$59.9 million, \$42.7 million and \$41.5 million for the years ended December 31, 2015, 2014 and 2013, respectively.

During the years ended December 31, 2015, 2014 and 2013, the Company recorded impairment charges totaling \$10.8 million, \$4.3 million and \$7.5 million, respectively, to write off certain property, plant and equipment amounts that were abandoned. These charges were related to our ongoing efforts to improve our operating efficiency and to consolidate certain locations, including our generics research and development operations and our corporate headquarters. These charges are included in the Asset impairment charges line item in our Consolidated Statement of Operations.

**NOTE 10. GOODWILL AND OTHER INTANGIBLES**
**Goodwill**

Changes in the carrying amount of our goodwill for the year ended December 31, 2015 were as follows (in thousands):

	Carrying Amount			
	U.S. Branded Pharmaceuticals	U.S. Generic Pharmaceuticals	International Pharmaceuticals	Total
<b>Balance as of December 31, 2013:</b>				
Goodwill	\$ 290,793	\$ 275,201	\$ —	\$ 565,994
Goodwill acquired during the period	841,139	796,436	737,050	2,374,625
Effect of currency translation	—	—	(42,844)	(42,844)
<b>Balance as of December 31, 2014:</b>				
Goodwill	\$ 1,131,932	\$ 1,071,637	\$ 694,206	\$ 2,897,775
Goodwill acquired during the period	544,344	4,718,297	7,660	5,270,301
Effect of currency translation	—	—	(109,442)	(109,442)
Goodwill impairment charges	(673,500)	—	(85,780)	(759,280)
<b>Balance as of December 31, 2015:</b>				
Goodwill	\$ 1,676,276	\$ 5,789,934	\$ 592,424	\$ 8,058,634
Accumulated impairment losses	\$ (673,500)	\$ —	\$ (85,780)	\$ (759,280)
	\$ 1,002,776	\$ 5,789,934	\$ 506,644	\$ 7,299,354

**Other Intangible Assets**

The following is a summary of other intangibles held by the Company at December 31, 2015 and December 31, 2014 (in thousands):

<b>Cost basis:</b>	<b>Balance as of December 31, 2014</b>	<b>Acquisitions (1)</b>	<b>Impairments (2)</b>	<b>Other (3)</b>	<b>Effect of Currency Translation</b>	<b>Balance as of December 31, 2015</b>
<b>Indefinite-lived intangibles:</b>						
In-process research and development	\$ 184,598	\$ 1,628,400	\$ (28,072)	\$ (35,710)	\$ (12,335)	\$ 1,736,881
<i>Total indefinite-lived intangibles</i>	<u>\$ 184,598</u>	<u>\$ 1,628,400</u>	<u>\$ (28,072)</u>	<u>\$ (35,710)</u>	<u>\$ (12,335)</u>	<u>\$ 1,736,881</u>
<b>Definite-lived intangibles:</b>						
Licenses (weighted average life of 10 years)	\$ 664,367	\$ 12,500	\$ —	\$ —	\$ —	\$ 676,867
Tradenames (weighted average life of 12 years)	21,315	—	(13,591)	—	(187)	7,537
Developed technology (weighted average life of 12 years)	2,242,118	4,901,716	(328,947)	30,247	(122,562)	6,722,572
<i>Total definite-lived intangibles (weighted average life of 12 years)</i>	<u>\$ 2,927,800</u>	<u>\$ 4,914,216</u>	<u>\$ (342,538)</u>	<u>\$ 30,247</u>	<u>\$ (122,749)</u>	<u>\$ 7,406,976</u>
<b>Total other intangibles</b>	<u><u>\$ 3,112,398</u></u>	<u><u>\$ 6,542,616</u></u>	<u><u>\$ (370,610)</u></u>	<u><u>\$ (5,463)</u></u>	<u><u>\$ (135,084)</u></u>	<u><u>\$ 9,143,857</u></u>

<b>Accumulated amortization:</b>	<b>Balance as of December 31, 2014</b>	<b>Amortization</b>	<b>Impairments</b>	<b>Other</b>	<b>Effect of Currency Translation</b>	<b>Balance as of December 31, 2015</b>
<b>Indefinite-lived intangibles:</b>						
In-process research and development	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
<i>Total indefinite-lived intangibles</i>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Definite-lived intangibles:</b>						
Licenses	\$ (426,413)	\$ (81,812)	\$ —	\$ —	\$ —	\$ (508,225)
Tradenames	(5,462)	(1,097)	—	—	15	(6,544)
Developed technology	(348,273)	(478,393)	—	—	10,233	(816,433)
<i>Total definite-lived intangibles</i>	<u>\$ (780,148)</u>	<u>\$ (561,302)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 10,248</u>	<u>\$ (1,331,202)</u>
<b>Total other intangibles</b>	<u><u>\$ (780,148)</u></u>	<u><u>\$ (561,302)</u></u>	<u><u>\$ —</u></u>	<u><u>\$ —</u></u>	<u><u>\$ 10,248</u></u>	<u><u>\$ (1,331,202)</u></u>
<b>Net other intangibles</b>	<u><u>\$ 2,332,250</u></u>					<u><u>\$ 7,812,655</u></u>

- (1) Includes intangible assets acquired primarily in connection with the acquisitions of Par, Auxilium, Aspen Holdings and other acquisitions. See Note 5. Acquisitions for further information.
- (2) Includes the impairment of certain intangible assets of our U.S. Branded Pharmaceuticals, U.S. Generic Pharmaceuticals and International Pharmaceuticals segments.
- (3) During the year ended December 31, 2015, certain IPR&D assets totaling \$35.7 million were put into service, partially offset by a reduction of \$5.5 million relating to measurement period adjustments to certain intangible assets acquired in 2014. See Note 5. Acquisitions for further information on measurement period adjustments.

Amortization expense for the years ended December 31, 2015, 2014 and 2013 totaled \$561.3 million, \$218.7 million and \$124.1 million, respectively. Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2015 is as follows (in thousands):

2016	\$ 820,936
2017	\$ 699,920
2018	\$ 618,317
2019	\$ 565,397
2020	\$ 540,241



Changes in the gross carrying amount of our other intangibles for the year ended December 31, 2015 were as follows (in thousands):

	Gross Carrying Amount
December 31, 2014	\$ 3,112,398
Auxilium acquisition	2,619,500
Par acquisition	3,627,000
Aspen Holdings acquisition	118,434
Other acquisitions	121,214
BELBUCA™ milestone	43,968
License extension of certain intangible assets	12,500
Impairment of certain U.S. Branded Pharmaceuticals intangible assets	(175,031)
Impairment of certain U.S. Generic Pharmaceuticals intangible assets	(181,000)
Impairment of certain International Pharmaceuticals intangible assets	(14,579)
Measurement period adjustments relating to acquisitions closed during 2014	(5,463)
Effect of currency translation	(135,084)
December 31, 2015	<u>\$ 9,143,857</u>

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.

As part of the annual and interim goodwill and intangible asset impairment assessments, we estimate the fair value of our intangible assets and reporting units through an income approach using discounted cash flow models. Our discounted cash flow models are highly reliant on various assumptions, such as estimates of future cash flows (including long-term growth rates and the variations in the amount and timing of such cash flows), discount rates, and the probability of achieving the estimated cash flows. 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 our October 1, 2015, 2014 and 2013 annual goodwill and indefinite-lived intangible assets impairment test ranged from 9.0% to 16.0%, from 8.5% to 15.5% and from 9.5% to 14.5%, respectively, depending on the overall risk associated with the particular assets and other market factors. We believe the discount rates and other inputs and assumptions are consistent with those that a market participant would use.

#### Goodwill

Given the results of our intangible asset assessment during the third quarter of 2015 for STENDRA® and certain TRT products, the Company initiated an interim goodwill impairment analysis of our Urology, Endocrinology and Oncology (UEO) reporting unit as of September 30, 2015. As a result of this interim analysis, the Company determined that the net book value of our UEO reporting unit exceeded its estimated fair value. The Company prepared this analysis on a preliminary basis to estimate the amount of a provisional impairment charge as of September 30, 2015, and determined that an impairment was probable and reasonably estimable. The preliminary fair value assessments were performed by the Company taking into consideration a number of factors, based upon the latest available information, including the preliminary results of a hypothetical purchase price allocation. As a result of the preliminary analysis, during the three months ended September 30, 2015, the Company recorded a provisional pre-tax, non-cash impairment charge of \$680.0 million in the Consolidated Statements of Operations, representing the difference between the estimated implied fair value of the UEO reporting unit's goodwill and its respective net book value.

The Company completed its UEO goodwill impairment analysis during the fourth quarter of 2015 and reduced the provisional pre-tax, non-cash impairment charge by \$6.5 million, for a net, pre-tax, non-cash impairment charge during the year ended December 31, 2015 of \$673.5 million. During the fourth quarter of 2015, the Company combined certain resources within the Branded business and management realigned how they review the segment's performance. As a result, we determined that our Pain and UEO reporting units should be combined into one Branded reporting unit for purposes of testing goodwill as of October 1, 2015. In addition to testing the Pain and UEO reporting units separately for goodwill impairment as of October 1, 2015, the Company also tested the combined Branded reporting unit for impairment. The impairment tests did not result in any additional charge for the quarter ended December 31, 2015. As of December 31, 2015, the remaining balance of goodwill for the Branded reporting unit was approximately \$1,002.8 million.

As part of the annual goodwill impairment test, the Company recorded a pre-tax, non-cash impairment charge of \$85.8 million in the Consolidated Statements of Operations, representing the difference between the estimated implied fair value of the Paladin Canada reporting unit's goodwill and its respective net book value, primarily due to the loss of exclusivity on certain products

sold in Canada. As of December 31, 2015, the remaining balance of goodwill for the Paladin Canada reporting unit was approximately \$420.4 million.

### **Intangible Assets**

A summary of significant other intangible asset impairment charges by reportable segment for the three years ended December 31, 2015 is included below.

#### *U.S. Branded Pharmaceuticals Segment*

A sustained downturn in the short-acting testosterone replacement therapy (TRT) market has caused underperformance across several of our TRT products, including Testim<sup>®</sup> and Natesto<sup>™</sup>. In addition, we have also experienced underperformance with respect to STENDRA<sup>®</sup>. As a result of this underperformance and a re-alignment of investment priorities towards higher growth and higher value assets such as XIAFLEX<sup>®</sup> and BELBUCA<sup>™</sup>, the Company concluded during the third quarter of 2015 that an impairment assessment was required to evaluate the recoverability of certain definite-lived intangible assets associated with these products. After performing this assessment, we recorded a pre-tax, non-cash impairment charge of approximately \$152.0 million during the third quarter of 2015, representing a full impairment of our Natesto<sup>™</sup> intangible asset and a partial impairment of our Testim<sup>®</sup> and STENDRA<sup>®</sup> intangible assets. As a result of the Company providing written notice to VIVUS on December 30, 2015 that we are terminating the STENDRA<sup>®</sup> License Agreement effective June 30, 2016, we recorded an additional pre-tax, non-cash impairment charge of approximately \$9.5 million, representing the remaining carrying amount of our STENDRA<sup>®</sup> intangible asset. Additionally, during the fourth quarter of 2015, we determined that the fair value of certain U.S. Branded Pharmaceuticals IPR&D assets were less than their respective carrying amounts, and we recorded a pre-tax, non-cash impairment charge of \$5.5 million representing the full carrying amount of the assets.

As part of the 2014 year-end financial close and reporting process, the Company concluded that an impairment assessment was required to evaluate the recoverability of a definite-lived license intangible asset related to OPANA<sup>®</sup> ER. After performing these assessments, we recorded a pre-tax, non-cash impairment charge of \$12.3 million, representing the remaining carrying amount of this asset.

#### *U.S. Generic Pharmaceuticals Segment*

During the year ended December 31, 2015, the Company identified certain market and regulatory conditions impacting the commercial potential of certain indefinite and definite-lived intangible assets in our U.S. Generic Pharmaceuticals segment. Accordingly, we tested these assets for impairment and determined that the carrying value of certain of these assets was no longer fully recoverable, resulting in pre-tax, non-cash asset impairment charges of \$70.2 million, \$72.4 million and \$38.4 million, respectively, during the second, third and fourth quarters of 2015.

As part of our definite-lived intangible asset impairment review process for 2013, the Company determined that the fair values of certain Qualitest IPR&D assets were less than the respective carrying amounts. Accordingly, in the fourth quarter of 2013, we recorded a pre-tax, non-cash impairment charge of \$17.0 million representing the full carrying amount of the assets.

#### *International Pharmaceuticals Segment*

As part of our definite-lived intangible asset impairment review processes for 2015, the Company recorded pre-tax, non-cash impairment charges of approximately \$14.6 million in our International Pharmaceuticals segment, representing the difference between the carrying amount of certain intangible assets and their estimated fair value.

### **NOTE 11. LICENSE AND COLLABORATION AGREEMENTS**

#### *Novartis AG, Novartis Consumer Health, Inc. and Sandoz, Inc.*

The Company has exclusive U.S. marketing rights to Voltaren<sup>®</sup> Gel (Voltaren<sup>®</sup> Gel) pursuant to a License and Supply Agreement entered into in 2008 with and among Novartis AG and Novartis Consumer Health, Inc. (Novartis) (the 2008 Voltaren<sup>®</sup> Gel Agreement).

During the term of the 2008 Voltaren<sup>®</sup> Gel Agreement, the Company is solely responsible to commercialize Voltaren<sup>®</sup> Gel and has agreed to purchase all of its requirements for Voltaren<sup>®</sup> Gel from Novartis. The price of product purchased under the 2008 Voltaren<sup>®</sup> Gel Agreement is fixed for the first year and subject to annual changes based upon changes in the producer price index and raw materials. Amounts purchased pursuant to the 2008 Voltaren<sup>®</sup> Gel Agreement were \$53.4 million, \$55.0 million and \$50.2 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Further, the minimum A&P Expenditures set forth in the 2008 Voltaren<sup>®</sup> Gel Agreement are determined based on a percentage of net sales of Voltaren<sup>®</sup> Gel, which may be reduced under certain circumstances, including Novartis's failure to supply Voltaren<sup>®</sup> Gel. Amounts incurred for such A&P Expenditures were \$5.0 million, \$5.5 million and \$8.1 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Voltaren® Gel royalties incurred during the years ended December 31, 2015, 2014 and 2013 were \$30.0 million, \$30.0 million and \$30.0 million, respectively, representing minimum royalties pursuant to the 2008 Voltaren® Gel Agreement.

Effective March 1, 2015, Novartis Consumer Health, Inc. assigned the 2008 Voltaren® Gel Agreement to its affiliate, Sandoz, Inc.

On December 11, 2015, Endo, Novartis AG and Sandoz entered into a new License and Supply Agreement (the 2015 Voltaren® Gel Agreement) effectively renewing our exclusive U.S. marketing and license rights to commercialize Voltaren® Gel (the Branded Licensed Product) and granting the Company the exclusive right to launch an authorized generic of Voltaren® Gel (the Generic Licensed Product, and, together with the Branded Licensed Product, the Licensed Product). Pursuant to the 2015 Voltaren® Gel Agreement, the former 2008 Voltaren® Gel Agreement will expire on June 30, 2016 in accordance with its terms. The 2015 Voltaren® Gel Agreement will become effective on July 1, 2016 and will be accounted for as a business combination as of the effective date.

Under the 2015 Voltaren® Gel Agreement, Endo will pay royalties to Novartis AG or Sandoz (as designated by Sandoz) on annual net sales of the Branded Licensed Product, subject to certain thresholds specified in the 2015 Voltaren® Gel Agreement. In addition, Endo has agreed to make certain guaranteed minimum annual royalty payments of \$30.0 million and contingent royalty payments, subject to certain limitations specified in the Agreement. The guaranteed minimum royalties will be creditable against royalty payments on an annual net sales of the Branded Licensed Product or (ii) the guaranteed minimum royalty for such 2015 Voltaren® Gel Agreement year. Endo and Novartis AG or Sandoz (as designated by Sandoz) will share any profits relating to net sales of the Generic Licensed Product as specified in the 2015 Voltaren® Gel Agreement. Novartis AG or Sandoz (as designated by Sandoz) is also eligible to receive a one-time milestone payment of \$25.0 million if annual sales of the Licensed Product exceed \$300.0 million.

During the term of the 2015 Voltaren® Gel Agreement, Endo has agreed to purchase all of its requirements for the Licensed Product from Sandoz. The price of product purchased by Endo under the 2015 Voltaren® Gel Agreement is fixed for the first year and is subject to annual changes based upon changes in the producer price index and raw materials as set forth in the 2015 Voltaren® Gel Agreement.

The exclusive marketing and license rights do not include the right to commercialize over-the-counter (OTC) equivalent product in the United States. The OTC rights are held by GlaxoSmithKline Consumer Healthcare Holdings Limited (GSK), who has agreed not to launch an OTC equivalent product prior to a specified time. In the event that GSK launches an OTC equivalent product before any person, other than GSK or its affiliates, launches either (i) an OTC version of 1% diclofenac gel product, or (ii) a generic to Voltaren® Gel, then Endo will receive certain royalty payments on net sales of such OTC equivalent product in the United States as set forth in the 2015 Voltaren® Gel Agreement; provided that, and subject to certain limitations and provisions as set forth in the 2015 Voltaren® Gel Agreement, as a condition to the payment of any and all such royalties, net sales of the Licensed Product in the United States must have exceeded a certain threshold as defined in the 2015 Voltaren® Gel Agreement prior to the launch of the OTC equivalent product.

The initial term of the 2015 Voltaren® Gel Agreement will be seven years, expiring on June 30, 2023. Thereafter, the 2015 Voltaren® Gel Agreement will automatically be extended for successive one year terms (each a Renewal Term) unless any party provides written notice of non-renewal to the other parties at least six months prior to the expiration of any Renewal Term after the first Renewal Term.

Among other standard and customary termination rights granted under the 2015 Voltaren® Gel Agreement, the 2015 Voltaren® Gel Agreement can be terminated by any party upon reasonable written notice, if the other party has committed a material breach that has not been remedied within ninety days from the giving of written notice. Endo may terminate the 2015 Voltaren® Gel Agreement by written notice upon the occurrence of specified events, including the launch in the United States of a generic to the Licensed Product. Sandoz may terminate the 2015 Voltaren® Gel Agreement upon reasonable written notice on or after the launch in the United States of an over-the-counter equivalent product by Sandoz, its affiliates or any third party that does not result in the declassification of the Licensed Product as a prescription product, following which net sales in any six month period under the 2015 Voltaren® Gel Agreement are less than a certain defined dollar amount.

#### *Strakan International Limited*

In August 2009, we entered into a License and Supply Agreement with Strakan International Limited, a subsidiary of ProStrakan Group plc. (ProStrakan), which was subsequently acquired by Kyowa Hakko Kirin Co. Ltd., for the exclusive right to commercialize Fortesta® Gel in the U.S. (the ProStrakan Agreement). Fortesta® Gel is a patented 2% testosterone transdermal gel for testosterone replacement therapy in male hypogonadism. A metered dose delivery system permits accurate dose adjustment to increase the ability to individualize patient treatment.

The Company received FDA approval for Fortesta® Gel in December 2010, which triggered a one-time approval milestone to ProStrakan for \$12.5 million. The approval milestone was recorded as an intangible asset and is being amortized into Cost of revenues on a straight-line basis over its estimated useful life. An additional milestone payment of \$5.0 million was triggered during the fourth quarter of 2015 pursuant to the terms of the ProStrakan Agreement. The milestone was recorded as an intangible asset and is being

amortized into Cost of revenue. ProStrakan could potentially receive up to approximately \$150.0 million in additional payments linked to the achievement of future commercial milestones related to Fortesta<sup>®</sup> Gel.

ProStrakan will exclusively supply Fortesta<sup>®</sup> Gel to Endo at a supply price based on a percentage of annual net sales subject to a minimum floor price as defined in the ProStrakan Agreement. Endo may terminate the ProStrakan Agreement upon six months' prior written notice at no cost to the Company.

#### *Grünenthal GmbH*

In December 2007, we entered into a License, Development and Supply Agreement (the Grünenthal Agreement) with Grünenthal for the exclusive clinical development and commercialization rights in Canada and the U.S. for an oral formulation of OPANA<sup>®</sup> ER, which is designed to be crush-resistant. In December 2011, the FDA approved a formulation of OPANA<sup>®</sup> ER designed to be crush-resistant, which is called OPANA<sup>®</sup> ER.

In the fourth quarter of 2011, the Company capitalized a one-time approval milestone to Grünenthal for \$4.9 million. We are amortizing this intangible asset into Cost of revenues over its estimated useful life. In the fourth quarter of 2013, the Company recorded an additional \$10.4 million as Cost of Revenues related to a commercial milestone. Additional amounts of approximately 53.9 million euros (approximately \$58.7 million at December 31, 2015) may become due upon achievement of additional future predetermined regulatory and commercial milestones. Endo will also make payments to Grünenthal based on net sales of any such product or products commercialized under this agreement, including the formulation of OPANA<sup>®</sup> ER approved by the FDA in December 2011.

Effective December 19, 2012, the Company and Grünenthal amended the Grünenthal Agreement whereby the Company became responsible for planning of packaging of finished product and certain other routine packaging quality obligations and Grünenthal agreed to reimburse the Company for the third-party costs incurred related to packaging as well as pay the Company a periodic packaging fee. The amendment also changed certain of the terms with respect to the floor price required to be paid by the Company in consideration for product supplied by Grünenthal. On February 18, 2014, the Company and Grünenthal amended the Grünenthal Agreement to define the responsibilities of the parties for certain additional clinical work to be performed for OPANA<sup>®</sup> ER.

#### *Bayer Schering*

In July 2005, we licensed exclusive U.S. rights from Schering AG, Germany, now Bayer Schering Pharma AG (Bayer Schering) to market a long-acting injectable testosterone preparation for the treatment of male hypogonadism that we refer to as Aveed<sup>®</sup> (the Bayer Schering Agreement). We were responsible for the development and commercialization of Aveed<sup>®</sup> in the U.S. Bayer Schering is responsible for manufacturing and supplying us with finished product. As part of the Bayer Schering Agreement, we agreed to pay to Bayer Schering up to \$30.0 million in up-front, regulatory, and commercialization milestone payments, including a \$5.0 million payment due upon approval by the FDA to market Aveed<sup>®</sup>. We also agreed to pay to Bayer Schering 25% of net sales of Aveed<sup>®</sup> to cover both the cost of finished product and royalties. The Bayer Schering Agreement expires ten years from the first commercial sale of Aveed<sup>®</sup>.

In October 2006, we entered into a supply agreement with Bayer Schering pursuant to which Bayer Schering agreed to manufacture and supply Indevus with all of its requirements for Aveed<sup>®</sup> for a supply price based on net sales of Aveed<sup>®</sup>. The supply price is applied against the 25% of net sales owed to Bayer Schering pursuant to the Bayer Schering Agreement. Either party may also terminate the BayerSchering Agreement in the event of a material breach by the other party.

On March 6, 2014, we announced that the FDA approved Aveed<sup>®</sup> for the treatment of hypogonadism in adult men, which is associated with a deficiency or absence of the male hormone testosterone. Aveed<sup>®</sup> became available in early March. Upon approval, EPSI made the aforementioned milestone payment of \$5.0 million to Bayer Schering. The approval milestone was recorded as an intangible asset and is being amortized into Cost of revenues on a straight-line basis over its estimated useful life. In the future, we could be obligated to pay milestones of up to approximately \$17.5 million based on continued market exclusivity of Aveed<sup>®</sup> or upon certain future sales milestones.

#### *BioSpecifics Technologies Corp.*

On January 29, 2015, we acquired Auxilium, which 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 by Auxilium in June 2004 to obtain exclusive worldwide rights to develop, market and sell certain products containing BioSpecifics' enzyme, which we refer to as XIAPLEX<sup>®</sup>. Auxilium's licensed rights concern the development and commercialization of products, other than dermal formulations labeled for topical administration, and currently, Auxilium's licensed rights cover the indications of Dupuytren's contracture (DC), Dupuytren's Nodules, Peyronie's Disease (PD), Adhesive Capsulitis, cellulite, canine lipomas, Plantar Fibromatosis and Lateral Hip Fat. Auxilium may further expand the BioSpecifics Agreement, at its option, to cover other indications as they are developed by Auxilium 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 a CCH Phase II clinical trial for the treatment of lipomas in humans. The Company has the option to license development and marketing rights to

the CCH human lipoma indication based on a full analysis of the data from the Phase II clinical trial, which would transfer responsibility for the future development costs to the Company and trigger an opt-in payment and potential future milestone and royalty payments to BioSpecifics. In 2013, BioSpecifics also concluded a CCH Phase II clinical trial for the treatment of lipomas in canines. The trial did not meet its primary endpoint of a statistically significant post-treatment difference in the mean percent change in lipoma; however, statistical significance was shown in secondary endpoints. The Company has opted in to the development of CCH in canine lipomas.

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. 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 Actelion Pharmaceuticals Ltd (Actelion), Asahi Kasei Pharma Corporation (Asahi Kasei) and Swedish Orphan Biovitrum AB (Sobi). 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 pays BioSpecifics an amount equal to a specified mark-up on the cost of goods related to supply of XIAFLEX<sup>®</sup> (which mark-up is capped at a specified percentage within the range of 5% to 15% of the cost of goods of XIAFLEX<sup>®</sup> for the applicable country) for products sold by the Company and its affiliates or its sublicensees.

#### *XIAFLEX<sup>®</sup> and XIAPEX<sup>®</sup> Out-license Agreements*

We are party to certain out-licensing agreements with Actelion, Asahi Kasei and Sobi (the XIAFLEX<sup>®</sup> Sublicensees), pursuant to which the XIAFLEX<sup>®</sup> Sublicensees have marketing, development and/or commercial rights for XIAFLEX<sup>®</sup> and XIAPEX<sup>®</sup> (the European Union trade name for XIAFLEX<sup>®</sup>) in a variety of countries outside of the U.S.

These agreements were entered into from 2011 to 2013 and extend, pursuant to the terms of each respective agreement and subject to each party's termination rights, as follows:

- The agreement with Actelion extends on a product-by-product and country-by-country basis from the date of the agreement until the last to occur of (i) the date on which the product is no longer covered by a valid claim of a patent or patent application controlled by the Company in such country, (ii) the 15th anniversary of the first commercial sale of the product in such country after receipt of required regulatory approvals, (iii) the achievement of a specified market share of generic versions of the product in such country, or (iv) the loss of certain marketing rights or data exclusivity in such country.
- The agreement with Asahi Kasei extends on a product-by-product basis from the date of the agreement until the last to occur of (i) the date on which the product is no longer covered by a valid claim of a patent, (ii) the 15th anniversary of the first commercial sale of the product, or (iii) the entry of a generic to XIAFLEX<sup>®</sup> in the Japanese market.
- The agreement with Sobi extends on a product-by-product basis from the date of the agreement until its 10th anniversary. The term will be automatically extended for sequential two year periods unless a notice of non-renewal is provided in writing to the other party at least six months prior to expiration of the then current term.

Under the Actelion and Sobi agreements, the Company, through its affiliate, is entitled to receive royalties based on net sales of the licensed product by the XIAFLEX<sup>®</sup> Sublicensees. These royalties are tiered as follows:

- Actelion—15%-25%, 20%-30%, and 25%-35% based on net sales of the licensed product;
- Sobi—45%-55%, 50%-60% and 55%-65% based on net sales of the licensed product, which also include payments for product supply and which percentages will decrease by approximately 10% upon the occurrence of certain manufacturing milestones or July 1, 2016, whichever is earlier.

The applicable royalty percentages increase from tier to tier upon the achievement of a specified threshold of aggregate annual net sales of the licensed product and may decrease if a generic is marketed in the applicable territory. Pursuant to each of these out-licensing agreements, the Company will be responsible for all clinical and commercial drug manufacturing and supply and, in certain cases, for development costs. The Company has determined that these contractual responsibilities, together with the development and commercialization rights provided by the Company, constitute multiple deliverables. In accordance with the accounting guidance on revenue recognition for multiple-element agreements, certain elements of these agreements meet the criteria for separation and are treated as a single unit of accounting, with the corresponding revenue recognized when earned. Deliverables that do not have stand-alone value to the XIAFLEX<sup>®</sup> Sublicensees are being accounted for as one unit of accounting, with the related revenue being recorded on a straight-line basis over the respective performance period.

The Japanese Ministry of Health, Labour and Welfare (MHLW) approved XIAFLEX<sup>®</sup> for manufacturing and marketing in Japan on July 3, 2015 for the indication of Dupuytren's contracture with a palpable cord and was subsequently listed on the Japanese National Health Insurance drug price standard on August 31, 2015. The Company's partner, Asahi Kasei Pharma Corporation, commercially launched the product in Japan in September 2015. Under the terms of the Asahi Kasei agreement, Endo received a \$20.0 million gross milestone payment in October 2015 as a result of the first commercial sale of XIAFLEX<sup>®</sup> in Japan. The Company will recognize the \$20.0 million of milestone revenue on a straight-line basis over the remaining term of the license agreement.

Revenue recognized related to these agreements was not material to the Consolidated Financial Statements for any of the periods presented.

*BioDelivery Sciences International, Inc.*

The Company is party to a worldwide license and development agreement (the BioDelivery Agreement) with BioDelivery Sciences International, Inc. (BioDelivery) for the exclusive rights to develop and commercialize BELBUCA™ (buprenorphine HCl) Buccal Film. The drug is a transmucosal form of buprenorphine, a partial mu-opiate receptor agonist, which incorporates a bioerodible mucoadhesive (BEMA®) technology. The NDA for BELBUCA™ was submitted in December 2014 and accepted by the U.S. Food and Drug Administration (FDA) in February 2015. On October 23, 2015, the FDA approved BELBUCA™ for the management of severe pain. BELBUCA™ became commercially available in the U.S. during February 2016.

As a result of the FDA approval of BELBUCA™, the Company capitalized a one-time approval milestone payment to BioDelivery for \$44.0 million in the fourth quarter of 2015. The Company is amortizing this intangible asset into Cost of revenues in the Consolidated Statements of Operations over its estimated useful life. During each of the first, second and fourth quarters of 2014, \$10.0 million of milestones were incurred related to the achievement of certain clinical milestones, resulting in a total of \$30.0 million recorded as Research and development expense during 2014. In addition, the Company will pay royalties based on net sales of the drug and could be obligated to pay additional commercial milestones of up to \$55.0 million.

**NOTE 12. ACCRUED EXPENSES**

Accrued expenses are comprised of the following for each of the years ended December 31, (in thousands):

	December 31, 2015	December 31, 2014
Returns and allowances	\$ 356,932	\$ 174,940
Rebates	331,492	497,362
Chargebacks	18,899	217,402
Other sales deductions	—	25,380
Accrued interest	132,035	69,616
Acquisition-related contingent consideration—short-term	65,265	4,282
Other	246,549	155,343
Total	<u>\$ 1,151,172</u>	<u>\$ 1,144,325</u>

Prior to December 31, 2015, the Company had classified product sales reserves for chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and allowances as well as fees for services (collectively, revenue reserves) as accrued expenses on its consolidated balance sheet. This classification was based on the Company's historical practices, at times, to settle these reserves in cash. In conjunction with our acquisition of Par in September 2015, we re-evaluated our planned settlement practice and determined that we will offset certain customer receivables with amounts due to the customers. As a result, we have classified \$898.8 million of revenue reserves as reductions from accounts receivable on our consolidated balance sheet as of December 31, 2015. We have treated this change on a prospective basis and will not adjust any amounts previously reported in our consolidated financial statements. Amounts related to similar reserves classified as accrued expenses on our consolidated balance sheet as of December 31, 2014 totaled \$441.5 million.

**NOTE 13. DEBT**

The following table presents the carrying amounts of the Company's total indebtedness at December 31, 2015 and December 31, 2014 (in thousands):

	December 31, 2015		December 31, 2014	
	Principal Amount	Unamortized Discount and Deferred Loan Costs	Principal Amount	Unamortized Discount and Deferred Loan Costs
1.75% Convertible Senior Subordinated Notes due 2015	\$ —	\$ —	\$ 98,818	\$ (1,759)
7.00% Senior Notes due 2019	—	—	499,875	(12,291)
7.00% Senior Notes due 2020	—	—	400,000	(14,049)
7.25% Senior Notes due 2022	400,000	(12,535)	400,000	(14,093)
5.75% Senior Notes due 2022	700,000	(10,088)	700,000	(11,431)
5.375% Senior Notes due 2023	750,000	(10,511)	750,000	(11,686)
6.00% Senior Notes due 2023	1,635,000	(27,694)	—	—
6.00% Senior Notes due 2025	1,200,000	(22,713)	—	—
Term Loan A Facility Due 2019	1,017,500	(13,831)	1,069,063	(16,247)
Term Loan B Facility Due 2021	2,800,000	(49,900)	421,812	(7,988)
Revolving Credit Facility	225,000	—	—	—
Other debt	134	—	6,540	—
Total long-term debt, net	\$ 8,727,634	\$ (147,272)	\$ 4,346,108	\$ (89,544)
Less current portion, net	328,705	—	155,937	—
Total long-term debt, less current portion, net	\$ 8,398,929	\$ (147,272)	\$ 4,190,171	\$ (89,544)

The total fair value of the Company's Total long-term debt, net at December 31, 2015 and December 31, 2014, was \$8.6 billion and \$4.4 billion, respectively. Total debt does not include debt classified as Liabilities held for sale on the Consolidated Balance Sheets.

The fair value of the Company's long-term debt is estimated using the quoted market prices for the same or similar debt issuances. Based on this valuation methodology, we determined these debt instruments represent Level 2 measurements within the fair value hierarchy.

The fair value of our 1.75% Convertible Senior Subordinated Notes was based on an income approach, which incorporated certain inputs and assumptions, including scheduled coupon and principal payments, the inherent conversion and put features in the notes and share price volatility assumptions based on historic volatility of the Company's ordinary shares and other factors. These fair value measurements are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy.

**Credit Facility**

Upon closing of the Paladin acquisition on February 28, 2014, certain subsidiaries of the Company entered into a credit agreement (the 2014 Credit Agreement) with Deutsche Bank AG New York Branch, as administrative agent, collateral agent, issuing bank and swingline lender and certain other lenders, which provided for a five-year senior secured term loan A facility in an aggregate principal amount of \$1.1 billion (the 2014 Term Loan A Facility), a seven-year senior secured term loan B facility in an aggregate principal amount of \$425.0 million (the 2014 Term Loan B Facility), and a five-year revolving credit facility in an aggregate principal amount of \$750.0 million (the 2014 Revolving Credit Facility). The 2014 Credit Agreement was entered into to refinance certain of our existing indebtedness, including our prior credit facility, and for general corporate purposes, including acquisitions.

In June 2015, certain subsidiaries of the Company entered into Amendment No. 1 to Credit Agreement (Amendment No. 1), with Deutsche Bank and certain other lenders, pursuant to which we amended the 2014 Credit Agreement to, among other things, (i) permit the acquisition by Endo Designated Activity Company, formerly known as Endo Limited (Endo DAC) or its affiliates of Par and (ii) permit an incremental revolving facility in an aggregate principal amount of \$250.0 million (the Incremental Revolving Facility), and one or more incremental term B loan facilities in an aggregate principal amount up to \$5.0 billion, in each case, in connection with the Par acquisition. Loans incurred under the 2014 Term Loan A Facility, the 2014 Term Loan B Facility and the Incremental Term Loan B Facility (as defined below) are recorded net of the unamortized portion of the original purchaser's discount. This discount is amortized to interest expense over the term of the Amended Credit Agreement (as defined below).

Simultaneously with the closing of the Par acquisition, on September 25, 2015, we entered into the Incremental Amendment to Credit Agreement, with Deutsche Bank and certain other lenders (the Incremental Amendment), pursuant to which we (i) increased

our revolving capacity to \$1,000.0 million pursuant to the Incremental Revolving Facility (ii) incurred an incremental term loan B facility (the Incremental Term Loan B Facility) in an aggregate principal amount of \$2,800.0 million (together with the Incremental Revolving Facility, the Par Incremental Facilities) and (iii) repaid in full the amount outstanding under the 2014 Term Loan B Facility. We refer to the 2014 Credit Agreement, as amended by Amendment No. 1 and the Incremental Amendment, and as further amended, restated, supplemented or otherwise modified, as the Amended Credit Agreement. There were \$225.0 million in revolving loans at December 31, 2015. We have \$773.0 million of remaining credit available through the revolving credit facilities as of December 31, 2015.

In connection with the Incremental Revolving Facility and the Incremental Term Loan B Facility, we incurred new debt issuance costs of approximately \$125.1 million, of which \$59.0 million was deferred and will be amortized as interest expense over the term of the Incremental Revolving Facility and the Incremental Term Loan B Facility. The remaining \$66.1 million and previously deferred debt issuance costs of \$7.9 million associated with the original Term Loan B Facility were charged to expense. These expenses were included in the Consolidated Statements of Operations as Other Expense (Income), Net and Loss on extinguishment of debt, respectively.

In addition to the Incremental Revolving Facility and the Incremental Term Loan B Facility, the Amended Credit Agreement also permits us to obtain (i) incremental revolving and/or term loan commitments of \$1.0 billion plus (ii) an unlimited amount of incremental revolving and/or term loan commitments if the Secured Leverage Ratio (as defined in the Amended Credit Agreement), at the time of incurrence of such incremental commitments and after giving effect thereto on a pro forma basis, is less than or equal to 3.00 to 1.00 (assuming for purposes of such calculation that any incremental revolving commitments incurred at the time of such calculation are fully drawn and without netting cash proceeds of any incremental facilities or, in lieu of loans under any incremental facilities, pari passu or junior secured or unsecured notes or junior secured term loans) from one or more of the existing lenders (or their affiliates) or other lenders (with the consent of the administrative agent) and, subject to compliance by the borrowers with the documentation and other requirements under the Amended Credit Agreement, without the need for consent from any of the existing lenders under the Amended Credit Agreement (other than those existing lenders that have agreed to provide such incremental facilities).

The Amended Credit Agreement contains affirmative and negative covenants that the Company believes to be usual and customary for a senior secured credit facility. The negative covenants include, among other things, limitations on capital expenditures, asset sales, mergers and acquisitions, indebtedness, liens, dividends, investments and transactions with the Company's affiliates. As of December 31, 2015, we were in compliance with all such covenants.

#### **6.00% Senior Notes Due 2025**

On January 27, 2015, Endo DAC, Endo Finance LLC and Endo Finco Inc. (collectively, the Issuers) issued \$1.20 billion in aggregate principal amount of 6.00% senior notes due 2025 (the 2025 Notes). The 2025 Notes were issued in a private offering for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. In connection with the 2025 Notes, we incurred new debt issuance costs of \$24.4 million, which were deferred and will be amortized over the term of the 2025 Notes.

The 2025 Notes are senior unsecured obligations of the Issuers and are guaranteed on a senior unsecured basis by all of our significant subsidiaries (other than Astora Women's Health Technologies, Grupo Farmacéutico Somar, S.A. de C.V., Laboratoris Paladin S.A. de C.V. and Litha Healthcare Group Limited) and certain of the Company's other subsidiaries. Interest on the 2025 Notes is payable semiannually in arrears on February 1 and August 1 of each year, beginning on August 1, 2015. The 2025 Notes will mature on February 1, 2025, subject to earlier repurchase or redemption in accordance with the terms of the 2025 Notes indenture.

The 2025 Notes were issued to (i) finance its acquisition of Auxilium, (ii) refinance certain indebtedness of Auxilium and (iii) pay related transaction fees and expenses.

On or after February 1, 2020, the Issuers may on any one or more occasions redeem all or a part of the 2025 Notes, at the redemption prices (expressed as percentages of principal amount) set forth below, plus accrued and unpaid interest and additional interest, if any, if redeemed during the twelve-month period beginning on February 1 of the years indicated below:

<b>Payment Dates (between indicated dates)</b>	<b>Redemption Percentage</b>
From February 1, 2020 to and including January 31, 2021	103.000 %
From February 1, 2021 to and including January 31, 2022	102.000 %
From February 1, 2022 to and including January 31, 2023	101.000 %
From February 1, 2023 and thereafter	100.000 %

In addition, at any time prior to February 1, 2020, the Issuers may on any one or more occasions redeem all or a part of the 2025 Notes at a specified redemption price set forth in the indenture, plus accrued and unpaid interest and additional interest, if any. In addition, prior to February 1, 2018, the Issuers may redeem up to 35% of the aggregate principal amount of the 2025 Notes with the net cash proceeds from specified equity offerings at a redemption price equal to 106.000% of the aggregate principal amount of the



2025 Notes redeemed, plus accrued and unpaid interest. If Endo DAC experiences certain change of control events, the Issuers must offer to repurchase the 2025 Notes at 101% of their principal amount, plus accrued and unpaid interest and additional interest, if any.

The 2025 Notes indenture contains covenants that, among other things, restrict Endo DAC's ability and the ability of its restricted subsidiaries to incur certain additional indebtedness and issue preferred stock, make restricted payments, sell certain assets, agree to payment restrictions on the ability of restricted subsidiaries to make payments to Endo DAC, create certain liens, merge, consolidate or sell substantially all of Endo DAC's assets, or enter into certain transactions with affiliates. These covenants are subject to a number of important exceptions and qualifications, including the fall away or revision of certain of these covenants upon the 2025 Notes receiving investment grade credit ratings.

Also on January 27, 2015, the Issuers and the guarantors of the 2025 Notes entered into a registration rights agreement under which they will be required to use their commercially reasonable efforts to (i) file with the SEC by March 31, 2016 an exchange offer registration statement pursuant to which they will offer, in exchange for the 2025 Notes, new notes having terms substantially identical in all material respects to those of the 2025 Notes (except the new notes will not contain terms with respect to transfer restrictions) (the A/B Exchange Offer), (ii) complete the A/B Exchange Offer by July 1, 2016 or, under specified circumstances, (iii) file a shelf registration statement with the SEC covering resales of the 2025 Notes. The Issuers may be required to pay additional interest if they fail to comply with the registration and exchange requirements set forth in the registration rights agreement.

#### **1.50% Convertible Senior Notes Due 2018**

On January 29, 2015, in connection with the consummation of the Merger Agreement between Endo and Auxilium, Endo entered into an agreement relating to Auxilium's \$350.0 million of 1.50% convertible senior notes due 2018 (the Auxilium Notes), pursuant to which the Auxilium Notes are no longer convertible into shares of Auxilium common stock and instead are convertible into cash and ordinary shares of Endo based on the weighted average of the cash and Endo ordinary shares received by Auxilium stockholders that affirmatively made an election in connection with the Merger. As a result of such elections, for each share of Auxilium common stock a holder of Auxilium Notes was previously entitled to receive upon conversion of Notes, such holder instead became entitled to receive \$9.88 in cash and 0.3430 Endo ordinary shares. Pursuant to this agreement, Endo became a co-obligor of Auxilium's obligations under the Auxilium Notes and expressly agreed to assume, jointly and severally with Auxilium, liability for (a) the due and punctual payment of the principal (and premium, if any) and interest, if any, on all of the Auxilium Notes issued under the corresponding indenture, (b) the due and punctual delivery of Endo ordinary shares and/or cash upon conversion of the Auxilium Notes by note holders and (c) the due and punctual performance and observance of all of the covenants and conditions of the corresponding indenture to be performed by Auxilium.

As further described in Note 5. Acquisitions, and as a result of the variability in the number of ordinary shares to be issued, the Auxilium Notes were initially recorded at their estimated fair value of \$571.1 million upon the acquisition of Auxilium. In accordance with accounting guidance for debt with conversion and other options, we separately accounted for the liability and equity components of the Auxilium Notes by allocating the proceeds between the liability component and the embedded conversion option, or equity component, due to our ability to settle the Auxilium Notes in a combination of cash and ordinary shares, with \$304.5 million allocated to debt and \$266.6 million allocated to Additional paid-in capital. The fair value of the liability component was determined using a discounted cash flow model with a discount rate consistent with that of a similar liability that does not have an associated convertible feature, based on comparable market transactions. Fair value of the equity component was determined using an integrated lattice valuation, which incorporates the conversion option and assumptions related to default.

Subsequent to the closing of the acquisition on January 29, 2015, during the first quarter of 2015, holders of the Auxilium Notes converted substantially all of the Auxilium Notes and received aggregate consideration consisting of \$148.9 million of cash and 5.2 million ordinary shares valued at \$408.6 million. The value of the ordinary shares issued resulted in an increase to Additional paid-in capital of \$408.6 million. In connection with these conversions, we charged \$5.4 million to expense, representing the differences between the fair value of the repurchased debt components and their carrying amounts. The expense was included in the Consolidated Statements of Operations as a Loss on extinguishment of debt. Additionally, we recorded a combined decrease to Additional paid-in capital in the amount of \$247.4 million during the first quarter of 2015, representing the fair value of the equity component of the repurchased Auxilium Notes.

#### **1.75% Convertible Senior Subordinated Notes Due 2015**

At December 31, 2014, our indebtedness included 1.75% Convertible Senior Subordinated Notes due April 15, 2015 (the Convertible Notes). In April 2015, we settled \$98.7 million aggregate principal amount of the Convertible Notes, which was the remaining outstanding principal balance of the Convertible Notes, for \$316.4 million, which included the issuance of 2,261,236 ordinary shares.

In connection with the April 2015 Convertible Notes settlement activity, we entered into an agreement with the note hedge counterparty to settle the related call options for the receipt of 2,261,236 of our ordinary shares. These ordinary shares were subsequently canceled by the Company. In addition, we entered into an agreement to terminate the related warrants in exchange for our agreement to deliver to the warrant counterparty approximately 1,792,379 ordinary shares, which we delivered in June 2015.

**6.00% Senior Notes Due 2023**

In July 2015, the Issuers issued \$1.64 billion in aggregate principal amount of 6.00% senior notes due July 2023 (the 2023 Notes). The 2023 Notes were issued in a private offering for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended.

In connection with the 2023 Notes issuance, we incurred new debt issuance costs of approximately \$29.1 million, which were deferred and are being amortized as interest expense over the term of the 2023 Notes.

The 2023 Notes are senior unsecured obligations of the Issuers and are guaranteed on a senior unsecured basis by all of our significant subsidiaries (other than Astora Women's Health Technologies, Grupo Farmacéutico Somar, S.A. de C.V., Laboratoris Paladin S.A. de C.V. and Litha Healthcare Group Limited) and certain of the Company's other subsidiaries. Interest on the 2023 Notes is payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2016. The 2023 Notes will mature on July 15, 2023, subject to earlier repurchase or redemption in accordance with the terms of the 2023 Notes indenture.

On or after July 15, 2018, the Issuers may on any one or more occasions redeem all or a part of the 2023 Notes, at the redemption prices (expressed as percentages of principal amount) set forth below, plus accrued and unpaid interest, if redeemed during the twelve-month period beginning on July 15 of the years indicated below:

<b>Payment Dates (between indicated dates)</b>	<b>Redemption Percentage</b>
From July 15, 2018 to and including July 14, 2019	104.500 %
From July 15, 2019 to and including July 14, 2020	103.000 %
From July 15, 2020 to and including July 14, 2021	101.500 %
From July 15, 2021 and thereafter	100.000 %

In addition, at any time prior to July 15, 2018, the Issuers may on any one or more occasions redeem all or a part of the 2023 Notes at a specified redemption price set forth in the indenture, plus accrued and unpaid interest. In addition, prior to July 15, 2018, the Issuers may redeem up to 35% of the aggregate principal amount of the 2023 Notes with the net cash proceeds from specified equity offerings at a redemption price equal to 106.000% of the aggregate principal amount of the 2023 Notes redeemed, plus accrued and unpaid interest. If Endo DAC experiences certain change of control events, the Issuers must offer to repurchase the 2023 Notes at 101% of their principal amount, plus accrued and unpaid interest.

The 2023 Notes indenture contains covenants that, among other things, restrict Endo DAC's ability and the ability of its restricted subsidiaries to incur certain additional indebtedness and issue preferred stock, make restricted payments, sell certain assets, agree to payment restrictions on the ability of restricted subsidiaries to make payments to Endo DAC, create certain liens, merge, consolidate or sell substantially all of Endo DAC's assets, or enter into certain transactions with affiliates. These covenants are subject to a number of important exceptions and qualifications, including the fall away or revision of certain of these covenants upon the 2023 Notes receiving investment grade credit ratings.

**Redemption of 2019 Senior Notes**

In July 2015, the Company's wholly-owned subsidiaries, Endo Finance LLC and Endo Finco Inc., redeemed all \$481.9 million aggregate principal amount outstanding of their 7.00% Senior Notes due 2019 (2019 Endo Finance Notes) and the Company's wholly-owned subsidiary, EHSI, redeemed all \$18.0 million aggregate principal amount outstanding of its 7.00% Senior Notes due 2019 (2019 EHSI Notes). The aggregate redemption price included a redemption fee of \$17.5 million, or 3.5% of the aggregate principal amount of the 2019 Endo Finance Notes and the 2019 EHSI Notes, plus accrued and unpaid interest to, but not including, the redemption date. In connection with the redemption, the Company expensed the previously deferred debt issuance costs of \$11.1 million and the redemption fee of \$17.5 million. These expenses totaled \$28.6 million and were included in the Consolidated Statements of Operations as a Loss on extinguishment of debt.

**Redemption of 2020 Senior Notes**

In November 2015, the Company's wholly-owned subsidiaries, Endo Finance LLC and Endo Finco Inc., redeemed all \$393.0 million aggregate principal amount outstanding of their 7.00% Senior Notes due 2020 (2020 Endo Finance Notes) and the Company's wholly-owned subsidiary, EHSI, redeemed all \$7.0 million aggregate principal amount outstanding of its 7.00% Senior Notes due 2020 (2020 EHSI Notes). The aggregate redemption price included a redemption fee of \$14.0 million, or 3.5% of the aggregate principal amount of the 2020 Endo Finance Notes and the 2020 EHSI Notes, plus accrued and unpaid interest to, but not including, the redemption date. In connection with the redemption, the Company expensed the previously deferred debt issuance costs of \$12.1 million and the redemption fee of \$14.0 million. These expenses totaled \$26.1 million and were included in the Consolidated Statements of Operations as a Loss on extinguishment of debt.

**Mandatorily Redeemable Preferred Stock due 2035**

In conjunction with the sale of the Men's Health and Prostate Health component of AMS to Boston Scientific Corporation, Boston Scientific Corporation purchased 60,000 shares of mandatorily redeemable Series B Senior Preferred Stock issued by AMS from EPI. The aggregate purchase price of these shares was \$60.0 million. The Series B Senior Preferred Stock, of which there were 100,000 authorized shares, was non-voting. All of the voting shares were retained by Endo.

On December 11, 2015, the Company redeemed all 60,000 shares of the Series B Senior Preferred Stock from Boston Scientific Corporation for \$61.6 million, including accrued and unpaid dividends, resulting in a gain on extinguishment of debt of \$0.3 million in the accompanying Consolidated Statements of Operations. The accrued dividends and amortization of issuance costs totaling \$2.1 million during the year ending December 31, 2015 are included in interest expense in the accompanying Consolidated Statements of Operations.

**Maturities**

Maturities on long-term debt for each of the next five years as of December 31, 2015 are as follows (in thousands):

	<b>December 31, 2015</b>
2016	\$ 328,705
2017	\$ 131,125
2018	\$ 179,250
2019	\$ 715,500
2020	\$ 28,000

**NOTE 14. COMMITMENTS AND CONTINGENCIES****Manufacturing, Supply and Other Service Agreements**

Our subsidiaries contract with various third party manufacturers, suppliers and service providers to provide raw materials used in our subsidiaries' products and semi-finished and finished goods, as well as certain packaging, labeling services, customer service support, warehouse and distribution services. These contracts include agreements with Novartis Consumer Health, Inc., Novartis AG, and Sandoz, Inc. (collectively, Novartis), Teikoku Seiyaku Co., Ltd., Noramco, Inc., Grünenthal GmbH, Sharp Corporation, UPS Supply Chain Solutions, Inc. and Jubilant HollisterStier Laboratories LLC. 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.

*Novartis License and Supply Agreement*

See Note 11. License and Collaboration Agreements for a description of the Company's commitments and contingencies under the 2008 and 2015 Voltaren® Gel Agreements.

*Teikoku Seiyaku Co., Ltd.*

Under the terms of the Company's agreement (the Teikoku Agreement) with Teikoku Seiyaku Co. Ltd. (Teikoku), a Japanese manufacturer, Teikoku manufactures Lidoderm® at its two Japanese facilities, located on adjacent properties, for commercial sale by the Company in the U.S. the Company also has an option to extend the supply area to other territories. The Company amended the Teikoku agreement on April 24, 2007, January 6, 2010, November 1, 2010 and February 25, 2015 (together, the Amended Agreement). The material components of the Amended Agreement are as follows:

- The Company agreed to issue firm purchase orders for a minimum number of patches per year through 2017, representing the noncancelable portion of the Amended Agreement. There is a lower minimum purchase requirement in effect subsequent to 2017. The Company has met its minimum purchase requirement for 2015.
- Teikoku agreed to fix the supply price of Lidoderm® for a period of time after which the price will be adjusted at future dates certain based on a price index defined in the Amended Agreement.
- Following cessation of the Company's obligation to pay royalties to Hind Healthcare Inc. (Hind) under the Sole and Exclusive License Agreement dated as of November 23, 1998, as amended, between Hind and the Company (the Hind Agreement), the Company began to pay to Teikoku annual royalties based on annual net sales of Lidoderm®.

- The Amended Agreement will not expire until December 31, 2021, unless terminated in accordance with its terms. After December 31, 2021, the Amended Agreement shall be automatically renewed on the first day of January each year unless terminated in accordance with its terms.
- Either party may terminate the Amended Agreement, following a 45-day cure period, in the event that the Company fails to issue firm purchase orders for the annual minimum quantity for each year after 2017.
- The Company is the exclusive licensee for any authorized generic for Lidoderm® until the later of August 15, 2017 or the date of the first commercial sale of the second non-Teikoku generic version of Lidoderm®.

Amounts purchased pursuant to the Teikoku Agreement, as amended, were \$48.3 million, \$45.1 million and \$167.0 million for the years ended December 31, 2015, 2014 and 2013, respectively.

On November 23, 2011, the Company's obligation to pay royalties to Hind under the Hind Agreement ceased. Accordingly, on November 23, 2011, pursuant to the terms of the Teikoku Agreement, the Company began to incur royalties to Teikoku based on annual net sales of Lidoderm®. The royalty rate is 6% of branded Lidoderm® net sales. Additionally, in May 2014, we launched an authorized generic lidocaine patch 5% (referred to as Lidoderm® authorized generic) and began to incur royalties on net sales of the authorized generic. During the years ended December 31, 2015, 2014 and 2013, we recorded \$17.8 million, \$19.1 million and \$35.0 million for these royalties to Teikoku, respectively. These amounts were included in our Consolidated Statements of Operations as Cost of revenues. At December 31, 2015, \$16.8 million is recorded as a royalty payable and included in Accounts payable in the accompanying Consolidated Balance Sheets.

#### *Noramco, Inc.*

Under the terms of our agreement (the Noramco Agreement) with Noramco, Inc. (Noramco), Noramco manufactured and supplied to us certain narcotic active drug substances, in bulk form, and raw materials for inclusion in our controlled substance pharmaceutical products. There were no minimum annual purchase commitments under the Noramco Agreement. However, we were required to purchase a fixed percentage of our annual requirements of each narcotic active drug substance covered by the Noramco Agreement from Noramco. The purchase price for these substances was equal to a fixed amount, adjusted on an annual basis. Originally, the Noramco Agreement was to expire on December 31, 2011, with automatic renewal provisions for unlimited successive one-year periods. In September 2011, we extended the Noramco Agreement through early 2012. On April 27, 2012, we entered into a new supply agreement with Noramco (the 2012 Noramco Agreement). Under the terms of this supply agreement, Noramco manufactures and supplies to us certain narcotic active drug substances, in bulk form, for inclusion in our controlled substance pharmaceutical products. There are no minimum annual purchase commitments under the 2012 Noramco Agreement. However, we are required to purchase from Noramco a fixed percentage of our annual requirements of each narcotic active drug substance covered by the 2012 Noramco Agreement. The purchase price for these substances is equal to a fixed amount, adjusted on an annual basis based on volume. The term of the 2012 Noramco Agreement is for four years with automatic renewal provisions for unlimited successive one-year periods. The Noramco Agreement may be terminated at any time upon mutual written agreement between the parties or by either party in certain circumstances upon providing sufficient written notice to the other party.

Amounts purchased from Noramco were \$42.0 million, \$76.0 million and \$66.1 million for the years ended December 31, 2015, 2014 and 2013, respectively.

#### *Grünenthal GmbH*

Pursuant to the terms of the Company's December 2007 License, Development and Supply Agreement with Grünenthal (the Grünenthal Agreement), Grünenthal agreed to manufacture and supply to the Company a crush-resistant formulation of OPANA® ER based on a supply price equal to a certain percentage of net sales of OPANA® ER, subject to a floor price. In the first quarter of 2012, we began production of the crush-resistant formulation of OPANA® ER at a third party manufacturing facility managed by Grünenthal. The Grünenthal Agreement will expire on the later of (i) the 15th anniversary of the date of first commercial sale of the product, (ii) the expiration of the last issued patent in the territory claiming or covering products or (iii) the expiration of exclusivity granted by the FDA for the last product developed under the Grünenthal Agreement. Either party may terminate the Grünenthal Agreement in certain circumstances upon providing sufficient written notice to the other party. Effective December 19, 2012, the Company and Grünenthal amended the Grünenthal Agreement whereby the Company became responsible for the planning of packaging of finished product and certain other routine packaging quality obligations and Grünenthal agreed to reimburse the Company for the third-party costs incurred related to packaging as well as pay the Company a periodic packaging fee. The amendment also changed certain of the terms with respect to the floor price required to be paid by the Company in consideration for product supplied by Grünenthal. On February 18, 2014, the Company and Grünenthal amended the Grünenthal Agreement to define the responsibilities of the parties for certain additional clinical work to be performed for OPANA® ER.

The Company's supply payments made to Grünenthal pursuant to the Grünenthal Agreement are recorded in Cost of revenues in our Consolidated Statements of Operations and must be paid in U.S. dollars within 45 days after each calendar quarter. We incurred \$28.5 million, \$32.9 million and \$35.3 million for the years ended December 31, 2015, 2014 and 2013, respectively.

### *Sharp Corporation*

Under the terms of our agreement (the Sharp Agreement) with Sharp Corporation (Sharp), a U.S. manufacturer, Sharp performs certain packaging and labeling services for Endo, including the packaging and labeling of Lidoderm® and Lidoderm® AG, our formulation of OPANA® ER designed to be crush-resistant, Valstar® and BELBUCA™ at its facilities in Allentown, Pennsylvania for commercial sale by us in the U.S. The Sharp Agreement is effective until March 2016 and is subject to renewal for additional one-year periods upon mutual agreement by both parties. Endo has the right to terminate the Sharp Agreement at any time upon 90 days' written notice to Sharp.

Amounts purchased pursuant to the Sharp agreement were \$3.3 million, \$2.0 million and \$7.8 million for the years ended December 31, 2015, 2014 and 2013, respectively.

### *UPS Supply Chain Solutions, Inc.*

Under the terms of this agreement, the Company utilizes UPS Supply Chain Solutions (UPS) to provide customer service support and warehouse, freight and distribution services for certain of its products in the U.S. The term of the agreement extends through June 30, 2020. The agreement may be terminated by either the Company or UPS (1) without cause upon prior written notice to the other party; (2) with cause in the event of an uncured material breach by the other party; and (3) if the other party becomes insolvent or bankrupt. In the event of termination of services provided under the Warehouse Distribution Services Schedule to the agreement (i) by the Company without cause or (ii) by UPS due to the Company's breach, failure by the Company to make payments when due, or the Company's insolvency, the Company would be required to pay UPS certain termination costs. Such termination costs would not be material to the Company's Consolidated Statements of Operations. On February 21, 2012, the Company amended this agreement to provide for a reduced pricing structure, which included new monthly fees, new variable fees and new termination fees. On August 16, 2013, the Company further amended this agreement to add another mode of transport permissible under the agreement. On June 19, 2015, the Company further amended this agreement to, among other things, extend the terms of certain service schedules and replace certain exhibits to the service schedules.

### *Jubilant HollisterStier Laboratories LLC*

On January 29, 2015, we acquired Auxilium, which is party to a supply agreement (the JHS Agreement) with Jubilant HollisterStier Laboratories LLC (JHS). Pursuant to the JHS Agreement, which was initially entered into in June 2008, JHS fills and lyophilizes the XIAFLEX® bulk drug substance, which is manufactured by Auxilium, and produces sterile diluent. The initial term of the agreement was three years, with automatic renewal provisions thereafter for subsequent two-year terms, unless or until either party provides notification prior to expiration of the then current term of the contract. Auxilium 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. Auxilium currently is the sole supplier of the active pharmaceutical ingredient for commercial supply of XIAFLEX®, but it is currently in the process of qualifying a new secondary manufacturer for XIAFLEX®.

Amounts purchased pursuant to the JHS Agreement were not material for any of the periods presented.

### **Milestones and Royalties**

See Note 11. License and Collaboration Agreements for a complete description of future milestone and royalty commitments pursuant to our acquisitions, license and collaboration agreements.

### **Legal Proceedings**

We and certain of our subsidiaries are involved in various claims, legal proceedings and governmental investigations that arise from time to time in the ordinary course of our business, including those relating to product liability, intellectual property, regulatory compliance and commercial matters, and including suits we have previously reported, such as propoxyphene litigation and average wholesale price litigation. These and other 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. While we cannot predict the outcome of these legal proceedings and we intend to defend vigorously our position, 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.

As of December 31, 2015, our reserve for loss contingencies totaled \$2.16 billion, of which \$2.09 billion relates to our product liability accrual for vaginal mesh cases. We had previously announced that we had reached master settlement agreements with several of the leading plaintiffs' law firms to resolve claims relating to vaginal mesh products sold by our AMS subsidiary. The agreements were entered into solely by way of compromise and settlement and are not in any way an admission of liability or fault. 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*

We and certain of our subsidiaries have been named as defendants in numerous lawsuits in various federal and state courts, as well as in Canada and other countries outside the U.S., alleging personal injury resulting from the use of certain of our products and the products of our subsidiaries. These matters are described in more detail below.

We believe that certain settlements and judgments, as well as legal defense costs, relating to certain product liability matters are or may be covered in whole or in part under our product liability 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 such 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 product liability insurance policies will likely be 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.

**Vaginal Mesh Cases.** In October 2008, the FDA issued a Public Health Notification (October 2008 Public Health Notification) regarding potential complications associated with transvaginal placement of surgical mesh to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). The notification provides recommendations and encourages physicians to seek specialized training in mesh procedures, to advise their patients about the risks associated with these procedures and to be diligent in diagnosing and reporting complications.

In July 2011, the FDA issued an update to the October 2008 Public Health Notification regarding mesh to further advise the public and the medical community of the potential complications associated with transvaginal placement of surgical mesh to treat POP and SUI. In the July 2011 update, the FDA stated that adverse events are not rare. Furthermore, the FDA questioned the relative effectiveness of transvaginal mesh as a treatment for POP as compared to non-mesh surgical repair. The July 2011 notification continued to encourage physicians to seek specialized training in mesh procedures, to consider and to advise their patients about the risks associated with these procedures and to be diligent in diagnosing and reporting complications.

In January 2012, the FDA ordered manufacturers of transvaginal surgical mesh used for POP and of single incision mini-slings for urinary incontinence, such as our AMS subsidiary, to conduct post-market safety studies and to monitor adverse event rates relating to the use of these products. AMS received a total of 19 class-wide post-market study orders regarding its pelvic floor repair and mini-sling products; however, the FDA agreed to place 16 of these study orders on hold for a variety of reasons. Three of these post-market study orders remain active and AMS is continuing the process of complying with these orders. In January 2016, the FDA issued a statement reclassifying surgical mesh for transvaginal POP repair from Class II to Class III. Surgical mesh for SUI repair remains a Class II device.

Since 2008, we and certain of our subsidiaries, including AMS, have been named as defendants in multiple lawsuits in the U.S. in various state courts and in a multidistrict litigation (MDL) in the Southern District of West Virginia (MDL No. 2325), in Canada, where various class action and individual complaints are pending, and in other countries alleging personal injury resulting from the use of transvaginal surgical mesh products designed to treat POP and SUI. Plaintiffs in these suits allege various personal injuries including chronic pain, incontinence and 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) regarding settling up to approximately 49,000 filed and unfiled mesh claims handled or controlled by the participating counsel. These MSAs, which were executed at various times since June 2013, were entered into solely by way of compromise and settlement and are 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 Qualified Settlement Funds (QSFs) into which funds may be deposited pursuant to certain schedules set forth in those agreements. All MSAs have participation thresholds requiring participation by the majority of claims represented by each law firm party to the MSA. If certain participation thresholds are not met, then we will have the right to terminate the settlement with that law firm. 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 Qualified Settlement Funds are included in restricted cash and cash equivalents in the December 31, 2015 Consolidated Balance Sheets.

Distribution of funds to any individual claimant is conditioned upon the receipt of documentation substantiating the validity of the claim, a full release and a dismissal of the entire action or claim as to all AMS parties and affiliates. Prior to receiving funds, an individual claimant shall represent and warrant that liens, assignment rights, or other claims that are identified in the claims administration process have been or will be satisfied by the individual claimant. 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 settlement shall be kept confidential by all parties and their counsel.

As previously disclosed, our estimated liability had historically included a reduction factor applied to the maximum number of potentially eligible claims resulting in a liability that was lower than the maximum payouts under the previously executed MSAs. This reduction factor was based on our estimate of likely duplicative claims and claims that would not ultimately obtain recovery under our MSAs or otherwise. During the second quarter of 2015, we adjusted the reduction factor from 21% to 18% based on the available claims processing information available to us at that time. Due to the actual number of claims processed and the lack of any meaningful reduction factor observed to date, we removed this assumption in its entirety from our estimated liability as of December 31, 2015. Eliminating the reduction factor assumption resulted in a \$401 million increase to our estimated liability and a corresponding pre-tax charge recorded in Discontinued operations, net of tax.

We expect that valid claims under the MSAs will continue to be settled. However, we intend to vigorously contest pending and future claims that are invalid or in excess of the maximum claim amounts under the MSAs. We are also aware of a substantial number of additional claims or potential claims, some of which may be invalid or contested, for which we lack sufficient information to determine whether any potential liability is probable, and such claims have not been included in our estimated product liability accrual. We intend to contest these claims vigorously.

As of the date of this report, we believe that the current product liability accrual includes all known claims for which liability is probable and estimable. In order to evaluate whether a mesh claim is probable of a loss, we must obtain and evaluate certain information pertaining to each individual claim, including but not limited to the following items; the name and social security number of the plaintiff, evidence of an AMS implant, the date of implant, the date the claim was first asserted to AMS, the date that plaintiff's counsel was retained, and most importantly, medical records establishing the injury alleged. Without access to at least this information and the opportunity to evaluate it, we are not in a position to determine whether a loss is probable for such claims. It is currently not possible to determine the validity or outcome of any additional or potential claims and such claims may result in additional losses that could have a material adverse effect on our business, financial condition, results of operations and cash flow. We will continue to monitor the situation, including with respect to any additional claims of which we may later become aware, and, if appropriate, make further adjustments to the product liability accrual based on new information.

During the fourth quarter of 2015, we recorded an \$834.0 million pre-tax charge to increase the estimated product liability accrual for vaginal mesh cases. The increase in our estimated liability reflects the impact of removing the reduction factor assumption described above, the execution of additional MSAs in 2016 and an increase in the number of claims probable of a loss as determined by our ongoing assessment of outstanding claims.

The following table presents the changes in the vaginal mesh Qualified Settlement Funds and product liability balance during the year ended December 31, 2015 (in thousands):

	Qualified Settlement Funds	Product Liability
Balance as of December 31, 2014	\$ 485,229	\$ 1,655,195
Additional charges	—	1,107,751
Cash distributions to Qualified Settlement Funds	743,132	—
Cash distributions to settle disputes from Qualified Settlement Funds	(649,391)	(649,391)
Cash distributions to settle disputes	—	(27,379)
Balance as of December 31, 2015	<u>\$ 578,970</u>	<u>\$ 2,086,176</u>

Approximately \$1.54 billion of the total liability amount shown above is classified as Current portion of legal settlement accrual, with the remainder to be paid over time in accordance with the MSA agreements and classified as Long-term legal settlement accrual, less current portion, net in the December 31, 2015 Consolidated Balance Sheets. Charges related to vaginal mesh product liability for all periods presented are reported in Discontinued operations, net of tax in our Consolidated Statements of Operations.

We expect to fund the payments under all current settlement agreements over the course of the next two years, with completion by December 31, 2017. As the funds are disbursed out of the Qualified Settlement Funds from time to time, the product 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 Qualified Settlement Funds, which will also decrease the product liability accrual but will not decrease restricted cash and cash equivalents.

In addition, we have been contacted regarding a civil investigation that has been initiated by a number of 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 have subsequently received additional subpoenas from other states. We are cooperating fully with this investigation. At this time, we cannot predict or determine the outcome of this investigation or reasonably estimate the amount or range of amounts of fines or penalties, if any, that might result from a settlement or an adverse outcome from this investigation.

**Testosterone Cases.** We and certain of our subsidiaries, including EPI and Auxilium Pharmaceuticals, Inc. (Auxilium), along with other pharmaceutical manufacturers, have been named as defendants in lawsuits alleging personal injury resulting from the use of prescription medications containing testosterone, including Fortesta® Gel, Delatestryl®, Testim®, TESTOPEL® and Striant®. Plaintiffs in these suits allege various personal injuries including pulmonary embolism, stroke, and other vascular and/or cardiac injuries and seek compensatory and/or punitive damages, where available. In June 2014, an MDL was formed to include claims involving all testosterone replacement therapies filed against EPI, Auxilium, and other manufacturers of such products, and certain transferable cases pending in federal court were coordinated in the Northern District of Illinois as part of MDL No. 2545. In addition to the federal cases filed against EPI and Auxilium that have been transferred to the Northern District of Illinois as tag-along actions to MDL No. 2545, litigation has also been filed against EPI in the Court of Common Pleas Philadelphia County and in certain other state courts. Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions, and cases brought in federal court will be transferred to the Northern District of Illinois as tag-along actions to MDL No. 2545. However, we cannot predict the timing or outcome of any such litigation, or whether any such additional litigation will be brought against us. We intend to contest the litigation vigorously and to explore all options as appropriate in our best interest. As of February 19, 2016, approximately 935 cases are currently pending against us; some of which may have been filed on behalf of multiple plaintiffs, and including a class action complaint filed in Canada.

In November 2015, the United States District Court for the Northern District of Illinois entered an order granting defendants' motion to dismiss claims involving certain testosterone products that were approved pursuant to abbreviated new drug applications, including TESTOPEL. Plaintiffs have filed a motion for reconsideration and clarification of this order.

In November 2014, a civil class action complaint was filed in 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 had paid for certain testosterone products, alleging that the marketing efforts of EPI, Auxilium, and other defendant manufacturers with respect to certain testosterone products constituted racketeering activity in violation of 18 U.S.C. §1962(c), and other civil Racketeer Influenced and Corrupt Organizations Act claims. Further, the complaint alleges that EPI, Auxilium, and other defendant manufacturers violated various state consumer protection laws through their marketing of certain testosterone products. In June 2015, plaintiffs filed a Second Amended Complaint. We are unable to predict the outcome of this matter or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss for this matter, if any, but we will explore all options as appropriate in our best interest.

#### *Department of Health and Human Services Subpoena and Related Matters*

As previously reported, we and our subsidiary, EPI, are in the process of responding to a Civil Investigative Demand (CID) issued by the State of Texas relating to Lidoderm® (lidocaine patch 5%), focused primarily on the sale, marketing and promotion of Lidoderm® in Texas. We are cooperating with the State's investigation. We are unable to predict the outcome of this matter or the ultimate legal and financial liability and at this time cannot reasonably estimate the possible loss or range of loss for this matter but will explore all options as appropriate in our best interest.

Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us.

#### *Qualitest Pharmaceuticals Civil Investigative Demands*

In April 2013, our subsidiaries, EPI and Qualitest, received CIDs from the U.S. Attorney's Office for the Southern District of New York. The CIDs request documents and information regarding the manufacture and sale of chewable fluoride tablets and other products sold by Qualitest. EPI and Qualitest reached a resolution of potential claims of the federal government and numerous states related to the manufacture and sale of certain chewable fluoride tablets that were the subject of these CIDs. In December 2015, that settlement was approved by the United States District Court for the Southern District of New York. The cost of this settlement has been incorporated into our legal loss contingency reserve.

#### *Unapproved Drug Litigation*

In September 2013, the State of Louisiana filed a Petition for Damages against certain of our subsidiaries, EPI, Qualitest and Boca, and over 50 other pharmaceutical companies alleging the defendants or their subsidiaries marketed products that were not approved by the FDA. See *State of Louisiana v. Abbott Laboratories, Inc., et al.*, C624522 (19th Jud. Dist. La.). The State of Louisiana sought damages, fines, penalties, attorneys' fees and costs under various causes of action. In October 2015, the court ordered judgment for Defendants on their exception for no right of action. The State of Louisiana is in the process of appealing that decision.

We intend to contest the above case vigorously and to explore other options as appropriate in our best interest. Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us. We are unable to predict the outcome of this matter or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss for this matter, if any.



### *Opioid-Related Litigations, Subpoenas and Document Requests*

In June 2014, Corporation Counsel for the City of Chicago filed suit in Illinois state court against multiple defendants, including our subsidiaries, Endo Health Solutions Inc. (EHSI) and EPI, for alleged violations of city ordinances and other laws relating to defendants' alleged opioid sales and marketing practices. In June 2014, the case was removed to the U.S. District Court for the Northern District of Illinois. In December 2014, defendants moved to dismiss the Amended Complaint and in May 2015, the Court issued an order granting that motion in part, dismissing the case as to EHS and EPI. In August 2015, Plaintiff filed its Second Amended Complaint against multiple defendants, including ESHI and EPI. In November 2015, defendants moved to dismiss the Second Amended Complaint.

In May 2014 and in June 2014, a lawsuit was filed in California Superior Court (Orange County) in the name of the People of the State of California, acting by and through County Counsel for Santa Clara County and the Orange County District Attorney, against multiple defendants, including our subsidiaries EHSI and EPI. The complaint asserts violations of California's statutory Unfair Competition and False Advertising laws, as well as asserting a claim for public nuisance, based on alleged misrepresentations in connection with sales and marketing of opioids, including OPANA<sup>®</sup>. Plaintiff seeks declaratory relief, restitution, civil penalties (including treble damages), abatement, an injunction, and attorneys' fees and costs. Defendants, which includes our subsidiaries, filed various motions attacking the pleadings, including one requesting that the Court refrain from proceeding under the doctrines of primary jurisdiction and equitable abstention. That motion was granted in August 2015, and the case has been stayed pending further proceedings and findings by the FDA.

In December 2015, a lawsuit was filed in the Chancery Court of the First Judicial District of Hinds County, Mississippi by the State of Mississippi, against multiple defendants, including our subsidiaries EHSI and EPI. The complaint alleges violations of Mississippi's Consumer Protection Act and various other claims arising out of defendants' alleged opioid sales and marketing practices. Plaintiff seeks declaratory relief, restitution, civil penalties, abatement, an injunction, and attorneys' fees and costs.

In September 2013, our subsidiaries, EPI and EHSI, received a subpoena from the State of New York Office of Attorney General seeking documents and information regarding the sales and marketing of OPANA<sup>®</sup>. In February 2016, EPI and EHSI agreed with the State of New York Office of Attorney General to an Assurance of Discontinuance pursuant to the provisions of New York law, whereby EPI and EHSI agreed to modify certain business practices related to the marketing and sale of OPANA<sup>®</sup>, as well as to pay certain monetary penalties. The cost of those penalties has been incorporated into our legal loss contingency reserve.

In September 2014, our subsidiaries, EPI and EHSI received a Request for Information from the State of Tennessee Office of the Attorney General and Reporter seeking documents and information regarding the sales and marketing of opioids, including OPANA<sup>®</sup> ER. In August 2015, our subsidiaries, EPI and EHSI received a subpoena from the State of New Hampshire Office of the Attorney General seeking documents and information regarding the sales and marketing of opioids, including OPANA<sup>®</sup> ER.

We are currently cooperating with the State of Tennessee Office of the Attorney General and Reporter, and the State of New Hampshire Office of the Attorney General in their respective investigations. With respect to the litigations brought on behalf of the City of Chicago, the People of the State of California and the State of Mississippi, we intend to contest those matters vigorously. We are unable to predict the outcome of these matters or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss, if any, for these matters but will explore all options as appropriate in our best interest.

### *Antitrust Litigation and Investigations*

Multiple direct and indirect purchasers of Lidoderm<sup>®</sup> have filed a number of cases against our subsidiary EPI and co-defendants Teikoku Seiyaku Co., Ltd., Teikoku Pharma USA, Inc. (collectively, Teikoku) and Actavis plc (now Allergan plc) and a number of its subsidiaries (collectively referred to herein as Allergan, Actavis or Watson). Certain of these actions have been asserted on behalf of classes of direct and indirect purchasers, while others are individual cases brought by one or more alleged direct or indirect purchasers. The complaints in these cases generally allege that EPI, Teikoku and Actavis entered into an anticompetitive conspiracy to restrain trade through the settlement of patent infringement litigation concerning U.S. Patent No. 5,827,529 (the '529 patent) and other patents. Some of the complaints also allege that Teikoku wrongfully listed the '529 patent in the Orange Book as related to Lidoderm<sup>®</sup>, that EPI and Teikoku commenced sham patent litigation against Actavis and that EPI abused the FDA citizen petition process by filing a citizen petition and amendments solely to interfere with generic companies' efforts to obtain FDA approval of their versions of Lidoderm<sup>®</sup>. The cases allege violations of Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1, 2) and various state antitrust and consumer protection statutes as well as common law remedies in some states. These cases generally seek damages, treble damages, disgorgement of profits, restitution, injunctive relief and attorneys' fees.

The U.S. Judicial Panel on Multidistrict Litigation, pursuant to 28 U.S.C. § 1407, issued an order in April 2014, transferring these cases as *In Re Lidoderm Antitrust Litigation*, MDL No. 2521, to the U.S. District Court for the Northern District of California. The cases are in the discovery phase of the litigation in accordance with the pre-trial schedule. Trial is currently scheduled to begin in 2017. Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions, and cases brought in federal court will be transferred to the Northern District of California as tag-along actions to *In Re Lidoderm Antitrust Litigation*.

Multiple direct and indirect purchasers of OPANA<sup>®</sup> ER have filed cases against our subsidiaries EHSI and EPI, and other pharmaceutical companies, including Penwest Pharmaceuticals Co., and Impax Laboratories Inc. (Impax), all of which have been

transferred and coordinated for pretrial proceedings in the Northern District of Illinois by the Judicial Panel on Multidistrict Litigation. Some of these cases have been filed on behalf of putative classes of direct and indirect purchasers, while others have been filed on behalf of individual retailers. These cases generally allege that the agreement reached by EPI and Impax to settle patent infringement litigation concerning multiple patents pertaining to OPANA<sup>®</sup> ER and EPI's introduction of the reformulation of OPANA<sup>®</sup> ER violated antitrust laws. The complaints allege violations of Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1, 2), various state antitrust and consumer protection statutes, as well as state common law. These cases generally seek damages, treble damages, disgorgement of profits, restitution, injunctive relief and attorneys' fees. In February 2016, the court issued orders denying defendants' motion to dismiss the claims of the direct purchasers and denied in part and granted in part defendants' motion to dismiss the claims of the indirect purchasers. We cannot predict whether or not additional cases similar to those described above will be filed by other plaintiffs or the timing or outcome of any such litigation.

We are unable to predict the outcome of these matters or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss for these matters, if any, but will explore all options as appropriate in our best interest.

In February 2014, our subsidiary, EPI received a CID (the February 2014 CID) from the U.S. Federal Trade Commission (the FTC). The FTC issued a second CID to EPI in March 2014 (the March 2014 CID). The February 2014 CID requests documents and information concerning EPI's settlement agreements with Actavis and Impax settling the OPANA<sup>®</sup> ER patent litigation, EPI's Development and Co-Promotion Agreement with Impax, and its settlement agreement with Actavis settling the Lidoderm<sup>®</sup> patent litigation, as well as information concerning the marketing and sales of OPANA<sup>®</sup> ER and Lidoderm<sup>®</sup>. The March 2014 CID requests documents and information concerning EPI's acquisition of U.S. Patent No. 7,852,482 (the '482 patent), as well as additional information concerning certain litigation relating to, and the marketing and sales of OPANA<sup>®</sup> ER. The FTC also issued subpoenas for investigational hearings (similar to depositions) to our employees and former employees.

In November 2014, EPI received a CID from the State of Florida Office of the Attorney General issued pursuant to the Florida Antitrust Act of 1980, Section 542.28 and seeking documents and other information concerning EPI's settlement agreement with Actavis settling the Lidoderm<sup>®</sup> patent litigation, as well as information concerning the marketing and sales of Lidoderm<sup>®</sup>.

In February 2015, EPI and EHSI received a CID for Production of Documents and Information from the State of Alaska Office of Attorney General issued pursuant to Alaska's Antitrust and Unfair Trade Practices and Consumer Protection law seeking documents and other information concerning settlement agreements with Actavis and Impax settling the OPANA ER patent litigation as well as information concerning EPI's settlement agreement with Actavis settling the Lidoderm patent litigation, as well as information concerning the marketing and sales of Lidoderm.

In February 2016, EPI received a subpoena from the State of South Carolina Office of the Attorney General seeking documents and other information concerning EPI's settlement agreement with Actavis settling the Lidoderm<sup>®</sup> patent litigation, as well as information concerning the marketing and sales of Lidoderm<sup>®</sup>.

In December 2014, our subsidiary, Par, received a Subpoena to Testify Before Grand Jury from the Antitrust Division of the DOJ and issued by the U.S. District Court for the Eastern District of Pennsylvania. The subpoena requests documents and information focused primarily on product and pricing information relating to Par's authorized generic version of Lanoxin (digoxin) oral tablets and Par's generic doxycycline products, and on communications with competitors and others regarding those products. Par is currently cooperating fully with the investigation.

In January 2009, the FTC filed a lawsuit against our subsidiary, Par, in the U.S. District Court for the Central District of California, which was subsequently transferred to the U.S. District Court for the Northern District of Georgia, and which alleged violations of antitrust law arising out of Par's settlement of certain patent litigation concerning the generic version of Androgel. The FTC complaint generally seeks a finding that Par's settlement agreement violates Section 5(a) of the Federal Trade Commission Act, and a permanent injunction against Par's ability to engage in certain types of patent settlements in the future. Beginning in February 2009, certain private plaintiffs, including distributors and retailers, filed similar litigation. Generally, the private plaintiff suits seek equitable relief, unspecified damages and costs.

In February 2010, the District Court granted a motion to dismiss the FTC's claims and granted in part and denied in part a motion to dismiss the claims of the private plaintiffs. In April 2012, the U.S. Court of Appeals for the 11<sup>th</sup> Circuit affirmed the District Court's decision on the motion to dismiss the FTC's claims. In September 2012, the District Court granted a motion for summary judgment against the private plaintiffs' claims of sham litigation. In July 2013, the Supreme Court of the U.S. reversed the Court of Appeals and District Court's decisions and remanded the case to the District Court for further proceedings. We intend to contest this litigation vigorously and to explore all options as appropriate in our best interest.

In February 2015, Par, received a CID from the Office of the Attorney General for the State of Alaska seeking production of certain documents and information regarding Par's settlement of the Androgel patent litigation as well as documents produced in the on-going litigation filed by the FTC.

We are currently cooperating with the FTC, the DOJ, the State of Florida Office of the Attorney General, the State of Alaska Office of the Attorney General, and the State of South Carolina Office of the Attorney General in their respective investigations.

Investigations similar to these antitrust matters described above may be brought by others. We are unable to predict the outcome of these investigations or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss for these investigations, if any, but will explore all options as appropriate in our best interest.

#### *False Claims Act Litigation*

The Attorneys General of Florida, Indiana and Virginia and the U.S. Office of Personnel Management (the USOPM) have issued subpoenas, and the Attorneys General of Michigan, Tennessee, Texas, and Utah have issued CIDs, to our subsidiary, Par, among other companies. The demands generally request documents and information pertaining to allegations that certain of Par's sales and marketing practices caused pharmacies to substitute ranitidine capsules for ranitidine tablets, fluoxetine tablets for fluoxetine capsules, and two 7.5 mg buspirone tablets for one 15 mg buspirone tablet, under circumstances in which some state Medicaid programs at various times reimbursed the new dosage form at a higher rate than the dosage form being substituted. Par has provided documents in response to these subpoenas to the respective Attorneys General and the USOPM. The aforementioned subpoenas and CIDs culminated in the federal and state law qui tam action brought on behalf of the U.S. and several states by Bernard Lisitza. The complaint was unsealed in August 2011. Lisitza's corrected second amended complaint generally seeks (i) a finding that defendants violated and be enjoined from future violations of the federal False Claims Act and state false claims acts; (ii) treble damages and maximum civil penalties for each violation of the federal False Claims Act and state false claims acts; (iii) an applicable percentage share of the proceeds; and (iv) expenses, fees, and costs. The U.S. intervened in this action and filed a separate complaint in September 2011, alleging claims for violations of the Federal False Claims Act and common law fraud. The U.S.'s second corrected complaint generally seeks (i) treble damages and civil penalties for violations under the federal False Claims Act and (ii) compensatory and punitive damages for common law fraud. The states of Michigan and Indiana have also intervened as to claims arising under their respective state false claim acts, common law fraud, and unjust enrichment. Michigan's complaint generally seeks (i) treble damages and civil penalties and (ii) common law compensatory and punitive damages. Indiana's amended complaint generally seeks treble damages, costs, and attorney's fees. We intend to vigorously defend these lawsuits. At this time, we are unable to predict the outcome of this matter or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss for this matter, if any.

#### *Megace ES® (megestrol acetate oral suspension) Cases*

In September 2011, our subsidiary, Par, along with EDT Pharma Holdings Ltd. (Elan) (now known as Alkermes Pharma Ireland Limited), filed a complaint against TWi Pharmaceuticals, Inc. (TWi) in the U.S. District Court for the District of Maryland alleging infringement of U.S. Patent No. 7,101,576 because TWi filed an ANDA with a Paragraph IV certification seeking FDA approval of a generic version of Megace® ES. A bench trial was held in October 2013, and in February 2014, the District Court issued a decision in favor of TWi, finding all asserted claims of the 7,101,576 patent invalid for obviousness. Par appealed. In August 2014, the District Court issued a preliminary injunction enjoining TWi's launch of its generic product pending disposition of the appeal. In December 2014, the Federal Circuit reversed the District Court's decision, remanding for further findings of fact. In March 2015, the District Court issued another preliminary injunction enjoining TWi's launch of its generic product pending disposition of the case on remand. In July 2015, the District Court issued a new decision in favor of TWi, finding all of the asserted claims invalid, and TWi launched its generic product. Par appealed again, and in December 2015, the District Court's decision in favor of TWi was affirmed without opinion. On February 22, 2016, TWi moved the District Court to recover its lost profits, which TWi alleges in the amount of \$16 million, resulting from the previous injunctions to which the District Court subjected TWi, as well as attorneys' fees and costs. The Company believes that a loss is probable and we have incorporated our best estimate of this loss into our reserve for loss contingencies. It is possible that the outcome of this matter could result in an additional loss above the amount reserved.

In June 2013, Par, along with Alkermes Pharma Ireland Limited, filed a complaint against Breckenridge Pharmaceutical, Inc. in the U.S. District Court for the District of Delaware, alleging infringement of U.S. Patent Nos. 6,592,903 and 7,101,576 because Breckenridge filed an ANDA with a Paragraph IV certification seeking FDA approval of a generic version of Megace® ES. The complaint sought (i) a finding of infringement, validity, and/or enforceability; and (ii) a permanent injunction be entered, terminating at the expiration of the patents-in-suit. A stipulation to stay the proceedings was entered in July 2014. In January 2016, we terminated the case by filing a stipulation of dismissal with prejudice.

In June 2015, Par, along with Alkermes Pharma Ireland Limited, filed a complaint against Breckenridge Pharmaceutical, Inc., TWi Pharmaceuticals, Inc., and TWi Pharmaceuticals USA, Inc. in the U.S. District Court for the District of Delaware alleging infringement of U.S. Patent No. 9,040,088 because the defendants had filed ANDAs seeking FDA approval of generic versions of Megace® ES. In August 2015, Par and Alkermes Pharma Ireland Limited filed an additional complaint in the same court against TWi and Breckenridge alleging infringement of U.S. Patent Nos. 9,101,540 and 9,101,549, followed by a third complaint in Delaware District Court alleging infringement of U.S. Patent No. 9,107,827. Our complaint sought (i) a finding of infringement, validity and/or enforceability; and (ii) a permanent injunction. In January 2016, we terminated the cases by filing stipulations of dismissal with prejudice.

#### *Paragraph IV Certifications on OPANA® ER*

In late 2012, two patents (U.S. Patent Nos. 8,309,122 and 8,329,216) were issued to EPI covering OPANA® ER (oxymorphone hydrochloride extended-release tablets CII). In December 2012, EPI filed a complaint against Actavis (now Allergan) in U.S. District

Court for the Southern District of New York for patent infringement based on its ANDA for a non-crush-resistant generic version of OPANA<sup>®</sup> ER. In May 2013 and June 2013, EPI filed similar suits in the U.S. District Court for the Southern District of New York against the following applicants for non-crush-resistant OPANA<sup>®</sup> ER: Roxane Laboratories, Inc. (Roxane) and Ranbaxy Laboratories Limited (Ranbaxy). Those suits allege infringement of U.S. Patent Nos. 7,851,482, 8,309,122, and 8,329,216. In July 2013, Actavis and Roxane were granted FDA approval to market all strengths of their respective non-crush-resistant formulations of OPANA<sup>®</sup> ER. A trial in this case was held from March 2015 through April 2015 in the U.S. District Court for the Southern District of New York. In August 2015, the Court issued an Opinion holding that all defendants infringed the claims of U.S. Patent Nos. 8,309,122 and 8,329,216. The Opinion also held that the defendants had failed to show that U.S. Patent Nos. 8,309,122 and 8,329,216 were invalid. The Court also issued an Order enjoining the defendants from launching their generic products until the expiration of U.S. Patent Nos. 8,309,122 and 8,329,216. That Order further ordered that Actavis withdraw its generic product within 60 days. In October 2015, the court issued an order tolling the 60 day period until it decides two post-trial motions before it. We cannot anticipate the timing of that decision. The time for appealing the Opinion and Order has not yet expired and we expect the defendants to appeal the decision. We intend to continue to vigorously assert our intellectual property and oppose appeals by the defendants.

We intend to defend vigorously our intellectual property rights and to pursue all available legal and regulatory avenues in defense of the non-crush-resistant formulation OPANA<sup>®</sup> ER, including enforcement of the product's intellectual property rights and approved labeling. However, there can be no assurance that we will be successful. If we are unsuccessful, competitors that already have obtained, or are able to obtain, FDA approval of their products may be able to launch their generic versions of non-crush-resistant OPANA<sup>®</sup> ER prior to the applicable patents' expirations. Additionally, we cannot predict or determine the timing or outcome of related litigation but will explore all options as appropriate in our best interest. In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of non-crush-resistant OPANA<sup>®</sup> ER and challenge the applicable patents.

From September 21, 2012 through October 30, 2013, EPI and its partner Grünenthal received Paragraph IV Notices from each of Teva Pharmaceuticals USA, Inc. (Teva), Amneal Pharmaceuticals, LLC (Amneal), ThoRx Laboratories, Inc. (ThoRx), Allergan, Impax and Ranbaxy, advising of the filing by each such company of an ANDA for a generic version of the formulation of OPANA<sup>®</sup> ER designed to be crush-resistant. These Paragraph IV Notices refer to U.S. Patent Nos. 8,075,872, 8,114,383, 8,192,722, 8,309,060, 8,309,122 and 8,329,216, which variously cover the formulation of OPANA<sup>®</sup> ER, a highly pure version of the active pharmaceutical ingredient and the release profile of OPANA<sup>®</sup> ER. EPI filed lawsuits against each of these filers in the U.S. District Court for the Southern District of New York. Each lawsuit was filed within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. We intend, and have been advised by Grünenthal that it too intends, to defend vigorously the intellectual property rights covering the formulation of OPANA<sup>®</sup> ER designed to be crush-resistant and to pursue all available legal and regulatory avenues in defense of crush-resistant OPANA<sup>®</sup> ER, including enforcement of the product's intellectual property rights and approved labeling. A trial in this case was held from March 2015 through April 2015 in the U.S. District Court for the Southern District of New York against the remaining filers. In August 2015, the Court issued an Opinion holding that all defendants infringed the claims of U.S. Patent Nos. 8,309,060, 8,309,122 and 8,329,216. The Opinion also held that the defendants had shown that U.S. Patent No. 8,309,060 was invalid, but that the defendants had failed to show that U.S. Patent Nos. 8,309,122 and 8,329,216 were invalid. The Court also issued an Order enjoining the defendants from launching their generic products until the expiration of U.S. Patent Nos. 8,309,122 and 8,329,216. The time for appealing that Opinion and Order has not yet expired and we expect the defendants to appeal the decision. We intend to continue to vigorously assert our intellectual property and oppose appeals by the defendants. However, there can be no assurance that we and/or Grünenthal will be successful. If we are unsuccessful and Teva, Amneal, ThoRx, Allergan or Impax is able to obtain FDA approval of its product, generic versions of crush-resistant OPANA<sup>®</sup> ER may be launched prior to the applicable patents' expirations in 2023 through 2029. Additionally, we cannot predict or determine the timing or outcome of this defense but will explore all options as appropriate in our best interest. In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of crush-resistant OPANA<sup>®</sup> ER and challenge the applicable patents.

In August 2014 and October 2014, the U.S. Patent Office issued U.S. Patent Nos. 8,808,737 and 8,871,779 respectively, which cover a method of using OPANA<sup>®</sup> ER and a highly pure version of the active pharmaceutical ingredient of OPANA<sup>®</sup> ER. In November 2014, EPI filed lawsuits against Teva, ThoRx, Actavis, Impax, Ranbaxy, Roxane, Amneal, and Sandoz Inc. 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 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.

#### *Paragraph IV Certification on Fortesta<sup>®</sup> Gel*

In January 2013, EPI and its licensor Strakan Limited received a notice from Watson (now Allergan) advising of the filing by Watson of an ANDA for a generic version of Fortesta<sup>®</sup> (testosterone) Gel. In February 2013, EPI filed a lawsuit against Watson in the U.S. District Court for the Eastern District of Texas, Marshall division. Because the suit was filed within the 45-day period under the Hatch-Waxman Act for filing a patent infringement action, we believe that it triggered an automatic 30-month stay of approval under the Act. A two-day trial was held on or about February 26 and 27, 2015. In August 2015, the court issued an Order holding that the

asserted patents are not invalid and are infringed by Watson's ANDA. As a result, the court ordered that that the effective date for the approval of Watson's ANDA to be the date no sooner than the latest expiration date of the '913 Patent and the '865 Patent in November of 2018. Watson filed an appeal in October 2015.

We intend, and have been advised by Strakan Limited that it too intends, to defend vigorously Fortesta® Gel and to pursue all available legal and regulatory avenues in defense of Fortesta® Gel, including enforcement of the product's intellectual property rights and approved labeling. However, there can be no assurance that we and/or Strakan will be successful. If we and/or Strakan are unsuccessful and Watson is able to obtain FDA approval of its product, Watson may be able to launch its generic version of Fortesta® Gel prior to the applicable patents' expirations in 2018. Additionally, we cannot predict or determine the timing or outcome of this litigation but will explore all options as appropriate in our best interest. In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of Fortesta® Gel and challenge the applicable patents.

#### Other Legal Proceedings

In addition to the above proceedings, 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 legal proceedings that arise from the normal course of our business. We cannot predict the timing or outcome of these claims and other proceedings. Currently, neither we nor our subsidiaries are involved in any other legal 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 2025. We lease automobiles, machinery and equipment and facilities under certain noncancelable operating leases that expire through 2024. 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 term of this lease is 12 years and includes three renewal options, each for an additional 60-month period. On September 4, 2014, the Company entered into a sublease agreement to lease approximately 60,000 square feet from January 1, 2015 to December 31, 2016 increasing to 90,000 square feet from January 1, 2017 to December 31, 2024. We will receive approximately \$21.5 million in minimum rental payments over the remaining term of the sublease.

Our 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, 2015, there was a liability of \$45.9 million related to this arrangement, \$4.1 million of which is included in Accounts payable and \$41.8 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, 2015 are as follows (in thousands):

	Capital Leases(1)	Operating Leases
2016	\$ 9,950	\$ 23,103
2017	8,114	16,292
2018	6,951	15,201
2019	7,051	12,471
2020	7,242	10,624
Thereafter	30,248	31,304
Total minimum lease payments	<u>\$ 69,556</u>	<u>\$ 108,995</u>
Less: Amount representing interest	6,628	
Total present value of minimum payments	<u>\$ 62,928</u>	
Less: Current portion of such obligations	9,950	
Long-term capital lease obligations	<u>\$ 52,978</u>	

(1) The direct financing arrangement is included under Capital Leases. Minimum payments have not been reduced by minimum sublease rentals of \$21.5 million due in the future under a noncancelable sublease.

Expense incurred under operating leases was \$20.1 million, \$8.5 million and \$18.7 million for the years ended December 31, 2015, 2014 and 2013, respectively.

**NOTE 15. OTHER COMPREHENSIVE LOSS**

The following table presents the tax effects allocated to each component of Other comprehensive loss for the years ended December 31 (in thousands):

	2015			2014			2013		
	Before-Tax Amount	Tax (Expense) Benefit	Net-of-Tax Amount	Before-Tax Amount	Tax Benefit (Expense)	Net-of-Tax Amount	Before-Tax Amount	Tax (Expense) Benefit	Net-of-Tax Amount
Net unrealized gain (loss) on securities:									
Unrealized gain (loss) arising during the period	\$ 2,349	\$ (50)	\$ 2,299	\$ (1,646)	\$ 547	\$ (1,099)	\$ 1,233	\$ (458)	\$ 775
Less: reclassification adjustments for loss realized in net loss	—	—	—	17	—	17	—	—	—
Net unrealized gains (losses)	2,349	(50)	2,299	(1,629)	547	(1,082)	1,233	(458)	775
Net unrealized gain (loss) on foreign currency:									
Foreign currency translation (loss) gain arising during the period	(263,425)	(21,297)	(284,722)	(121,417)	28	(121,389)	682	32	714
Less: reclassification adjustments for loss realized in net loss	25,557	158	25,715	—	—	—	—	—	—
Foreign currency translation (loss) gain	(237,868)	(21,139)	(259,007)	(121,417)	28	(121,389)	682	32	714
Fair value adjustment on derivatives designated as cash flow hedges:									
Fair value adjustment on derivatives designated as cash flow hedges arising during the period	—	—	—	—	—	—	853	(307)	546
Less: reclassification adjustments for cash flow hedges settled and included in net loss	—	—	—	—	—	—	(232)	84	(148)
Net unrealized fair value adjustment on derivatives designated as cash flow hedges	—	—	—	—	—	—	621	(223)	398
Other comprehensive (loss) income	\$ (235,519)	\$ (21,189)	\$ (256,708)	\$ (123,046)	\$ 575	\$ (122,471)	\$ 2,536	\$ (649)	\$ 1,887

Reclassification adjustments out of Other comprehensive (loss) income are reflected in the Consolidated Statements of Operations as Other expense (income) net, with respect to the realized loss on securities or Discontinued operations, net of tax, with respect to the realized loss from foreign currency translation.

The following is a summary of the accumulated balances related to each component of Other comprehensive loss, net of taxes, at December 31, 2015 and December 31, 2014 (in thousands):

	December 31, 2015	December 31, 2014
Net unrealized gains (losses)	\$ 1,815	\$ (484)
Foreign currency translation loss	(386,020)	(123,604)
Accumulated other comprehensive loss	<u>\$ (384,205)</u>	<u>\$ (124,088)</u>

#### NOTE 16. SHAREHOLDERS' EQUITY

In prior periods, our Consolidated Financial Statements presented the accounts of EHSI. On October 31, 2013, Endo International plc was incorporated in Ireland as a private limited company and re-registered effective February 18, 2014 as a public limited company. It was established for the purpose of facilitating the business combination between EHSI and Paladin. On February 28, 2014 we became the successor registrant of EHSI and Paladin in connection with the consummation of certain transactions. In addition, on February 28, 2014, the shares of Endo International plc began trading on the NASDAQ under the symbol "ENDP," the same symbol under which Endo Health Solutions Inc.'s shares previously traded, as well as on the Toronto Stock Exchange under the symbol "ENL". References throughout to "ordinary shares" refer to EHSI's common shares, 350,000,000 authorized, par value \$0.01 per share, prior to the consummation of the transactions and to Endo International plc's ordinary shares, 1,000,000,000 authorized, par value \$0.0001 per share, subsequent to the consummation of the transactions.

In addition, on February 11, 2014 the Company issued 4,000,000 euro deferred shares of US\$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.

On January 29, 2015, the Company acquired Auxilium for total consideration of \$2.6 billion. The consideration included 18,609,835 ordinary shares valued at \$1.52 billion.

On June 10, 2015, we completed the sale of 27,627,628 ordinary shares, including 3,603,603 ordinary shares sold upon the exercise in full by the underwriters of their option to purchase additional ordinary shares from us, at a price of \$83.25 per share, for aggregate gross proceeds to us of \$2,300.0 million, before fees, in order to finance a portion of the Par acquisition (described in more detail in Note 5. Acquisitions).

On September 25, 2015, the Company acquired Par for total consideration of \$8.14 billion, including the assumption of Par debt. The consideration included 18,069,899 ordinary shares valued at \$1.33 billion.

During the year ended December 31, 2015, the Company completed a buy-out of the noncontrolling interest associated with our Litha subsidiary. The following table reflects the effect on the Company's equity for the year ended December 31, 2015 (in thousands):

Adjustment to Accumulated other comprehensive loss related to the reallocation (from noncontrolling to controlling interests) of foreign currency translation loss attributable to our noncontrolling interest in Litha	\$ (3,904)
Decrease in noncontrolling interests for buy-out of Litha	(32,732)
Decrease in additional paid-in capital for buy-out of Litha	(2,972)
Total cash consideration paid related to buy-out of Litha	<u>\$ (39,608)</u>

#### Share Repurchase Program

The Company has broad shareholder authority to conduct share repurchases of its ordinary shares, as our shareholders granted to the Company a general authority (the 2014 Share Buyback Authority) to make overseas market purchases (as defined by section 212 of the Irish Companies Act 1990 (the 1990 Act)) of shares of the Company on such terms and conditions as our Board of Directors may approve, but subject to the provisions of the 1990 Act and certain other provisions.

Pursuant to the 2014 Share Buyback Authority, in April 2015, our Board of Directors approved a share buyback program (the 2015 Share Buyback Program). The 2015 Share Buyback Program authorizes the Company to redeem in the aggregate \$2.5 billion of its outstanding ordinary shares. In accordance with Irish Law and the Company's Articles of Association, all ordinary shares redeemed shall be cancelled upon redemption.



In November 2015, the Company entered into a program to repurchase up to \$250.0 million of its ordinary shares under the 2015 Share Buyback Program. The Company purchased approximately 4.4 million of its ordinary shares during November 2015 totaling \$250.0 million, not including related fees.

#### NOTE 17. SHARE-BASED COMPENSATION

As discussed in Note 1. Description of Business the operating results of the Company's AMS and HealthTronics 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 17. Share-based Compensation have not been adjusted to exclude the impact of these businesses.

##### *Stock Incentive Plans*

As of December 31, 2014, the Company's approved stock incentive plans included the Endo International plc 2000, 2004, 2007, 2010 and Assumed Stock Incentive Plans.

In June 2015, the Company's shareholders approved the 2015 Stock Incentive Plan (the 2015 Plan). Under the 2015 Plan, 10.0 million ordinary shares, which included the transfer of 5.0 million ordinary shares available to be granted under the 2010 Stock Incentive Plan as of the date the 2015 Plan became effective, were reserved for the grant of stock options (including incentive stock options), stock appreciation rights, restricted stock awards, performance awards and other share-based awards, which may be issued at the discretion of the Company's board of directors from time to time. Upon the 2015 Plan becoming effective, all other existing stock incentive plans were terminated.

At December 31, 2015, approximately 12.7 million ordinary shares were reserved for future issuance upon exercise of options granted or to be granted under the 2015 Plan. As of December 31, 2015, stock options, restricted stock awards, performance stock units and restricted stock units have been granted under this plan.

All share-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as an expense in the income statement over the requisite service period.

The Company recognized share-based compensation expense of \$98.8 million, \$32.7 million and \$39.0 million during the years ended December 31, 2015, 2014 and 2013, respectively. The share-based compensation expense recognized during the year ended December 31, 2015 includes a charge related to the acceleration of Auxilium employee equity awards at closing of \$37.6 million and \$11.4 million of expense related to certain AMS equity awards modified in conjunction with the anticipated sale of the business. The AMS amounts are recorded in Discontinued Operations, net of tax. As of December 31, 2015, the total remaining unrecognized compensation cost related to all non-vested share-based compensation awards amounted to \$75.0 million.

Presented below is the allocation of share-based compensation as recorded in our Consolidated Statements of Operations for the years ended December 31 (in thousands).

	2015	2014	2013
Selling, general and administrative expenses	\$ 79,928	\$ 21,690	\$ 24,982
Research and development expenses	2,388	3,670	4,740
Cost of revenues	2,241	1,479	—
Discontinued operations (Note 3)	14,231	5,832	9,276
Total share-based compensation expense	<u>\$ 98,788</u>	<u>\$ 32,671</u>	<u>\$ 38,998</u>

##### *Stock Options*

During the years ended December 31, 2015, 2014 and 2013, the Company granted stock options to employees of the Company as part of their annual share compensation award and, in certain circumstances, upon their commencement of service with the Company. For all of the Company's share-based compensation plans, the fair value of each option grant was estimated at the date of grant using the Black-Scholes option-pricing model. Black-Scholes 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, 2015 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding as of January 1, 2013	8,824,705	\$ 27.93		
Granted	593,709	\$ 30.81		
Exercised	(3,836,560)	\$ 25.32		
Forfeited	(1,291,043)	\$ 32.73		
Expired	(45,022)	\$ 30.06		
Outstanding as of December 31, 2013	4,245,789	\$ 29.30		
Granted	736,948	\$ 75.13		
Exercised	(1,528,295)	\$ 27.09		
Forfeited	(371,410)	\$ 39.76		
Expired	(19,680)	\$ 24.56		
Outstanding as of December 31, 2014	3,063,352	\$ 40.15		
Granted	794,757	\$ 77.27		
Exercised	(880,885)	\$ 30.93		
Forfeited	(201,397)	\$ 72.24		
Expired	(7,260)	\$ 45.20		
Outstanding as of December 31, 2015	2,768,567	\$ 51.56	5.35	\$ 46,340,769
Vested and expected to vest as of December 31, 2015	2,616,444	\$ 50.26	5.20	\$ 46,165,754
Exercisable as of December 31, 2015	1,384,900	\$ 35.82	3.90	\$ 38,473,019

The range of exercise prices for the above stock options outstanding at December 31, 2015 is from \$14.65 to \$89.68.

The total intrinsic value of options exercised during the years ended December 31, 2015, 2014 and 2013 was \$27.2 million, \$41.4 million and \$97.1 million, respectively. The weighted average grant date fair value of the stock options granted in the years ended December 31, 2015, 2014 and 2013 was \$21.09, \$20.28 and \$9.37 per option, respectively, determined using the following assumptions:

	2015	2014	2013
Average expected term (years)	4.0	4.0	5.0
Risk-free interest rate	1.3%	1.3%	0.8%
Dividend yield	—	—	—
Expected volatility	32%	32%	33%

As of December 31, 2015, the weighted average remaining requisite service period of the non-vested stock options was 2.4 years. As of December 31, 2015, the total remaining unrecognized compensation cost related to non-vested stock options amounted to \$17.0 million.

#### *Restricted Stock Units and Performance Share Units*

During the years ended December 31, 2015, 2014 and 2013, the Company granted restricted stock units (RSUs) and performance share units (PSUs) to employees of the Company as part of their annual share compensation award and, in certain circumstances, periodic grants which includes equity awarded upon their commencement of service with the Company.

For grants prior to 2013, PSUs were tied to both the Company's overall revenue and its total shareholder return (TSR) relative to the TSR of a selected industry group. During 2013, PSU grants were only tied to TSR relative to the TSR of a selected industry group, with maximum payout levels based on absolute stock 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 goals. TSR relative to peers is considered a market condition while cumulative revenue performance is considered a performance condition under applicable authoritative guidance. The PSUs linked to revenue performance were marked to market on a recurring basis based on management's expectations of future revenues.

Starting in 2014 and continuing in 2015, PSU grants are tied to the attainment of absolute compounded annual growth rate (CAGR) for the Company's ordinary share price, which is considered a market condition under applicable authoritative guidance.

Each award covers 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 goals.

Also starting in 2014 and continuing in 2015, the Company approved a share matching program (Matched PSUs), which is applicable to all executive leadership team members, excluding Mr. De Silva. The program allows participants to make a direct investment in Endo ordinary shares during a pre-defined period, which the Company would immediately grant a Matched PSU for each qualifying ordinary share purchased up to the employee's base salary. The Matched PSUs would vest on the third anniversary of the date issued to the employee if the CAGR of the Company's ordinary shares is at least 10% over the three-year period. This program can be offered on a periodic basis, and the initial offering period was open from November 2014 through December 2015, not including blackout periods.

A summary of our restricted and performance stock units for the years ended December 31, 2015 is presented below:

	Number of Shares	Aggregate Intrinsic Value
Outstanding as of January 1, 2013	2,423,612	
Granted	1,543,221	
Forfeited	(899,954)	
Vested	(804,451)	
Outstanding as of December 31, 2013	2,262,428	
Granted	609,357	
Forfeited	(374,463)	
Vested	(842,569)	
Outstanding as of December 31, 2014	1,654,753	
Granted	927,214	
Forfeited	(251,351)	
Vested	(523,763)	
Outstanding as of December 31, 2015	1,806,853	\$ 111,925,522
Vested and expected to vest as of December 31, 2015	1,693,411	\$ 98,500,246

As of December 31, 2015, the weighted average remaining requisite service period of these units was 1.9 years. The weighted average grant date fair value of the units granted during the years ended December 31, 2015, 2014 and 2013 was \$72.34, \$73.70 and \$31.55 per unit, respectively. As of December 31, 2015, the total remaining unrecognized compensation cost related to non-vested RSUs and PSUs amounted to \$35.0 million and \$23.0 million, respectively.

#### *Employee Stock Purchase Plan*

The Endo International plc Employee Stock Purchase Plan (ESPP) is a Company-sponsored plan that enables employees to voluntarily elect, in advance of any of the four quarterly offering periods ending March 31, June 30, September 30 and December 31 of each year, to contribute up to 10% of their eligible compensation, subject to certain limitations, to purchase ordinary shares at 90% of the lower of the closing price of Endo ordinary shares on the first or last trading day of each offering period. The maximum number of shares that a participant may purchase in any calendar year is equal to \$25,000 divided by the closing selling price per ordinary share on the first day of the offering period, subject to certain adjustments. Compensation expense is calculated in accordance with the applicable accounting guidance and is based on the share price at the beginning or end of each offering period and the purchase discount. Obligations under the ESPP may be satisfied by the reissuance of treasury stock, by the Company's purchase of shares on the open market or by the authorization of new shares. The maximum number of shares available under the ESPP, pursuant to the terms of the ESPP plan document, is 1% of the common shares outstanding on April 15, 2011 or approximately 1.2 million shares. The ESPP shall continue in effect until the earlier of (i) the date when no shares are available for issuance under the ESPP, at which time the ESPP shall be suspended pursuant to the terms of the ESPP plan document, or (ii) December 31, 2022, unless earlier terminated. Compensation expense during the years ended December 31, 2015 and 2014 related to the Employee Stock Purchase Plan (ESPP) totaled \$0.8 million and \$0.6 million, respectively. The Company issued 67,867 ordinary shares with a cost totaling \$4.3 million during the year ended December 31, 2015 pursuant to the ESPP and 75,450 ordinary shares with a cost totaling \$4.6 million during the year ended December 31, 2014.

**NOTE 18. OTHER EXPENSE (INCOME), NET**

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

	2015	2014	2013
Watson litigation settlement income, net	\$ —	\$ —	\$ (50,400)
Net gain on sale of certain early-stage drug discovery and development assets	—	(5,200)	—
Foreign currency gain, net	(23,058)	(10,054)	(21)
Equity loss (earnings) from unconsolidated subsidiaries, net	3,217	(8,325)	(1,482)
Other than temporary impairment of equity investment	18,869	—	—
Legal settlement	(12,500)	—	—
Costs associated with unused financing commitments	78,352	—	—
Other miscellaneous	(1,189)	(8,745)	(1,156)
Other expense (income), net	<u>\$ 63,691</u>	<u>\$ (32,324)</u>	<u>\$ (53,059)</u>

Fluctuations in foreign currency rates are primarily driven by our increased global presence subsequent to the acquisitions of Paladin and Somar as well as foreign currency rate movements. During 2015, the Company recognized an other than temporary impairment of our Litha joint venture investment totaling \$18.9 million, reflecting the excess carrying value of this investment over its estimated fair value. In addition, the Company incurred \$78.4 million during 2015 related to unused commitment fees primarily associated with financing for the Par acquisition.

**NOTE 19. INCOME TAXES**

Our operations are conducted through our various subsidiaries in a number of countries throughout the world. We have provided for income taxes based upon the tax laws and rates in the countries in which our operations are conducted and income and loss from operations is subject to taxation.

The components of our (loss) income from continuing operations before income tax by geography for the years ended December 31 are as follows (in thousands):

	2015	2014	2013
United States	\$ (626,740)	\$ (33,459)	\$ 385,366
International	(811,124)	133,334	—
Total (loss) income from continuing operations before income tax	<u>\$ (1,437,864)</u>	<u>\$ 99,875</u>	<u>\$ 385,366</u>

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

	2015	2014	2013
<b>Current:</b>			
U.S. Federal	\$ (308,909)	\$ 30,385	\$ 93,212
U.S. State	(5,600)	16,270	10,980
International	16,722	(2,550)	—
Total current income tax	<u>\$ (297,787)</u>	<u>\$ 44,105</u>	<u>\$ 104,192</u>
<b>Deferred:</b>			
U.S. Federal	(779,757)	(31,922)	36,369
U.S. State	(70,221)	(7,740)	(1,336)
International	(9,376)	(620)	—
Total deferred income tax	<u>\$ (859,354)</u>	<u>\$ (40,282)</u>	<u>\$ 35,033</u>
Excess tax benefits of stock compensation exercised	19,676	33,501	4,315
Valuation allowance	—	943	202
Total income tax	<u>\$ (1,137,465)</u>	<u>\$ 38,267</u>	<u>\$ 143,742</u>

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 (in thousands):

	2015	2014	2013
Notional U.S. federal income tax provision at the statutory rate	\$ (503,271)	\$ 34,956	\$ 134,878
State income tax, net of federal benefit	(45,823)	10,095	5,554
Research and development credit	(5,549)	(2,535)	(6,002)
Uncertain tax positions	30,974	2,494	2,779
Residual tax on non-U.S. net earnings (1)	(359,831)	(52,246)	—
Change in valuation allowance	278,339	952	—
Effects of outside basis differences	(111,920)	—	—
Worthless stock deduction	(674,210)	—	—
Impairment of goodwill	248,403	—	—
Effect of permanent items:			
Branded prescription drug fee	10,753	16,336	12,060
Domestic production activities deduction	—	5,468	(6,835)
Transaction-related expenses	9,872	5,889	2,643
Excise tax	—	15,398	—
Executive compensation limitation	467	3,590	417
Extinguishment of debt	—	(5,802)	—
Share based compensation	950	2,227	—
Audit settlements	—	(1,875)	—
Other	(16,619)	3,320	(1,752)
Income tax	<u>\$ (1,137,465)</u>	<u>\$ 38,267</u>	<u>\$ 143,742</u>

(1) Excludes nondeductible charges and other items which are broken out separately in the table.

During the year ended December 31, 2015, the Company recorded a \$674.2 million net tax benefit predominantly related to a worthless stock deduction directly attributable to mesh product liability losses. The Company will claim the worthless stock deduction on its 2015 U.S. Federal and State income tax returns.

Deferred income taxes result from temporary differences between the amount of assets and liabilities recognized for financial reporting and tax purposes. The components of the net deferred income tax liability were as follows, excluding assets and liabilities held for sale, shown on the balance sheets for the years ended December 31 are as follows (in thousands):

	2015	2014
<b>Deferred tax assets:</b>		
Accrued expenses and customer allowances	\$ 285,342	\$ 644,858
Compensation related to stock options	22,532	15,415
Net operating loss carryforward	635,030	108,823
Loss on capital assets	7,210	10,642
Research and development credit carryforward	56,489	13,085
Uncertain tax positions	8,211	6,574
Prepaid royalties	—	5,190
Tax credit carryforwards	96,952	12,249
Deferred interest expense	290,600	—
Other	7,564	23,173
<b>Total gross deferred income tax assets</b>	<b>\$ 1,409,930</b>	<b>\$ 840,009</b>
<b>Deferred tax liabilities:</b>		
Fixed assets and intangible assets	\$ (1,759,009)	\$ (894,714)
Deferred interest expense	—	(6,012)
Outside basis difference	(59,434)	—
Prepaid royalties	(413)	—
Other	(25,978)	(9,238)
<b>Total gross deferred income tax liabilities</b>	<b>\$ (1,844,834)</b>	<b>\$ (909,964)</b>
Valuation allowance	(426,991)	(40,646)
<b>Net deferred income tax liability</b>	<b>\$ (861,895)</b>	<b>\$ (110,601)</b>

At December 31, 2015, the Company had the following significant deferred tax assets for certain tax credits net of unrecognized tax benefits (in millions):

Jurisdiction	2015	Begin to Expire
<b>Canada</b>		
Investment tax credits	\$ 3.2	2017
<b>United States</b>		
Alternative minimum tax	\$ 66.6	Indefinite
Research and development credits	\$ 56.3	2026
Foreign tax credits	\$ 25.3	2025

At December 31, 2015, the Company had the following significant deferred tax assets for net operating and capital loss carryforwards for tax purposes net of unrecognized tax benefits (in millions):

Jurisdiction	2015	Begin to Expire
<b>Ireland</b>	\$ 7.3	Indefinite
<b>Luxembourg</b>	\$ 325.0	Indefinite
<b>United States</b>		
Federal ordinary losses	\$ 222.4	2020
State-capital losses	\$ 5.1	2026
State-ordinary losses	\$ 71.7	2016

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, 2015 and 2014, the valuation allowance was \$427.0 million and \$40.6 million, respectively. During the years ended December 31, 2014 and 2013, the Company increased its valuation allowance in the amount of \$386.3 million and \$22.8 million, respectively. The net increase in the Company's valuation allowance as of December 31, 2015 was split into three main components: \$14.7 million related to current year acquisitions, \$25.9 million relating to state tax benefits, and \$349.4 million relating to losses within jurisdictions that the Company was unable to support the recognition of a deferred tax asset. The significant increase in the Company's valuation allowance in 2014 was primarily due to the acquisition of Paladin.

At December 31, 2015, the Company had the following significant valuation allowances for tax purposes (in millions):

Jurisdiction	2015
Canada	\$ 1.4
Ireland	\$ 26.7
Luxembourg	\$ 325.0
Mexico	\$ 3.7
Netherlands	\$ 1.2
South Africa	\$ 1.2
United States	\$ 67.3

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 permanently reinvested, the investments are essentially permanent in duration, or we have concluded that no additional tax liability will arise as a result of the distribution of such earnings. As of December 31, 2015, certain subsidiaries had approximately \$915.4 million of cumulative undistributed earnings that have been retained indefinitely and reinvested in our global operations, including working capital; property, plant, and equipment; intangible assets; and research and development activities. A liability could arise if our intention to permanently 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 permanently reinvested earnings or the basis differences related to investments in subsidiaries. Our current plans do not demonstrate a need to repatriate cash and cash equivalents that are designated as permanently reinvested in order to fund our operations, including investing and financing activities.

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. These accruals for tax-related uncertainties are based on the Company's best estimate of potential tax exposures. When particular matters arise, a number of years may elapse before such matters are audited and finally resolved. Favorable resolution of such matters could be recognized as a reduction to the Company's effective tax rate in the year of resolution. Unfavorable resolution of any particular issue could increase the effective tax rate and may require the use of cash in the year of resolution.

As of December 31, 2015, the Company had total unrecognized income tax benefits of \$328.9 million. If recognized in future years, \$293.3 million of these currently unrecognized income tax benefits would impact the income tax provision and effective tax rate. As of December 31, 2014, we had total unrecognized income tax benefits of \$115.8 million. If recognized in future years, \$109.2 million of these unrecognized income tax benefits would impact the income tax provision and effective tax rate. The following table summarizes the activity related to unrecognized income tax benefits (in thousands):

	Unrecognized Tax Benefit Federal, State, and Foreign Tax
UTB Balance at January 1, 2013	\$ 58,917
Gross additions for current year positions	2,076
Gross additions for prior period positions	4,618
Gross reductions for prior period positions	(2,390)
Decrease due to lapse of statute of limitations	(4,592)
UTB Balance at December 31, 2013	\$ 58,629
Gross additions for current year positions	6,008
Gross additions for prior period positions	873
Gross reductions for prior period positions	(6,647)
Decrease due to lapse of statute of limitations	(5,067)
Decrease due to settlements	(597)
Additions related to acquisitions	54,750
Currency translation adjustment	(2,619)
UTB Balance at December 31, 2014	\$ 105,330
Gross additions for current year positions	65,439
Gross reductions for prior period positions	(234)
Gross additions for prior period positions	3,460
Decrease due to lapse of statute of limitations	(75)
Additions related to acquisitions	150,152
Currency translation adjustment	(7,825)
UTB Balance at December 31, 2015	\$ 316,247
Accrued interest and penalties	12,664
Total UTB balance including accrued interest and penalties	\$ 328,911
Current portion	\$ —
Non-current portion	\$ 328,911

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, 2015, we had recorded \$12.7 million of accrued interest and penalties related to uncertain tax positions on the Consolidated Balance Sheet, all of which was recorded in income taxes. As of December 31, 2014, the balance of accrued interest and penalties was \$10.5 million, all of which was recorded in income taxes. During the years ended December 31, 2015, 2014, and 2013, we recognized expense of \$1.6 million, expense of \$4.6 million, and benefit of \$0.9 million, respectively, related to interest and penalties.

Our U.S. subsidiaries file income tax returns on a unitary, consolidated, or stand-alone basis in multiple state and local jurisdictions, which generally have statutes of limitations ranging from three to four years. Various state and local income tax returns are currently in the process of examination.

Our non-U.S. subsidiaries file income tax returns in the countries in which they have operations. Generally, these countries have statutes of limitations ranging from three to 10 years. Various non-U.S. subsidiary income tax returns are currently in the process of examination by taxing authorities.

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, 2015, under applicable statutes, the following tax years remained subject to examination in the major tax jurisdictions indicated:



Jurisdiction	Open Years
Canada	2010 through 2015
India	2011 through 2015
Ireland	2012 through 2015
Luxembourg	2013 through 2015
Mexico	2010 through 2015
South Africa	2010 through 2015
United States - federal, state and local	2005 through 2015

**NOTE 20. NET (LOSS) INCOME PER SHARE**

The following is a reconciliation of the numerator and denominator of basic and diluted net loss per share for the years ended December 31 (in thousands, except share data):

	2015	2014	2013
Numerator:			
(Loss) income from continuing operations	\$ (300,399)	\$ 61,608	\$ 241,624
Less: Net loss from continuing operations attributable to noncontrolling interests	(283)	(399)	—
(Loss) income from continuing operations attributable to Endo International plc ordinary shareholders	(300,116)	62,007	241,624
Loss from discontinued operations attributable to Endo International plc ordinary shareholders, net of tax	(1,194,926)	(783,326)	(926,963)
Net loss attributable to Endo International plc ordinary shareholders	<u>\$ (1,495,042)</u>	<u>\$ (721,319)</u>	<u>\$ (685,339)</u>
Denominator:			
For basic per share data—weighted average shares	197,100	146,896	113,295
Dilutive effect of ordinary share equivalents	—	2,600	2,453
Dilutive effect of various convertible notes and warrants	—	7,234	4,081
For diluted per share data—weighted average shares	<u>197,100</u>	<u>156,730</u>	<u>119,829</u>

Basic net loss per share data is computed based on the weighted average number of ordinary shares outstanding during the period. Diluted loss per share data is computed based on the weighted average number of ordinary shares outstanding and, if there is net income from continuing operations attributable to Endo ordinary shareholders during the period, the dilutive impact of ordinary share equivalents outstanding during the period. Ordinary share equivalents are measured under the treasury stock method.

All stock options and stock awards were excluded from the diluted share calculation for the year ended December 31, 2015 because their effect would have been anti-dilutive, as the Company was in a loss position.

The 1.75% Convertible Senior Subordinated Notes due April 15, 2015 were only included in the dilutive net loss per share calculations using the treasury stock method during periods in which the average market price of our ordinary shares was above the applicable conversion price of the Convertible Notes, or \$29.20 per share, and the impact would not have been anti-dilutive. In these periods, under the treasury stock method, we calculated the number of shares issuable under the terms of these notes based on the average market price of the shares during the period, and included that number in the total diluted shares outstanding for the period.

We entered into convertible note hedge and warrant agreements, which have subsequently been settled, that, in combination, had the economic effect of reducing the dilutive impact of the Convertible Notes. However, we separately analyzed the impact of the convertible note hedge and the warrant agreements on diluted weighted average shares outstanding. As a result, the purchases of the convertible note hedges were excluded because their impact would have been anti-dilutive. The treasury stock method was applied when the warrants were in-the-money with the proceeds from the exercise of the warrant used to repurchase shares based on the average share price in the calculation of diluted weighted average shares. Until the warrants were in-the-money, they had no impact to the diluted weighted average share calculation.

The dilutive impact of the Auxilium Notes was calculated using the if-converted method, assuming the notes were converted at the time of issuance.

## **NOTE 21. SAVINGS AND INVESTMENT PLAN AND DEFERRED COMPENSATION PLANS**

### ***Savings and Investment Plan***

Endo established a defined contribution Savings and Investment Plan (the Endo 401(k) Plan) covering all employees. Employee contributions can be made on a pre-tax basis under section 401(k) of the Internal Revenue Code (the Code). Effective January 1, 2014, the Endo 401(k) Plan was amended to modify the employer matching contributions such that the Company will match 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% of the participants' contributions subject to limitations under section 401(k) of the Code. This compares to 100% of the first 6% of eligible cash compensation that a participant contributes to the Endo 401(k) Plan, which was in effect until December 31, 2013. Participants are immediately vested with respect to their own contributions and the Company's matching contributions.

Costs incurred for contributions made by us to the 401(k) plans amounted to \$8.6 million, \$7.5 million and \$11.4 million for the years ended December 31, 2015, 2014 and 2013, respectively.

### ***Executive Deferred Compensation Plan***

In December 2007, Endo's Board of Directors (the Board) adopted an executive deferred compensation plan (the Executive Deferred Compensation Plan) and a 401(k) restoration plan (the 401(k) Restoration Plan) both effective as of January 1, 2008. Both plans cover employees earning over the Internal Revenue Code plan compensation limit, which would include the chief executive officer, chief financial officer and other named executive officers. The Executive Deferred Compensation Plan allows for deferral of up to 50% of the bonus, with payout to occur as elected, either in a lump sum or in installments, and up to 100% of restricted stock units granted, with payout to occur either in a lump sum or in installments. Under the 401(k) Restoration Plan the participant may defer the amount of base salary and bonus that would have been deferrable under the Company's Savings and Investment Plan (up to 50% of salary and bonus) if not for the qualified plan statutory limits on deferrals and contributions. Payment occurs as elected, either in lump sum or in installments.

### ***Directors Stock Election Plan***

In December 2007, Endo established a directors stock election plan (the Directors Stock Election Plan). The purpose of this plan is to provide non-employee directors the opportunity to have some, or all of their retainer fees delivered in the form of Endo ordinary shares. The amount of shares will be determined by dividing the portion of cash fees elected to be received as shares by the closing price of the shares on the day the payment would have otherwise been paid in cash.

## **NOTE 22. SUBSEQUENT EVENTS**

### ***Astora***

On February 24, 2016, the Company's Board of Directors decided to wind down Astora business operations in order to begin bringing finality to the Company's mesh-related product liability. The Company is now actively conducting a wind down process and working to efficiently transition physicians to alternative products. The Company will cease business operations for Astora by March 31, 2016. As a result, the Company anticipates recording a restructuring charge during the first quarter of 2016, primarily for employee terminations and other closing activities. This amount will be included in Discontinued operations, net of tax in the Consolidated Statements of Operations.

**NOTE 23. QUARTERLY FINANCIAL DATA (UNAUDITED)**

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share data)			
<b>2015 (1)</b>				
Total revenues	\$ 714,128	\$ 735,166	\$ 745,727	\$ 1,073,697
Gross profit	\$ 329,862	\$ 296,308	\$ 303,268	\$ 263,629
Income (loss) from continuing operations	\$ 150,492	\$ (90,894)	\$ (803,706)	\$ 443,709
Discontinued operations, net of tax	\$ (226,210)	\$ (159,632)	\$ (246,782)	\$ (562,302)
Net loss attributable to Endo International plc	\$ (75,718)	\$ (250,419)	\$ (1,050,442)	\$ (118,463)
Net loss per share attributable to Endo International plc ordinary shareholders—Basic:				
Continuing operations	\$ 0.89	\$ (0.49)	\$ (3.84)	\$ 1.98
Discontinued operations	(1.34)	(0.86)	(1.18)	(2.51)
Basic	<u>\$ (0.45)</u>	<u>\$ (1.35)</u>	<u>\$ (5.02)</u>	<u>\$ (0.53)</u>
Net loss per share attributable to Endo International plc ordinary shareholders—Diluted:				
Continuing operations	\$ 0.85	\$ (0.49)	\$ (3.84)	\$ 1.97
Discontinued operations	(1.28)	(0.86)	(1.18)	(2.50)
Diluted	<u>\$ (0.43)</u>	<u>\$ (1.35)</u>	<u>\$ (5.02)</u>	<u>\$ (0.53)</u>
Weighted average shares—Basic	169,653	185,328	209,274	224,147
Weighted average shares—Diluted	176,825	185,328	209,274	225,321
<b>2014 (2)(3)</b>				
Total revenues	\$ 470,842	\$ 592,848	\$ 654,116	\$ 662,877
Gross profit	\$ 258,163	\$ 289,403	\$ 312,923	\$ 288,697
(Loss) income from continuing operations	\$ (47,401)	\$ 40,575	\$ 48,953	\$ 19,481
Discontinued operations, net of tax	\$ (385,877)	\$ (20,189)	\$ (301,002)	\$ (72,724)
Net (loss) income attributable to Endo International plc	\$ (436,912)	\$ 21,160	\$ (252,084)	\$ (53,483)
Net (loss) income per share attributable to Endo International plc ordinary shareholders—Basic:				
Continuing operations	\$ (0.37)	\$ 0.27	\$ 0.32	\$ 0.13
Discontinued operations	(3.04)	(0.13)	(1.96)	(0.48)
Basic	<u>\$ (3.41)</u>	<u>\$ 0.14</u>	<u>\$ (1.64)</u>	<u>\$ (0.35)</u>
Net (loss) income per share attributable to Endo International plc ordinary shareholders—Diluted:				
Continuing operations	\$ (0.37)	\$ 0.25	\$ 0.31	\$ 0.12
Discontinued operations	(3.04)	(0.12)	(1.90)	(0.46)
Diluted	<u>\$ (3.41)</u>	<u>\$ 0.13</u>	<u>\$ (1.59)</u>	<u>\$ (0.34)</u>
Weighted average shares—Basic	128,135	152,368	153,309	153,772
Weighted average shares—Diluted	128,135	163,369	158,975	159,213

(1) Income (loss) from continuing operations for the year ended December 31, 2015 was impacted by (1) acquisition-related and integration items of \$34.6 million, \$44.2 million, \$(27.7) million and \$54.1 million during the first, second, third and fourth quarters, respectively; these costs are net of a benefit due to changes in the fair value of contingent consideration of \$0.8 million, \$2.5 million, and \$80.3 million during the first, second and third quarters, respectively and an charge of \$17.9 million during the fourth quarter (2) asset impairment charges of \$7.0 million, \$70.2 million, \$923.6 million and \$139.9 million during the first, second, third and fourth quarters (3) inventory step-up and certain manufacturing costs that will be eliminated pursuant to integration plans of \$39.9 million, \$48.9 million, \$42.9 million and \$117.7 million during the first, second, third and fourth quarters, respectively (4) certain integration costs and separation benefits incurred in connection with continued efforts to enhance the Company's operations and other miscellaneous costs of \$41.8 million, \$5.8 million, \$22.7 million and \$55.2 million during the first, second, third and fourth quarters, respectively (5) other charges related to litigation-related and

other contingent matters totaling \$13.0 million, \$6.9 million and \$17.2 million during the first, second and fourth quarters, respectively (6) loss on extinguishment of debt of \$1.0 million, \$40.9 million and \$25.6 million during the first, third and fourth quarters, respectively (7) costs associated with unused financing commitments of \$11.8 million, \$2.3 million and \$64.3 million during the first, second and third quarters, respectively, (8) a charge of \$18.9 million for an other than temporary impairment of equity investment of during the second quarter and (9) a charge of \$37.6 million for the acceleration of Auxilium employee equity awards at closing during the first quarter.

- (2) (Loss) income from continuing operations for the year ended December 31, 2014 was impacted by (1) acquisition-related and integration items of \$45.3 million, \$19.6 million, \$2.7 million and \$9.8 million during the first, second, third and fourth quarters, respectively (2) asset impairment charges of \$22.5 million during the fourth quarter (3) inventory step-up and certain manufacturing costs that will be eliminated pursuant to integration plans of \$3.6 million, \$19.1 million, \$17.4 million and \$25.5 million during the first, second, third and fourth quarters, respectively (4) certain integration costs and separation benefits incurred in connection with continued efforts to enhance the Company's operations and other miscellaneous costs of \$(1.9) million, \$11.4 million, \$7.5 million and \$8.7 million during the first, second, third and fourth quarters, respectively (5) other charges related to litigation-related and other contingent matters totaling \$4.0 million, \$3.1 million and \$35.0 million during the second, third and fourth quarters, respectively (6) a charge for an additional year of the branded prescription drug fee in accordance with U.S. Internal Revenue Service (IRS) regulations issued in the third quarter of 2014 of \$25.0 million and (7) amounts related to expense for the reimbursement of directors' and certain employees' excise tax liabilities pursuant to Section 4985 of the Internal Revenue Code of \$60.0 million, \$(4.7) million and \$(1.0) million during the first, second and third quarters, respectively.
- (3) In the fourth quarter of 2014, the Company recorded certain measurement period adjustments reflecting changes in the preliminary estimated fair values of certain assets and liabilities acquired in connection with the Company's various 2014 business combinations, including adjustments to intangible assets and inventory, among others. The Company considered the impact of these adjustments on the comparative financial information presented, which related primarily to intangible asset amortization expense and inventory step-up costs, and determined that the retrospective impact was not material to the Company's Consolidated Financial Statements for any of the periods presented. Accordingly, in the fourth quarter of 2014, the Company recorded combined pre-tax charges for intangible asset amortization and inventory step-up of approximately \$9.2 million which included the cumulative effect of these measurement period adjustments, a portion of which related to each of the first, second and third quarters of 2014. This amount was recorded to Cost of revenues.

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.

The majority of the assets and liabilities of the AMS business are classified as held for sale in the Consolidated Balance Sheets for all periods presented. Depreciation and amortization expense are not recorded on assets held for sale. The operating results of this business is reported as Discontinued operations, net of tax in the Consolidated Statements of Operations for all periods presented. For additional information, see Note 3. Divestitures.

**Exhibit Index**

<u>Exhibit No.</u>	<u>Title</u>
2.1	Amended and Restated Agreement and Plan of Merger, dated as of November 17, 2014, by and among Auxilium Pharmaceuticals, Inc., Endo International plc, Endo U.S. Inc., and Avalon Merger Sub Inc. (incorporated by reference to Annex A of the prospectus on Form 424B3 filed with the Commission on December 24, 2014)
2.2	Agreement and Plan of Merger by and among Generics International (US), Inc., DAVA Pharmaceuticals, Inc. and certain other parties listed therein, dated June 24, 2014 (incorporated by reference to Exhibit 10.1 of the Endo International plc Current Report on Form 8-K, filed with the Commission on June 26, 2014)
2.3	Purchase Agreement, dated March 2, 2015, by and among American Medical Systems Holdings, Inc., Endo Health Solutions Inc., and Boston Scientific Corporation (incorporated by reference to Exhibit 10.239 of the Endo International plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the Commission May 11, 2015)
2.4	Agreement and Plan of Merger, dated as of May 18, 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) (incorporated by reference to Exhibit 2.1 of the Endo International plc Current Report on Form 8-K, filed with the Commission on May 21, 2015)
3.1	Certificate of Incorporation on re-registration as a public limited company of Endo International plc (incorporated by reference to Exhibit 3.1 of the Endo International plc Current Report on Form 8-K12B, filed with the Commission on February 28, 2014)
3.2	Memorandum and Articles of Association of Endo International plc (incorporated by reference to Exhibit 3.2 of the Endo International plc Current Report on Form 8-K12B, filed with the Commission on February 28, 2014)
4.1	Specimen Share Certificate of Endo International plc (incorporated by reference to Exhibit 4.3 of the Endo International plc Form S-8, filed with the Commission on February 28, 2014)
4.2	Indenture among the Company, 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) (incorporated by reference to Exhibit 4.3 of the Endo Health Solutions Inc. Current Report on Form 8-K, filed with the Commission on 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, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated September 26, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011 (incorporated by reference to Exhibit 10.157 of the Endo Health Solutions Inc. Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Commission on 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 (incorporated by reference to Exhibit 10.3 of the Endo International plc Current Report on Form 8-K, filed with the Commission on April 17, 2014)
4.5	Indenture, dated December 19, 2013, between 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) (incorporated by reference to Exhibit 4.1 of the Endo Health Solutions Inc. Current Report on Form 8-K, filed with the Commission on 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 (incorporated by reference to Exhibit 4.1 of Endo International plc's Current Report on Form 8-K, filed with the Commission on 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 (filed herewith)

- 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) (incorporated by reference to Exhibit 10.5 of the Endo International plc Current Report on Form 8-K, filed with the Commission on 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 (filed herewith)
- 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) (incorporated by reference to Exhibit 10.9 of the Endo International plc Current Report on Form 8-K, filed with the Commission on May 7, 2014)
- 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) (incorporated by reference to Exhibit 10.1 of the Endo International plc Current Report on Form 8-K, filed with the Commission on 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 (filed herewith)
- 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) (incorporated by reference to Exhibit 10.3 of the Endo International plc Current Report on Form 8-K, filed with the Commission on July 1, 2014)
- 4.14 Indenture, dated January 27, 2015, among 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) (incorporated by reference to Exhibit 10.1 of the Endo International plc Current Report on Form 8-K, filed with the Commission on January 27, 2015)
- 4.15 Supplemental Indenture, dated March 27, 2015, among 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 (filed herewith)
- 4.16 Registration Rights Agreement, dated January 27, 2015, by and among 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) (incorporated by reference to Exhibit 10.3 of the Endo International plc Current Report on Form 8-K, filed with the Commission on January 27, 2015)
- 4.17 Indenture, dated July 9, 2015, among 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) (incorporated by reference to Exhibit 10.1 of the Endo International plc Current Report on Form 8-K, filed with the Commission on July 9, 2015)
- 4.18 Shareholders Agreement, dated as of May 18, 2015, by and among Endo International plc and the signatories thereto (incorporated by reference to Exhibit 10.2 of the Endo International plc Current Report on Form 8-K, filed with the Commission on May 21, 2015)
- 4.19 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 (incorporated by reference to Exhibit 10.2 to the Auxilium Current Report on Form 8-K, filed with the Commission on April 29, 2013)
- 10.1 Amended and Restated Executive Deferred Compensation Plan (incorporated by reference to Exhibit 10.11 of the Endo Health Solutions Inc. Annual Report on Form 10-K for the year ended December 31, 2012, filed with the Commission on March 1, 2013)
- 10.2 Amended and Restated 401(k) Restoration Plan (incorporated by reference to Exhibit 10.12 of the Endo Health Solutions Inc. Annual Report on Form 10-K for the year ended December 31, 2012, filed with the Commission on March 1, 2013)
- 10.3 Directors Deferred Compensation Plan (incorporated by reference to Exhibit 10.13 of the Endo Health Solutions Inc. Annual Report on Form 10-K for the year ended December 31, 2012, filed with the Commission on March 1, 2013)

- 10.4\* Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd. (incorporated by reference to Exhibit 10.14 of the Endo Health Solutions Inc. Registration Statement filed with the Commission on June 9, 2000)
- 10.4.1\* First Amendment, dated April 24, 2007, to the Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc. (incorporated by reference to Exhibit 10.14.1 of the Endo Health Solutions Inc. Current Report on Form 8-K, filed with the Commission on April 30, 2007)
- 10.4.2\* Second Amendment, effective December 16, 2009, to the Supply and Manufacturing Agreement, dated as of November 23, 1998 and as amended as of April 24, 2007, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc. (incorporated by reference to Exhibit 10.14.2 of the Endo Health Solutions Inc. Current Report on Form 8-K, filed with the Commission on January 11, 2010)
- 10.4.3\* Third Amendment, effective November 1, 2010, to the Supply and Manufacturing Agreement, dated as of November 23, 1998 and as amended as of December 16, 2009, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc. (incorporated by reference to Exhibit 10.14.3 of the Endo Health Solutions Inc. Form 10-Q for the Quarter ended September 30, 2010 filed with the Commission on November 2, 2010)
- 10.4.4\* Fourth Amendment, effective February 25, 2015, to the Supply and Manufacturing Agreement, dated as of November 23, 1998 and as amended as of November 1, 2010, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc. (incorporated by reference to Exhibit 10.14.4 of the Endo International plc Annual Report on Form 10-K for the year ended December 31, 2014, filed with the Commission on March 2, 2015)
- 10.5\* Supply Agreement, dated as of April 27, 2012, between Endo Pharmaceuticals and Noramco, Inc. (incorporated by reference to Exhibit 10.17 of the Endo Health Solutions Inc. Quarterly Report on Form 10-Q for the Quarter Ended March 31, 2012, filed with the Commission on May 1, 2012)
- 10.6 Executive Employment Agreement between Endo and Ivan P. Gergel, dated as of October 27, 2011 (incorporated by reference to Exhibit 10.122 of the Endo Health Solutions Inc. Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2011, filed with the Commission on October 31, 2011)
- 10.7 Executive Employment Agreement between Endo and Rajiv De Silva, dated as of February 24, 2013 and effective as of March 18, 2013 (incorporated by reference to Exhibit 10.1 of the Endo Health Solutions Inc. Current Report on Form 8-K, filed with the Commission on February 25, 2013)
- 10.8 Endo International plc Amended and Restated Employee Stock Purchase Plan (incorporated by reference to Exhibit 4.9 of the Endo International plc Form S-8, filed with the Commission on February 28, 2014)
- 10.9\* Development, License and Supply Agreement, dated as of December 18, 2007, between Endo Pharmaceuticals and Grünenthal GmbH (incorporated by reference to Exhibit 10.139 of the Endo Health Solutions Inc. Quarterly Report on Form 10-Q for the Quarter Ended March 31, 2012 filed with the Commission on May 1, 2012)
- 10.9.1\* First Amendment to Development, License and Supply Agreement, dated as of December 19, 2012, between Endo Pharmaceuticals and Grünenthal GmbH (incorporated by reference to Exhibit 10.139.1 of the Endo Health Solutions Inc. Form 10-K for the year ended December 31, 2012 filed with the Commission on March 1, 2013)
- 10.9.2\* Second Amendment to Development, License and Supply Agreement, dated as of February 18, 2014, between Endo Pharmaceuticals and Grünenthal GmbH (incorporated by reference to Exhibit 10.139.2 of the Endo Health Solutions Inc. Form 10-K for the year ended December 31, 2013 filed with the Commission on March 3, 2014)
- 10.10 Executive Employment Agreement between Endo Health Solutions Inc. and Suketu P. Upadhyay, dated as of September 4, 2013 and effective as of September 23, 2013 (incorporated by reference to Exhibit 10.1 of the Endo Health Solutions Inc. Current Report on Form 8-K, filed with the Commission on September 10, 2013)
- 10.11 Executive Employment Agreement between Endo Health Solutions Inc. and Donald W. DeGolyer, dated as of May 24, 2013 and effective as of August 1, 2013 (incorporated by reference to Exhibit 10.147 of the Endo Health Solutions Inc. Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Commission on March 3, 2014)
- 10.12 Credit Agreement, dated as of February 28, 2014, among Endo Limited, Endo Management Limited, Endo Luxembourg Holding Company S.a.r.l., Endo Luxembourg Finance Company I S.a.r.l., Endo LLC (formerly known as NIMA Acquisition, LLC), the lenders from time to time party thereto, and Deutsche Bank AG New York Branch, as administrative agent, collateral agent, issuing bank and swingline lender (incorporated by reference to Exhibit 4.3 of the Endo International plc Current Report on Form 8-K, filed with the Commission on February 28, 2014)
- 10.13 Amendment No. 1 to Credit Agreement, dated as of June 12, 2015, by and among Endo Luxembourg Finance Company I S.à.r.l and Endo LLC, as borrowers, the subsidiary guarantors party thereto, the lenders and other financial institutions party thereto and Deutsche Bank AG New York Branch, as administrative agent (incorporated by reference to Exhibit 10.1 of the Endo International plc Current Report on Form 8-K, filed with the Commission on June 15, 2015)

- 10.14 Incremental Amendment, dated as of September 25, 2015, by and among Endo Designated Activity Company, Endo Management Limited, Endo Luxembourg Holding Company S.à r.l., Endo Luxembourg Finance Company I S.à.r.l., as borrower, Endo LLC, as borrower, the subsidiary guarantors party thereto, the lenders party thereto and Deutsche Bank AG New York Branch, as administrative agent (incorporated by reference to Exhibit 10.1 of the Endo International plc Current Report on Form 8-K, with the Commission on September 28, 2015)
- 10.15 Executive Employment Agreement between Endo Health Solutions Inc., a wholly-owned subsidiary of Endo International plc, and Susan Hall, dated as of March 6, 2014 and effective March 10, 2014 (incorporated by reference to Exhibit 10.1 of the Endo International plc Current Report on Form 8-K, filed with the Commission on March 13, 2014)
- 10.15.1 First Amendment to Executive Employment Agreement between Endo Health Solutions Inc., a wholly-owned subsidiary of Endo International plc, and Susan Hall, dated as of April 21, 2014 and effective April 22, 2014 (incorporated by reference to Exhibit 10.162.1 of the Endo International plc Quarterly Report on Form 10-Q for the Quarter ended March 31, 2014, filed with the Commission on May 9, 2014)
- 10.16 Retention Agreement, dated as of January 8, 2015, between Endo Health Solutions Inc. and Caroline B. Manogue (incorporated by reference to Exhibit 10.207 of the Endo International plc Annual Report on Form 10-K for the year ended December 31, 2014, filed with the Commission on March 2, 2015)
- 10.17 Executive Employment Agreement by and between American Medical Systems, Inc. and Camille Farhat, effective as of July 17, 2012 (incorporated by reference to Exhibit 10.208 of the Endo International plc Annual Report on Form 10-K for the year ended December 31, 2014, filed with the Commission on March 2, 2015)
- 10.18\* Second Amended and Restated Development and License Agreement, dated August 31, 2011, by and between BioSpecifics Technologies Corp. and Auxilium (incorporated by reference to Exhibit 10.1 to the Auxilium Current Report on Form 8-K, filed with the Commission on September 1, 2011)
- 10.18.1\* 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 (filed herewith)
- 10.19\* Supply Agreement, dated June 26, 2008, between Auxilium and Hollister-Stier Laboratories LLC (incorporated by reference to Exhibit 10.1 to the Auxilium Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, filed with the Commission on August 8, 2008)
- 10.20 Executive Employment Agreement between Endo Health Solutions Inc. and Matthew J. Maletta, effective as of April 28, 2015 (incorporated by reference to Exhibit 10.1 of the Endo International plc Current Report on Form 8-K, filed with the Commission on April 30, 2015)
- 10.21 Endo International plc 2015 Stock Incentive Plan (incorporated by reference to Exhibit 4.2 of the Endo International plc Registration Statement on Form S-8, filed with the Commission on June 15, 2015)
- 10.22 Form of Stock Option Agreement to Optionee under the Endo International plc 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.273 of the Endo International plc Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed with the Commission August 10, 2015)
- 10.23 Form of Stock Award Agreement to Participant under the Endo International plc 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.274 of the Endo International plc Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed with the Commission August 10, 2015)
- 10.24 Form of Performance Award Agreement to Participant under the Endo International plc 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.275 of the Endo International plc Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed with the Commission August 10, 2015)
- 10.25 Form of Matched Performance Award Agreement to Participant under the Endo International plc 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.276 of the Endo International plc Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed with the Commission August 10, 2015)
- 10.26 Executive Employment Agreement between Endo Health Solutions, Inc. and Paul V. Campanelli, effective as of September 25, 2015 (incorporated by reference to Exhibit 10.310 of the Endo International plc Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed with the Commission November 9, 2015)
- 10.27 License and Supply Agreement by and by and among Novartis, AG, Novartis Consumer Health, Inc. and Endo Pharmaceuticals dated as of March 4, 2008 (incorporated by reference to Exhibit 10.31 of the Endo International plc Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed with the Commission November 9, 2015)
- 10.27.1 Amendment No. 1 to the License and Supply Agreement by and by and among Novartis, AG, Novartis Consumer Health, Inc. and Endo Pharmaceuticals dated as of March 28, 2008 (incorporated by reference to Exhibit 10.31.1 of the Endo International plc Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed with the Commission November 9, 2015)



10.27.2	Amendment No. 2 to License and Supply Agreement, by and among Novartis AG, Novartis Consumer Health, Inc. and Endo Pharmaceuticals dated as of December 31, 2012 (incorporated by reference to Exhibit 10.31.2 of the Endo International plc Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed with the Commission November 9, 2015)
10.28*	Amended and Restated License and Supply Agreement by and among Novartis, AG, Sandoz Inc. and Endo Ventures Limited dated as of December 11, 2015 (filed herewith)
10.29*	License and Commercialization Agreement, dated October 10, 2013, by and between VIVUS, Inc. and Auxilium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.14 to the Auxilium Annual Report on Form 10-K, filed with the Commission on February 28, 2014)
10.30*	Commercial Supply Agreement, dated October 10, 2013, by and between VIVUS, Inc. and Auxilium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.15 to the Auxilium Annual Report on Form 10-K, filed with the Commission on February 28, 2014)
10.31	Notice of Termination, effective as of June 30, 2016, of (i) the License and Commercialization Agreement by and between Auxilium and VIVUS and (ii) the Commercial Supply Agreement, by and between Endo Ventures (by assignment from Auxilium) and VIVUS (incorporated by reference to Exhibit 10.1 of the Endo International plc Current Report on Form 8-K, filed with the Commission on December 30, 2015)
10.32	Form of Indemnification Agreement (filed herewith)
10.33	Executive Employment Agreement between Endo Health Solutions, Inc. and Rajiv De Silva, effective as of March 18, 2016 (filed herewith)
16.1	Letter Regarding Change in Certifying Accountant, dated June 13, 2014 (incorporated by reference to Exhibit 16.1 of the Endo International plc Current Report on Form 8-K, filed with the Commission on June 13, 2014)
21	Subsidiaries of the Registrant
23.1	Consent of PricewaterhouseCoopers LLP
23.2	Consent of Deloitte & Touche LLP
24	Power of Attorney
31.1	Certification of the President and Chief Executive Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
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
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
101	The following materials from Endo International plc's Annual Report on Form 10-K for the year ended December 31, 2015, 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 Stockholders' Equity, (v) the Consolidated Statements of Cash Flows and (vi) the Notes to Consolidated Financial Statements
*	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

## SUPPLEMENTAL INDENTURE

SUPPLEMENTAL INDENTURE (this “*Supplemental Indenture*”), dated as of March 27, 2015, among the Issuer, the Co-Obligor, the Guarantors (each, as defined in the Indenture referred to below) and Wells Fargo Bank, National Association, as trustee under the Indenture referred to below (the “*Trustee*”).

## WITNESSETH

WHEREAS, Endo Finance Co., a Delaware corporation, has heretofore executed and delivered to the Trustee an indenture, dated as of December 19, 2013, as supplemented, amended and restated by a supplemental indenture, dated as of February 28, 2014, and as further supplemented by a supplemental indenture, dated as of May 28, 2014, a supplemental indenture, dated as of July 10, 2014, a supplemental indenture, dated as of August 11, 2014, a supplemental indenture, dated as of December 22, 2014, a supplemental indenture, dated as of February 3, 2015, and a supplemental indenture, dated as of March 20, 2015 in each case, among Endo Finance LLC, a Delaware limited liability company and successor to Endo Finance Co., Endo Finco Inc., a Delaware corporation, the Guarantors party thereto and the Trustee (as so supplemented, amended and restated, the “*Indenture*”), providing for the issuance of 5.75% Senior Notes due 2022 (the “*Notes*”);

WHEREAS, this Supplemental Indenture has not resulted in a material modification of the Notes for Foreign Account Tax Compliance Act purposes; and

WHEREAS, pursuant to Section 9.01 of the Indenture, the Issuer, the Co-Obligor, the Guarantors and the Trustee are authorized to execute and deliver this Supplemental Indenture.

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt of which is hereby acknowledged, the Issuer, the Co-Obligor, the Guarantors and the Trustee mutually covenant and agree for the equal and ratable benefit of the Holders of the Notes as follows:

1. CAPITALIZED TERMS. Capitalized terms used herein without definition shall have the meanings assigned to them in the Indenture.
2. AMENDMENT OF INDENTURE.
  - 2.1 The Indenture is hereby amended by adding the paragraph at the end of Section 10.05 to read in its entirety as follows:

“Notwithstanding anything to the contrary contained in this Indenture, the Company shall not be entitled to the provisions of Sections 10.05(a) through 10.05(c) and Section 10.05(e).”

3. NO RECOURSE AGAINST OTHERS. No director, officer, employee, incorporator or stockholder of the Issuer, the Co-Obligor or any Guarantor, as such, will have any liability for any obligations of the Issuer, Co-Obligor or the Guarantors under the Notes, the Indenture, this Supplemental Indenture, the Note Guarantees or for any claim based on, in respect of, or by reason of, such obligations or their creation. Each Holder of Notes by accepting a Note waives and releases all such liability. The waiver and release are part of the consideration for issuance of the Notes. The waiver may not be effective to waive liabilities under the federal securities laws.

4. NEW YORK LAW TO GOVERN; WAIVER OF JURY TRIAL. THIS SUPPLEMENTAL INDENTURE SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK. EACH OF THE ISSUER, THE CO-OBLIGOR AND THE GUARANTORS CONSENTS AND IRREVOCABLY SUBMITS TO THE JURISDICTION OF ANY NEW YORK STATE OR U.S. FEDERAL COURT LOCATED IN THE BOROUGH OF MANHATTAN, CITY OF NEW YORK, COUNTY OF NEW YORK, STATE OF NEW YORK IN RELATION TO ANY LEGAL ACTION OR PROCEEDING (I) ARISING OUT OF, RELATING TO OR IN CONNECTION WITH THIS INDENTURE, AS SUPPLEMENTED, THE NOTES, THE GUARANTEES AND ANY RELATED DOCUMENTS AND/OR (II) ARISING UNDER ANY U.S. FEDERAL OR U.S. STATE SECURITIES LAWS IN RESPECT OF THE NOTES, THE GUARANTEES AND ANY SECURITIES ISSUED PURSUANT TO THE TERMS OF THE INDENTURE, AS SUPPLEMENTED. EACH OF THE ISSUER, THE CO-OBLIGOR AND THE GUARANTORS WAIVES ANY OBJECTION TO PROCEEDINGS IN ANY SUCH COURTS, WHETHER ON THE GROUND OF VENUE OR ON THE GROUND THAT THE PROCEEDINGS HAVE BEEN BROUGHT IN AN INCONVENIENT FORUM. THE ISSUER, THE CO-OBLIGOR, THE TRUSTEE AND EACH OF THE GUARANTORS HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS SUPPLEMENTAL INDENTURE, THE NOTES OR THE TRANSACTIONS CONTEMPLATED HEREBY.

5. COUNTERPARTS. The parties may sign any number of copies of this Supplemental Indenture. Each signed copy (which may be provided via facsimile or other electronic transmission) shall be an original, but all of them together represent the same agreement.

6. EFFECT OF HEADINGS. The Section headings herein are for convenience only and shall not affect the construction hereof.

7. THE TRUSTEE. The Trustee shall not be responsible in any manner whatsoever for or in respect of the validity or sufficiency of this Supplemental Indenture or for or in respect of the recitals contained herein, all of which recitals are made solely by the Issuer, the Co-Obligor and the Guarantors.

IN WITNESS WHEREOF, the parties hereto have caused this Supplemental Indenture to be duly executed and attested, all as of the date first above written.

ENDO FINANCE LLC

as an Issuer

by ENDO LUXEMBOURG FINANCE COMPANY I

S.À R.L., its sole member

By: /s/John D. Boyle

Name: John D. Boyle

Title: A Manager

By: /s/Joost Tulkens

Name: Joost Tulkens

Title: B Manager

ENDO FINCO INC.  
as an Issuer

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Secretary

ENDO LLC  
ENDO US. INC.  
each, as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Secretary

DAVA PHARMACEUTICALS, INC.  
ENDO HEALTH SOLUTIONS INC.  
ENDO PHARMACEUTICALS INC.  
ENDO PHARMACEUTICALS SOLUTIONS INC.  
ENDO PHARMACEUTICALS VALERA INC.  
GENERIC INTERNATIONAL (US PARENT), INC.  
GENERIC INTERNATIONAL (US MIDCO), INC.  
GENERIC INTERNATIONAL (US HOLDCO), INC.  
GENERIC INTERNATIONAL (US), INC.  
AMERICAN MEDICAL SYSTEMS HOLDINGS, INC.  
AMERICAN MEDICAL SYSTEMS, LLC  
AMS RESEARCH, LLC  
AMS SALES, LLC  
LASERSCOPE  
each, as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

GENERICS BIDCO I, LLC  
VINTAGE PHARMACEUTICALS, LLC  
GENERICS BIDCO II, LLC  
MOORES MILL PROPERTIES LLC  
WOOD PARK PROPERTIES LLC  
QUARTS SPECIALTY PHARMACEUTICALS LLC  
each, as a Guarantor  
by GENERICS INTERNATIONAL (US), INC.,  
its manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary



LEDGEMONT ROYALTY SUB LLC  
as a Guarantor  
by ENDO PHARMACEUTICALS SOLUTIONS INC.,  
its manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

BOCA PHARMACAL, LLC,  
as a Guarantor  
by GENERICS INTERNATIONAL (US), INC., its  
sole member

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

DAVA INTERNATIONAL, LLC,  
as a Guarantor  
by DAVA PHARMACEUTICALS, INC., its sole member

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

DAVA CAPITAL MANAGEMENT, INC.,  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

AUXILIUM INTERNATIONAL HOLDINGS, INC.  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

SLATE PHARMACEUTICALS, INC.  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

TIMM MEDICAL TECHNOLOGIES, INC.  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

ACTIENT PHARMACEUTICALS LLC  
as a Guarantor

By: AUDILIUM PHARMACEUTICALS, INC.,  
its manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

ACTIENT THERAPEUTICS LLC  
as Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

AUXILIUM US HOLDINGS, LLC  
as a Guarantor

By: AUXILIUM PHARMACEUTICALS, INC.,  
its manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

AUXILIUM PHARMACEUTICALS, INC.  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

70 MAPLE AVENUE, LLC  
as a Guarantor

By: ACTIENT PHARMACEUTICALS LLC,  
its manager

By: AUXILIUM PHARMACEUTICALS, INC.,  
its manager

By: /s/Deanna Voss

Name: Deanna Voss  
Title: Assistant Secretary

TIMM MEDICAL HOLDINGS, LLC  
as Guarantor

By: ACTIENT PHARMACEUTICALS LLC,  
its manager

By: AUXILIUM PHARMACEUTICALS, INC.,  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

APHRODITE WOMEN'S HEALTH, LLC  
as a Guarantor

By: AMERICAN MEDICAL SYSTEMS HOLDINGS, INC., its  
manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

ENDO LIMITED  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

ENDO VENTURES LIMITED  
as Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

ENDO MANAGEMENT LIMITED  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

ENDO FINANCE LIMITED  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

ENDO FINANCE II LIMITED  
as a Guarantor

By: /s/Orla Dunlea

Name: Orla Dunlea

Title: Director



ENDO LUXEMBOURG HOLDING COMPANY S.À R.L.  
as a Guarantor

By: /s/John D. Boyle  
Name: John D. Boyle  
Title: A Manager

By: /s/Joost Tulkens  
Name: Joost Tulkens  
Title: B Manager

ENDO LUXEMBOURG FINANCE COMPANY I S.À R.L.  
as a Guarantor

By: /s/John D. Boyle  
Name: John D. Boyle  
Title: A Manager

By: /s/Joost Tulkens  
Name: Joost Tulkens  
Title: B Manager

ENDO LUXEMBOURG FINANCE COMPANY II S.À R.L.  
as a Guarantor

By: /s/John D. Boyle  
Name: John D. Boyle  
Title: A Manager

By: /s/Joost Tulkens  
Name: Joost Tulkens  
Title: B Manager

PALADIN LABS CANADIAN HOLDING INC.  
as a Guarantor

By: /s/Mark Beudet  
Name: Mark Beudet  
Title: President

PALADIN LABS INC.  
as a Guarantor

By: /s/Mark Beudet  
Name: Mark Beudet  
Title: President

ENDO VENTURES BERMUDA LIMITED, as a  
Guarantor

By: /s/Susan Hall  
Name: Susan Hall  
Title: Director

ENDO GLOBAL VENTURES  
as a Guarantor

By: /s/Susan Hall  
Name: Susan Hall  
Title: Director

ENDO NETHERLANDS B.V., as a Guarantor

By: /s/Robert J. Cobuzzi

Name: Robert J. Cobuzzi

Title: Managing Director A

By: /s/Gert Jan Rietberg

Name: Jan Rietberg

Title: Managing Director B

ENDO VENTURES CYPRUS LIMITED  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

AUXILIUM UK LTD  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

WELLS FARGO BANK, NATIONAL ASSOCIATION  
as a Guarantor

By: /s/Yana Kislenko  
Name: Yana Kislenko  
Title: Vice President

## SUPPLEMENTAL INDENTURE

SUPPLEMENTAL INDENTURE (this “*Supplemental Indenture*”), dated as of March 27, 2015, among the Issuers, the Guarantors (both, as defined in the Indenture referred to below) and Wells Fargo Bank, National Association, as trustee under the Indenture referred to below (the “*Trustee*”).

## WITNESSETH

WHEREAS, Endo Finance LLC, a Delaware limited liability company, and Endo Finco Inc., a Delaware corporation, have heretofore executed and delivered to the Trustee an indenture, dated as of May 6, 2014, as supplemented by a supplemental indenture, dated as of May 28, 2014, a supplemental indenture, dated as of July 10, 2014, a supplemental indenture, dated as of August 11, 2014, a supplemental indenture, dated as of December 22, 2014, a supplemental indenture, dated as of February 3, 2015, and a supplemental indenture, dated as of March 20, 2015 in each case, among the Issuers, the Guarantors party thereto and the Trustee (as so supplemented, the “*Indenture*”), providing for the issuance of 7.25% Senior Notes due 2022 (the “*Notes*”);

WHEREAS, this Supplemental Indenture has not resulted in a material modification of the Notes for Foreign Account Tax Compliance Act purposes; and

WHEREAS, pursuant to Section 9.01 of the Indenture, the Issuers, the Guarantors and the Trustee are authorized to execute and deliver this Supplemental Indenture.

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt of which is hereby acknowledged, the Issuers, the Guarantors and the Trustee mutually covenant and agree for the equal and ratable benefit of the Holders of the Notes as follows:

1. CAPITALIZED TERMS. Capitalized terms used herein without definition shall have the meanings assigned to them in the Indenture.
2. AMENDMENT OF INDENTURE.

2.1 Section 10.02(B) of the Indenture is hereby amended and restated in its entirety to read as follows:

“Notwithstanding anything to the contrary contained in this Indenture, the aggregate obligations and exposure of each of Endo Luxembourg Finance Company II S.à r.l. and any other Guarantor established in Luxembourg which is not a direct or indirect parent of any Issuer (a “Luxembourg Guarantor”) in respect of the obligations of the Issuers under the Notes, shall not exceed the maximum amount that can be hereby guaranteed by the relevant Luxembourg Guarantor without rendering such guarantee, as it relates to such Luxembourg Guarantor, voidable under applicable law relating to corporate benefit, fraudulent conveyance or fraudulent transfer or similar laws affecting the rights of creditors generally. For the avoidance of doubt, this Section 10.02(B) does not apply to Endo Luxembourg Holding Company S.à r.l. and Endo Luxembourg Finance Company I S.à r.l.”

2.2 The Indenture is hereby amended by adding the paragraph at the end of Section 10.05 to read in its entirety as follows:



“Notwithstanding anything to the contrary contained in this Indenture, the Company shall not be entitled to the provisions of Sections 10.05(a) through 10.05(c) and Section 10.05(e).”

3. NO RECOURSE AGAINST OTHERS. No director, officer, employee, incorporator or stockholder of the Issuers or any Guarantor, as such, will have any liability for any obligations of the Issuers or the Guarantors under the Notes, the Indenture, this Supplemental Indenture, the Note Guarantees or for any claim based on, in respect of, or by reason of, such obligations or their creation. Each Holder of Notes by accepting a Note waives and releases all such liability. The waiver and release are part of the consideration for issuance of the Notes. The waiver may not be effective to waive liabilities under the federal securities laws.

4. NEW YORK LAW TO GOVERN; WAIVER OF JURY TRIAL. THIS SUPPLEMENTAL INDENTURE SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK. EACH OF THE ISSUERS AND THE GUARANTORS CONSENTS AND IRREVOCABLY SUBMITS TO THE JURISDICTION OF ANY NEW YORK STATE OR U.S. FEDERAL COURT LOCATED IN THE BOROUGH OF MANHATTAN, CITY OF NEW YORK, COUNTY OF NEW YORK, STATE OF NEW YORK IN RELATION TO ANY LEGAL ACTION OR PROCEEDING (I) ARISING OUT OF, RELATING TO OR IN CONNECTION WITH THIS INDENTURE, AS SUPPLEMENTED, THE NOTES, THE GUARANTEES AND ANY RELATED DOCUMENTS AND/OR (II) ARISING UNDER ANY U.S. FEDERAL OR U.S. STATE SECURITIES LAWS IN RESPECT OF THE NOTES, THE GUARANTEES AND ANY SECURITIES ISSUED PURSUANT TO THE TERMS OF THE INDENTURE, AS SUPPLEMENTED. EACH OF THE ISSUERS AND THE GUARANTORS WAIVES ANY OBJECTION TO PROCEEDINGS IN ANY SUCH COURTS, WHETHER ON THE GROUND OF VENUE OR ON THE GROUND THAT THE PROCEEDINGS HAVE BEEN BROUGHT IN AN INCONVENIENT FORUM. EACH OF THE ISSUERS, THE TRUSTEE AND THE GUARANTORS HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS SUPPLEMENTAL INDENTURE, THE NOTES OR THE TRANSACTIONS CONTEMPLATED HEREBY.

5. COUNTERPARTS. The parties may sign any number of copies of this Supplemental Indenture. Each signed copy (which may be provided via facsimile or other electronic transmission) shall be an original, but all of them together represent the same agreement.

6. EFFECT OF HEADINGS. The Section headings herein are for convenience only and shall not affect the construction hereof.

7. THE TRUSTEE. The Trustee shall not be responsible in any manner whatsoever for or in respect of the validity or sufficiency of this Supplemental Indenture or for or in respect of the recitals contained herein, all of which recitals are made solely by the Issuers and the Guarantors.

IN WITNESS WHEREOF, the parties hereto have caused this Supplemental Indenture to be duly executed and attested, all as of the date first above written.

ENDO FINANCE LLC

as an Issuer

by ENDO LUXEMBOURG FINANCE COMPANY I

S.À R.L., its sole member

By: /s/John D. Boyle

Name: John D. Boyle

Title: A Manager

By: /s/Joost Tulkens

Name: Joost Tulkens

Title: B Manager

ENDO FINCO INC.  
as an Issuer

By: /s/Deanna Voss

Name: Deanna Voss

Title: Secretary

ENDO LLC  
ENDO U.S. INC.  
each as Guarantor

By: /s/Deanna Voss

Name: Deanna Voss

Title: Secretary

DAVA PHARMACEUTICALS, INC.  
ENDO HEALTH SOLUTIONS INC.  
ENDO PHARMACEUTICALS INC.  
ENDO PHARMACEUTICALS SOLUTIONS INC.  
ENDO PHARMACEUTICALS VALERA INC.  
GENERICS INTERNATIONAL (US PARENT), INC.  
GENERICS INTERNATIONAL (US MIDCO), INC.  
GENERICS INTERNATIONAL (US HOLDCO), INC.  
GENERICS INTERNATIONAL (US), INC.  
AMERICAN MEDICAL SYSTEMS HOLDINGS, INC.  
AMERICAN MEDICAL SYSTEMS, LLC  
AMS RESEARCH, LLC  
AMS SALES, LLC  
LASERSCOPE  
each, as a Guarantor

By: /s/Deanna Voss

Name: Deanna Voss

Title: Assistant Secretary

GENERICS BIDCO I, LLC  
VINTAGE PHARMACEUTICALS, LLC  
GENERICS BIDCO II, LLC  
MOORES MILL PROPERTIES LLC  
WOOD PARK PROPERTIES LLC  
QUARTS SPECIALTY PHARMACEUTICALS LLC  
each, as a Guarantor  
by GENERICS INTERNATIONAL (US), INC.,  
its manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

LEDGEMONT ROYALTY SUB LLC  
as a Guarantor  
by ENDO PHARMACEUTICALS SOLUTIONS INC.,  
its manager

By: /s/Deanna Voss

\_\_\_\_\_  
Name: Deanna Voss

Title: Assistant Secretary

BOCA PHARMACAL, LLC,  
as a Guarantor  
by GENERICS INTERNATIONAL (US), INC., its  
sole member

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

DAVA INTERNATIONAL, LLC,  
as a Guarantor  
by DAVA PHARMACEUTICALS, INC., its sole member

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

DAVA CAPITAL MANAGEMENT, INC.,  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary



AUXILIUM INTERNATIONAL HOLDINGS, INC.  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

SLATE PHARMACEUTICALS, INC.  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

TIMM MEDICAL TECHNOLOGIES, INC.  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

ACTIENT PHARMACEUTICALS LLC  
as a Guarantor

By: AUDILIUM PHARMACEUTICALS, INC.,  
its manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

ACTIENT THERAPEUTICS LLC  
as Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

AUXILIUM US HOLDINGS, LLC  
as a Guarantor

By: AUXILIUM PHARMACEUTICALS, INC.,  
its manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

AUXILIUM PHARMACEUTICALS, INC.  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

70 MAPLE AVENUE, LLC  
as a Guarantor

By: ACTIENT PHARMACEUTICALS LLC,  
its manager

By: AUXILIUM PHARMACEUTICALS, INC.,  
its manager

By: /s/Deanna Voss

Name: Deanna Voss  
Title: Assistant Secretary

TIMM MEDICAL HOLDINGS, LLC  
as Guarantor

By: ACTIENT PHARMACEUTICALS LLC,  
its manager

By: AUXILIUM PHARMACEUTICALS, INC.,  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

APHRODITE WOMEN'S HEALTH, LLC  
as a Guarantor

By: AMERICAN MEDICAL SYSTEMS HOLDINGS, INC., its  
manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

ENDO LIMITED  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

ENDO VENTURES LIMITED  
as Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

ENDO MANAGEMENT LIMITED  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

ENDO FINANCE LIMITED  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

ENDO FINANCE II LIMITED  
as a Guarantor

By: /s/Orla Dunlea

Name: Orla Dunlea

Title: Director

ENDO LUXEMBOURG HOLDING COMPANY S.À R.L.  
as a Guarantor

By: /s/John D. Boyle  
Name: John D. Boyle  
Title: A Manager

By: /s/Joost Tulkens  
Name: Joost Tulkens  
Title: B Manager

ENDO LUXEMBOURG FINANCE COMPANY I S.À R.L.  
as a Guarantor

By: /s/John D. Boyle  
Name: John D. Boyle  
Title: A Manager

By: /s/Joost Tulkens  
Name: Joost Tulkens  
Title: B Manager

ENDO LUXEMBOURG FINANCE COMPANY II S.À R.L.  
as a Guarantor

By: /s/John D. Boyle  
Name: John D. Boyle  
Title: A Manager

By: /s/Joost Tulkens  
Name: Joost Tulkens  
Title: B Manager

PALADIN LABS CANADIAN HOLDING INC.  
as a Guarantor

By: /s/Mark Beudet  
Name: Mark Beudet  
Title: President

PALADIN LABS INC.  
as a Guarantor

By: /s/Mark Beudet  
Name: Mark Beudet  
Title: President



ENDO VENTURES BERMUDA LIMITED, as a  
Guarantor

By: /s/Susan Hall  
Name: Susan Hall  
Title: Director

ENDO GLOBAL VENTURES  
as a Guarantor

By: /s/Susan Hall  
Name: Susan Hall  
Title: Director

ENDO NETHERLANDS B.V., as a Guarantor

By: /s/Robert J. Cobuzzi

Name: Robert J. Cobuzzi

Title: Managing Director A

By: /s/Gert Jan Rietberg

Name: Jan Rietberg

Title: Managing Director B

ENDO VENTURES CYPRUS LIMITED  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

AUXILIUM UK LTD  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

WELLS FARGO BANK, NATIONAL ASSOCIATION  
as a Guarantor

By: /s/Yana Kislenko  
Name: Yana Kislenko  
Title: Vice President

## SUPPLEMENTAL INDENTURE

SUPPLEMENTAL INDENTURE (this “*Supplemental Indenture*”), dated as of March 27, 2015, among the Issuers, the Guarantors (both, as defined in the Indenture referred to below) and Wells Fargo Bank, National Association, as trustee under the Indenture referred to below (the “*Trustee*”).

## WITNESSETH

WHEREAS, Endo Finance LLC, a Delaware limited liability company, and Endo Finco Inc., a Delaware corporation, have heretofore executed and delivered to the Trustee an indenture, dated as of June 30, 2014, as supplemented by a supplemental indenture, dated as of July 10, 2014, a supplemental indenture, dated as of August 11, 2014, a supplemental indenture, dated as of December 22, 2014, a supplemental indenture, dated as of February 3, 2015, and a supplemental indenture, dated as of March 20, 2015 in each case, among the Issuers, the Guarantors party thereto and the Trustee (the “*Indenture*”), providing for the issuance of 5.375% Senior Notes due 2023 (the “*Notes*”);

WHEREAS, this Supplemental Indenture has not resulted in a material modification of the Notes for Foreign Account Tax Compliance Act purposes; and

WHEREAS, pursuant to Section 9.01 of the Indenture, the Issuers, the Guarantors and the Trustee are authorized to execute and deliver this Supplemental Indenture.

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt of which is hereby acknowledged, the Issuers, the Guarantors and the Trustee mutually covenant and agree for the equal and ratable benefit of the Holders of the Notes as follows:

1. CAPITALIZED TERMS. Capitalized terms used herein without definition shall have the meanings assigned to them in the Indenture.

2. AMENDMENT OF INDENTURE.

2.1 Section 10.02(B) of the Indenture is hereby amended and restated in its entirety to read as follows:

“Notwithstanding anything to the contrary contained in this Indenture, the aggregate obligations and exposure of each of Endo Luxembourg Finance Company II S.à r.l. and any other Guarantor established in Luxembourg which is not a direct or indirect parent of any Issuer (a “*Luxembourg Guarantor*”) in respect of the obligations of the Issuers under the Notes, shall not exceed the maximum amount that can be hereby guaranteed by the relevant Luxembourg Guarantor without rendering such guarantee, as it relates to such Luxembourg Guarantor, voidable under applicable law relating to corporate benefit, fraudulent conveyance or fraudulent transfer or similar laws affecting the rights of creditors generally. For the avoidance of doubt, this Section 10.02(B) does not apply to Endo Luxembourg Holding Company S.à r.l. and Endo Luxembourg Finance Company I S.à r.l.”

2.2 The Indenture is hereby amended by adding the paragraph at the end of Section 10.05 to read in its entirety as follows:

“Notwithstanding anything to the contrary contained in this Indenture, the Company shall not be entitled to the provisions of Sections 10.05(a) through 10.05(c) and Section 10.05(e).”

3. NO RECOURSE AGAINST OTHERS. No director, officer, employee, incorporator or stockholder of the Issuers or any Guarantor, as such, will have any liability for any obligations of the Issuers or the Guarantors under the Notes, the Indenture, this Supplemental Indenture, the Note Guarantees or for any claim based on, in respect of, or by reason of, such obligations or their creation. Each Holder of Notes by accepting a Note waives and releases all such liability. The waiver and release are part of the consideration for issuance of the Notes. The waiver may not be effective to waive liabilities under the federal securities laws.

4. NEW YORK LAW TO GOVERN; WAIVER OF JURY TRIAL. THIS SUPPLEMENTAL INDENTURE SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK. EACH OF THE ISSUERS AND THE GUARANTORS CONSENTS AND IRREVOCABLY SUBMITS TO THE JURISDICTION OF ANY NEW YORK STATE OR U.S. FEDERAL COURT LOCATED IN THE BOROUGH OF MANHATTAN, CITY OF NEW YORK, COUNTY OF NEW YORK, STATE OF NEW YORK IN RELATION TO ANY LEGAL ACTION OR PROCEEDING (I) ARISING OUT OF, RELATING TO OR IN CONNECTION WITH THIS INDENTURE, AS SUPPLEMENTED, THE NOTES, THE GUARANTEES AND ANY RELATED DOCUMENTS AND/OR (II) ARISING UNDER ANY U.S. FEDERAL OR U.S. STATE SECURITIES LAWS IN RESPECT OF THE NOTES, THE GUARANTEES AND ANY SECURITIES ISSUED PURSUANT TO THE TERMS OF THE INDENTURE, AS SUPPLEMENTED. EACH OF THE ISSUERS AND THE GUARANTORS WAIVES ANY OBJECTION TO PROCEEDINGS IN ANY SUCH COURTS, WHETHER ON THE GROUND OF VENUE OR ON THE GROUND THAT THE PROCEEDINGS HAVE BEEN BROUGHT IN AN INCONVENIENT FORUM. EACH OF THE ISSUERS, THE TRUSTEE AND THE GUARANTORS HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS SUPPLEMENTAL INDENTURE, THE NOTES OR THE TRANSACTIONS CONTEMPLATED HEREBY.

5. COUNTERPARTS. The parties may sign any number of copies of this Supplemental Indenture. Each signed copy (which may be provided via facsimile or other electronic transmission) shall be an original, but all of them together represent the same agreement.

6. EFFECT OF HEADINGS. The Section headings herein are for convenience only and shall not affect the construction hereof.

7. THE TRUSTEE. The Trustee shall not be responsible in any manner whatsoever for or in respect of the validity or sufficiency of this Supplemental Indenture or for or in respect of the recitals contained herein, all of which recitals are made solely by the Issuers and the Guarantors.

IN WITNESS WHEREOF, the parties hereto have caused this Supplemental Indenture to be duly executed and attested, all as of the date first above written.

ENDO FINANCE LLC

as an Issuer

by ENDO LUXEMBOURG FINANCE COMPANY I

S.À R.L., its sole member

By: /s/John D. Boyle

Name: John D. Boyle

Title: A Manager

By: /s/Joost Tulkens

Name: Joost Tulkens

Title: B Manager



ENDO FINCO INC.  
as an Issuer

By: /s/Deanna Voss

Name: Deanna Voss

Title: Secretary

ENDO LLC  
ENDO U.S. INC.  
each as Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Secretary

DAVA PHARMACEUTICALS, INC.  
ENDO HEALTH SOLUTIONS INC.  
ENDO PHARMACEUTICALS INC.  
ENDO PHARMACEUTICALS SOLUTIONS INC.  
ENDO PHARMACEUTICALS VALERA INC.  
GENERIC INTERNATIONAL (US PARENT), INC.  
GENERIC INTERNATIONAL (US MIDCO), INC.  
GENERIC INTERNATIONAL (US HOLDCO), INC.  
GENERIC INTERNATIONAL (US), INC.  
AMERICAN MEDICAL SYSTEMS HOLDINGS, INC.  
AMERICAN MEDICAL SYSTEMS, LLC  
AMS RESEARCH, LLC  
AMS SALES, LLC  
LASERSCOPE  
each, as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

GENERICS BIDCO I, LLC  
VINTAGE PHARMACEUTICALS, LLC  
GENERICS BIDCO II, LLC  
MOORES MILL PROPERTIES LLC  
WOOD PARK PROPERTIES LLC  
QUARTS SPECIALTY PHARMACEUTICALS LLC  
each, as a Guarantor  
by GENERICS INTERNATIONAL (US), INC.,  
its manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

LEDGEMONT ROYALTY SUB LLC  
as a Guarantor  
by ENDO PHARMACEUTICALS SOLUTIONS INC.,  
its manager

By: /s/Deanna Voss

Name: Deanna Voss

Title: Assistant Secretary

BOCA PHARMACAL, LLC,  
as a Guarantor  
by GENERICS INTERNATIONAL (US), INC., its  
sole member

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

DAVA INTERNATIONAL, LLC,  
as a Guarantor  
by DAVA PHARMACEUTICALS, INC., its sole member

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

DAVA CAPITAL MANAGEMENT, INC.,  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

AUXILIUM INTERNATIONAL HOLDINGS, INC.  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

SLATE PHARMACEUTICALS, INC.  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

TIMM MEDICAL TECHNOLOGIES, INC.  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

ACTIENT PHARMACEUTICALS LLC  
as a Guarantor

By: AUDILIUM PHARMACEUTICALS, INC.,  
its manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

ACTIENT THERAPEUTICS LLC  
as Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

AUXILIUM US HOLDINGS, LLC  
as a Guarantor

By: AUXILIUM PHARMACEUTICALS, INC.,  
its manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

AUXILIUM PHARMACEUTICALS, INC.  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

70 MAPLE AVENUE, LLC  
as a Guarantor

By: ACTIENT PHARMACEUTICALS LLC,  
its manager

By: AUXILIUM PHARMACEUTICALS, INC.,  
its manager



By: /s/Deanna Voss

---

Name: Deanna Voss

Title: Assistant Secretary

TIMM MEDICAL HOLDINGS, LLC  
as Guarantor

By: ACTIENT PHARMACEUTICALS LLC,  
its manager

By: AUXILIUM PHARMACEUTICALS, INC.,  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

APHRODITE WOMEN'S HEALTH, LLC  
as a Guarantor

By: AMERICAN MEDICAL SYSTEMS HOLDINGS, INC., its  
manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

ENDO LIMITED  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

ENDO VENTURES LIMITED  
as Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

ENDO MANAGEMENT LIMITED  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

ENDO FINANCE LIMITED  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

ENDO FINANCE II LIMITED  
as a Guarantor

By: /s/Orla Dunlea

---

Name: Orla Dunlea

Title: Director

ENDO LUXEMBOURG HOLDING COMPANY S.À R.L.  
as a Guarantor

By: /s/John D. Boyle  
Name: John D. Boyle  
Title: A Manager

By: /s/Joost Tulkens  
Name: Joost Tulkens  
Title: B Manager

ENDO LUXEMBOURG FINANCE COMPANY I S.À R.L.  
as a Guarantor

By: /s/John D. Boyle  
Name: John D. Boyle  
Title: A Manager

By: /s/Joost Tulkens  
Name: Joost Tulkens  
Title: B Manager

ENDO LUXEMBOURG FINANCE COMPANY II S.À R.L.  
as a Guarantor

By: /s/John D. Boyle  
Name: John D. Boyle  
Title: A Manager

By: /s/Joost Tulkens  
Name: Joost Tulkens  
Title: B Manager

PALADIN LABS CANADIAN HOLDING INC.  
as a Guarantor

By: /s/Mark Beudet  
Name: Mark Beudet  
Title: President

PALADIN LABS INC.  
as a Guarantor

By: /s/Mark Beudet  
Name: Mark Beudet  
Title: President

ENDO VENTURES BERMUDA LIMITED, as a  
Guarantor

By: /s/Susan Hall  
Name: Susan Hall  
Title: Director

ENDO GLOBAL VENTURES  
as a Guarantor

By: /s/Susan Hall  
Name: Susan Hall  
Title: Director

ENDO NETHERLANDS B.V., as a Guarantor

By: /s/Robert J. Cobuzzi  
Name: Robert J. Cobuzzi  
Title: Managing Director A

By: /s/Gert Jan Rietberg  
Name: Jan Rietberg  
Title: Managing Director B



ENDO VENTURES CYPRUS LIMITED  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

AUXILIUM UK LTD  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

WELLS FARGO BANK, NATIONAL ASSOCIATION  
as a Guarantor

By: /s/Yana Kislenko

Name: Yana Kislenko

Title: Vice President

## SUPPLEMENTAL INDENTURE

SUPPLEMENTAL INDENTURE (this “*Supplemental Indenture*”), dated as of March 27, 2015, among the Issuers, the Guarantors (both, as defined in the Indenture referred to herein) and Wells Fargo Bank, National Association, as trustee under the Indenture referred to below (the “*Trustee*”).

## WITNESSETH

WHEREAS, Endo Limited, a private limited company incorporated under the laws of Ireland, Endo Finance LLC, a Delaware limited liability company, and Endo Finco Inc., a Delaware corporation, have heretofore executed and delivered to the Trustee an indenture, dated as of January 27, 2015, as supplemented by a supplemental indenture, dated as of February 3, 2015, and a supplemental indenture, dated as of March 20, 2015, in each case, by and among the parties thereto (the “*Indenture*”), providing for the issuance of 6.00% Senior Notes due 2025 (the “*Notes*”);

WHEREAS, this Supplemental Indenture has not resulted in a material modification of the Notes for Foreign Account Tax Compliance Act purposes; and

WHEREAS, pursuant to Section 9.01 of the Indenture, the Issuers, the Guarantors and the Trustee are authorized to execute and deliver this Supplemental Indenture.

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt of which is hereby acknowledged, the Issuers, the Guarantors and the Trustee mutually covenant and agree for the equal and ratable benefit of the Holders of the Notes as follows:

1. CAPITALIZED TERMS. Capitalized terms used herein without definition shall have the meanings assigned to them in the Indenture.
2. AMENDMENT OF INDENTURE.
  - 2.1 Section 10.02(B) of the Indenture is hereby amended and restated in its entirety to read as follows:

“Notwithstanding anything to the contrary contained in this Indenture, the aggregate obligations and exposure of each of Endo Luxembourg Finance Company II S.à r.l. and any other Guarantor established in Luxembourg which is not a direct or indirect parent of any Issuer (a “Luxembourg Guarantor”) in respect of the obligations of the Issuers under the Notes, shall not exceed the maximum amount that can be hereby guaranteed by the relevant Luxembourg Guarantor without rendering such guarantee, as it relates to such Luxembourg Guarantor, voidable under applicable law relating to corporate benefit, fraudulent conveyance or fraudulent transfer or similar laws affecting the rights of creditors generally. For the avoidance of doubt, this Section 10.02(B) does not apply to Endo Luxembourg Holding Company S.à r.l. and Endo Luxembourg Finance Company I S.à r.l.”

3. NO RECOURSE AGAINST OTHERS. No director, officer, employee, incorporator or stockholder of the Issuers or any Guarantor, as such, will have any liability for any obligations of the Issuers or the Guarantors under the Notes, this Supplemental Indenture, the Note Guarantees or for any claim based on, in respect of, or by reason of, such obligations or their creation.

Each Holder of Notes by accepting a Note waives and releases all such liability. The waiver and release are part of the consideration for issuance of the Notes. The waiver may not be effective to waive liabilities under the federal securities laws.

4. NEW YORK LAW TO GOVERN; WAIVER OF JURY TRIAL. THIS SUPPLEMENTAL INDENTURE SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK. EACH OF THE ISSUERS AND THE GUARANTORS CONSENTS AND IRREVOCABLY SUBMITS TO THE JURISDICTION OF ANY NEW YORK STATE OR U.S. FEDERAL COURT LOCATED IN THE BOROUGH OF MANHATTAN, CITY OF NEW YORK, COUNTY OF NEW YORK, STATE OF NEW YORK IN RELATION TO ANY LEGAL ACTION OR PROCEEDING (I) ARISING OUT OF, RELATING TO OR IN CONNECTION WITH THIS INDENTURE, AS SUPPLEMENTED, THE NOTES, THE GUARANTEES AND ANY RELATED DOCUMENTS AND/OR (II) ARISING UNDER ANY U.S. FEDERAL OR U.S. STATE SECURITIES LAWS IN RESPECT OF THE NOTES, THE GUARANTEES AND ANY SECURITIES ISSUED PURSUANT TO THE TERMS OF THE INDENTURE, AS SUPPLEMENTED. EACH OF THE ISSUERS AND THE GUARANTORS WAIVES ANY OBJECTION TO PROCEEDINGS IN ANY SUCH COURTS, WHETHER ON THE GROUND OF VENUE OR ON THE GROUND THAT THE PROCEEDINGS HAVE BEEN BROUGHT IN AN INCONVENIENT FORUM. EACH OF THE ISSUERS, THE TRUSTEE AND THE GUARANTORS HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS SUPPLEMENTAL INDENTURE, THE NOTES OR THE TRANSACTIONS CONTEMPLATED HEREBY.

5. COUNTERPARTS. The parties may sign any number of copies of this Supplemental Indenture. Each signed copy (which may be provided via facsimile or other electronic transmission) shall be an original, but all of them together represent the same agreement.

6. EFFECT OF HEADINGS. The Section headings herein are for convenience only and shall not affect the construction hereof.

7. THE TRUSTEE. The Trustee shall not be responsible in any manner whatsoever for or in respect of the validity or sufficiency of this Supplemental Indenture or for or in respect of the recitals contained herein, all of which recitals are made solely by the Issuers and the Guarantors.

IN WITNESS WHEREOF, the parties hereto have caused this Supplemental Indenture to be duly executed and attested, all as of the date first above written.

ENDO LIMITED  
as an Issuer

By: /s/Orla Dunlea

Name: Orla Dunlea

Title: Director

ENDO FINANCE LLC  
as an Issuer  
by ENDO LUXEMBOURG FINANCE COMPANY I  
S.À R.L., its sole member

By: /s/John D. Boyle  
Name: John D. Boyle  
Title: A Manager

By: /s/Joost Tulkens  
Name: Joost Tulkens  
Title: B Manager

ENDO FINCO INC.  
as an Issuer

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Secretary



ENDO LLC  
ENDO US. INC.  
each, as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Secretary

DAVA PHARMACEUTICALS, INC.  
ENDO HEALTH SOLUTIONS INC.  
ENDO PHARMACEUTICALS INC.  
ENDO PHARMACEUTICALS SOLUTIONS INC.  
ENDO PHARMACEUTICALS VALERA INC.  
GENERIC INTERNATIONAL (US PARENT), INC.  
GENERIC INTERNATIONAL (US MIDCO), INC.  
GENERIC INTERNATIONAL (US HOLDCO), INC.  
GENERIC INTERNATIONAL (US), INC.  
AMERICAN MEDICAL SYSTEMS HOLDINGS, INC.  
AMERICAN MEDICAL SYSTEMS, LLC  
AMS RESEARCH, LLC  
AMS SALES, LLC  
LASERSCOPE  
each, as a Guarantor

By: /s/Deanna Voss

Name: Deanna Voss

Title: Assistant Secretary

GENERICS BIDCO I, LLC  
VINTAGE PHARMACEUTICALS, LLC  
GENERICS BIDCO II, LLC  
MOORES MILL PROPERTIES LLC  
WOOD PARK PROPERTIES LLC  
QUARTS SPECIALTY PHARMACEUTICALS LLC  
each, as a Guarantor  
by GENERICS INTERNATIONAL (US), INC.,  
its manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

LEDGEMONT ROYALTY SUB LLC  
as a Guarantor  
by ENDO PHARMACEUTICALS SOLUTIONS INC.,  
its manager

By: /s/Deanna Voss

\_\_\_\_\_  
Name: Deanna Voss

Title: Assistant Secretary

BOCA PHARMACAL, LLC,  
as a Guarantor  
by GENERICS INTERNATIONAL (US), INC., its  
sole member

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

DAVA INTERNATIONAL, LLC,  
as a Guarantor  
by DAVA PHARMACEUTICALS, INC., its sole member

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

DAVA CAPITAL MANAGEMENT, INC.,  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

AUXILIUM INTERNATIONAL HOLDINGS, INC.  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

SLATE PHARMACEUTICALS, INC.  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

TIMM MEDICAL TECHNOLOGIES, INC.  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

ACTIENT PHARMACEUTICALS LLC  
as a Guarantor

By: AUDILIUM PHARMACEUTICALS, INC.,  
its manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

ACTIENT THERAPEUTICS LLC  
as Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

AUXILIUM US HOLDINGS, LLC  
as a Guarantor

By: AUXILIUM PHARMACEUTICALS, INC.,  
its manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

AUXILIUM PHARMACEUTICALS, INC.  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

70 MAPLE AVENUE, LLC  
as a Guarantor

By: ACTIENT PHARMACEUTICALS LLC,  
its manager

By: AUXILIUM PHARMACEUTICALS, INC.,  
its manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

TIMM MEDICAL HOLDINGS, LLC  
as Guarantor

By: ACTIENT PHARMACEUTICALS LLC,  
its manager

By: AUXILIUM PHARMACEUTICALS, INC.,  
as a Guarantor

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary

APHRODITE WOMEN'S HEALTH, LLC  
as a Guarantor

By: AMERICAN MEDICAL SYSTEMS HOLDINGS, INC., its  
manager

By: /s/Deanna Voss  
Name: Deanna Voss  
Title: Assistant Secretary



ENDO VENTURES LIMITED  
as Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

ENDO MANAGEMENT LIMITED  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

ENDO FINANCE LIMITED  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

ENDO FINANCE II LIMITED  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

ENDO LUXEMBOURG HOLDING COMPANY S.À R.L.  
as a Guarantor

By: /s/John D. Boyle  
Name: John D. Boyle  
Title: A Manager

By: /s/Joost Tulkens  
Name: Joost Tulkens  
Title: B Manager

ENDO LUXEMBOURG FINANCE COMPANY I S.À R.L.  
as a Guarantor

By: /s/John D. Boyle  
Name: John D. Boyle  
Title: A Manager

By: /s/Joost Tulkens  
Name: Joost Tulkens  
Title: B Manager

ENDO LUXEMBOURG FINANCE COMPANY II S.À R.L.  
as a Guarantor

By: /s/John D. Boyle  
Name: John D. Boyle  
Title: A Manager

By: /s/Joost Tulkens  
Name: Joost Tulkens  
Title: B Manager

PALADIN LABS CANADIAN HOLDING INC.  
as a Guarantor

By: /s/Mark Beudet  
Name: Mark Beudet  
Title: President

PALADIN LABS INC.  
as a Guarantor

By: /s/Mark Beudet  
Name: Mark Beudet  
Title: President

ENDO VENTURES BERMUDA LIMITED, as a  
Guarantor

By: /s/Susan Hall  
Name: Susan Hall  
Title: Director

ENDO GLOBAL VENTURES  
as a Guarantor

By: /s/Susan Hall  
Name: Susan Hall  
Title: Director

By: /s/Robert J. Cobuzzi  
Name: Robert J. Cobuzzi  
Title: Managing Director A

By: /s/Gert Jan Rietberg  
Name: Jan Rietberg  
Title: Managing Director B

ENDO VENTURES CYPRUS LIMITED  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

AUXILIUM UK LTD  
as a Guarantor

By: /s/Orla Dunlea  
Name: Orla Dunlea  
Title: Director

WELLS FARGO BANK, NATIONAL ASSOCIATION  
as a Guarantor

By: /s/Yana Kislenko  
Name: Yana Kislenko  
Title: Vice President



The confidential portions of this exhibit have been filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities and Exchange Act of 1934, as amended. REDACTED PORTIONS OF THIS EXHIBIT ARE MARKED BY AN

\*\*\*.

*Execution Copy*

AMENDED AND RESTATED LICENSE AND SUPPLY AGREEMENT

by and among

NOVARTIS, AG,

SANDOZ INC.

and

ENDO VENTURES LIMITED

Dated as of December 11, 2015

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## AMENDED AND RESTATED LICENSE AND SUPPLY AGREEMENT

THIS AMENDED AND RESTATED LICENSE AND SUPPLY AGREEMENT (this “Agreement”), dated as of December 11, 2015 (the “Execution Date”) and effective as of July 1, 2016 (the “Effective Date”), by and among NOVARTIS, AG, a Swiss corporation having a principal place of business in Basel, Switzerland (“NOVARTIS AG”), SANDOZ INC., a Delaware corporation having a principal place of business at 100 College Rd. West, Princeton, NJ 08540 (“SANDOZ,” and together with NOVARTIS AG, the “NOVARTIS Parties”) and ENDO VENTURES LIMITED, an Irish private company limited by shares having a principal place of business at First Floor, Minerva House, Simonscourt Road Ballsbridge, Dublin 4, Ireland (“ENDO”). Each of the NOVARTIS Parties and ENDO is referred to herein individually as a “Party” and collectively as the “Parties.”

WHEREAS, the NOVARTIS Parties have certain rights in the Territory in and to the Licensed Products;

WHEREAS, NOVARTIS AG, ENDO PHARMACEUTICALS INC., a Delaware corporation (“EPI”) and NOVARTIS Consumer Health, Inc., a Delaware corporation (“NCH”) entered into a certain License and Supply Agreement, dated as of March 4, 2008 (the “Original Agreement”) pursuant to which NCH granted a license to EPI to Commercialize the Branded Licensed Product for use in the Territory and in the Field on the terms and conditions set forth therein;

WHEREAS, NCH subsequently assigned its rights and obligations under the Original Agreement to SANDOZ pursuant to the terms of a certain letter agreement by and between NCH and SANDOZ, dated as of March 1, 2015;

WHEREAS, the current term of the Original Agreement is set to expire on June 30, 2016; and

WHEREAS, the Parties desire to have this Agreement supersede the Original Agreement as of the Effective Date in all respects.

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

### **SECTION 1** **DEFINITIONS**

Capitalized terms used in this Agreement, whether used in the singular or plural, except as otherwise expressly set forth herein, shall have the meanings set forth below:

- 1.1 “Accounting Standards” with respect to a Person shall mean that such Person shall maintain records and books of accounts in accordance with U.S. Generally Accepted Accounting Principles; provided, that with respect to the NOVARTIS Parties, Accounting Standards shall mean that it shall maintain records and books of accounts in accordance with IFRS (International Financial Reporting Standards).

- 1.2 “Act” shall mean the U.S. Food, Drug and Cosmetic Act, as amended from time to time (21 U.S.C. § 301 et seq.), together with any rules and regulations promulgated thereunder.
- 1.3 “Actual Royalties” shall have the meaning set forth in Section 6.1(d).
- 1.4 “Adverse Event” shall mean any untoward medical occurrence in a patient, consumer or clinical investigation subject associated with the use of the Licensed Products that does not necessarily have a causal relationship with this treatment. An Adverse Event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of any Licensed Product, whether or not related to such Licensed Product. In addition, all cases of apparent drug-drug interaction, pregnancy (with or without outcome), exposure during breastfeeding, paternal exposure, lack of efficacy, overdose, drug abuse and misuse, drug maladministration or accidental exposure and dispensing errors are collected and databased even if no Adverse Event has been reported.
- 1.5 “Affiliate” shall mean any Person who directly or indirectly controls or is controlled by or is under common control with a Party. For purposes of this definition, “control” or “controlled” shall mean ownership directly or through one or more Affiliates, of more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or more than fifty percent (50%) of the equity interests in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby a Party controls or has the right to control the Board of Directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity. For clarity, and without limiting the foregoing, ENDO acknowledges that Par Pharmaceutical Holdings Inc. (and any Affiliate of such Person) is an Affiliate of ENDO.
- 1.6 “Agreement” shall have the meaning set forth in the introductory paragraph.
- 1.7 “Agreement Quarter” shall mean, with respect to the first Agreement Quarter, the period beginning on the Effective Date and ending on the last day of the first full calendar quarter following the Effective Date, and each calendar quarter thereafter. For the purpose of clarity, the term “calendar quarter” refers to each three-month quarter in a calendar year (*i.e.*, January through March, April through June, July through September and October through December).
- 1.8 “Agreement Semester” shall mean each six (6) month period in an Agreement Year, with the first Agreement Semester consisting of the first two (2) Agreement Quarters of the Agreement Year and the second Agreement Semester consisting of the third (3rd) and fourth (4th) Agreement Quarters of the Agreement Year. Notwithstanding the foregoing, the first Agreement Semester shall commence on the Effective Date and end on December 31, 2016.
- 1.9 “Agreement Year” shall mean, with respect to the first Agreement Year, the period beginning on the Effective Date and ending on June 30, 2017, and with respect to each Agreement Year thereafter, the 12-month period ending on each anniversary of June 30, 2017, during the Term of this Agreement.



- 1.10 “Applicable Laws” shall mean the applicable provisions of any and all national, regional, provincial, territorial, state and local laws, treaties, statutes, rules, regulations, administrative codes, and ordinances, and any and all directives, and orders or administrative decisions of any Governmental Authority having jurisdiction over or related to the subject matter in question, including the PhRMA Code, the rules, regulations, guidelines and other requirements of OPDP regulatory requirements, HIPAA, and the FCPA and other Anti-Corruption Laws, which are applicable to the subject matter of this Agreement.
- 1.11 “Applicable Senior Officers” shall mean the Chief Executive Officer (or any designee thereof) of ENDO and the Vice President of Commercial Operations (or any designee thereof) of SANDOZ.
- 1.12 “Approval” shall mean any approval, registration, license or authorization from any Governmental Authority in any jurisdiction required for the manufacture, development, marketing, promotion, sale, storage or transport of a product in such jurisdiction.
- 1.13 “Approval Application” shall mean the submission to the relevant Governmental Authority of an appropriate application seeking any Approval.
- 1.14 “Audit Rights Holder” shall have the meaning set forth in Section 11.2(a).
- 1.15 “Audit Team” shall have the meaning set forth in Section 11.2(b).
- 1.16 “Auditee” shall have the meaning set forth in Section 11.2(a).
- 1.17 “Binding Forecast” shall have the meaning set forth in Section 4.5.
- 1.18 “Brand Fee” shall mean the annual fee for manufacturers and importers of branded prescription drugs payable by ENDO as a result of Section 9008 of the Patient Protection and Affordable Care Act of 2010 and any amendments thereto.
- 1.19 “Branded Binding Forecast” shall have the meaning set forth in Section 4.4.
- 1.20 “Branded Licensed Product” shall mean Voltaren<sup>®</sup> Gel (diclofenac sodium topical gel 1%) as approved by the FDA under the Licensed Product NDA for sale as an Rx Product in the Field in the Territory.
- 1.21 “Branded Rolling Forecast” shall have the meaning set forth in Section 4.4.
- 1.22 “Business Day” shall mean any day other than a Saturday, a Sunday or a day on which commercial banks in New York City are authorized or required by Law to remain closed.
- 1.23 “BTC Product” shall mean an OTC Product that has been approved by the FDA for sale to consumers without a prescription subject to the requirement that such product be placed “behind-the-counter” in the pharmacy and dispensed by a pharmacy employee.
- 1.24 “CMS” shall have the meaning set forth in Section 4.17(b).

- 1.25 “Commercialization Expenses” shall mean all direct and indirect expenses incurred or to be incurred in connection with Commercializing the Licensed Products in the Territory, including advertising and promotional expenses, field force expenses, MSL expenses, costs associated with Managed Markets activities, market research costs, distribution costs and submission fees payable to OPDP for review of Promotional Materials, to the extent such fees are now or hereafter payable pursuant to the Act or other Applicable Laws.
- 1.26 “Commercialize” shall mean to market, promote, distribute, offer to sell, sell and/or have sold a product and/or conduct other commercialization activities, and “Commercialization” means commercialization activities relating to a product, including activities relating to marketing, promoting, distributing, offering for sale, and/or selling of such product or having such product sold to trade, institutional, prescriber, payer, pharmacist and patient customers or otherwise.
- 1.27 “Confidential Information” shall mean all information or materials possessed or developed by any Party or their respective Affiliates, whether before or after the Effective Date, related to such Party’s or its Affiliates’ business, including the manufacture, Development and/or Commercialization of any pharmaceutical products hereunder, including any information or materials on substances, formulations, techniques, technology, equipment, data, reports, Know-How, sources for and methods of supply, patent position and business plans; provided, however, that Confidential Information shall not include information or material that (i) is already in the receiving Party’s or its Affiliate’s lawful possession at the time of disclosure by the disclosing Party, as established by relevant documentary evidence; (ii) is already in the public domain as of the Effective Date by reason of prior publication or otherwise; (iii) is received by a receiving Party or an Affiliate thereof on an unrestricted basis from a Third Party other than the disclosing Party, where such Third Party is authorized to disclose such information; (iv) becomes part of the public domain after the Effective Date through no act, omission or fault of the receiving Party; or (v) is similar in nature to the purported confidential information but which the receiving Party can demonstrate has been independently created, as established by relevant documentary evidence.
- 1.28 “Contingent Royalties” shall have the meaning forth in Section 6.1(c).
- 1.29 “Control” or “Controlled” shall mean with respect to any intellectual property right of a Person, that the Person owns or has a license to such intellectual property right and has the ability to grant access, a license, or a sublicense to such intellectual property right as provided for in this Agreement without violating an agreement with, or infringing any rights of, a Third Party.
- 1.30 “Corporate Names” shall have the meaning set forth in Section 10.1(a).
- 1.31 “CSO” shall mean a Third Party contract sales organization primarily engaged in providing sales representatives to promote and detail pharmaceutical products.
- 1.32 “Damages” shall have the meaning set forth in Section 14.1(a).
- 1.33 “DDR” shall have the meaning set forth in Section 4.17(b).

- 1.34 “Delivery Location” shall have the meaning set forth in Section 4.7(c).
- 1.35 “Develop” or “Development” shall mean development activities with respect to a pharmaceutical product, including pre-clinical research and development, clinical development (including Phase IV Clinical Studies), regulatory development, product approval and registration.
- 1.36 “Development Costs” shall mean direct and indirect costs and expenses incurred in connection with the Development of a pharmaceutical product, including the costs of clinical studies, the preparation, collation and/or validation of data from such clinical studies, preparation of medical writing and publishing and the preparation and filing of Approval Applications (including FDA user fees) and all other costs incurred in seeking Approvals with respect to the product. Without limitation of the foregoing, Development Costs shall include:
- (a) all Out-of-Pocket Costs incurred with respect to any of the foregoing;
  - (b) the direct and indirect costs of internal scientific, medical or technical regulatory personnel (including personnel expense, travel expenses and infrastructure costs) engaged in Development activities with respect to the product, which costs shall be determined based on the FTE Rate;
  - (c) the costs of clinical supply, including: (i) costs of clinical supplies; (ii) expenses incurred to purchase and/or package comparator drugs; and (iii) costs and expenses of the disposal of clinical samples; and
  - (d) the costs of identification, synthesis, qualification and/or validation of the drug substance.
- 1.37 “Development Plan” shall mean each Development plan for Development of the Licensed Products, as described in Sections 7.1(b) and 7.2, prepared by NOVARTIS AG or ENDO, as the case may be, and reviewed (and approved, in the case of a Development Plan submitted by ENDO, if required in Section 7.2) by the other Party.
- 1.38 “Disputed Product” shall have the meaning set forth in Section 4.10(c).
- 1.39 “DTC” shall have the meaning set forth in Section 3.7.
- 1.40 “Effective Date” shall have the meaning set forth in the introductory paragraph.
- 1.41 “ENDO” shall have the meaning set forth in the introductory paragraph.
- 1.42 “ENDO CIA” shall have the meaning set forth in Section 3.13.
- 1.43 “ENDO Expenses” shall mean ENDO’s expenses related to the sale, distribution (*e.g.*, chargeback processing, order fulfillment, shipping, warehousing and collection) and support for the Generic Licensed Product, which shall be calculated as \*\*\* of Net Sales.

- 1.44 “Execution Date” shall have the meaning set forth in the introductory paragraph.
- 1.45 “Facility” shall have the meaning set forth in Section 4.3.
- 1.46 “Failure of Supply” shall have the meaning set forth in Section 6.1(e)(i).
- 1.47 “FCPA” shall mean the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.) as amended.
- 1.48 “FDA” shall mean the United States Food and Drug Administration and any successor agency thereto.
- 1.49 “Field” shall mean use in the treatment of pain associated with osteoarthritis in joints amenable to topical treatment, subject to Sections 7.1(b) and (c).
- 1.50 “Firm Order” shall have the meaning set forth in Section 4.6(c).
- 1.51 “Force Majeure” shall have the meaning set forth in SECTION 15.
- 1.52 “FTE Rate” shall mean a rate of \$250,000 per annum for the time of a full-time equivalent person year.
- 1.53 “Generic Binding Forecast” shall have the meaning set forth in Section 4.5.
- 1.54 “Generic Diclofenac Product” shall mean, with the exception of any Generic Licensed Product, any diclofenac topical 1% Rx Product approved by the FDA for sale as an AB-rated generic version of the Branded Licensed Product or any other designation adopted by the FDA that allows such product to be fully substitutable for the Branded Licensed Product at the pharmacy level without additional approval of the prescriber.
- 1.55 “Generic Entry” shall mean the first Launch of a Generic Diclofenac Product by a Third Party.
- 1.56 “Generic Licensed Product” shall mean the authorized generic of the Branded Licensed Product, under the Licensed Product NDA and for sale as an Rx Product in the Field in the Territory.
- 1.57 “Generic Rolling Forecast” shall have the meaning set forth in Section 4.5.
- 1.58 “Generic Withdrawal Period” shall mean any period of time after the Launch of a Generic Entry where there is no Generic Entry available in commercial quantities to major retail chains, major pharmaceutical wholesalers and managed care providers in the Territory.
- 1.59 “Good Manufacturing Practices” or “GMP” or “GMP Requirements” shall mean current Good Manufacturing Practices as such term is defined from time to time by the FDA or other relevant Governmental Authority having jurisdiction over the manufacture or sale of the Licensed Products pursuant to its regulations, guidelines or otherwise.

- 1.60 “Governmental Authority” shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member, which has competent and binding authority to decide, mandate, regulate, enforce, or otherwise control the activities of the Parties or their Affiliates contemplated by this Agreement.
- 1.61 “Guaranteed Minimum Sales Royalties” shall have the meaning set forth in Section 6.1(b).
- 1.62 “Healthcare Professional” shall mean any member of the medical, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, purchase, supply or administer a medicinal product.
- 1.63 “HIPAA” shall mean the Health Insurance Portability and Accountability Act.
- 1.64 “Indemnified Party” shall have the meaning set forth in Section 14.1(a).
- 1.65 “Indemnifying Party” shall have the meaning set forth in Section 14.1(a).
- 1.66 “Initial Manufacturing Meeting Date” shall have the meaning set forth in Section 4.2.
- 1.67 “Initial Term” shall have the meaning set forth in Section 16.1(a).
- 1.68 “Know-How” shall mean unpatented and proprietary technical information, know-how, data, knowledge, techniques, discoveries, inventions, specifications, designs, clinical design and measurement, test results, regulatory filings and approvals, trade secrets and other information (whether or not patentable). As used in this definition, “unpatented” shall mean that the subject matter of such Know-How is not claimed in a Patent. As used in this definition, “Patent” shall not include pending, non-published patent applications.
- 1.69 “Launch” shall mean, with respect to a pharmaceutical product, the launch of such product for commercial sale in the Territory, with the date of Launch being the first date of commercial sale of such product in the Territory.
- 1.70 “Licensed Products” shall mean individually and collectively as the context may require, the Branded Licensed Product and the Generic Licensed Product.
- 1.71 “Licensed Product NDA” shall mean the NOVARTIS AG Voltaren<sup>®</sup> Gel NDA #22-122 as approved by the FDA on October 17, 2007, and any subsequent supplements or amendments related to the maintenance thereof.
- 1.72 “Licensed Product Warranties” shall have the meaning set forth in Section 4.10(a).
- 1.73 “Line Extension” shall have the meaning set forth in SECTION 9.
- 1.74 “Managed Markets” shall mean the segments of the U.S. Healthcare system for the Licensed Product composed of managed market entities and institutional customers (*e.g.*, pharmacy)

benefit managers, health plans, wholesale distributors, retail chains, long term care pharmacy providers, employers, the United States Government, and state and local governments).

- 1.75 “Managed Markets Information Service” shall mean MediMedia (or if MediMedia is no longer providing such reports, a similar Third Party information service mutually acceptable to the Parties); provided that, in the event that data reported by such service are the basis for triggering the right of ENDO to terminate this Agreement in accordance with Section 16.3(c), then SANDOZ shall have the right to request that such data be confirmed by IMS Plan Track or Fingerpoint Formulary (or if either of such entities is no longer providing such reports, a similar Third Party information service mutually acceptable to the Parties). In the event that the two information services do not agree as to whether there has been a decrease of twenty five percent (25%) or more in “covered lives,” a Third Party mutually designated by the Parties shall verify with the Managed Markets as to whether the Licensed Products are reimbursed. For the avoidance of doubt, if any such service is no longer providing the referenced reports such that a successor service is used, the number of “covered lives” in both periods being compared shall be those reported by the successor service.
- 1.76 “Manufacturing Plan for Authorized Generic” shall have the meaning set forth in Section 4.2.
- 1.77 “Material Adverse Effect” shall have the meaning set forth in Section 12.3(a).
- 1.78 “MSL” shall mean Medical Science Liaison.
- 1.79 “NCH” shall have the meaning set forth in the recitals hereto.
- 1.80 “NDA” shall mean a New Drug Application, as described in the FDA regulations, 21 CFR § 314.50, including all amendments and supplements to the application.
- 1.81 “Net Sales” with respect to a product shall mean the gross amount invoiced by or on behalf of a Party or its Affiliates, licensees or sublicensees for such product sold to Third Parties other than licensees or sublicensees, in bona fide, arm’s-length transactions, less the following deductions, determined in accordance with such Party’s standard accounting methods as generally and consistently applied by such Party, to the extent included in the gross invoiced sales price of the product or otherwise directly paid or incurred by such Party, its Affiliates, licensees or sublicensees acting on its behalf with respect to the sale of such product:
- (i) normal and customary trade and quantity discounts actually allowed and properly taken directly with respect to sales of the product;
  - (ii) amounts repaid or credited by reasons of defects, recalls, returns, rebates and allowances of goods or because of retroactive price reductions specifically identifiable to the product;
  - (iii) chargebacks, rebates (or the equivalent thereof) and other amounts paid on sale or dispensing of the product;

- (iv) rebates (or the equivalent thereof) and administrative fees paid to medical healthcare organizations, to group purchasing organizations or to trade customers in line with approved contract terms or other normal and customary understandings and arrangements;
- (v) amounts payable resulting from governmental (or agency thereof) mandated rebate programs or chargeback programs;
- (vi) tariffs, duties, excise, sales, value-added and other taxes (other than taxes based on income) and charges of Governmental Authorities;
- (vii) cash discounts for timely payment;
- (viii) rebates paid to wholesalers for inventory management programs;
- (ix) amounts repaid or credited or provisions made for uncollectible amounts on previously sold products; and
- (x) required distribution commissions/fees (such as fees related to services provided pursuant to distribution service agreements with major wholesalers) payable to any Third Party providing distribution services to such Party so long as such commissions/fees are consistent with the distribution commissions/fees payable in respect to other branded Rx Products commercialized by such Party;

all as determined in accordance with such Party's usual and customary accounting methods, which shall be in accordance with the Accounting Standards. Sales from a Party to its Affiliates, licensees or sublicensees shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are charged to Third Parties shall not be deducted from the invoice price in the calculation of Net Sales

Further:

- (a) In the case of any sale or other disposal of a product between or among a Party and its Affiliates, licensees and sublicensees, for resale, Net Sales shall be calculated as above only on the value charged or invoiced on the first arm's-length sale thereafter to a Third Party;
- (b) In the case of any sale which is not invoiced or is delivered before invoice, Net Sales shall be calculated at the time of shipment or when the product is paid for, if paid for before shipment or invoice; and
- (c) In the case of any sale or other disposal for value, such as barter or counter-trade, of any product, or part thereof, other than in an arm's-length transaction exclusively for money and excluding any patient assistance programs, Net Sales shall be calculated as above on the value of the non-cash consideration received or the fair market price (if higher) of the product in the country of sale or disposal.

- 1.82 “Notice of Rejection” shall have the meaning set forth in Section 4.10(b).
- 1.83 “NOVARTIS AG” shall have the meaning set forth in the introductory paragraph.
- 1.84 “NOVARTIS AG Know-How” shall mean all Know-How Controlled by NOVARTIS AG or its Affiliates that relates to the Licensed Products or the manufacture, use, Development or Commercialization thereof.
- 1.85 “NOVARTIS AG Patents” shall mean all Patents Controlled by NOVARTIS AG or its Affiliates which include at least one claim which would be infringed (or, in the case of a patent application, if issued, would be infringed) by the manufacture, use, Development or Commercialization of the Licensed Products.
- 1.86 “NOVARTIS AG Technology” shall mean the NOVARTIS AG Patents and NOVARTIS AG Know-How, except for the SANDOZ Technology.
- 1.87 “NOVARTIS Parties” shall have the meaning set forth in the introductory paragraph.
- 1.88 “NOVARTIS Profit Share” shall have the meaning set forth in Section 6.2.
- 1.89 “NSAID” shall mean a non-steroidal anti-inflammatory drug.
- 1.90 “OIG” shall mean the Office of the Inspector General.
- 1.91 “OPDP” shall mean the United States Office of Prescription Drug Program, formerly known as the United States Office of Medical Policy, Division of Drug Marketing, Advertising and Communications.
- 1.92 “Original Agreement” shall have the meaning set forth in the recitals hereto.
- 1.93 “OTC Equivalent Product” shall mean any diclofenac topical dispersible product approved by the FDA for sale in the Territory as an OTC Product, whether or not the Launch of such product results in the declassification of the Licensed Product as an Rx Product.
- 1.94 “OTC Launch Six Month Reference Period” shall mean the first six calendar months following the Launch on any OTC Equivalent Product.
- 1.95 “OTC Launch Three Month Reference Periods” shall mean either of the first two three-calendar month periods after the OTC Launch Six Month Reference Period.
- 1.96 “OTC Product” shall mean a pharmaceutical product for use in humans that has been approved by the FDA for sale to customers and/or patients in the Territory without a prescription. For the avoidance of doubt, a BTC Product shall constitute an OTC Product.
- 1.97 “OTC Switch” shall have the meaning set forth in Section 8.1.
- 1.98 “Out-of-Pocket Costs” shall mean direct expenses paid or payable to Third Parties and specifically identifiable as relating to and incurred to manufacture, Develop or Commercialize the Licensed Products.



- 1.99 “Party” shall have the meaning set forth in the introductory paragraph.
- 1.100 “Patents” shall mean (a) patents and patent applications (including provisional applications and applications for certificates of invention); (b) any patents issuing from such patent applications (including certificates of invention); (c) all patents and patent applications based on, corresponding to, or claiming the priority date(s) of any of the foregoing; (d) any reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; and (e) term extensions, supplementary protection certificates and the like.
- 1.101 “PDMA” shall mean the Prescription Drug Marketing Act of 1987, as amended, and the regulations promulgated thereunder.
- 1.102 “Person” shall mean and include an individual, partnership, joint venture, limited liability company, a corporation, a firm, a trust, an unincorporated organization and a government or other department or agency thereof.
- 1.103 “Pharmacovigilance Agreement” shall mean the Pharmacovigilance Agreement by and between the Parties.
- 1.104 “Phase IV Clinical Study” shall mean any post-marketing Approval clinical study, whether initiated by a Party or at the request of an applicable Governmental Authority, to delineate additional information about a drug’s risks, benefits, and optimal use, including safety surveillance studies, pharmacoeconomic studies, pharmacoepidemiology studies, studies relating to different dosing or schedules of administration, studies of the use of the drug in other patient populations or other stages of the disease, or studies of the use of the drug over a longer period of time.
- 1.105 “PhRMA Code” shall mean the PhRMA (Pharmaceutical Research and Manufacturers Association) Code on Interacting with Healthcare Professionals, as in effect from time to time. The current PhRMA Code is attached hereto as Schedule 1.105.
- 1.106 “PPI Adjusted Purchase Price” shall have the meaning set forth in Section 4.11(b)(i).
- 1.107 “Producer Price Index Figure” means the producer price index industry data figure for pharmaceutical preparations (PCU 2834) as published by the Bureau of Labor Statistics of the United States Department of Labor (Internet website address: <http://www.bls.gov/data/home.htm>).
- 1.108 “Product Brand Equity” shall mean Voltaren® brand essence, brand personality and brand look and feel used in advertising and promotion for the Branded Licensed Product as provided by NOVARTIS AG to ENDO on March 4, 2008 and as updated by NOVARTIS AG from time to time. Anything in this Agreement to the contrary notwithstanding, ENDO shall make changes in the manner it performs its obligations hereunder that are affected by updates in the Product Brand Equity as soon as commercially reasonable.
- 1.109 “Product Liability Claims” shall have the meaning set forth in Section 14.2(a).

- 1.110 “Product Trade Dress” shall mean the trade dress of the Branded Licensed Product and the Generic Licensed Product (if different from the Branded Licensed Product), including applicable color, palette and typeface.
- 1.111 “Product Trademark” shall mean the Voltaren<sup>®</sup> trademark, U.S. Registration No. 960282, the Man and Path design trademark, U.S. Trademark Application No. 77/258978, the JOY OF MOVEMENT TM, U.S. Trademark Application No. 77/053235, and any accompanying logos, Product Trade Dress and/or indicia of origin, including applicable branding, tagline and icon.
- 1.112 “Professional” shall mean a physician and other health care practitioner who is permitted under the Laws of the United States to prescribe the Licensed Products.
- 1.113 “Profits” shall mean, for any Agreement Quarter, Generic Licensed Product Net Sales less SANDOZ Costs for Generic Licensed Product sold, Brand Fee and ENDO Expenses during such Agreement Quarter, and shall not rely on the methods of determining profit under United States Generally Accepted Accounting Principles.
- 1.114 “Promotional Materials” shall have the meaning set forth in Section 3.4.
- 1.115 “Purchase Orders” shall mean an order from ENDO specifying requested delivery dates and quantities of the Licensed Products to be manufactured by or on behalf of SANDOZ.
- 1.116 “Recall Expenses” shall have the meaning set forth in Section 4.12(c)(ii).
- 1.117 “Rejected Products” shall have the meaning set forth in Section 4.10(b).
- 1.118 “Renewal Term” shall have the meaning set forth in Section 16.1(a).
- 1.119 “Representatives” shall mean, with respect to a Person, the employees, consultants, officers, directors, representatives and permitted sublicensees and subcontractors of such Person, including, in the case of ENDO, all CSOs, MSLs and field-based Managed Market personnel.
- 1.120 “Required Phase IV Clinical Studies” shall mean Phase IV Clinical Studies required by the FDA to be conducted as a condition to its Approval of the Licensed Product NDA.
- 1.121 “Rolling Forecast” shall have the meaning set forth in Section 4.5.
- 1.122 “Rx Product” shall mean a pharmaceutical product for use in humans that has been approved by the FDA for sale to customers and/or patients in the Territory with a prescription written by a Professional.
- 1.123 “Sales Representative” shall mean an individual, whether employed or engaged by ENDO, its Affiliates or Representatives, including a CSO, who engages in detailing and other promotional efforts with respect to the Licensed Products and who has been appropriately trained and equipped, in accordance with the terms of Sections 3.2 and 3.3, to make sales calls concerning the Licensed Products and its approved indications in accordance with this Agreement.

- 1.124 “SANDOZ” shall have the meaning set forth in the introductory paragraph.
- 1.125 “SANDOZ Costs” shall mean SANDOZ’s costs for procuring the Generic Licensed Product from SANDOZ’s manufacturer, as initially set forth on Schedule 4.11(a) hereto and subject to adjustment as provided in Section 4.11(b).
- 1.126 “SANDOZ License” shall mean the exclusive license granted to SANDOZ with respect to the Licensed Product NDA.
- 1.127 “SANDOZ Technology” shall mean the Licensed Product NDA and all clinical studies conducted by or on behalf of SANDOZ in support of the Licensed Product NDA.
- 1.128 “SANDOZ Warehouse” shall have the meaning set forth in Section 4.7(b).
- 1.129 “Specifications” shall mean the requirements and standards, including packaging requirements, for the Licensed Products as set forth on Schedule 4.3, as amended or supplemented from time to time by Law.
- 1.130 “Technology” shall mean Patents and Know-How.
- 1.131 “Term of this Agreement” or “Term” shall have the meaning set forth in Section 16.1(b).
- 1.132 “Territory” shall mean the United States.
- 1.133 “Third Party” shall mean any Person other than a Party or any Affiliate of a Party.
- 1.134 “United States” or “U.S.” shall mean the United States of America, its territories and possessions, including the Commonwealth of Puerto Rico.
- 1.135 “WAC” shall have the meaning set forth in Section 4.17(e).
- 1.136 Interpretation.
- (a) When used in this Agreement the words “include”, “includes” and “including” shall be deemed to be followed by the words “without limitation.”
  - (b) Any terms defined in the singular shall have a comparable meaning when used in the plural, and vice-versa.
  - (c) All references to recitals, Articles, Sections, Exhibits, Schedules and Appendices shall be deemed references to recitals, Articles, Sections, Exhibits, Schedules and Appendices to this Agreement.
  - (d) This Agreement shall be deemed drafted jointly by all the parties hereto and shall not be specifically construed against a Party hereto based on any claim that such Party or its counsel drafted this Agreement.

**SECTION 2**  
**GRANT**

- 2.1 **License.** Subject to the terms and conditions of this Agreement, the NOVARTIS Parties hereby grant to ENDO: (a) the exclusive (even as to the NOVARTIS Parties) right and license to Commercialize the Branded Licensed Product under the NOVARTIS AG Technology and the SANDOZ Technology and the Product Trademark in the Field in the Territory in accordance with this Agreement; and (b) subject to the remainder of this SECTION 2, the exclusive (even as to the NOVARTIS Parties) right and license to Commercialize the Generic Licensed Product under the NOVARTIS AG Technology and the SANDOZ Technology in the Field in the Territory in accordance with this Agreement. ENDO shall have the right to sublicense any of the foregoing rights solely to its Affiliates. ENDO and its Affiliates shall have sole control over the Commercialization of the Licensed Products for the Term of this Agreement and shall be responsible for paying all Commercialization Expenses in connection therewith. Except as expressly provided in this Agreement (such as ENDO's right to engage a CSO and sublicense its rights to Affiliates and have certain activities and obligations performed through its Affiliates), the rights and licenses granted to ENDO under this Agreement shall not be sublicensed, assigned or transferred to any non-Affiliate. Nothing in this Agreement shall prevent ENDO from performing any of its obligations hereunder or exercising any of its rights hereunder through Affiliates or subcontractors, except that ENDO may not subcontract its control over marketing of the Licensed Products to a Third Party subcontractor. ENDO shall remain responsible for performance of any obligations that it sublicenses or subcontracts, including to any ENDO Affiliates.
- 2.2 **Manufacturing & Launch of the Generic Licensed Product.**
- (a) Upon written notice from ENDO, ENDO and SANDOZ shall meet and confer regarding Development and manufacturing of a Generic Licensed Product, and shall negotiate in good faith and enter into a Manufacturing Plan for Authorized Generic in accordance with Section 4.2.
  - (b) Following the entering into the Manufacturing Plan for Authorized Generic pursuant to Section 2.2(a), the decision to authorize the Launch of a Generic Licensed Product is reserved to ENDO, exercised at its reasonable discretion, upon written notice to SANDOZ.
  - (c) Information provided by one Party to another Party under this Section 2.2 shall constitute Confidential Information of the disclosing Party.
- 2.3 **Compliance With Law.** Each of the Parties shall, and shall cause each of its Affiliates and respective Representatives to, perform its obligations under this Agreement in accordance with Applicable Law. No Party or any of its Affiliates shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any Applicable Law.
- 2.4 **Reservation of Rights; NOVARTIS AG Know-How.**

- (a) ENDO acknowledges that, notwithstanding any other provision of this Agreement, all rights of the NOVARTIS Parties and their respective Affiliates not specifically granted herein to ENDO or its Affiliates are expressly reserved to the NOVARTIS Parties or their respective Affiliates, as applicable. Without limiting the foregoing, in no event is ENDO or its Affiliates granted any rights or licenses to or with respect to any generic pharmaceutical product (other than the Generic Licensed Product), any OTC Product or any other diclofenac topical gel.
- (b) ENDO acknowledges and agrees that, notwithstanding the license grant in Section 2.1, neither NOVARTIS AG nor any Affiliate thereof shall be under any obligation to disclose to ENDO any NOVARTIS AG Know-How, including the Licensed Product NDA or any data therein, all of which shall constitute NOVARTIS AG Confidential Information.

2.5 Product Trade Dress and Domain Names Related to Licensed Product. All trademarks, trade dress, copyrights and domain names used in association with the Branded Licensed Product or otherwise created and used in association with the Generic Licensed Products shall remain the property of NOVARTIS AG and/or its Affiliates. Such intellectual property, and any such intellectual property that is confusingly similar to this intellectual property, shall not be used, applied-for or registered in the Territory by ENDO or its Affiliates. NOVARTIS AG shall have the sole discretion to determine the proper use of trademarks, Product Trade Dress, copyrights and domain names. Notwithstanding the foregoing: (a) in no event shall any trademarks, trade dress, copyrights or domain names used by ENDO or any of its Affiliates as of the Execution Date (other than the rights granted to ENDO under the Product Trademark hereunder) become the property of NOVARTIS AG (provided such trademarks, trade dress, copyrights or domain names are not confusingly similar to the current or past Product Trade Dress for the Branded Licensed Product); and (b) ENDO grants no license or any other right to NOVARTIS AG in any such trademarks, trade dress, copyrights or domain names.

### **SECTION 3**

#### **COMMERCIALIZATION**

3.1 Commercialization. ENDO shall be solely responsible to Commercialize the Branded Licensed Product under the Product Trademark, itself (or through its Affiliates) and, subject to Section 2.2, to Commercialize the Generic Licensed Product, in each case in the Field in the Territory during the Term of this Agreement. All Commercialization activities shall be conducted in accordance with the terms of this Agreement. Subject to the preceding sentence, ENDO shall (and shall require such Affiliates) to use commercially reasonable efforts to Commercialize the Licensed Products in the Territory. ENDO shall (itself and through its Affiliates) be solely responsible for all Commercialization Expenses relating to the Licensed Products.

3.2 Compliance with Laws.

- (a) Without limiting its other obligations hereunder, ENDO covenants and agrees to ensure that (A) no Sales Representative utilized by ENDO or an ENDO Affiliate

hereunder shall have been (1) convicted of an offense related to any federal or state health care program; (2) excluded or otherwise rendered ineligible for Federal or State health care program participation or (3) debarred under Subsection (a) or (b) of Section 306 of the Act, and (B) no Person on any FDA Clinical Investigator enforcement lists will participate in the Commercialization of the Licensed Products by or on behalf of ENDO or ENDO's Affiliates, including the following: (1) Disqualified/Totally Restricted List, (2) Restricted List and (3) Adequate Assurances List. ENDO further covenants that, if at any time it becomes aware that any Sales Representative who participated or is participating in the Commercialization of the Licensed Products is on, or is being added to, the FDA Debarment List or any FDA Clinical Investigator Enforcement Lists, ENDO will provide notice of this to SANDOZ within forty-eight (48) hours of its becoming aware of this fact and shall, subject to Applicable Law, immediately terminate such person from conducting any activity under this Agreement.

- (b) In connection with any activity under this Agreement, ENDO (and ENDO shall cause any ENDO Affiliates) and all Sales Representatives of ENDO or such ENDO Affiliates shall comply in all material respects with the Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, April 2003, PDMA, Applicable Laws governing the storage and distribution of pharmaceutical samples and aggregate spending on physician gifts, entertainment and expenses, the PhRMA Code, Sec. 1128B(b) of the Social Security Act, the AMA Guidelines on Gifts to Physicians from Industry, the Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, HIPAA and all other Applicable Laws.

### 3.3 Training.

- (a) ENDO shall (or ENDO shall cause an Affiliate to) be solely responsible for training the Sales Representatives in the detailing and promotion of the Licensed Products, at its expense (including the cost of training materials). All training materials will be developed by ENDO and its Affiliates and approved by the respective Parties.
- (b) As part of their overall training program, ENDO's Sales Representatives shall (and shall cause any ENDO Affiliates' Sales Representatives to) complete and comply with the Adverse Event reporting instructions provided by ENDO, a copy of which shall be provided to SANDOZ. Sales Representatives shall be trained by ENDO (itself or by its Affiliates) in connection with compliance with Applicable Law, including the requirements of Section 3.2(b), prior to engaging in promotion of the Licensed Products.

- 3.4 Promotional Materials. ENDO shall be responsible for developing and disseminating all promotional, advertising, communication and educational materials relating to the Commercialization of the Licensed Products hereunder (collectively, "Promotional Materials"). All Promotional Materials shall comply with Applicable Law and must comply with the Product Trademark, Product Brand Equity and NCH's Voltaren<sup>®</sup> gel style and branding guidelines that were sent to ENDO by NCH on March 4, 2008. As between the

NOVARTIS Parties and ENDO, but subject to Section 2.4, ENDO shall own all right, title, and interest in and to any such Promotional Materials, including applicable copyrights and trademarks. SANDOZ shall have the right to review all Promotional Materials. ENDO shall consider all comments of SANDOZ in good faith and SANDOZ shall have final approval rights with respect to matters involving Product Trademark or Product Brand Equity. However, creative concepts that are used in the advertising and promotion for the Licensed Products shall require approval of the Parties, and in the event the Parties do not agree, the concept that tests higher in Third Party concept-testing shall be the concept that is adopted; provided, that the Parties have jointly developed the concepts to be tested and have approved the action standards, such approval not to be unreasonably withheld or delayed. For the avoidance of doubt, neither SANDOZ nor any other of the NOVARTIS Parties shall be responsible for any Out-of-Pocket Costs incurred with respect to jointly developed creative concepts so long as any such costs incurred by or on behalf of SANDOZ have been reviewed and approved by ENDO before they are incurred. Further, no Promotional Materials to be submitted to OPDP under the Licensed Product NDA shall be used if NOVARTIS reasonably objects based on legal, medical or regulatory grounds. SANDOZ shall review and submit comments to Promotional Materials promptly. If the Parties reasonably disagree as to the approval or compliant execution of a Promotional Material, they shall convene the heads of regulatory, legal and compliance from each of SANDOZ and ENDO to conduct a joint executive review of the Promotional Material and to decide on the approval, rejection or otherwise of such Promotional Material. Unless otherwise subject to the aforementioned joint executive review and subject to the next sentence, if ENDO has not received comments within five (5) Business Days for Promotional Materials which, in the aggregate including all pieces under review at the same time, are under ten (10) pages in length or within ten (10) Business Days for longer Promotional Materials, such Promotional Materials will be deemed to have been approved by SANDOZ. All Promotional Materials shall be provided to SANDOZ sufficiently in advance of first use so as to enable it to file such materials with OPDP and otherwise comply with its reporting obligations.

- 3.5 Licensed Product Claims. ENDO shall not (and shall cause its Affiliates and Representatives, including Sales Representatives, not to) make any medical or promotional claim for the Licensed Products beyond the scope of the relevant Approval(s) then in effect in the Territory for the Licensed Products. ENDO may distribute information concerning the Licensed Products or their use, including scientific articles, reference publications and healthcare economic information, in accordance with Applicable Laws, including Section 401 of the FDA Modernization Act of 1997, and subject to regulatory review and approval by SANDOZ.
- 3.6 Use of Product Trade Dress for Generic Licensed Products. Subject to Section 2.5, ENDO and its Affiliates shall be permitted to use the Product Trade Dress in connection with the Commercialization of the Generic Licensed Product. Except for the rights granted in the prior sentence, ENDO shall not use any of the NOVARTIS Parties' trademarks, trade names or trade dress or any trademarks, trade names or trade dress which are confusingly similar to any of NOVARTIS Parties' trademarks, trade names or trade dress, in connection with the Commercialization of Generic Licensed Product. Following initial Launch of the

Generic Licensed Product, any changes to the Product Trade Dress, including label changes for the Generic Licensed Product, whether requested by the Parties or by any Governmental Authority, shall be at ENDO's sole cost and expense.

- 3.7 Direct-to-Consumer Advertising. During the Term of this Agreement, ENDO shall determine whether or not to develop direct-to-consumer advertising ("DTC") plans and the execution thereof. ENDO shall coordinate with SANDOZ regarding DTC advertising strategies and plans, but final decision-making authority and the cost and expense associated with such DTC advertising shall be borne by ENDO. For the avoidance of doubt, all Promotional Materials and use of Product Trademark and Product Brand Equity in connection with any DTC advertising shall be subject to approval by SANDOZ.
- 3.8 Medical Science Liaisons. ENDO or an Affiliate thereof shall provide and direct all activities of MSLs for the Licensed Products and shall bear all costs related to MSLs. All activities under this Section 3.8 shall comply with the SANDOZ MSL Guidance Document attached as Schedule 3.8
- 3.9 Managed Markets Field Activities; Costs. ENDO or an Affiliate thereof shall be solely responsible for all Managed Markets field activities for the Licensed Product in the Territory, at its sole cost and expense.
- 3.10 Call Centers. SANDOZ or an Affiliate thereof shall implement a call center for providing medical information services to hospitals, physicians, health care providers and patients. SANDOZ shall bear all costs related to the call center.
- 3.11 Pricing; Booking of Sales; Distribution; Diversion.
- (a) ENDO or an Affiliate thereof shall have the sole right and responsibility to determine pricing for Licensed Products sold in the Territory.
  - (b) ENDO or an Affiliate thereof shall have the sole right and responsibility to record, fill orders and perform related services (such as all aspects of order processing, invoicing and collection) for all sales of the Licensed Products in the Territory. Notwithstanding any other provision of this Agreement to the contrary, ENDO hereby agrees that it shall not include or bundle Licensed Products as part of a multiple product offering with any other products or services, except with the prior written consent of SANDOZ.
  - (c) ENDO shall have the sole right and responsibility to warehouse and distribute the Licensed Products.
  - (d) ENDO is prohibited from selling any topical gel product containing one percent (1%) diclofenac outside of the Territory. ENDO shall use commercially reasonable efforts to ensure that the Licensed Products are not sold to known diverters and SANDOZ shall use commercially reasonable efforts to ensure that any topical gel product containing one percent (1%) diclofenac that references the Licensed Product NDA or uses the Product Trademark (other than a Line Extension or any OTC Equivalent Product, subject to Section 8.1) is not sold to known diverters. In



furtherance of the foregoing, ENDO agrees to use procedures to prevent diversion of the Licensed Products, and SANDOZ agrees to use procedures to prevent diversion of any topical gel product containing one percent (1%) diclofenac that references the Licensed Product NDA or uses the Product Trademark (other than a Line Extension or any OTC Equivalent Product, subject to Section 8.1), in each case which are no less stringent than procedures generally used on their respective other products.

- 3.12 Commercialization Efforts. Excluding during a Failure of Supply, ENDO or an Affiliate thereof shall use commercially reasonable efforts to maintain levels of safety stock of Generic Licensed Product, if applicable, consistent with its own practices.
- 3.13 Compliance Program. ENDO shall maintain a compliance program that meets the requirements of all Applicable Laws, including but not limited to the 2003 OIG Compliance Program Manual for Pharmaceutical Manufacturers. ENDO represents that such compliance program shall include a written code of conduct, a disclosure program (to allow the anonymous reporting of potential misconduct) and field force monitoring and is designed to ensure compliance with FDA promotional requirements, Federal health care program requirements and the Corporate Integrity Agreement entered into by ENDO Pharmaceuticals Inc. on February 21, 2014 (“ENDO CIA”). ENDO represents that, as required by the ENDO CIA: (a) ENDO will subject the Licensed Products under the ENDO CIA, (b) ENDO will report to the OIG matters that it identifies as Reportable Events (as defined by the ENDO CIA) in accordance with the ENDO CIA (if such Reportable Events involve the Licensed Products, ENDO shall notify the Chief Compliance Officer of SANDOZ, in writing, within ten (10) business days of reporting such an Event to the OIG, including any investigation or mitigation plans); (c) ENDO’s Chief Compliance Officer and certain management personnel will submit certifications to the OIG ; and (d) ENDO will conduct risk assessment and mitigation planning (RAMP) on Government Reimbursed Products (as defined and required by the ENDO CIA), including the Licensed Products. To the extent ENDO provides SANDOZ with correspondence to the OIG related to a Reportable Event, SANDOZ will treat this information as strictly confidential and proprietary information subject to statutory protection under federal law. ENDO also shall provide to SANDOZ an annual report summarizing the compliance program status for the Licensed Products, including Reportable Events and any Reportable Events involving the Licensed Products under the ENDO CIA.
- 3.14 Pharmaceutical Samples. If ENDO chooses to conduct a direct-to-practitioner sampling program for the Licensed Products, ENDO represents and warrants that its sampling program is designed to comply with all Applicable Laws, including the PDMA, the ENDO CIA and all federal or state transparency reporting regulations. ENDO shall cooperate with SANDOZ to ensure appropriate reporting of samples under federal and state transparency regulations. ENDO shall provide SANDOZ with a copy of any report submitted to any federal or state government agency involving the provision of such samples, including reports on losses, diversions, theft and sample loss threshold (SLT) deviations.

**SECTION 4**  
**MANUFACTURE AND SUPPLY**

- 4.1 Engagement. During the Term and subject to the terms and conditions set forth herein, ENDO hereby agrees to purchase all of its requirements for Licensed Products from SANDOZ, and SANDOZ agrees to manufacture (or have manufactured on SANDOZ's behalf), supply and sell to ENDO, all of ENDO's orders for Licensed Products which ENDO submits to SANDOZ from time to time and which SANDOZ accepts in accordance with Section 4.5.
- 4.2 At-Risk Manufacture of Generic Licensed Product. In connection with any notice from ENDO to SANDOZ to commence Development and manufacturing of a Generic Licensed Product pursuant to Section 2.2, the NOVARTIS Parties promptly shall meet on a mutually agreed upon date (the "Initial Manufacturing Meeting Date") and shall confer and negotiate the terms and conditions of a "Manufacturing Plan for Authorized Generic" that sets forth their respective obligations with respect to the Development and manufacture of a sufficient initial quantity of Generic Licensed Product to have in inventory in anticipation of such product Launch. The Manufacturing Plan for Authorized Generic shall include details of (i) Development, including regulatory approvals, label changes, and other Product Trade Dress changes, if any, (ii) manufacturing requirements, manufacturing site, inventory requirements, and artwork and Product Trade Dress for finished goods, (iii) the lead time for the manufacture and delivery of finished goods with respect to such Generic Licensed Product, (iv) an allocation of manufacturing capacity between Branded Licensed Product and Generic Licensed Product, and (v) a good faith estimate of costs for such Development and manufacture. ENDO is responsible for costs and expenses of manufacture of such initial quantities of Generic Licensed Product. If ENDO and SANDOZ are unable to fully negotiate and execute the Manufacturing Plan for Authorized Generic within sixty (60) days after the Initial Manufacturing Meeting Date, then ENDO may submit orders for what it in good faith, reasonably believes to be the initial Launch quantities of Generic Licensed Product (and, in which instance, ENDO acknowledges that such orders for Generic Licensed Product shall reduce on a 1:1 basis the manufacturing capacity available to Branded Licensed Product, without such reduction being deemed a Failure of Supply) pursuant to Section 4.6 (except that the lead time for such initial Launch quantities shall be twenty (20) weeks after the approval of necessary artwork) and SANDOZ shall be obligated to fill such orders.
- 4.3 Warranty. All Licensed Products supplied by SANDOZ to ENDO hereunder shall, at the time they are delivered to the carrier by SANDOZ at the SANDOZ Warehouse (as defined in Section 4.6(b) below), (a) comply with the Specifications, (b) be consistent, as applicable, with the Licensed Product NDA, and (c) have been manufactured for SANDOZ in NOVARTIS AG's manufacturing facility in Wehr, Germany (the "Facility") in a manner compliant with GMP Requirements and all Applicable Laws, it being agreed and understood that SANDOZ may change the location of the Facility, at any time and from time to time, upon prior written notice to ENDO.
- 4.4 Forecasts; Maximum and Minimum Purchases – Branded Licensed Product. In order to assist SANDOZ in the planning of production runs for Branded Licensed Products, ENDO will, at least thirty (30) days in advance of the commencement of each calendar month during each Agreement Year, provide SANDOZ with a twenty-four (24) month (or such number of months remaining in the Term) rolling production forecast (the "Branded Rolling Forecast") of the quantities of Branded Licensed Products that ENDO estimates it will order

during such period. The Branded Rolling Forecast shall be updated by ENDO monthly by the tenth (10th) Business Day of the first month covered by the Branded Rolling Forecast. The first four (4) months (or such lesser number of months remaining in the Term) of each such Branded Rolling Forecast, as so updated, for Branded Licensed Products will be binding (the “Branded Binding Forecast”) on ENDO and SANDOZ, subject to the maximum supply capacity restrictions set forth in Section 4.6(a). ENDO shall purchase or pay for, in each case, in accordance with this Agreement, all Branded Licensed Products covered by each Branded Binding Forecast. The forecast for any month included within the Branded Binding Forecast may not be changed in any subsequent forecast without prior written SANDOZ approval. ENDO will forecast Branded Licensed Products by number of lots. Each forecast will be made by ENDO in good faith, taking into account reasonable projections of requirements for Branded Licensed Products. Notwithstanding the foregoing, for each Branded Binding Forecast, the aggregate forecasted quantities of Branded Licensed Products will not be more than the greater of (A) ten percent (10%) or (B) one (1) lot, over or under the forecasted amounts, as set forth in the immediately preceding Branded Binding Forecast delivered hereunder.

- 4.5 Forecasts; Maximum and Minimum Purchases – Generic Licensed Product. Upon ENDO’s notice (in accordance with Section 2.2) to Commercialize the Generic Licensed Product, and in order to assist SANDOZ in the planning of production runs for Generic Licensed Products, ENDO will, at least thirty (30) days in advance of the commencement of each calendar month during each Agreement Year, provide SANDOZ with a twenty-four (24) month (or such number of months remaining in the Term) rolling production forecast (the “Generic Rolling Forecast” and, together with the Branded Rolling Forecast, the “Rolling Forecasts”) of the quantities of Generic Licensed Products that ENDO estimates it will order during such period. The initial quantities of Generic Licensed Product included in the Generic Rolling Forecast shall be provided from the quantities manufactured and delivered pursuant to Section 4.2, after SANDOZ has provided a Certificate of Analysis (in the form attached hereto as Schedule 4.7(a)) with respect to such quantities. The Generic Rolling Forecast shall be updated by ENDO monthly by the tenth (10th) Business Day of the first month covered by the Generic Rolling Forecast. The first four (4) months (or such lesser number of months remaining in the Term) of each such Generic Rolling Forecast, as so updated, for Generic Licensed Products will be binding (the “Generic Binding Forecast” and, together with the Branded Binding Forecast, the “Binding Forecasts”) on ENDO and SANDOZ, subject to the maximum supply capacity restrictions set forth in Section 4.6(a). ENDO shall purchase or pay for, in each case, in accordance with this Agreement, all Generic Licensed Products covered by each Generic Binding Forecast. The forecast for any month included within the Generic Binding Forecast may not be changed in any subsequent forecast without prior written SANDOZ approval. ENDO will forecast Generic Licensed Products by number of lots. Each forecast will be made by ENDO in good faith, taking into account reasonable projections of requirements for Generic Licensed Products. Notwithstanding the foregoing, for each Generic Binding Forecast, the aggregate forecasted quantities of Generic Licensed Products will not be more than the greater of (A) ten percent (10%) or (B) one (1) lot, over or under the forecasted amounts, as set forth in the immediately preceding Generic Binding Forecast delivered hereunder.

#### 4.6 Orders.

- (a) Except to the extent the Parties may otherwise agree in writing with respect to a particular shipment, ENDO will place orders by way of written purchase orders for Licensed Products at least twelve (12) weeks in advance of ENDO's requested dates for delivery at the Delivery Location. Each purchase order will specifically refer to this Agreement and will specify the amount of Licensed Products ordered, the requested delivery date (subject to the immediately preceding sentence), the transportation method and carrier and any special instructions requested. The minimum size of any order of Licensed Products placed by ENDO will be one (1) lot and orders for Licensed Products will be in full lot increments and will specify presentation. SANDOZ shall promptly notify ENDO of any change in lot size. In addition, with respect to a given month, ENDO shall not, without SANDOZ's approval, submit purchase orders for Licensed Products that aggregate more than one (1) lot over the forecasted amounts for such month contained in the most recent Binding Forecast delivered hereunder, and, in any event, shall not submit orders for Licensed Products that exceed SANDOZ's maximum supply capacity unless prior written approval is received from SANDOZ. Upon written request from ENDO, SANDOZ shall provide an update of its maximum supply capacity (for both Branded Licensed Products and Generic Licensed Products separately and/or in the aggregate, as clearly identified by SANDOZ) to ENDO, from time to time (but not more than once per calendar year throughout the Term of the Agreement. ENDO shall not submit any purchase orders with respect to any month beyond the Term.
- (b) The purchase orders will be delivered to such location as SANDOZ designates in writing to ENDO from time to time. Each purchase order will be deemed received on the date that SANDOZ actually receives the relevant purchase order.
- (c) SANDOZ will accept all purchase orders that comply with this SECTION 4 and the applicable Binding Forecast. SANDOZ may reject any purchase order that does not comply with this SECTION 4 and the applicable Binding Forecast. Purchase orders will be accepted via formal written acknowledgement by SANDOZ to ENDO. Acknowledgment will be sent to ENDO within ten (10) Business Days from SANDOZ's receipt of the purchase order, if SANDOZ accepts the purchase order. If acknowledgment accepting the purchase order is not received by ENDO, SANDOZ and ENDO will cooperate in good faith to resolve promptly the issues that give rise to the basis for SANDOZ's rejection thereof. Any purchase order accepted by SANDOZ in accordance with the foregoing shall constitute a "Firm Order."
- (d) SANDOZ will supply Licensed Products pursuant to each Firm Order accepted in a timely manner, subject to Sections 4.6(a) and 4.8; provided, that each Firm Order will be deemed to have been fully satisfied, as to quantity, if the quantity of Licensed Products actually delivered to ENDO is equal to or greater than ninety percent (90%) of the quantity of Licensed Products set forth in the relevant Firm Order; provided further that SANDOZ will use commercially reasonable efforts to supply one hundred percent (100%) of the quantity of Licensed Products ordered.

- (e) ENDO shall not be required to take receipt at SANDOZ's Warehouse of a lot of Licensed Product with less than eighteen (18) months of expiry or eighty percent (80%) of the original shelf life (rounded up to the nearest whole month), whichever is greater; provided that ENDO and SANDOZ may nonetheless negotiate in good faith for ENDO to purchase any such lot.

#### 4.7 Delivery.

- (a) SANDOZ will supply Licensed Products to ENDO pursuant to Firm Orders placed by ENDO and accepted by SANDOZ, in each case, in accordance with the terms of this Agreement. Delivery dates as set forth in any Firm Order will be deemed to be estimated only until SANDOZ confirms acceptance of the order in writing in accordance with Section 4.6(c). SANDOZ shall deliver with each such shipment a Certificate of Analysis in the form attached hereto as Schedule 4.7(a), signed by an authorized employee of SANDOZ (or its manufacturing Affiliate) stating that the relevant shipment of Licensed Product meets the Specifications and other customary documentation, including a bill of lading and packing list.
- (b) The terms of delivery for the Licensed Products shall be Ex Works (Incoterms 2010) SANDOZ's approved warehousing facility located at Planzer Transport AG, Salinenstrasse 63A, 4133 PRATTELN, SWITZERLAND (the "SANDOZ Warehouse"), it being agreed and understood that SANDOZ may change the location of the SANDOZ Warehouse, at any time and from time to time, upon prior written notice to ENDO. No products of any Third Party shall be shipped with the Licensed Products.
- (c) ENDO will reimburse SANDOZ for all related freight, insurance charges, taxes, import and export duties, inspection fees and other charges applicable to the sale and transport of Licensed Product purchased by ENDO, as well as costs of transportation and loss of Licensed Product due to damage or destruction occurring at any time after the Licensed Product has been delivered to the common carrier mutually selected by the Parties at the SANDOZ Warehouse. SANDOZ will provide ENDO with an itemized list of charges. Upon receipt of the Licensed Product from SANDOZ, the designated common carrier, as licensee of ENDO with respect to delivery of the Licensed Product from the SANDOZ Warehouse to ENDO's designated distribution center in Memphis, Tennessee or other location designated by ENDO (the "Delivery Location"), shall conduct a visual inspection for any external physical damage to the goods delivered by SANDOZ before transport to the Delivery Location. Title to and risk of loss of or damage to Licensed Product shall remain with SANDOZ and pass to ENDO only upon delivery to the common carrier at the SANDOZ Warehouse. All shipments shall be accompanied by appropriate transportation and other agreed upon documentation.
- (d) All units of Licensed Product supplied to ENDO hereunder shall be properly prepared for safe and lawful shipment and shall be supplied in finished for sale form, which are sealed in sales unit packages and contained in outer shipping containers ready for sale. Any change in packaging for Licensed Product may be requested by ENDO,

and SANDOZ shall use its commercially reasonable efforts to accommodate the request, provided, that (i) any proposed packaging change shall comply with Applicable Law and SANDOZ standard operating procedures, as in effect and disclosed to ENDO from time to time, (ii) all Licensed Product packaged in existing packaging material is first purchased by ENDO prior to implementing any packaging change, and (iii) ENDO shall fully reimburse SANDOZ for all direct and indirect costs (including materials and labor) of implementing the packaging change, including the cost of obsolescence of existing stocks and raw materials, equipment and increased production costs going forward (within a budget that ENDO has previously reviewed and approved). Any change in packaging may be requested by SANDOZ (including changes requested by appropriate personnel in the SANDOZ Warehouse), subject to the approval of ENDO, such approval not to be unreasonably withheld or delayed and the cost of which will be borne by SANDOZ. Until new trade dress for the Licensed Product has been approved and can be reasonably implemented (as mutually agreed by the Parties pursuant to an implementation plan), ENDO will accept all of SANDOZ's inventory on hand and supply in production in their current trade dress.

4.8 Raw Materials. SANDOZ will be entitled to order sufficient quantities of long lead time components, including raw materials, to meet ENDO's Binding Forecasts. SANDOZ will use commercially reasonable efforts to order and obtain such long lead time components (raw materials) to enable it to manufacture and supply Licensed Products to ENDO pursuant to this Agreement. Any obsolescence costs and disposal fees occurring as the result of any Binding Forecast, labeling or packaging changes will be the responsibility of ENDO, except as provided in Section 4.6(e).

4.9 Standard of Performance. Notwithstanding anything else to the contrary contained in this Agreement, SANDOZ's obligation to supply Licensed Product in response to a Firm Order will be to use the same diligence in its efforts to manufacture and supply such Licensed Product to ENDO pursuant to this Agreement that SANDOZ uses to manufacture and supply like product for itself and its Affiliates.

4.10 Quality Assurance.

- (a) Non-Conforming Licensed Product. SANDOZ will, at its expense, arrange for all Licensed Product which does not comply with the warranties in Section 4.3 (the "Licensed Product Warranties") to be destroyed in accordance with Applicable Laws and SANDOZ policy. Notwithstanding any other provisions of this Agreement, ENDO agrees, if so requested by SANDOZ in writing, to return to SANDOZ, at SANDOZ's expense, any such Licensed Products.
- (b) Rejection of Delivered Licensed Product. Within twenty (20) days following delivery of Licensed Product to the Delivery Location in accordance with Section 4.7(c) above, ENDO may perform or cause to be performed such samplings and tests using validated and compendial test methods described in the Licensed Product NDA to determine whether Licensed Product meets the Specifications and the Licensed Product Warranties. Licensed Product may be rejected solely for failure to meet the

Specifications and Licensed Product Warranties, and/or for failure to meet the requirements set forth in Section 4.6(e), in each case, at the time of delivery to the common carrier at the SANDOZ Warehouse. Any Licensed Product not rejected by ENDO within such twenty (20) day period or, in the case of latent defects in the Licensed Product, within thirty (30) days from the date that ENDO actually discovers defects in the Licensed Product, will be deemed accepted by ENDO; provided that such time period shall be extended in the event ENDO had not timely received all necessary documentation related to the shipment of such Licensed Product and notifies SANDOZ. If ENDO wishes to reject Licensed Product (the "Rejected Products"), ENDO will (i) within such twenty (20) day period, notify SANDOZ in writing of its rejection of the Licensed Product and the reason therefor or (ii) within thirty (30) days from the date that ENDO actually discovers defects (in the case of latent defects) in the Licensed Product, notify SANDOZ in writing of its rejection of the Licensed Product and the reason therefor (each notice referred to in clause (i) and (ii), a "Notice of Rejection"). In the event that ENDO rejects delivery of Licensed Product, SANDOZ shall have thirty (30) days following receipt of a Notice of Rejection to confirm or object to such Notice of Rejection. In the event that SANDOZ confirms in writing (or is deemed to have confirmed by a failure to respond within such 30-day period) a Notice of Rejection, as ENDO's sole and exclusive remedy for such non-conforming product, SANDOZ will either replace the Rejected Products or pay over to ENDO the replacement cost of the Rejected Products (assuming that such Rejected Products had been fully conforming).

- (c) Disputed Products. If SANDOZ timely objects to a Notice of Rejection, an independent laboratory which is acceptable to both Parties will test the Rejected Products in dispute (the "Disputed Product") using the validated and compendial test methods set forth in the Licensed Product NDA and any other applicable GMP test method used by SANDOZ at the time the Disputed Product was manufactured, all of which test methods will be validated. If such laboratory finds that the Disputed Product meets the Specifications, ENDO will pay the fees of such laboratory related to such testing and validation of testing and will promptly pay for the Disputed Product and reimburse all amounts paid by SANDOZ to ENDO with respect to such Disputed Product pursuant to Section 4.10(b). If such laboratory finds that the Disputed Product fails to meet the Specifications, SANDOZ will pay the fees of such laboratory related to such testing and validation of testing and will promptly provide a refund or replace the Disputed Product in each case in accordance with Section 4.10(b) above. Both Parties agree to accept and be bound by the findings of such independent laboratory.

#### 4.11 Pricing and Payments.

(a) Prices.

- (i) The prices payable by ENDO for Branded Licensed Product purchased hereunder are set forth on Schedule 4.11(a) hereto and will be subject to adjustment as provided in Section 4.11(b).

- (ii) The prices payable by ENDO for Generic Licensed Product purchased hereunder are set forth on Schedule 4.11(a) hereto and will be subject to adjustment as provided in Section 4.11(b).
- (iii) Purchases of Branded Licensed Product and Generic Licensed Product shall be paid by ENDO within \*\*\* following the date of Licensed Product delivery and invoice by SANDOZ.

(b) Purchase Price Adjustments.

- (i) The prices for Licensed Products as set forth in Section 4.11(a) above will be modified at the commencement of each Agreement Year after Agreement Year 1 as set forth in this Section 4.11(b). The price for each Agreement Year after Agreement Year 1 will be determined by multiplying the applicable price set forth above by a fraction, the denominator of which will be the Producer Price Index Figure published on or nearest to January 1, 2016, and the numerator of which will be the Producer Price Index Figure published on or nearest to the first day of the Agreement Year for which the price is being determined (as so adjusted from time to time, the "PPI Adjusted Purchase Price").
- (ii) The PPI Adjusted Purchase Price shall be subject to increase in the event that SANDOZ experiences any documented increase of more than five percent (5%) in the cost of any raw materials (including active pharmaceutical ingredient), packaging or other Licensed Product components used in the manufacture of Licensed Product; provided, however, that the PPI Adjusted Purchase Price shall only be increased to the extent that raw material price increases exceed, in the aggregate, all increases in the Producer Price Index Figure since the Effective Date of the Agreement. Correspondingly, the PPI Adjusted Purchase Price shall be subject to decrease in order to reflect any change in production cost for Licensed Product as a result of the decrease of more than five percent (5%) in the cost of any raw materials (including active pharmaceutical ingredient), packaging or other Licensed Product components. SANDOZ shall, at ENDO's request, provide reasonable documentation evidencing such changes in production costs.
- (c) Taxes, etc. ENDO will bear the cost of any taxes, levies, duties or fees of a similar kind, nature or description whatsoever applicable to the sale and transportation of Licensed Product sold by SANDOZ to ENDO hereunder (other than taxes in the nature of franchise or income taxes of SANDOZ), and ENDO will pay to SANDOZ all such sums within thirty (30) days of receipt of demand for payment by SANDOZ.
- (d) Separate Sale. Each shipment of Licensed Product to ENDO will constitute a separate sale, obligating ENDO to pay therefor, whether said shipment is in whole or only partial fulfillment of any order or confirmation issued in connection therewith.

4.12 Regulatory Matters; Records.



- (a) Inspections. SANDOZ will be responsible for handling and responding to any FDA or other Governmental Entity audits or inspections with respect to the manufacture of Licensed Products hereunder. To the extent SANDOZ requires the assistance of ENDO in connection with any such audit or inspection, ENDO agrees to cooperate and assist SANDOZ.
- (b) Reporting. SANDOZ will be responsible for any reporting of matters regarding the manufacture of Licensed Product hereunder to the FDA or other Governmental Authority. SANDOZ will advise ENDO of any occurrences or information that arises out of the manufacturing activities of SANDOZ or its contractors that have or could reasonably be expected to have adverse regulatory compliance or reporting consequences concerning Licensed Product.

(c) Recalls.

- (i) Recalls. Each of the Parties agrees to maintain or cause to be maintained such traceability records as are necessary to permit a recall, withdrawal, field alert or field correction of any Licensed Product. In the event SANDOZ believes that it is required to initiate a recall, field alert, withdrawal or field correction with respect to any Licensed Product provided under this Agreement, SANDOZ will immediately notify ENDO in writing. In the event that ENDO believes that a recall, field alert, withdrawal, or field correction is necessary for Licensed Product provided under this Agreement, ENDO will immediately notify SANDOZ. Determination of a voluntary recall, field alert, withdrawal, or field correction shall be made by SANDOZ in its sole discretion following reasonable, in light of the circumstances, consultation with and consideration of ENDO's views.
- (ii) Cost of Recall. In the event that any Licensed Product supplied hereunder is recalled or quarantined, or is subject to stop-sale action, whether voluntary or by governmental action, it is agreed and understood that any expenses of such action, including administrative costs, reasonable fees of any experts or attorneys that may be utilized by either Party, and any government fines or penalties related to such recall, quarantine or stop-sale ("Recall Expenses") will be borne by the Party upon whose act or omission is the cause of the recall, quarantine or stop-sale action.

4.13 Alternate Supply. In the event that SANDOZ is unable to supply Licensed Products to ENDO in accordance with this SECTION 4, SANDOZ shall use commercially reasonable efforts to identify and qualify an alternate supplier capable of supplying Licensed Product on substantially the same terms and conditions set forth herein for the period that SANDOZ is unable to supply the Licensed Products. During any such period in which an alternate source of supply is being provided through a Third Party, SANDOZ's obligations under this SECTION 4 shall be suspended.

4.14 Allocation of Licensed Product. In the event that SANDOZ, subject to the terms and conditions of this Agreement, manufactures any 1% diclofenac gel product for use or

distribution outside of the Territory, and without limiting SANDOZ's obligations under this Agreement and ENDO's rights to enforce such obligations as set forth herein, in the event of a prospective shortage of capacity based on the then-current maximum supply capacity, SANDOZ shall use commercially reasonable efforts to cause its manufacturing Affiliate to reasonably allocate, based on historical and forecasted needs, quantities of all 1% diclofenac gel product among ENDO, SANDOZ, SANDOZ Affiliates and any other Person that has licensed any 1% diclofenac gel product from SANDOZ outside of the Territory.

- 4.15 Safety Stock. Except in the event of a Failure of Supply, ENDO shall maintain at the Delivery Location safety stock of Licensed Product in a minimum amount equal to twelve weeks of prospective customer demand based on the then-applicable Rolling Forecast, which amount may be adjusted from time to time upon the mutual written agreement of SANDOZ and ENDO based upon historical experience and performance.
- 4.16 Quality Agreement. Within ninety (90) days following the Effective Date, the Parties shall convene to review the current Quality Agreement between the Parties and amend or revise the agreement, as necessary, so as to cover the Generic Licensed Product. Notwithstanding any provision in this Agreement to the contrary, in no event shall SANDOZ be obligated to supply ENDO any Generic Licensed Product until the Quality Agreement has been amended or revised to include Generic Licensed Product.
- 4.17 Price Reporting and Related Government Contracting.
- (a) During the Term of the Agreement, with respect to price reporting of the Licensed Products, ENDO shall be solely responsible for (i) calculating and reporting prices for Licensed Products under the Medicaid Drug Rebate Program, as codified at 42 U.S.C. § 1396r-8, including making all decisions with respect thereto, in its discretion, and (ii) providing any related certifications to applicable Government Authorities, and (iii) reporting and compliance with all state Applicable Law requirements regarding price disclosure and reporting. ENDO shall not sell Licensed Products under the National Drug Code of SANDOZ. Neither SANDOZ nor ENDO shall have any responsibility or liability for decisions made or actions taken by the other Party under this Section 4.17(a). SANDOZ and ENDO shall each supply the other Party with any information reasonably requested by the other Party that is needed for such Party to perform its responsibilities under this Section 4.17(a).
- (b) CMS DDR Price Reporting. ENDO shall maintain responsibility for the Centers for Medicare & Medicaid Services' ("CMS") Drug Data Reporting ("DDR") system for the Licensed Products bearing an ENDO labeler code.
- (c) Public Health Service (PHS). ENDO shall have responsibility for all aspects of PHS contract pricing for the Licensed Products.
- (d) Federal Supply Schedule (FSS). ENDO shall have responsibility for all aspects of FSS pricing and non-Federal Average Manufacturer Price reporting for the Licensed Products.

- (e) Pricing Compendia. ENDO will be responsible for notifying the various pricing Compendia of the availability of Licensed Products and the Wholesale Acquisition Cost (“WAC”) pricing as established by ENDO for the Licensed Products. The applicable SANDOZ representative will be included in such notification and will communicate to the Compendia as necessary in order to grant ENDO the exclusive right to report and update the information for the Licensed Products.
- (f) Information provided by one Party to another Party under this Section 4.17 shall constitute Confidential Information of the disclosing Party.

## **SECTION 5**

### **REGULATORY AFFAIRS**

- 5.1 Regulatory Affairs. Notwithstanding any other provision of this Agreement, SANDOZ shall retain exclusive authority and responsibility for all interactions with Governmental Authorities and other Persons with regard to all regulatory matters relating to the Licensed Product, including (i) obtaining, maintaining and updating the Licensed Product NDA and product labeling as required by Applicable Law, including without limitation any supplementary filing or amendment necessary for ENDO to Commercialize the Generic Licensed Product, and (ii) obtaining, maintaining and updating all Approvals and other regulatory requirements required in order for ENDO to Commercialize the Branded Licensed Product and the Generic Licensed Product. Without limiting the foregoing, SANDOZ shall retain exclusive authority and responsibility for: (i) filing all supplement and Approval Applications and supporting documentation necessary for obtaining Approvals or otherwise complying with Applicable Law; (ii) all contacts with Governmental Authorities responsible for granting such Approvals; (iii) reporting of any adverse drug reactions to such Governmental Authorities; and (iv) controlling any disputes or legal proceedings regarding the regulatory status of the Licensed Product. SANDOZ shall promptly submit all applicable materials, including Promotional Materials, prepared or required to be prepared by ENDO to the OPDP. ENDO and its Affiliates shall cooperate and provide to SANDOZ and its Affiliates any assistance reasonably required by SANDOZ or its Affiliates in connection with its obligations under this Section 5.1.
- 5.2 Complaints Regarding Licensed Products. Licensed Product complaint reports received by ENDO which are not deemed to be an Adverse Event shall be reported to SANDOZ within thirty (30) days of receipt by ENDO. Licensed Product complaint reports received by either NOVARTIS Party which are not deemed to be an Adverse Event shall be reported to ENDO within thirty (30) days of receipt by such NOVARTIS Party. ENDO also will provide a written response on each complaint to each complainant with a simultaneous copy to SANDOZ to the extent such complaint relates to the manufacture of Licensed Product by SANDOZ hereunder, to the extent required by Applicable Law.
- 5.3 Adverse Event Reporting; Cooperation. ENDO agrees to provide to SANDOZ all reasonable assistance and take all actions reasonably requested by SANDOZ that are necessary to enable SANDOZ to comply with any Law applicable to the Licensed Product and any conditions or obligations relating to any Approval, including SANDOZ’s meeting of its reporting and other obligations under Section 5.1. Such assistance and actions shall include compliance

with the Pharmacovigilance Agreement. To the extent there is any conflict between the Adverse Event provisions in this Section 5.3 and the terms of the Pharmacovigilance Agreement, the terms of the Pharmacovigilance Agreement shall prevail.

ENDO shall forward to SANDOZ any information, including, but not limited to, initial and follow up reports, that becomes known to ENDO from any source in any form relating to any Adverse Event or any Adverse Event with an associated product quality complaint for the Licensed Product as soon as it becomes available, but in any event within twenty-four (24) hours of becoming aware of such information, by transmitting it to the Customer Relationship Center at 1-800-452-0051. The Customer Relationship Center is available 24 hours per day, 7 days per week.

ENDO shall notify the SANDOZ of any communication received from any Governmental Authority relating to any Adverse Event or other safety issue for any Licensed Product, within twenty-four (24) hours of receiving such communication, by transmitting any written communication documentation and a written synopsis of any oral communication to SANDOZ's head of Drug Safety.

5.4 Ownership. Notwithstanding any other provision of this Agreement, all Approval Applications and Approvals relating to the Licensed Products shall be owned by SANDOZ (directly or indirectly by a Third Party licensor to SANDOZ). As between the Parties, any such Approval Applications, Approvals, supporting documentation and data shall be treated by the Parties as Confidential Information of SANDOZ.

5.5 Regulatory Notification; Notification to ENDO of FDA Meetings. Each Party shall notify the other Parties promptly upon receiving any regulatory communication from the FDA or any other Governmental Authority, with respect to any: (i) substantial safety or efficacy issue with respect to any Licensed Product; (ii) advertising or promotional claims with respect to any Licensed Product; or (iii) labeling with respect to any Licensed Product. SANDOZ shall notify ENDO in the event that SANDOZ has any major meeting (such as an end of Phase II meeting) with the FDA with respect to obtaining OTC Equivalent Product approval in respect of the Licensed Products or the Development and/or Commercialization of any OTC Equivalent Product to a Licensed Product, conducting studies for new indications with respect to any Licensed Product, or Line Extensions in relation to any Licensed Product and/or Development and/or Commercialization of any Generic Diclofenac Product, or files for any Approval with respect to the foregoing.

## **SECTION 6**

### **COMPENSATION**

In addition to the other obligations of ENDO hereunder, ENDO shall pay the NOVARTIS Parties the amounts set forth in this SECTION 6 as consideration for the rights granted to ENDO under this Agreement.

6.1 Royalties.

- (a) Royalty Rates. ENDO shall pay royalties to the NOVARTIS Parties (as designated by SANDOZ) on annual Net Sales of Branded Licensed Product by ENDO, its Affiliates and their respective permitted sublicensees at the applicable rates set forth below.

<u>Aggregate Annual Net Sales of Branded Licensed Product during any Agreement Year</u>	<u>Royalty Rate</u>
The Portion of annual Net Sales less than \$200 million	15.0%
The Portion of annual Net Sales between \$200 million and \$300 million	20.0%
The Portion of annual Net Sales over \$300 million	25.0%

- (b) Guaranteed Minimum Sales Royalties. For so long as there has not been a Generic Entry, ENDO shall pay to the NOVARTIS Parties (as designated by SANDOZ) the following amounts as minimum royalties for the applicable Agreement Year (the "Guaranteed Minimum Sales Royalties"). The Guaranteed Minimum Sales Royalties shall be additive to the Contingent Royalties, not in lieu of such payments:

<u>Agreement Year</u>	<u>Amount</u>
Year 1	***
Year 2	***
Year 3	***
Year 4	***
Year 5	***
Year 6	***
Year 7	***
Each Renewal Term	***

Guaranteed Minimum Sales Royalties (but not Contingent Royalties) shall be applied against royalty payments on an Agreement Year basis such that ENDO's obligation with respect to each Agreement Year is to pay the greater of (i) royalties payable pursuant to Section 6.1(a) or (ii) the Guaranteed Minimum Sales Royalties for such Agreement Year. In furtherance thereof, with respect to each Agreement Quarter, ENDO shall pay the NOVARTIS Parties (as designated by SANDOZ) an amount equal to (A) the greater of (1) Section 6.1(a) royalties calculated on an Agreement Year-to-date basis or (2) the Guaranteed Minimum Sales Royalties for such Agreement Year-to-date period (applying 25% of the Guaranteed Minimum Sales Royalties for such Agreement Year to each Agreement Quarter) minus (B) all royalties (exclusive of Contingent Royalties) previously paid for that Agreement Year (or if such amount is a negative number, there will be no royalty payment due).

- (c) Contingent Royalties. For so long as there has not been a Generic Entry, ENDO shall pay to the NOVARTIS Parties (as designated by SANDOZ) the following amounts as additional annual royalty payments (“Contingent Royalties”). The Contingent Royalties shall be additive to the Guaranteed Minimum Sales Royalties, not in lieu of such payments:

<u>Agreement Year</u>	<u>Amount</u>
Year 1, Payable on the Effective Date (July 1, 2016)	***
Year 1, Payable within forty-five (45) days after the first Agreement Quarter (calendar Q3 2016) pursuant to Section 6.1(d)	***
Year 1, Payable within forty-five (45) days after the second Agreement Quarter (calendar Q4 2016) pursuant to Section 6.1(d)	***
Year 1, Payable within forty-five (45) days after the third Agreement Quarter (calendar Q1 2017) pursuant to Section 6.1(d)	***
Year 1, Payable within forty-five (45) days after the fourth Agreement Quarter (calendar Q2 2017) pursuant to Section 6.1(d)	***
Year 2, Payable within forty-five (45) days after the first Agreement Quarter (calendar Q3 2017) pursuant to Section 6.1(d)	***
Year 2, Payable within forty-five (45) days after the second Agreement Quarter (calendar Q4 2017) pursuant to Section 6.1(d)	***
Year 2, Payable within forty-five (45) days after the third Agreement Quarter (calendar Q1 2018) pursuant to Section 6.1(d)	***
Year 2, Payable within forty-five (45) days after the fourth Agreement Quarter (calendar Q2 2018) pursuant to Section 6.1(d)	***
Year 3, Payable within forty-five (45) days after the first Agreement Quarter (calendar Q3 2018) pursuant to Section 6.1(d)	***
Year 3, Payable within forty-five (45) days after the second Agreement Quarter (calendar Q4 2018) pursuant to Section 6.1(d)	***
Year 3, Payable within forty-five (45) days after the third Agreement Quarter (calendar Q1 2019) pursuant to Section 6.1(d)	***
Year 3, Payable within forty-five (45) days after the fourth Agreement Quarter (calendar Q2 2019) pursuant to Section 6.1(d)	***
Year 4, Payable within forty-five (45) days after the first Agreement Quarter (calendar Q3 2019) pursuant to Section 6.1(d)	***
Year 4, Payable within forty-five (45) days after the second Agreement Quarter (calendar Q4 2019) pursuant to Section 6.1(d)	***

- (d) Royalty Reports and Payments. Within forty-five (45) days after each Agreement Quarter during the Term of this Agreement, ENDO will provide to SANDOZ a written report showing each of: (a) the actual Net Sales of the Branded Licensed Product during such quarter by ENDO, its Affiliates and permitted sublicensees (including gross sales and deductions taken to calculate Net Sales), (b) the portion of the Guaranteed Minimum Sales Royalties applicable to such quarter, (c) the portion of the royalties which accrued under Section 6.1(a) with respect to such Net Sales (“Actual Royalties”) and the basis of calculating such Actual Royalties, (d) the portion of the Contingent Royalties applicable to such quarter, and (e) the further amount due in accordance with Section 6.2, if applicable, for such Agreement Quarter. Such report shall be accompanied by payment of all amounts owed for such Agreement Quarter in accordance with Section 6.1 and Section 6.2. If any error in the calculation of Net Sales in accordance with this Agreement or other adjustment, discount, credit or rebate in the calculation of Net Sales in accordance with this Agreement results in an adjustment (up or down) in the amount of royalties due, the amount of such adjustment shall be reflected in the next royalty payment; provided, that if this Agreement is no longer in effect, the applicable Party shall pay to the other Party the amount of such adjustment promptly following written notice thereof. ENDO shall notify SANDOZ within thirty (30) days after it agrees to any increase in distribution commissions/fees referred to in clause (x) of the definition of Net Sales in Section 1.81.
- (e) Certain Adjustments to Guaranteed Minimum Sales Royalties. The obligation to make Guaranteed Minimum Sales Royalty payments and Contingent Royalty payments is absolute and such payments shall be non-refundable, except as follows:
- (i) in the event of any failure of SANDOZ to fulfill Firm Orders for Branded Licensed Product in accordance with SECTION 4 resulting in a Branded Licensed Product “out of stock” such that ENDO has no inventory of Branded Licensed Product on hand in any of its distribution centers or in any of its warehouses for at least fourteen (14) consecutive days during any Agreement Year, provided, that for purposes of this Section 6.1(e)(i), Firm Orders shall be deemed fulfilled upon delivery of the applicable shipment of Branded Licensed Product to the designated common carrier at the SANDOZ Warehouse (“Failure of Supply”), and such out of stock is not attributable to a Force Majeure, then: (i) the Guaranteed Minimum Sales Royalties for such Agreement Year shall each be reduced by an amount equal to the result obtained by the following equation (A) the Guaranteed Minimum Sales Royalties, (B) divided by 365, with such quotient then multiplied by (C) two times the number of days during the Failure of Supply in excess of such fourteen (14) day period; and (ii) the Contingent Royalties otherwise payable for any Agreement Quarter during which a Failure of Supply has occurred shall each be reduced by an amount equal to the result obtained by the following equation (A) the Contingent Royalties payable for such Agreement Quarter, (B) divided by \*\*\*\*, with such quotient then multiplied by (C) \*\*\*\* the number of days during the Failure of Supply in excess of such fourteen

(14) day period. In order for SANDOZ to validate the occurrence of a Failure of Supply, ENDO shall provide to SANDOZ documentation evidencing such out of stock for fourteen consecutive days signed by ENDO's Applicable Senior Officer certifying the accuracy and completeness of such documentation;

- (ii) in the event a Failure of Supply continues for a period in excess of forty five (45) days, ENDO and SANDOZ shall meet as promptly as possible and attempt, in good faith, to agree on additional reductions to ENDO's future obligations hereunder, including Guaranteed Minimum Sales Royalties and Contingent Royalties to the extent necessary to appropriately reflect the impact on Net Sales of the Branded Licensed Product, if any, caused solely and directly by such Failure of Supply. In the event the Parties are unable to agree, the matter shall be resolved in accordance with the Third Party Dispute Resolution Procedures; and
- (iii) in the event of the Launch in the Territory by any Person (other than ENDO or its Affiliates) of: (1) a Generic Diclofenac Product; or (2) an OTC Equivalent Product to a Licensed Product, then in each case the obligation to pay Guaranteed Minimum Sales Royalties and the obligation to pay Contingent Royalties shall terminate for the remainder of the Term of the Agreement effective as of the date of such Launch, with the amount of Guaranteed Minimum Sales Royalties, and the obligation to pay Contingent Royalties, applicable to the portion of the Agreement Year in which such event occurs preceding such event being reduced on a pro-rated basis (based on the number of days preceding such event out of a 365-day year);
- (iv) in the event of the Launch in the Territory of any OTC Equivalent Product by any Third Party or by any Party who does not reference the Licensed Product NDA:
  - (1) the obligation to pay Guaranteed Minimum Sales Royalties shall be reduced by fifty percent (50%) for the remainder of the Term of the Agreement (except as set forth below) effective as of the date of such Launch;
  - (2) if at the expiration of the first six (6) months following the Launch of such OTC Equivalent Product, Net Sales of the Licensed Products have not declined by at least five percent (5%), as compared to Net Sales during the six (6) calendar months before such Launch, the obligation to pay Guaranteed Minimum Sales Royalties at the rates set forth in Section 6.1(b) shall be permanently (except as set forth below) restored and any reduced Guaranteed Minimum Sales Royalties paid by ENDO under clause (1) shall be paid to the NOVARTIS Parties (as designated by SANDOZ), if applicable, within 30 days;



- (3) if at the expiration of either of the first two back-to-back three (3) month periods (each, an “OTC Launch Three Month Reference Period”) immediately following the Launch of such OTC Equivalent Product, Net Sales of the Branded Licensed Product have declined, as compared to Net Sales of the Branded Licensed Product during the three calendar month period before such Launch, by twenty-five percent (25%) or more, or if at the last day of the OTC Launch Three Month Reference Period the number of “covered lives” eligible for third-party reimbursement in respect to purchases of Branded Licensed Product as referenced by the Managed Markets Information Service in its most recent report have declined by twenty-five percent (25%) or more as compared to the number of “covered lives” immediately prior to such Launch, ENDO shall no longer be obligated to pay any Guaranteed Minimum Sales Royalties for the remainder of the Term of the Agreement effective as of the end of the OTC Launch Three Month Reference Periods and ENDO shall not be obligated to repay any amount referred to in clause (2).

Except as expressly set forth in this Agreement, Guaranteed Minimum Sales Royalties and Contingent Royalties shall not be reduced, limited, recouped or credited for any reason.

- 6.2 Profits on Generic Licensed Product. In lieu of any royalties on the Generic Licensed Product (but with no effect on any royalties payable on the Branded Licensed Product), ENDO shall pay the NOVARTIS Parties (as designated by SANDOZ) Profits relating to Net Sales of the Generic Licensed Product for the remainder of the Term as follows: ENDO shall receive \*\*\* and the NOVARTIS Parties (as designated by SANDOZ) shall receive \*\*\* of all Profits resulting from sales of the Generic Licensed Product. Within 45 days after the end of each Agreement Quarter, or within 60 days after each Agreement Year-end, as applicable, ENDO shall deliver to the NOVARTIS Parties (as designated by SANDOZ): (i) a report setting forth (A) the actual Net Sales of the Generic Licensed Product by ENDO, its Affiliates and permitted sublicensees during the Agreement Quarter (including the gross sales and deductions taken to calculate Net Sales), and (B) the Profits for such Agreement Quarter, including a calculation of the NOVARTIS Parties’ share thereof which shall be \*\*\* of such Profits (the “NOVARTIS Profit Share”); and (ii) payment of the NOVARTIS Profit Share. To be clear, ENDO is responsible for 100% of any cost or expenses, and net losses, resulting from the sales of Generic Licensed Product, without any contribution hereunder by NOVARTIS or any of its Affiliates, even if the NOVARTIS Profit Share would otherwise be calculated as an amount less than zero dollars.
- 6.3 Sales Milestone. ENDO shall pay the NOVARTIS Parties (as designated by SANDOZ) a non-refundable, non-recoupable, non-creditable sales milestone of \$25,000,000 upon the first achievement of Agreement Year Net Sales in excess of \$300,000,000. The above sales milestone, if payable, shall be payable only once. If payable, payment of the above sales milestone shall be due to the NOVARTIS Parties (as designated by SANDOZ) within forty-five (45) days after the end of the Agreement Quarter in which the milestone was reached.

## SECTION 7

**DEVELOPMENT OF THE LICENSED PRODUCTS AND  
NEW INDICATIONS**

7.1 Development of Branded Licensed Product.

- (a) Branded Licensed Product Development. SANDOZ shall be solely responsible for all Development of the Branded Licensed Product, at its discretion, subject to Section 7.3. SANDOZ is under no obligation to conduct any Development of the Branded Licensed Product, other than Required Phase IV Clinical Studies. ENDO and its Affiliates shall not, directly or through any Third Party, initiate, sponsor, fund or otherwise conduct any clinical study or Development activities with respect to the Branded Licensed Product, except as otherwise permitted by this SECTION 7. ENDO shall cooperate and provide to SANDOZ any assistance reasonably required by SANDOZ in connection with Development of the Branded Licensed Product.
- (b) Development by ENDO. Notwithstanding Section 7.1(a), ENDO shall be entitled to conduct clinical studies with respect to the Branded Licensed Product, provided that it pays all Development Costs related thereto and conducts any such study in accordance with a Development Plan submitted for review and approval of SANDOZ. SANDOZ shall be entitled to reject any proposed clinical study if, among other reasons, such study may have an adverse impact on the Development or Commercialization of the Branded Licensed Product, any Line Extension, or any other new indication study. The Field shall be expanded to include any approved new indications for the Licensed Products in the Territory based on the results of such clinical studies. SANDOZ shall have full access and reference rights on an exclusive basis to clinical studies and related Technology to enable SANDOZ to effect an OTC Switch and to Commercialize the resulting OTC Product.
- (c) New Indications Developed by SANDOZ. In addition, in the event that SANDOZ proposes to Develop the Branded Licensed Product for use in an indication outside the Field and ENDO pays for the Development Costs incurred or to be incurred by or on behalf of SANDOZ in order to obtain FDA Approval for such new indication, then, upon Approval by the FDA of such new indication for the Branded Licensed Product, the Field shall be expanded to include such new indication, provided that SANDOZ shall have the OTC Switch rights with respect to the Branded Licensed Product for such new indication as set forth in SECTION 8 and full access rights to such results to enable SANDOZ to effect an OTC Switch. SANDOZ shall provide reasonable written notice to ENDO in the event that it determines to pursue any new indication for the Branded Licensed Product.

7.2 Development Plans; Clinical Studies. Prior to initiating any clinical studies of the Licensed Products in the Territory for which ENDO is obligated to provide funding pursuant to Section 7.1, SANDOZ shall submit a Development Plan for review and approval by ENDO. Thereafter, an updated Development Plan shall be submitted by SANDOZ to ENDO at least ninety (90) days prior to the beginning of each Agreement Year. Each Development Plan will incorporate a Development budget and will set forth the plan for the Development of the Licensed Products for use in the Territory for the applicable Agreement Year, including:

(a) costs and expenses to be incurred in connection with the Development of the Licensed Products; (b) clinical studies and regulatory plans for the Development of the Licensed Products; (c) protocols for, or description of studies related to, the Development of the Licensed Products; (d) quality control and quality assurance standards for the Development of the Licensed Products; and (e) standards for product safety and regulatory compliance in connection with the Development of the Licensed Products. For the avoidance of doubt, SANDOZ shall not be required to submit a Development Plan for any clinical studies that ENDO is not required to fund pursuant to Sections 7.1 or 7.3.

7.3 Development Costs.

(a) Development Costs incurred in connection with Development of the Branded Licensed Product shall be allocated between the Parties as follows:

	<b>ENDO</b>	<b>SANDOZ</b>
Required Phase IV Clinical Studies	100% up to Maximum Amount of \$5 million	100% of excess over Maximum Amount
Competitive Defense Study	100% up to Maximum Amount of \$6 million	100% of excess over Maximum Amount
Pediatric Exclusivity Study	100% up to Maximum Amount of \$4 million	100% of excess over Maximum Amount
Other clinical studies requested by the FDA for the Rx Product that SANDOZ elects to conduct	50%	50%
Other clinical studies initiated by SANDOZ not at the request of the FDA	0	100%
Clinical studies which are either initiated by ENDO or initiated by SANDOZ for which ENDO has agreed to pay for new indications for the Licensed Product	100%	0

(b) ENDO shall reimburse SANDOZ for Development Costs for which it is responsible in accordance with and subject to the foregoing allocations and limitations. For the purpose of clarity, SANDOZ shall be solely responsible for all Development Costs in excess of any relevant Maximum Amount set forth in Section 7.3(a). Except with respect to Required Phase IV Clinical Studies, for which SANDOZ will retain ultimate authority, and except as set forth below with respect to a Pediatric Exclusivity Study, ENDO shall have final decision-making authority as to whether any clinical study it is obligated to fund will be conducted; provided, that (i) SANDOZ shall have sole decision-making authority with respect to all other aspects of any such clinical study and (ii) once ENDO approves initiation of a clinical study, it shall not withdraw such approval. ENDO will pay for a Pediatric Exclusivity

Study if it receives confirmation in the form of a written FDA communication which identifies a pediatric study which can reasonably be conducted and submitted in sufficient time to obtain regulatory exclusivity for the Licensed Product.

**SECTION 8**  
**OTC SWITCH RIGHTS**

- 8.1 **OTC Switch of Licensed Product.** SANDOZ and/or its Affiliates shall have the exclusive right, at its sole discretion, to effect a switch of the Branded Licensed Product from an Rx Product to an OTC Product in the Territory (an “OTC Switch”) by filing an amendment or supplement to the Licensed Product NDA or taking any other action necessary or advisable in connection therewith to effect the OTC Switch, and thereafter to Commercialize such OTC Product. For the avoidance of doubt, an OTC Switch may be effected for one or more indications included in the Field from time to time. ENDO shall cooperate fully with SANDOZ in connection with an OTC Switch, including, providing any materials required by SANDOZ to support the OTC Switch. SANDOZ shall notify ENDO when it submits a filing to the FDA in respect of an OTC Equivalent Product to a Licensed Product.
- 8.2 **Royalty.** If, during the Term, GlaxoSmithKline Consumer Healthcare Holdings Limited or any of its Affiliates, directly or indirectly Launches an OTC Equivalent Product to the Licensed Product referencing the Licensed Product NDA in the Territory before the occurrence of either (a) any Person other than GlaxoSmithKline Consumer Healthcare Holdings Limited or its Affiliates Launching in the Territory an OTC Product version of a 1% diclofenac gel product, or (b) a Generic Entry, then, from the date of such Launch and for a five (5) year period thereafter, SANDOZ or its Affiliate will make quarterly royalty payments to ENDO on Net Sales of such OTC Equivalent Product in the Territory by GlaxoSmithKline Consumer Healthcare Holdings Limited or its Affiliates, at the rates set forth below, provided that, as a condition to the payment of any and all such royalties, Net Sales of the Licensed Product in the Territory shall have exceeded \$175,000,000 for the twelve (12) month period prior to the Launch of such OTC Equivalent Product by GlaxoSmithKline Consumer Healthcare Holdings Limited or its Affiliates, it being agreed and understood that the foregoing condition shall be deemed to have been satisfied if such Net Sales do not exceed \$175,000,000 as a result of any breach of this Agreement by any NOVARTIS Party, including, without limitation, a Failure of Supply resulting in such shortfall.

<u>Year Following Launch of the OTC Equivalent Product by SANDOZ</u>	<u>Royalty Rate</u>
1	5.0%
2	10.0%
3	15.0%
4	10.0%
5	5.0%

Notwithstanding any other provision hereof, ENDO shall not be entitled to any compensation with respect to the OTC Switch or OTC Equivalent Product except for the foregoing royalties, if applicable. For the avoidance of doubt, the above royalties shall be due and payable to ENDO (A) if such Launch causes the declassification of the Branded Licensed Product as an RX Product, or (B) if such Launch does not cause the declassification of the Branded Licensed Product as an RX Product, and (i) at the expiration of any of the first four calendar quarters after such Launch, Net Sales of the Branded Licensed Product for any such calendar quarter have declined, as compared to Net Sales during the three-calendar month period before such Launch, by \*\*\* or more, or (ii) at the expiration of any of the first four calendar quarters after such Launch, the number of “covered lives” eligible for third party reimbursement in respect to purchases of Branded Licensed Product as referenced by the Managed Markets Information Service in its most recent report have declined by \*\*\* or more as compared to the number of “covered lives” immediately prior to such Launch.

- 8.3 Right of First Negotiation on Certain ENDO Products. Prior to ENDO offering such rights to any Third Party, the Parties shall negotiate in good faith for a period of ninety (90) days from written notice by ENDO to SANDOZ with respect to the terms and conditions of a license or collaboration between the Parties on the marketing, promotion, distribution and/or sale in the Territory of Frova<sup>®</sup> or Lidoderm<sup>®</sup> as an OTC Product. If the Parties are unable to agree upon terms and conditions of such a license or collaboration on or before the expiration of such ninety (90) day period, then ENDO shall thereafter have the right to Develop and Commercialize itself or enter into a license or other collaboration with any Third Party with respect to such OTC Product and SANDOZ shall have no rights with respect thereto, provided that any license or collaboration that ENDO enters into or proposes to enter into within the 180 day period following the end of such negotiation period must be on terms and conditions in the aggregate no more favorable to such Third Party than those last offered to SANDOZ during the negotiation period, it being agreed and understood that after the expiration of such 180-period, this Section 8.3 shall no longer apply with regard to the product that was the subject of such proposed license or collaboration (*i.e.*, Frova<sup>®</sup> or Lidoderm<sup>®</sup>, as applicable). To be clear, the aforementioned rights of first negotiation are not triggered by SANDOZ (or its designee) approaching or presenting ENDO with a proposal to Develop or Commercialize such ENDO products, but by the written notice from ENDO as described above in this Section 8.3.

## **SECTION 9**

### **LINE EXTENSIONS**

For the purposes of this Agreement, the Licensed Products for new indications funded by SANDOZ without reimbursement from ENDO or any diclofenac topical dispersible product in formulations different from the Licensed Products or concentrations other than 1% to be Developed and Commercialized as an Rx Product, shall be deemed to be a “Line Extension.” SANDOZ retains all rights to research, Develop, and, subject to receipt of applicable Approvals, Commercialize Line Extensions inside and outside the Territory.

## **SECTION 10**

### **INTELLECTUAL PROPERTY**

#### 10.1 Corporate Names and Trademarks.

- (a) Each Party or its Affiliates, as applicable, shall retain all right, title and interest in and to its respective corporate name and logo and any other derivative or form thereof (collectively, "Corporate Names"), and each Party shall file, prosecute, and maintain legal protection for such Corporate Names at their own expense. Each Party shall have full control and authority over any claim, suit, or other proceeding relating to the Corporate Name of it or its Affiliates.
- (b) The Branded Licensed Product shall be promoted and sold in the Territory under the Product Trademark. Except as expressly set forth herein and subject to the rights reserved to ENDO and its Affiliates in Section 2.5, ENDO shall have no rights in or to the Product Trademark or the goodwill pertaining thereto or in any Product Trade Dress, trademark, tradename or goodwill in respect of the Generic Licensed Product. NOVARTIS AG (or its Affiliates, as applicable) shall own and retain all rights to association of trademark, trade dress, service marks, domain names, copyrights, or goodwill associated therewith, and all use of the Product Trademark and Product Trade Dress by ENDO and its Affiliates shall, at all times inure to the benefit of NOVARTIS AG (or its Affiliates, as applicable). ENDO shall utilize the Product Trademark only on Promotional Materials used for the purposes contemplated herein. ENDO agrees that upon termination or expiration of the Term of this Agreement, and the expiration of the time it is permitted to sell Licensed Products under Section 16.5(b), ENDO shall (and shall cause its Affiliates and permitted subcontractors to) discontinue forthwith all use of the Product Trademark. All uses by ENDO of the Product Trademark shall comply with this Agreement and Applicable Law.
- (c) NOVARTIS AG or an Affiliate thereof shall be solely responsible to maintain and enforce the Product Trade Dress and Product Trademark, and maintain the goodwill pertaining thereto, at NOVARTIS AG's expense.

10.2 Ownership and Rights with Respect to Newly Created Technology. All Technology relating to any Licensed Product created or Invented solely by SANDOZ and its Affiliates, solely by ENDO or its Affiliates or jointly by SANDOZ and ENDO or their respective Affiliates and resulting from activities under this Agreement shall be owned by SANDOZ or an Affiliate thereof; provided, that ENDO shall be entitled to use such Technology as set forth in SECTION 2.

10.3 Third-Party Infringement. If any Party believes that a Third Party is infringing the Product Trademark or any SANDOZ Technology in the Territory, such Party shall promptly notify the other Party hereto. At its sole discretion, SANDOZ (or its Affiliates, as appropriate) shall have the sole right and responsibility to conduct all Third Party infringement actions relating to the Product Trademark or any SANDOZ Technology in the Territory. The costs of any infringement action brought by SANDOZ (or its Affiliates) against a Third Party shall be borne by SANDOZ. ENDO and its Affiliates shall assist SANDOZ and its Affiliates at its expense and cooperate in any such infringement litigation, including actions in federal court, state court and the U.S. Patent and Trademark Office, at SANDOZ's (or its Affiliates')

reasonable request. Any Damages obtained as a result of any such action and any funds received as part of a settlement of any such action shall first be allocated in a proportional manner to the litigation expenses of each Party, and SANDOZ shall receive any amount remaining after such expenses are reimbursed.

## SECTION 11

### **BOOKS AND RECORDS;**

### **AUDITS; TAXES; PAYMENT CURRENCY; AND OTHER TERMS**

- 11.1 **Books and Records.** The Parties shall, and shall cause each of their respective Affiliates to, keep complete, true and accurate books and records in accordance with the defined Accounting Standards. The Parties will keep such books and records for at least three (3) years following the end of the Agreement Year to which they pertain. Such books of accounts shall be kept at the Party's principal place of business. Each Party shall, and shall cause each of its respective Affiliates to, permit auditors, as provided in Section 11.2, to visit and inspect, during regular business hours and under the guidance of officers of the Party being inspected, and to examine the books of account of such Party or such Affiliate and discuss the affairs, finances and accounts of such Party or such Affiliate with, and be advised as to the same by, its and their officers and independent accountants.
- 11.2 **Audits.** The Parties shall have audit rights as described in this Section 11.2; provided, that audits may only be conducted for the purpose of determining or reconciling calculations made in respect of (i) Net Sales; (ii) Development Costs (to the extent that ENDO is funding such costs), or (iii) Manufacturing costs related to adjustments in the price of the Licensed Product under Section 4.10(b).
- (a) For the purposes of the audit rights described in this Section 11.2, the Party subject to an audit in any given year will be referred to as the "Auditee" and the other Party who has audit rights will be referred to as the "Audit Rights Holder."
  - (b) Each Party may, upon request and at its expense (except as provided for herein), cause an internationally-recognized independent accounting firm selected by it, other than one to whom the Auditee has a reasonable objection (the "Audit Team"), to audit during ordinary business hours the books and records of the Auditee and the correctness of any payment made or required to be made to or by such Auditee, and any report underlying such payment (or lack thereof), pursuant to the terms of this Agreement. Prior to commencing its work pursuant to this Agreement, the Audit Team shall enter into an appropriate confidentiality agreement with the Auditee.
  - (c) In respect of each audit of the Auditee's books and records: (i) the Auditee may only be audited once per calendar year, unless a prior audit reveals any material discrepancy, in which case, more frequent audits will be permitted; (ii) no records for any given Agreement Year may be audited more than once for the same purpose, unless a prior audit reveals any material discrepancy, in which case, more frequent audits will be permitted; and (iii) the Audit Rights Holder shall only be entitled to audit books and records of the Auditee from the three (3) Agreement Years prior to the Agreement Year in which the audit request is made.

- (d) In order to initiate an audit for a particular Agreement Year, the Audit Rights Holder must provide written notice to the Auditee. The Audit Rights Holder shall provide the Auditee with notice of one or more proposed dates of the audit not less than forty-five (45) calendar days prior to the first proposed date. The Auditee will reasonably accommodate the scheduling of such audit. The Auditee shall reasonably cooperate with such audit.
- (e) The audit report and basis for any determination by an Audit Team shall be made available for review and comment by the Auditee, and the Auditee shall have the right, at its expense, to request a further determination by such Audit Team as to matters which the Auditee disputes (to be completed no more than thirty (30) calendar days after the first determination is provided to such Auditee and to be limited to the disputed matters). If the Parties disagree as to such further determination, the Audit Rights Holder and the Auditee shall mutually select an internationally-recognized independent accounting firm that shall make a final determination as to the remaining matters in dispute that shall be binding upon the Parties.

If the audit shows any under-reporting or underpayment, or overcharging by any Party, that under-reporting, underpayment or overcharging shall be reported to the Audit Rights Holder and the underpaying or overcharging Party shall remit such underpayment or reimburse such overcompensation to the underpaid or overcharged Party within thirty (30) calendar days of receiving the audit report. Further, if the audit for an Agreement Year shows an under-reporting or underpayment or an overcharge by any Party for that period in excess of ten percent (10%) of the amounts properly determined, the underpaying or overcharging Party, as the case may be, shall reimburse the applicable underpaid or overcharged Party, for its respective audit fees and reasonable out-of-pocket expenses in connection with said audit, which reimbursement shall be made within thirty (30) calendar days of receiving appropriate invoices and other support for such audit-related costs.

- 11.3 Accounting Standards. All costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with Accounting Standards, as generally and consistently applied by the Parties.
- 11.4 Taxes. Any withholding or other taxes that either Party or its Affiliates are required by Law to withhold or pay on behalf of the other Party, with respect to any payments to it hereunder, shall be deducted from such payments and paid to the applicable Governmental Authority contemporaneously with the remittance to the other Party; provided, however, that the withholding Party shall furnish the other Party with proper evidence of the taxes so paid. Each Party shall furnish the other Party with appropriate documents to secure application of the most favorable rate of withholding tax under Applicable Law.
- 11.5 Payment Currency. All amounts due under this Agreement shall be paid to the designated Party in United States Dollars.
- 11.6 Payments. The Parties agree that, unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, amounts due by one Party to the other shall be payable by wire transfer of immediately available funds in United States dollars within thirty (30)



days after receipt of the corresponding statement or invoice to a bank account, details of which are to be communicated by the receiving party. If a Party fails to pay any invoiced amount when due, interest may be charged by the other Party equal to the lesser of one percent (1%) or the highest rate permitted by Applicable Law on the outstanding amount for each month or portion thereof that such amount is overdue.

## **SECTION 12**

### **REPRESENTATIONS AND WARRANTIES**

- 12.1 **Mutual Representations and Warranties.** Each of the NOVARTIS Parties, severally and not jointly, and ENDO represents and warrants to the other as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement; (c) the execution and delivery by it of this Agreement and the performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other material agreement or arrangement by which it is bound; (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof, except as such enforcement may be limited by (i) bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting the rights and remedies of creditors and (ii) general principles of equity (regardless of whether such enforcement is considered in a proceeding in equity or at law); and (e) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf.
- 12.2 **Representations and Warranties of ENDO.** ENDO represents and warrants to the NOVARTIS Parties as follows:
- (a) ENDO is not insolvent and will not be insolvent as a result of, or immediately following, execution of this Agreement, under any bankruptcy, receivership or insolvency law, and has been paying its debts as they become due and within vendor terms, in all material respects;
  - (b) ENDO has or will have cash available in sufficient amounts so as to enable it to satisfy its payment obligations hereunder as and when they become due; and
  - (c) neither ENDO nor any of its Affiliates, nor, to ENDO's knowledge, any of their respective officers, directors, employees or agents has been (i) convicted of an offense related to any federal or state health care program; (ii) excluded or otherwise rendered ineligible for Federal or State health care program participation; (iii) debarred under Subsection (a) or (b) of Section 306 of the Act or (iv) debarred by the FDA under the provisions of the Generic Drug Enforcement Act of 1992, as amended, or any other Applicable Laws.
- 12.3 **Representations and Warranties of the NOVARTIS Parties.** Each of the NOVARTIS Parties, severally and not jointly, represents and warrants to ENDO as follows:

- (a) NOVARTIS AG is the owner of, or has exclusive rights to, the Product Trademark and SANDOZ has the exclusive license to the Licensed Product NDA for purposes of Commercializing the Branded Licensed Product, in each case free and clear of liens and encumbrances that would reasonably be expected to have a material adverse effect on the rights granted to ENDO under this Agreement (a "Material Adverse Effect"). The NOVARTIS Parties have not granted rights in the Product Trademark or the Licensed Product NDA to any Third Party which are inconsistent with the rights granted to ENDO under this Agreement or would have a Material Adverse Effect;
- (b) As of the Effective Date, the SANDOZ License is still in full force and effect and SANDOZ has not granted rights in the Licensed Product NDA to any Third Party which are inconsistent with the terms of this Agreement or which would have a Material Adverse Effect on ENDO;
- (c) To the knowledge of the NOVARTIS Parties, each facility owned or controlled by any of the NOVARTIS Parties or any of their respective Affiliates and currently used in the manufacture of the Licensed Products is in compliance with all Applicable Laws, except for any non-compliance that would not reasonably be expected to have a Material Adverse Effect;
- (d) Neither of the NOVARTIS Parties has received any written claims challenging the ownership, validity or scope of the Product Trademark or the Licensed Product NDA or any other SANDOZ Technology that would reasonably be expected to have a Material Adverse Effect. To the knowledge of the NOVARTIS Parties, no Person has any intellectual property rights in the Territory that would reasonably be expected to prevent the NOVARTIS Parties or ENDO from performing its obligations hereunder in accordance with this Agreement, in either case, in any material respect;
- (e) The NOVARTIS Parties will not create, incur, or permit to exist on or to the Product Trademark or the Licensed Product NDA any lien or claim, in each case that would reasonably be expected to have a Material Adverse Effect;
- (f) SANDOZ has provided ENDO, or given ENDO access to, true and complete paper or electronic copies of the Licensed Product NDA and material FDA correspondence relating to the Licensed Product NDA, provided that any information relating to the clinical programs for the Licensed Products was not disclosed or was redacted. (ii) In Developing the Licensed Products, to its knowledge, SANDOZ has not misappropriated any trade secret of any Third Party which misappropriation would reasonably be expected to have a Material Adverse Effect; and
- (g) Each of the NOVARTIS Parties must comply, and must cause its employees and subcontractors to comply, with all Applicable Laws in its performance of activities contemplated under this Agreement.

12.4 **DISCLAIMER OF WARRANTIES.** EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NO PARTY HERETO MAKES ANY, AND EACH PARTY HERETO

HEREBY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS, GUARANTEES, OR WARRANTIES, IMPLIED, STATUTORY OR OTHERWISE, IN CONNECTION WITH THIS AGREEMENT, THE LICENSED PRODUCTS (INCLUDING THE SAFETY OR EFFICACY THEREOF) OR OTHERWISE WITH RESPECT TO THE SUBJECT MATTER HEREOF, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, NON-INFRINGEMENT OR COVERAGE OF ANY PRODUCT BY OR VALIDITY OF ANY PATENTS, AND ANY AND ALL WARRANTIES THAT MAY ARISE OUT OF COURSE OF DEALING, COURSE OF PERFORMANCE, OR USAGE OF TRADE. EXCEPT AS SET FORTH IN SECTION 12.3(f) ABOVE, NEITHER SANDOZ, ITS AFFILIATES NOR ANY OTHER PERSON SHALL HAVE OR BE SUBJECT TO ANY LIABILITY TO ENDO OR ANY OTHER PERSON RESULTING FROM THE DISTRIBUTION TO ENDO, OR ENDO'S USE OF, ANY INFORMATION, DOCUMENTS OR MATERIALS MADE AVAILABLE TO ENDO IN ANY "DATA ROOMS", MANAGEMENT PRESENTATIONS OR IN ANY OTHER FORM IN EXPECTATION OF THE TRANSACTIONS CONTEMPLATED HEREBY.

### **SECTION 13** **CONFIDENTIALITY**

- 13.1 **Confidential Information.** Each Party acknowledges that all Confidential Information provided by another Party or its respective Affiliates is confidential or proprietary to such other Party or its respective Affiliates and agrees to (i) maintain such information in confidence during the Term of this Agreement and for a period of five (5) years thereafter and (ii) use such information solely for the purpose of performing its respective obligations hereunder. Each of the NOVARTIS Parties and ENDO covenants that neither it nor any of its respective Affiliates shall disclose any such information except to its or its Affiliates' Representatives or GlaxoSmithKline Consumer Healthcare Holdings Limited, solely for purposes of performing its obligations under this Agreement; provided, that such Representatives and GlaxoSmithKline Consumer Healthcare Holdings Limited are subject to substantially the same confidentiality obligations as the Parties hereunder. The foregoing confidentiality obligations shall not apply to Confidential Information which is required to be disclosed to a Governmental Authority by Applicable Law, in which case the disclosing Party shall promptly notify the other Party of such disclosure and the procedures, such as a protective order, instituted to protect the confidentiality of the Confidential Information to be disclosed.
- 13.2 **Injunctive Relief.** Each Party acknowledges that damages resulting from disclosure of the Confidential Information will be an inadequate remedy and that, in the event of any such disclosure or any indication of an intent to disclose such information, a Party (or its Affiliates) owning such information will be entitled to injunctive relief or other equitable relief in addition to any and all remedies available at law or in equity, including the recovery of damages and reasonable attorneys' fees.
- 13.3 **Publicity.** ENDO agrees not to issue any press releases or other non-promotion related written communications to the media, including question and answer documents and standby statements, concerning this Agreement without the prior written consent of SANDOZ to the

form, timing and content of any such release or other non-promotion related written communication except as set forth below; provided, that SANDOZ shall have sole approval of all scientific publications, subject to the right of ENDO to review and provide comments with respect to any such publications, which SANDOZ shall consider in good faith. ENDO shall provide SANDOZ a reasonable opportunity (but no less than seventy-two (72) hours, except as required by Law) to review such press release or other non-promotion related written communication in order to provide its consent, which consent shall not be unreasonably withheld or delayed. SANDOZ shall provide ENDO a reasonable opportunity (but no less than seventy-two (72) hours, except as required by Law) to review any press release or other non-promotion related written communications to the media to be issued or made by SANDOZ with respect to this Agreement or the promotion of the Licensed Product in the Territory in order for ENDO to provide its comments with respect thereto, which will be considered by SANDOZ in good faith but with no obligation on the part of SANDOZ to accept. Except as required by Law or by the rules of a nationally recognized stock exchange, neither Party (nor their respective Affiliates) shall disclose to any Third Party, under any circumstances, any terms of this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld. In the event a disclosure is required by Law or by the rules of a nationally recognized stock exchange, the Parties shall coordinate with each other with respect to the timing, form and content of such required disclosure. In the event the Parties are unable to agree on the form or content of any such required disclosure, such disclosure shall be limited to the minimum required, as determined by the disclosing Party in consultation with its legal counsel.

## **SECTION 14**

### **INDEMNITY; PRODUCT LIABILITY**

#### **14.1 Indemnity.**

- (a) Each Party (the “Indemnifying Party”) shall indemnify and hold harmless the other Party, its Affiliates and their respective officers, directors, employees and agents (collectively, the “Indemnified Party”) from and against all claims, demands, losses, liabilities, damages, fines, costs and expenses, including reasonable attorneys’ fees and costs and amounts paid in settlement (collectively, “Damages”), arising out of:
- (i) the negligence, recklessness, bad faith, intentional wrongful acts or omissions of the Indemnifying Party or its Affiliates or Representatives in connection with activities undertaken pursuant to this Agreement, except to the extent that Damages arise out of the negligence, recklessness, bad faith or intentional wrongful acts, or omissions committed by the Indemnified Party or its Affiliates (or, to the extent permitted under this Agreement, their respective Representatives working on their behalf); and
  - (ii) breach by the Indemnifying Party or its Affiliates or Representatives of the covenants and agreements of, or the representations and warranties made by it in, this Agreement.

- (b) Except as otherwise provided in SECTION 10, the Party entitled to indemnification under this SECTION 14 shall notify the Party potentially responsible for such indemnification promptly of becoming aware of any claim or claims asserted or threatened against the Indemnified Party which could give rise to a right of indemnification under this Agreement; provided, however, that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices its rights hereunder.
- (c) Except as otherwise provided in SECTION 10, and except in connection with any claim based on actual or alleged violation of Law, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by the plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (ii) the Indemnified Party consents to such compromise or settlement; provided, that such consent shall not be required if such compromise or settlement does not involve (A) any admission of legal wrongdoing by the Indemnified Party, (B) any payment by the Indemnified Party that is not indemnified hereunder or (C) the imposition of any equitable relief against the Indemnified Party.
- (d) Except as otherwise provided in SECTION 10, the Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 14.1 and if such claim is being defended by the Indemnifying Party, the Indemnified Party shall bear its own costs and expenses with respect to such participation.

#### 14.2 Product Liability.

- (a) ENDO shall indemnify and hold the NOVARTIS Parties harmless, in the manner set forth in Section 14.1, for Damages arising out of or resulting from any claims, actions, suits, proceedings, hearings, investigations or demands of Third Parties that involve death or bodily injury to any individual, including any product liability actions (collectively, "Product Liability Claims"), other than any such Damages which are set forth in Section 14.2(b).
- (b) The NOVARTIS Parties shall indemnify and hold ENDO harmless, in the manner set forth in Section 14.1, for Damages arising out of or resulting from Product Liability Claims attributable to such NOVARTIS Party's negligence, recklessness, bad faith, intentional wrongful acts, or breach of this Agreement, including the failure of any Licensed Product to meet the Specifications, the requirements of the Licensed Product NDA, GMP Requirements and/or all Applicable Laws, or to a manufacturing defect.

### **SECTION 15** **FORCE MAJEURE**

- 15.1 **Force Majeure.** In the event of strikes, lock-outs, earthquakes, fires, storms, floods, wars, acts of terrorism, explosions or, in the case of SANDOZ's obligations, unavailability of raw materials for Licensed Product due to any of the aforementioned events ("Force Majeure"), the Parties agree that, if either SANDOZ or ENDO finds itself wholly or partially unable to fulfill its respective obligations in this Agreement by reasons of Force Majeure, the Party affected will advise the other Party in writing of its inability to perform, giving a detailed explanation of the occurrence of the event which excuses performance as soon as possible after the cause or event has occurred. If such notice is given, the performance of the Party giving the notification, except the payment of funds (subject to the provision below), shall be abated, and any time deadlines shall be extended for so long as performance may be prevented by Force Majeure. Except for the payment of funds that are or become due and payable, neither Party shall be required to make up any performance that was prevented by Force Majeure. Anything herein to the contrary notwithstanding, ENDO shall not be obligated to make Guaranteed Minimum Sales Royalty payments, Contingent Royalty payments, or any payment of the NOVARTIS Profit Share during the period of time that SANDOZ is unable to meet its obligations in respect of manufacture and delivery of Licensed Products as a result of Force Majeure.

**SECTION 16**  
**TERM AND TERMINATION**

16.1 **Term.**

- (a) The term of this Agreement shall begin on the Effective Date and expire at the end of the seventh (7th) Agreement Year (*i.e.*, on June 30, 2023), unless extended in accordance with this subsection (a) or sooner terminated as provided in this Agreement (the "Initial Term"). The term of this Agreement shall be extended for a period of one (1) year (each, a "Renewal Term") at the expiration of the Initial Term and each Renewal Term, as applicable, unless any Party shall provide written notice of non-renewal to the other Parties at least six (6) months prior to the expiration of any Renewal Term after the first Renewal Term.
- (b) As used herein, the "Term of this Agreement" or the "Term" shall mean the Initial Term and the Renewal Terms, if any.

- 16.2 **Automatic Termination.** This Agreement shall automatically terminate upon the Launch in the Territory of any OTC Equivalent Product by SANDOZ, its respective Affiliates or a Third Party that results in the declassification of the Licensed Products as Rx Products.

- 16.3 **Termination.** This Agreement shall be terminable forthwith upon reasonable written notice, if one or more of the following events should occur:

- a. by any Party, if the other Party commits a material breach of this Agreement, which breach shall not have been remedied within (i) ninety (90) days from the giving of written notice requiring such breach (other than a payment default) to be remedied if such breach is capable of being cured during such ninety (90) day period, or (ii)

thirty (30) days from the giving of notice by either Party to the other of default by the other Party in any payment required under this Agreement;

- b. by ENDO, by written notice on or after the Launch in the Territory of a Generic Diclofenac Product;
- c. by ENDO, by written notice given on or after the Launch in the Territory of an OTC Equivalent Product that does not result in the declassification of the Licensed Product as an Rx Product (i) by any NOVARTIS Party or their respective Affiliates, or (ii) by any Third Party, if, in the case of (ii), (I) at the expiration of the OTC Launch Six Month Reference Period, Net Sales of any Licensed Product have declined, as compared to Net Sales during the six month period before such Launch, by twenty five percent (25%) or more, or (II) at the expiration of either of the OTC Launch Three Month Reference Periods, Net Sales for such OTC Launch Three Month Reference Period have declined, as compared to Net Sales during the three calendar month period before such Launch, by twenty five percent (25%) or more, or if at the last day of the OTC Launch Three Month Reference Period, the number of “covered lives” eligible for third party reimbursement in respect to purchases of Licensed Product as referenced by the Managed Markets Information Service in its most recent report have declined by twenty five percent (25%) or more as compared to the number of “covered lives” immediately prior to such Launch;
- d. by ENDO in the event that Net Sales in any Agreement Semester are less than \$25,000,000;
- e. by SANDOZ, by written notice given on or after the Launch in the Territory of an OTC Equivalent Product by SANDOZ, its Affiliates or any Third Party that does not result in the declassification of the Licensed Products as an Rx Product, following which Net Sales in any Agreement Semester are less than \$25,000,000;
- f. by ENDO in the event that (i) any Licensed Product becomes subject to a validated safety signal of significant concerns regarding patient safety with respect to such Licensed Product, or (ii) any Party receives notice from a Governmental Authority, independent review committee, data safety monitoring board or another similar clinical trial or post-marketing monitoring body concluding significant concern regarding a patient safety issue with respect to any Licensed Product, in the case of (i) or (ii) which would reasonably be expected to seriously impact the long-term viability of such Licensed Product;
- g. by any Party, if any other Party becomes incapable, for a period of one hundred and eighty (180) days, of performing any of its material obligations under this Agreement because of Force Majeure, despite such adversely affected Party’s commercially reasonable efforts to perform;
- h. by any Party, if any other Party commences a voluntary case or other proceeding seeking liquidation, reorganization or other relief with respect to itself or its debts under any bankruptcy, insolvency or other similar Law now or hereafter in effect or

seeking the appointment of a trustee, receiver, liquidator, custodian or similar official of it or of any substantial part of its property, or shall consent to any such relief or to the appointment of or taking possession by any such official in an involuntary case or other proceeding commenced against it, or shall make a general assignment for the benefit of creditors, or shall fail generally to pay its debts as they become due, or shall take any corporate action to authorize any of the foregoing;

- i. by any Party, if any other Party has an involuntary case or other proceeding commenced against it seeking liquidation, reorganization or other relief with respect to it or its debts under any bankruptcy, insolvency or other similar Law now or hereafter in effect or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property, and such involuntary case or other proceeding remains undismitted and unstayed for a period of ninety (90) days; or an order for relief is entered against such Party under applicable bankruptcy Laws as now or hereafter in effect;
- j. by any Party, if any other Party is unable to pay its debts as they become due, has explicitly or implicitly suspended payment of any debts as they become due (except debts contested in good faith), or if the creditors of such Party have taken over its management; and
- k. by ENDO, at any time after January 1, 2020, upon six (6) months' prior written notice to the NOVARTIS Parties.

16.4 Survival of Obligations. Notwithstanding any expiration or termination of this Agreement, (a) neither SANDOZ nor ENDO shall be relieved of any liabilities or obligations incurred by such Party prior to such termination and (b) Section 2.4, Section 2.5, SECTION 4 (to the extent applicable to Section 16.5(b)), Section 4.12 (with respect to each Party's reporting obligations with respect to matters occurring prior to the expiration or termination), 5.1 through 5.4, 6.1 (to the extent applicable to Section 16.5), 7.1(b) and (c) (solely with respect to SANDOZ's switch rights and access to data from clinical studies), 8.2, SECTION 10, SECTION 11, SECTION 13, SECTION 14, 16.4, 16.5, 16.6, SECTION 17 (only insofar as such Section relates to the obligations of the Parties prior to such termination or expiration) and SECTION 18 shall survive any expiration or termination of this Agreement.

16.5 Effect of Expiration or Termination.

- a. General. Notwithstanding any other rights or obligations a Party or its Affiliates may have under this Agreement or under Law, except as otherwise provided herein, upon expiration or termination of this Agreement, (i) all rights and licenses granted by any NOVARTIS Party to ENDO and its Affiliates and all rights and licenses granted by ENDO to any NOVARTIS Party and its Affiliates hereunder shall terminate and revert to the Party granting such rights and all of the Parties' obligations under this Agreement shall, except as specifically provided in Section 16.4 or this 16.5, cease, terminate and be of no further force and effect from and after the effective date of expiration or termination, and (ii) any Contingent Royalties or Guaranteed Minimum Sales Royalties that would otherwise be payable hereunder shall be



prorated through the effective date of expiration or termination. The Parties and their Affiliates shall cooperate in informing relevant Governmental Authorities of the cessation of ENDO's activities in relation to the Licensed Products. In addition, the Parties shall, and shall ensure that their respective Affiliates, promptly return or destroy (subject to written certification of the latter) to the other Parties all written Confidential Information, and all copies thereof (except one copy which may be kept for record-keeping purposes only), belonging to such other Parties.

- b. Supply Obligations. Following expiration or termination of this Agreement, ENDO shall continue to be responsible for all returns, rebates, refunds, chargebacks, open purchase orders, any applicable disposal costs and other payments or obligations in respect of Licensed Products sold during the Term of this Agreement. Subject to the terms and conditions of this Agreement, including SECTION 4, SANDOZ shall provide sufficient Licensed Products to ENDO in order to allow ENDO to meet the requirements of all open purchase orders. For a period of up to six (6) months following expiration or termination of this Agreement, to the extent permitted by Applicable Law, ENDO shall be permitted to sell Licensed Products, subject to paying royalties under Section 6.1(a), to fulfill such open purchase orders and otherwise to sell off its inventory, including that purchased pursuant to the next sentence. In addition, upon the written request of SANDOZ made within thirty (30) days of the expiration of the Term, ENDO shall purchase from SANDOZ (i) all Licensed Products then held in inventory by SANDOZ or its Affiliates for sale in the Territory, at the price set forth in Section 4.11(a) and (ii) all raw materials and other components held in inventory by SANDOZ or its Affiliates for use in connection with the manufacture of Licensed Products for sale in the Territory, at SANDOZ Cost, to the extent such items relate to binding purchase orders from customers and reasonable levels of safety stock.

- 16.6 Remedies. Except as otherwise expressly set forth in this Agreement, the termination provisions of this SECTION 16 are in addition to any other relief and remedies available to either Party at law in equity or otherwise.

## **SECTION 17**

### **INSURANCE**

- 17.1 Insurance. ENDO and SANDOZ shall each at its own expense obtain and maintain insurance of the type and amount described in this SECTION 17. No Party shall do or omit to do any act, matter or thing which could prejudice or render voidable any such insurance. The insurance obligations hereunder may be met by a program of self-insurance.

The Parties agree that each will maintain during the performance of this Agreement the following insurance in amounts no less than that specified for each type:

- (a) General liability insurance with combined limits of not less than \$1,000,000 per occurrence and \$1,000,000 per accident for bodily injury, including death and property damage;

- (b) Worker's compensation and disability insurance in the amount required by the Law of the State in which the Party's employees are located and employers liability insurance with limits of not less than \$1,000,000 per occurrence;
- (c) Auto liability insurance with combined limits of not less than \$1,000,000 per occurrence and \$1,000,000 per accident for bodily injury, including death and property damage; and
- (d) Excess liability insurance with combined limits of not less than \$3,000,000 per occurrence and \$3,000,000 per accident for bodily injury, including death and property damage.

Each Party will provide to the other Parties evidence of its insurance and not less than thirty (30) days prior written notice of any cancellation of its coverage or reduction in coverage from the requirements stated herein.

**SECTION 18**  
**MISCELLANEOUS**

- 18.1 Governing Law. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof.
- 18.2 Jurisdiction. Subject to Section 18.3, any disputes between the Parties relating to this Agreement shall be subject to the exclusive jurisdiction and venue of the federal courts located in the Southern District of New York (without restricting any right of appeal), and the Parties hereby waive any objection which they may have now or hereafter to the laying of venue of any proceedings in such courts and to any claim that such proceedings have been brought in an inconvenient forum, and further agree that a judgment or order in any such proceedings shall be binding upon each of them and may be enforced in the courts of any other jurisdiction.
- 18.3 Dispute Resolution. In the event of any dispute under this Agreement, the Parties shall refer such dispute to the Applicable Senior Officers for attempted resolution by good faith negotiations within thirty (30) days after such referral is made. If the Applicable Senior Officers are unable to resolve the dispute within the time allotted, the Applicable Senior Officers shall select a mediator with appropriate expertise in the subject matter to which the dispute relates, who will be engaged to resolve the dispute. If the Parties are unable to resolve their dispute through mediation within ninety (90) days after selection of the mediator(s), either Party may seek appropriate legal and/or equitable recourse in a court of competent jurisdiction (subject to Section 18.2).
- 18.4 Waiver. Waiver by a Party of a breach hereunder by any Party shall not be construed as a waiver of any succeeding breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision

(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

18.5 Notices. All notices required or permitted hereunder shall be given in writing and sent by confirmed facsimile transmission, or mailed postage prepaid by certified or registered mail (return receipt requested), or sent by a nationally recognized express courier service, or hand-delivered at the following address:

If to NOVARTIS AG:

NOVARTIS, AG  
Lichtstrasse 35  
CH-4056 Basel  
Switzerland  
Facsimile: 41 61 3247826  
Attention: General Counsel

With a copy to:

Sandoz, Inc.  
100 College Rd. West  
Princeton, NJ 08540  
Attention: President

If to SANDOZ:

Sandoz, Inc.  
100 College Rd. West  
Princeton, NJ 08540  
Attention: President

With a copy to:

NOVARTIS, AG  
Lichtstrasse 35  
CH-4056 Basel  
Switzerland  
Facsimile: 41 61 3247826  
Attention: General Counsel

If to ENDO:

ENDO Ventures Limited  
First Floor, Minerva House  
Simmons Court Road Ballsbridge

Dublin 4, Ireland  
Attention: Chief Legal Officer  
FAX 353 1-268-2029

With a copy to:

Drinker Biddle & Reath LLP  
One Logan Square, Suite 2000  
Philadelphia, PA 19103-6996  
Facsimile: (215) 988-2757  
Attention: Neil K. Haimm

All notices shall be deemed made upon receipt by the addressee as evidenced by the applicable written receipt.

- 18.6 Entire Agreement. This Agreement (including the Exhibits and Schedules) contains the complete understanding of the Parties with respect to the subject matter hereof and supersedes all prior understandings and writings relating to the subject matter hereof and specifically supersedes the terms of the Original Agreement as of the Effective Date. The Parties further hereby provide notice of non-renewal under the Original Agreement.
- 18.7 Amendments. No provision in this Agreement shall be supplemented, deleted, amended or waived except in a writing executed by each of the NOVARTIS Parties and ENDO.
- 18.8 Headings. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement.
- 18.9 Severability. If any provision of this Agreement is held unenforceable by a court or tribunal of competent jurisdiction because it is invalid or conflicts with any Law of any relevant jurisdiction, the validity of the remaining provisions shall not be affected. The Parties shall negotiate a substitute provision that, to the extent possible, accomplishes the original business purpose of the Parties.
- 18.10 Assignment. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Party without the prior written consent of the other Parties, which consent shall not be unreasonably withheld. Notwithstanding the first sentence of this Section 18.10, (a) either Party may assign this Agreement (i) to any Affiliate of such Party or (ii) to any other Person who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise and (b) SANDOZ and/or NOVARTIS AG may assign this Agreement to GlaxoSmithKline Consumer Healthcare Holdings Limited (or an Affiliate thereof), provided, that, in each instance the Affiliate or acquiring Person or assignee affirmatively assumes and agrees in writing to perform and comply with all of the obligations of such Party under this Agreement as they apply to such Party and its Affiliates, and in the case of (ii) only provides a copy thereof to the other Party upon consummation of such transaction. Except with respect to an assignment by SANDOZ and/or NOVARTIS AG pursuant to clause (b) above or by

SANDOZ to NOVARTIS AG, the assigning Party shall remain liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.

- 18.11 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.
- 18.12 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.
- 18.13 Third-Party Beneficiaries. Except as expressly provided in Section 14.1, none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party including any creditor of any Party hereto. No such Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto.
- 18.14 Relationship of the Parties; Tax Treatment. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other except as expressly provided in this Agreement. Neither the NOVARTIS Parties nor ENDO shall have any responsibility for the hiring, termination or compensation of the other Parties' employees or for any employee compensation or benefits of the other Parties' employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, ENDO's legal relationship under this Agreement to the NOVARTIS Parties shall be that of independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint venturers. This Agreement shall not be construed, nor will either Party construe it, as a partnership for tax purposes.
- 18.15 Specific Performance. Each of the Parties acknowledges and agrees that the other Party may be damaged irreparably in the event any of the provisions of this Agreement are not performed in all material respects or otherwise are breached. Accordingly, and notwithstanding anything herein to the contrary, each of the Parties agrees that the other Party will be entitled to injunctive relief to prevent breaches of the provisions of this Agreement, and/or to enforce specifically this Agreement and the terms and provisions hereof, in any action instituted in any court or tribunal having jurisdiction over the Parties and the matter, without posting any bond or other security, and that such injunctive relief shall be in addition to any other remedies to which such Party may be entitled, at law or in equity.
- 18.16 Further Assurances and Actions. Each of the Parties hereto, upon the request of any other Party hereto, shall, without further consideration, do, execute, acknowledge and deliver or cause to be done, executed, acknowledged or delivered all such further acts, deeds, documents, assignments, transfers, conveyances, powers of attorney and assurances as may be reasonably necessary to effectuate any of the provisions of this Agreement.

18.17 LIMITATION OF DAMAGES. IN NO EVENT SHALL ENDO OR THE NOVARTIS PARTIES BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOSS OF PROFITS) SUFFERED BY THE OTHER PARTIES, EXCEPT FOR ANY SUCH DAMAGES PAID TO A THIRD PARTY AS PART OF A THIRD-PARTY CLAIM, PROVIDED, THAT THE FOREGOING SHALL NOT PRECLUDE A PARTY FROM SEEKING ANY SUCH DAMAGES RESULTING FROM FRAUD (INCLUDING ANY WILLFUL MISREPRESENTATION, WILLFUL MISCONDUCT OR WILLFUL CONCEALMENT BY A PARTY) AND/OR WILLFUL BREACH.

IN WITNESS WHEREOF, NOVARTIS AG, SANDOZ and ENDO have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

NOVARTIS, AG

By /s/Christian Rehm

Name: Christian Rehm

Title: Authorized Signatory

By /s/Susan Jones

Name: Susan Jones

Title: Authorized Signatory

SANDOZ, INC.

By /s/Peter Goldschmidt

Name: Peter Goldschmidt

Title: President Sandoz US,  
Head N. America,  
Sandoz Inc.

ENDO VENTURES LIMITED

By /s/Robert Cobuzzi

Name: Robert Cobuzzi

Title: President

[Signature Page to Amended and Restated License and Supply Agreement]

SCHEDULE 1.105  
PhRMA CODE

CODE ON INTERACTIONS  
WITH HEALTHCARE PROFESSIONALS



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## Preamble

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents research-based pharmaceutical and biotechnology companies. Our members develop and market new medicines to enable patients to live longer and healthier lives.

Ethical relationships with healthcare professionals are critical to our mission of helping patients by developing and marketing new medicines. An important part of achieving this mission is ensuring that healthcare professionals have the latest, most accurate information available regarding prescription medicines, which play an ever-increasing role in patient healthcare. This document focuses on our interactions with healthcare professionals that relate to the marketing of our products.

Appropriate marketing of medicines ensures that patients have access to the products they need and that the products are used correctly for maximum patient benefit. Our relationships with healthcare professionals are critical to achieving these goals because they enable us to-

- inform healthcare professionals about the benefits and risks of our products to help advance appropriate patient use,
- provide scientific and educational information,
- support medical research and education, and
- obtain feedback and advice about our products through consultation with medical experts.

In interacting with the medical community, we are committed to following the highest ethical standards as well as all legal requirements. We are also concerned that our interactions with healthcare professionals not be perceived as inappropriate by patients or the public at large. This Code is to reinforce our intention that our interactions with healthcare professionals are professional exchanges designed to benefit patients and to enhance the practice of medicine. The Code is based on the principle that a healthcare professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the healthcare professional's medical knowledge and experience.

Therefore, PhRMA adopts this updated and enhanced voluntary Code on relationships with U.S. healthcare professionals. This Code reflects and builds upon the standards and principles set forth in its predecessor, the PhRMA Code on Interactions with Healthcare Professionals that took effect on July 1, 2002. Like the 2002 edition, this Code addresses interactions with respect to marketed products and related pre-launch activities. PhRMA member companies' relationships with clinical investigators and other individuals and entities as they relate to the clinical research process are addressed in the PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results.

This updated Code will take effect in January 2009.

### 1. Basis of Interactions

Our relationships with healthcare professionals are regulated by multiple entities and are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical education.

Promotional materials provided to healthcare professionals by or on behalf of a company should: (a) be accurate and not misleading; (b) make claims about a product only when properly substantiated; (c) reflect the balance between

risks and benefits; and (d) be consistent with all other Food and Drug Administration (FDA) requirements governing such communications.

## **2. Informational Presentations by Pharmaceutical Company Representatives and Accompanying Meals**

Informational presentations and discussions by industry representatives and others speaking on behalf of a company provide healthcare providers with valuable scientific and clinical information about medicines that may lead to improved patient care.

In order to provide important scientific information and to respect healthcare professionals' abilities to manage their schedules and provide patient care, company representatives may take the opportunity to present information during healthcare professionals' working day, including mealtimes. In connection with such presentations or discussions, it is appropriate for occasional meals to be offered as a business courtesy to the healthcare professionals as well as members of their staff attending presentations, so long as the presentations provide scientific or educational value and the meals (a) are modest as judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication.

Any such meals offered in connection with informational presentations made by field sales representatives or their immediate managers should also be limited to in-office or in-hospital settings.

Inclusion of a healthcare professional's spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a company is not appropriate. Offering "take-out" meals or meals to be eaten without a company representative being present (such as "dine & dash" programs) is not appropriate.

## **3. Prohibition on Entertainment and Recreation**

Company interactions with healthcare professionals are professional in nature and are intended to facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on education and informational exchange and to avoid the appearance of impropriety, companies should not provide any entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional who is not a salaried employee of the company. Such entertainment or recreational benefits should not be offered, regardless of (1) the value of the items; (2) whether the company engages the healthcare professional as a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose.

Modest, occasional meals are permitted as long as they are offered in the appropriate circumstances and venues as described in relevant sections of this Code.

## **4. Pharmaceutical Company Support for Continuing Medical Education**

Continuing medical education (CME), also known as independent medical education (IME), helps physicians and other medical professionals to obtain information and insights that can contribute to the improvement of patient care, and therefore, financial support from companies is appropriate. Such financial support for CME is intended to support education on a full range of treatment options and not to promote a particular medicine. Accordingly, a company should separate its CME grant-making functions from its sales and marketing departments. In addition, a company should develop objective criteria for making CME grant decisions to ensure that the program funded by

the company is a bona fide educational program and that the financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment.

Since the giving of any subsidy directly to a healthcare professional by a company may be viewed as an inappropriate cash gift, any financial support should be given to the CME provider, which, in turn, can use the money to reduce the overall CME registration fee for all participants. The company should respect the independent judgment of the CME provider and should follow standards for commercial support established by the Accreditation Council for Continuing Medical Education (ACCME) or other entity that may accredit the CME. When companies underwrite CME, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines. The company should not provide any advice or guidance to the CME provider, even if asked by the provider, regarding the content or faculty for a particular CME program funded by the company.

Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending CME, either directly to the individuals participating in the event or indirectly to the event's sponsor (except as set out in Section 9 below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals participating in the CME event.

A company should not provide meals directly at CME events, except that a CME provider at its own discretion may apply the financial support provided by a company for a CME event to provide meals for all participants.

## **5. Pharmaceutical Company Support for Third-Party Educational or Professional Meetings**

Third-party scientific and educational conferences or professional meetings can contribute to the improvement of patient care, and therefore, financial support from companies is appropriate. A conference or meeting is any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.

Since the giving of any subsidy directly to a healthcare professional by a company may be viewed as an inappropriate cash gift, any financial support should be given to the conference's sponsor, which, in turn, can use the money to reduce the overall conference registration fee for all attendees. When companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines.

Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending third-party scientific or educational conferences or professional meetings, either directly to the individuals attending the conference or indirectly to the conference's sponsor (except as set out in Section 9 below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals attending the conference or meeting.

## **6. Consultants**

Consulting arrangements with healthcare professionals allow companies to obtain information or advice from medical experts on such topics as the marketplace, products, therapeutic areas and the needs of patients. Companies use this advice to inform their efforts to ensure that the medicines they produce and market are meeting the needs of patients. Decisions regarding the selection or retention of healthcare professionals as consultants should be made

based on defined criteria such as general medical expertise and reputation, or knowledge and experience regarding a particular therapeutic area. Companies should continue to ensure that consultant arrangements are neither inducements nor rewards for prescribing or recommending a particular medicine or course of treatment.

It is appropriate for consultants who provide advisory services to be offered reasonable compensation for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Any compensation or reimbursement made in conjunction with a consulting arrangement should be reasonable and based on fair market value.

Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses. The following factors support the existence of a bona fide consulting arrangement (not all factors may be relevant to any particular arrangement):

- a written contract specifies the nature of the consulting services to be provided and the basis for payment of those services;
- a legitimate need for the consulting services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
- the criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;
- the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;
- the retaining company maintains records concerning and makes appropriate use of the services provided by consultants;
- the venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting; specifically, resorts are not appropriate venues.

While modest meals or receptions may be appropriate during company-sponsored meetings with healthcare professional commercial consultants, companies should not provide recreational or entertainment events in conjunction with these meetings.

It is not appropriate to pay honoraria or travel or lodging expenses to non-faculty and non-consultant healthcare professional attendees at company-sponsored meetings, including attendees who participate in interactive sessions.

## **7. Speaker Programs and Speaker Training Meetings**

Healthcare professionals participate in company-sponsored speaker programs in order to help educate and inform other healthcare professionals about the benefits, risks and appropriate uses of company medicines. Any healthcare professional engaged by a company to participate in such external promotional programs on behalf of the company will be deemed a speaker for purposes of this Code, and the requirements of Section 7 apply to company interactions with that healthcare professional in his or her capacity as a speaker. Company decisions regarding the selection or retention of healthcare professionals as speakers should be made based on defined criteria such as general medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and communications skills. Companies should continue to ensure that speaking arrangements are neither inducements nor rewards for prescribing a particular medicine or course of treatment.

Speaker training is an essential activity because the FDA holds companies accountable for the presentations of their speakers. It is appropriate for healthcare professionals who participate in programs intended to train speakers for company-sponsored speaker programs to be offered reasonable compensation for their time, considering the value of the type of services provided, and to be offered reimbursement for reasonable travel, lodging, and meal expenses. Such compensation and reimbursement should only be offered when (1) the participants receive extensive training on the company's drug products or other specific topic to be presented and on compliance with FDA regulatory requirements for communications; (2) this training will result in the participants providing a valuable service to the company; and (3) the participants meet the general criteria for bona fide consulting arrangements (as discussed in Section 6 above). Speaker training sessions should be held in venues that are appropriate and conducive to informational communication and training about medical information; specifically, resorts are not appropriate venues.

Any compensation or reimbursement made to a healthcare professional in conjunction with a speaking arrangement should be reasonable and based on fair market value. Each company should, individually and independently, cap the total amount of annual compensation it will pay to an individual healthcare professional in connection with all speaking arrangements. Each company also should develop policies addressing the appropriate use of speakers, including utilization of speakers after training and the appropriate number of engagements for any particular speaker over time.

Speaker programs may include modest meals offered to attendees and should occur in a venue and manner conducive to informational communication.

While speaker programs offer important educational opportunities to healthcare professionals, they are distinct from CME programs, and companies and speakers should be clear about this distinction. For example, speakers and their materials should clearly identify the company that is sponsoring the presentation, the fact that the speaker is presenting on behalf of the company, and that the speaker is presenting information that is consistent with FDA guidelines. Beyond providing all speakers with appropriate training, companies should periodically monitor speaker programs for compliance with FDA regulatory requirements for communications on behalf of the company about its medicines.

## **8. Healthcare Professionals Who Are Members of Committees That Set Formularies or Develop Clinical Practice Guidelines**

Healthcare professionals who are members of committees that set formularies of covered medicines or develop clinical practice guidelines that may influence the prescribing of medicines often have significant experience in their fields. That experience can be of great benefit to companies and ultimately to patients if these individuals choose to serve as speakers or commercial consultants for companies. To avoid even the appearance of impropriety, companies should require any healthcare professional who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for the company to disclose to the committee the existence and nature of his or her relationship with the company. This disclosure requirement should extend for at least two years beyond the termination of any speaker or consultant arrangement.

Upon disclosure, healthcare professionals who serve as speakers or consultants for companies should be required to follow the procedures set forth by the committee of which they are a member, which may include recusing themselves from decisions relating to the medicine for which they have provided speaking or consulting services.

## **9. Scholarships and Educational Funds**

Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution. "Carefully selected educational conferences" are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

#### **10. Prohibition of Non-Educational and Practice-Related Items**

Providing items for healthcare professionals' use that do not advance disease or treatment education - even if they are practice-related items of minimal value (such as pens, note pads, mugs and similar "reminder" items with company or product logos) - may foster misperceptions that company interactions with healthcare professionals are not based on informing them about medical and scientific issues. Such non-educational items should not be offered to healthcare professionals or members of their staff, even if they are accompanied by patient or physician educational materials.

Items intended for the personal benefit of healthcare professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) likewise should not be offered.

Payments in cash or cash equivalents (such as gift certificates) should not be offered to healthcare professionals either directly or indirectly, except as compensation for bona fide services (as described in Sections 6 and 7). Cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest.

It is appropriate to provide product samples for patient use in accordance with the Prescription Drug Marketing Act.

#### **11. Educational Items**

It is appropriate for companies, where permitted by law, to offer items designed primarily for the education of patients or healthcare professionals if the items are not of substantial value (\$100 or less) and do not have value to healthcare professionals outside of his or her professional responsibilities. For example, an anatomical model for use in an examination room is intended for the education of the patients and is therefore appropriate, whereas a DVD or CD player may have independent value to a healthcare professional outside of his or her professional responsibilities, even if it could also be used to provide education to patients, and therefore is not appropriate.

Items designed primarily for the education of patients or healthcare professionals should not be offered on more than an occasional basis, even if each individual item is appropriate.

#### **12. Prescriber Data**

Companies use non-patient identified prescriber data to facilitate the efficient flow of information to healthcare professionals. Such prescriber data, which does not identify individual patients, may serve many purposes, including enabling companies to: (a) impart important safety and risk information to prescribers of a particular drug; (b) conduct research; (c) comply with FDA mandated risk management plans that require drug companies to identify and interact with physicians who prescribe certain drugs; (d) track adverse events of marketed prescriptions drugs; and (e) focus marketing activities on those healthcare professionals who would most likely benefit from information about a particular drug.

Companies that choose to use non-patient identified prescriber data to facilitate communications with healthcare professionals should use this data responsibly. For example, companies should (a) respect the confidential nature of prescriber data; (b) develop policies regarding the use of the data; (c) educate employees and agents about those policies; (d) maintain an internal contact person to handle inquiries regarding the use of the data; and (e) identify appropriate disciplinary actions for misuse of this data.

In addition, companies should respect and abide by the wishes of any healthcare professional who asks that his or her prescriber data not be made available to company sales representatives. Companies may demonstrate this respect by following the rules of voluntary programs that facilitate prescribers' ability to make this choice.

### **13. Independence and Decision Making**

No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices.

### **14. Training and Conduct of Company Representatives**

Pharmaceutical company representatives play an important role in delivering accurate, up-to-date information to healthcare professionals about the approved indications, benefits and risks of pharmaceutical therapies. These representatives often serve as the primary point of contact between the companies who research, develop, manufacture and market life-saving and life-enhancing medicines and the healthcare professionals who prescribe them. As such, the company representatives must act with the highest degree of professionalism and integrity.

Companies should ensure that all representatives who are employed by or acting on behalf of the companies and who visit healthcare professionals receive training about the applicable laws, regulations and industry codes of practice, including this Code, that govern the representatives' interactions with healthcare professionals. In addition, companies should train their representatives to ensure that they have sufficient knowledge of general science and product-specific information to provide accurate, up-to-date information, consistent with FDA requirements.

Companies should provide updated or additional training in all of these areas as needed for their representatives who visit healthcare professionals.

Companies should also assess their representatives periodically to ensure that they comply with relevant company policies and standards of conduct. Companies should take appropriate action when representatives fail to comply.

### **15. Adherence to Code**

All companies that interact with healthcare professionals about pharmaceuticals should adopt procedures to assure adherence to this Code.

Companies that publicly announce their commitment to abide by the Code and who complete an annual certification that they have policies and procedures in place to foster compliance with the Code will be identified by PhRMA on a public web site. The certification must be signed by the company's Chief Executive Officer and Chief Compliance Officer. The web site will identify the companies who commit to abide by the Code; provide contact information for their Chief Compliance Officers; and, at the appropriate time, publish the status of each company's annual certification.



Any comments received by PhRMA relating to a company's observance of the Code or conduct that is addressed by the Code will be referred by PhRMA to the relevant company's Chief Compliance Officer.

In addition, companies are encouraged to seek external verification periodically, meaning at least once every three years, that the company has policies and procedures in place to foster compliance with the Code. PhRMA will prepare general guidance for such external verification and will identify on its web site if a company has sought and obtained verification of its compliance policies and procedures from an external source.

## **PhRMA CODE**

### **Questions & Answers**

#### **Q.1**

Under the Code, may items such as stethoscopes be offered to healthcare professionals?

**A.** No. Under the Code only items designed primarily for the education of patients or healthcare professionals may occasionally be offered to healthcare professionals, if the items are not of substantial value and do not have a value to healthcare professionals outside of their professional responsibilities. While medical equipment, such as stethoscopes, obviously plays an important role in patient care, such equipment is primarily designed for patient treatment, not for patient or healthcare professional education, and therefore it would be inappropriate for companies to offer such equipment to healthcare professionals.

#### **Q.2**

Under the Code, could a company provide healthcare professionals with pens or clipboards designed to be used by healthcare professionals or patients in the healthcare professional's office along with brochures that provide educational information about the company's product?

**A.** No. The Code states that providing healthcare professionals with items that do not advance disease or treatment education is not appropriate, even if these items are practice-related items of minimal value, such as clipboards, pens, mugs or similar items with or without company logos or product names printed on them. Providing such non-educational items could foster misperceptions that the company's interactions with healthcare professionals are not based on providing information about products or health conditions, and therefore companies should not offer non-educational items to healthcare professionals or their staff, even if they are accompanied by educational materials. It would, however, be appropriate for a company to distribute educational brochures without pens or clipboards. These same guidelines apply with regard to the distribution of items to healthcare professionals at third-party scientific and educational conferences or professional meetings.

#### **Q.3**

Under the Code, what are examples of permissible items that may be provided to educate healthcare professionals?

**A.** The Code states that it is appropriate for companies, where permitted by law, to occasionally offer items primarily designed for the education of patients or healthcare professionals, as long as such items are not of substantial value (\$100 or less) and do not have a value to the healthcare professionals outside of their professional responsibilities. For example, companies may provide educational items such as a medical text book, a subscription to a relevant scientific journal, or copies of relevant clinical treatment guidelines.

#### **Q.4**

Under the Code, what types of patient education items may companies provide to healthcare professionals to help them in educating their patients?

**A.** Where permitted by law, companies may occasionally offer to healthcare professionals items designed to help educate patients, such as anatomical models for examination rooms, informational sheets and brochures, patient self-assessment and tracking tools, or written materials that inform patients about adherence to medicine regimens, healthy lifestyle choices or the availability of patient assistance programs. Such items should not be of substantial value, i.e. they should be \$100 or less.

Companies may also provide to healthcare professionals educational items designed for use by patients to assist in the administration of their treatment or management of their conditions. Such items should only be provided to healthcare professionals for patients where the items are permitted by law, may be considered essential to proper treatment or compliance and where delivery through a healthcare professional is an appropriate method of delivery to the patient. For example, companies may provide through healthcare professionals patient starter kits that help enhance the patients' appropriate use of the prescribed medicine. Providing non-educational items to healthcare professionals for patient use is not appropriate, even if these items are of minimal value, such as pedometers, stopwatches, or other general fitness items.

**Q.5**

Under the Code, may golf balls and sports bags be provided if they bear a company or product name?

**A.** No. As stated in the prior version of the Code, golf balls and sports bags, even if of minimal value, do not advance disease or treatment education and therefore should not be offered, regardless of whether they bear a company or product name.

**Q.6**

Under the Code, may healthcare professionals be provided with gasoline for their cars if they are provided with product information at the same time?

**A.** No. As stated in the prior version of the Code, items intended for the personal benefit of a healthcare professional should not be offered.

**Q.7**

The Code states that company representatives or their immediate managers working in company field sales organizations may conduct informational presentations and discussions accompanied by occasional, modest meals in the healthcare professional's office or hospital setting. What types of presentations and meals would this include?

**A.** An informational presentation or discussion conducted by company representatives or their immediate managers working in field sales may be accompanied by an occasional modest meal in the office or hospital setting. Such modest meals may only be offered provided that the manner of presentation is conducive to a scientific or educational interchange and is not part of an entertainment or recreational event. For example, a sales representative who is providing scientific or educational information regarding a company's products to one or a few healthcare practitioners working in the same office, could provide a modest meal (e.g., sandwiches or pizza) to physicians and staff attending the representative's informational presentation in the physician's office at lunch time. Providing such modest meals on more than an occasional basis would not be appropriate.

**Q.8**

Can a field sales representative of Company B conduct an informational presentation accompanied by a meal for a healthcare professional in a restaurant down the street from a hospital?

**A.** No. An informational presentation or discussion conducted by a field sales representative or her immediate manager may only be accompanied occasionally by a meal if the presentation is held in the healthcare professional's office or hospital. This is to ensure that any meal offered by field sales representatives or their managers is merely incidental to a substantive interaction with a healthcare professional in the office or hospital setting where the

healthcare professional typically conducts professional conversations. In addition, any meal offered must be modest as judged by local standards; the presentation must not be part of an entertainment or recreational event; and the presentation must be provided in a manner conducive to informational communication. If a hospital practitioner does not have an office conducive to informational communication, then a presentation may be provided in a hospital cafeteria or other meeting space within the hospital and may be accompanied by a modest meal.

**Q.9**

A field sales representative of Company X provides pizza for the staff of a medical office during lunch time. Is this consistent with the Code?

**A.** Providing an occasional meal would be consistent with the Code if the sales representative will provide an informational presentation to the medical staff in conjunction with the meal of modest value, so long as the location of the in-office presentation is conducive to scientific or educational communication. Merely dropping off food for the office staff, however, would not be consistent with the Code.

**Q.10**

A field sales representative of Company X invites physicians to meet to hear a scientific and educational presentation about a new drug at the café at a nearby bookstore. Lunch is provided by the representative and, following the presentation (which is in small groups), each physician is given a gift certificate for books in the amount of \$30. Does this conform to the Code?

**A.** No. While the presentation may present scientific or educational information, a company field sales representative should not provide even a modest meal to healthcare professionals outside of the office or hospital setting (except under the limited circumstances where the field sales representative attends a company-sponsored speaker program to provide logistical support and help monitor compliance with FDA requirements - see Question 13 below). In addition, an open-ended gift certificate is a cash equivalent. A medical textbook, a book on patient care, or a gift certificate redeemable solely for a medical textbook or book on patient care could be provided if it is not of substantial value (\$100 or less).

**Q.11**

A district sales manager at Company C invites 30 physicians to a corporate suite at a professional baseball game for a 45-minute scientific and educational presentation followed by a buffet and the three-hour game. Does this conform to the Code?

**A.** No. The provision of entertainment and/or recreational activities, including entertainment at sporting events in connection with an educational or scientific presentation or discussion, is inconsistent with the Code, just as in the prior version. In addition, under the Code, informational presentations by company representatives or their immediate managers in field sales organizations may only be accompanied by a modest meal if the presentations occur in the healthcare professional's office or hospital setting.

**Q.12**

Under the Code, could a senior business executive employed by a company provide a healthcare professional with an occasional meal outside of the healthcare professional's office or hospital?

**A.** The Code does not prohibit company employees other than field sales representatives or their immediate managers from providing an occasional meal incidental to a substantive interaction with a healthcare professional outside of his or her office or hospital, as long as (1) the meal is modest as judged by local standards; (2) the meal is not part of an entertainment or recreational event; and (3) the interaction takes place in a venue and manner conducive to informational communication.

**Q.13**

Company Y would like to engage an expert physician to discuss recent advances in therapy for a group of local healthcare professionals, and would like to meet and provide a meal to attendees in the private room of a local restaurant. Under what circumstances can this comply with the Code? Could a local field representative in the company's sales organization attend the event for purposes of assisting the outside speaker and helping to assure that the content of the presentation complies with FDA requirements?

**A.** The Code contemplates that a company may engage a healthcare professional to provide medical or scientific information to a group of healthcare professionals on behalf of the company. Such speaker programs may include modest meals offered to attendees and may occur in locations outside of the office or hospital setting, as long as they occur in a venue and manner conducive to informational communication. In this case, Company Y's chosen location of a private room in a local restaurant may be conducive to informational discussion, and the meal provided to attendees should be modest as judged by local standards. In addition, Company Y should follow the provisions of Section 7 of the Code on speaker programs. For example, Company Y should make sure that the speaker is appropriately trained and that the speaker and her materials clearly identify the company sponsoring the presentation and the fact that the speaker is presenting on behalf of the company. In addition, Company Y should periodically monitor its speaker programs for compliance with FDA regulatory requirements. It would be appropriate for a local field representative in the company's sales organization to attend a speaker program for purposes of assisting the speaker with logistics and helping to assure that the content of the presentation complies with FDA requirements.

**Q.14**

Under what circumstances would the Code permit a company to provide entertainment or recreational activities to healthcare practitioners?

**A.** Under the Code, companies may not provide entertainment or recreational activities to healthcare practitioners who are not employees of the companies in any context, including situations where those practitioners are providing a legitimate service to the companies, such as when they act as bona fide consultants on an advisory board or are trained at a speaker-training meeting. Thus, companies should not invite healthcare professionals to sporting events, concerts, or shows, or provide them with recreational activities such as hunting, fishing, boating, ski trips, or golf outings, even if those entertainment events or recreational activities are intended to facilitate informational interchanges between the company representative and the healthcare professional. Similarly, it would be inappropriate to provide these types of entertainment and recreational events in conjunction with promotional scientific presentations by medical experts.

**Q.15**

Company A retains a small group of 15 nationally known physicians regarding a therapeutic area relevant to company A's products to advise on general medical and business issues and provide guidance on product development and research programs for those products. These physicians are paid fees that are typical of the fees paid to thought leaders in this therapeutic area. They normally meet once or twice a year at resort locations to discuss the latest product data, research programs and Company plans. Does this comply with the Code? If it does, is it appropriate to pay for the spouse of the healthcare professional to attend, as well?

**A.** No, this arrangement for engaging healthcare professionals to obtain advice on the company's commercial operations does not appear to comply with the Code. It is appropriate for companies to engage healthcare professionals to provide bona fide advisory services as long as the number of healthcare professionals is reasonably necessary to achieve an identified purpose, and they are paid compensation that is reasonable and at fair market value for the services provided. It would not be appropriate, however, to hold such a consultant meeting at a resort venue. In this case, the number of advisors seems reasonably small and the scope of services seems to be reasonably well defined. The advisors seem to have been selected based on their expertise in the areas where advice is needed. The compensation appears consistent with the Code's provision that consultant fees should be reasonable and based on fair market value. Nevertheless, holding consultant meetings at resort locations is not appropriate under the Code. The facilities chosen should be conducive to the services provided as well as reasonable and appropriate to the

conduct of the meeting. In addition, only modest meals may be offered to such consultants, and companies should not provide recreational or entertainment events to the healthcare professional consultants in conjunction with these meetings. It would not be appropriate to pay for the cost of the spouse of the advisor. If the spouse attends, it should be at the cost of the advisor.

**Q.16**

Company A considers whether to invite 300 physicians/consultants to a two-day and one-night speaker-training program at a regional golf resort. All attendees would be compensated for their participation, and their expenses would be reimbursed. Prospective speakers would be selected based on recommendations of the Company's district managers and an assessment of their qualifications by the Company's medical or scientific personnel. Each of the attendees would be required to sign an agreement in advance covering the services they will provide. They would be educated by a faculty on the full range of data surrounding the disease state and the Company's drug product, on presentation skills, and on FDA regulatory requirements. The Company needs to train 300 speakers in order to ensure that enough speakers will actually be available when needed. Training sessions take both days, and the Company provides for a few hours of golf and expensive meals, such as lobster and filet mignon. Does this program conform to the Code? If so, is it appropriate to pay for a spouse of the healthcare professional, as well?

**A. No.** This arrangement would not conform with the Code. Speaker training is an essential activity because the FDA holds companies accountable for the presentations of their speakers. However, the Code provides that speaker training meetings should be held at appropriate venues and specifically states that resorts are not appropriate venues for training speakers. Moreover, providing entertainment (e.g., golf) and expensive meals to a healthcare professional in a speaker training program would not comply with the Code, although modest meals may be offered to attendees. The Company does appear to satisfy provisions in the Code that require potential speakers to be selected based on defined criteria such as medical expertise, knowledge and experience and to undergo extensive training that would result in a valuable service being provided to the company. The arrangement also appears to meet reasonable indicia of a bona fide consulting relationship. The number of speakers being trained is important; if significantly more participants were trained than the company plans to use as speakers, this arrangement would not comply with the Code. The amount of time spent training speakers should be reasonable in relation to the material that has to be covered. The compensation and lodging offered to prospective speakers should be evaluated to assure that it is reasonable compensation for their time and based on fair market value. It would not be appropriate to pay for the cost of the spouse of the healthcare professional. If the spouse attends, it should be at the cost of the healthcare professional.

**Q.17**

A sales representative invites a physician out for a round of golf and lunch following the golf. The physician is very busy and is difficult to see in her office. The cost of the golf and the lunch combined are \$65. Does this comply with the Code?

**A. No.** As stated in the prior version of the Code, it is inconsistent with the Code to provide entertainment or recreational activities such as golf. In addition, occasional, modest meals provided by a representative or his immediate manager working in a field sales organization are limited to in-office or in-hospital settings in conjunction with informational presentations and discussions.

**Q.18**

Under the Code, may a healthcare professional's spouse or other guest be included in a meal with a pharmaceutical company representative that is provided in connection with an informational presentation by or on behalf of the company, if the healthcare professional pays for the spouse or guest?

**A. No.** The Code provides that it is not appropriate to include a spouse or guest at a meal in connection with an informational presentation, regardless of who pays for their meal, unless the spouse or guest would independently qualify as a healthcare professional for whom the informational presentation is appropriate.

**Q.19**

A company is asked to fund a CME program as a “platinum” level supporter. This level of support includes the opportunity for the company to directly sponsor a lunch at the event. May the company become a “platinum” level supporter?

**A.** It is appropriate under the Code for a company to provide funding to a CME provider, which the provider can use at its discretion to provide meals for all participants. However, a company should not control how the provider spends the funding, and a company should not sponsor or host a meal directly at a CME program. A company may fund a CME program at a particular level of support designated by the CME provider and be publicized for providing that level of support, as long as the company does not separately promote, publicize or otherwise take advantage of any option to be identified as the sponsor of a meal.

**Q.20**

A national specialty society is holding its three-day annual conference, which includes business meetings, entertainment, and a half day of educational programs for which physicians may receive CME credit. May a company sponsor a reception or lunch at the conference?

**A.** The Code provides that a company should not provide or sponsor meals directly at CME events. However, at third party conferences or professional meetings at which CME activities comprise only a part of the conference or meeting, a company may sponsor a meal or reception at the conference if it is permitted by the group holding the conference or meeting and is clearly separate from the CME portions of the program. In such cases, any meals or receptions sponsored by a company should be modest and clearly subordinate to the amount of time spent at other aspects of the meeting. In addition, companies should be mindful of standards set forth by ACCME or other accrediting bodies that may apply in these circumstances.

**Q.21**

May a company publicize its interest in a general topic for a CME program for which a grant would be provided?

**A.** Yes, a company may communicate to multiple CME providers or the public a general topic for a CME program that might be of interest to physicians. For example, a company may publicize that it will consider funding the topics of new treatments or disease management techniques in a particular therapy area such as diabetes or hypertension. However, the company should follow CME accreditation standards considering the nature and specificity of the CME topics that the company may propose, keeping in mind the Code’s statement that financial support for CME is intended to support education on a full range of treatment options and not to promote a particular medicine. In addition, the company may not suggest the speakers or review or make any suggestions concerning the specific content of a particular CME program, even if asked by the CME provider.

**Q.22**

Under the Code, may a company make a charitable contribution such as purchasing a table at a fundraising dinner or a foursome slot at a fundraising golf tournament?

**A.** Yes, but the company may not invite healthcare professionals to attend the event at its expense. The company may use some or all of its allotment for its own employees, and return any unused portion to the sponsoring organization to use as it wishes.

**Q.23**

Under the Code, may a company compensate a consultant for bona fide services by providing an item with a legitimate patient benefit in lieu of paying an honorarium or fee?

A. If the consulting arrangement otherwise complies with the Code, and the fair market value of the item represents reasonable compensation for the services provided, this may be permissible. However, it would be important to comply with all applicable recordkeeping and reporting requirements, just as with cash compensation. The written agreement for the consulting services should set forth the compensation and its fair market value, and disclose that this is taxable income.

**Q.24**

Does the Code apply to interactions with physician office managers, receptionists, and similar personnel who may not be healthcare professionals?

A. Although the Code does not directly apply to persons who are not healthcare professionals, it would be difficult to separate a company's interactions with any of a physician's employees from those directly with the physician. Therefore, the Code should be followed under these circumstances.

**Q.25**

Does the Code address the issue of disclosure of company interactions with healthcare professionals who are members of committees that develop formularies or clinical practice guidelines?

A. Yes. The Code states that, to avoid even the appearance of impropriety, companies that have retained a healthcare professional member of a formulary or clinical practice guideline committee as a commercial consultant or speaker should require the health care professional to disclose to the committee the existence and nature of his or her relationship with the company. This disclosure requirement should extend for at least two years beyond the termination of any consultant or speaker arrangement. Upon disclosure, healthcare professionals should be required to follow the procedures set by the committee of which they are a member; these procedures may include a requirement that healthcare professionals recuse themselves from decisions relating to the medicine about which they provided speaking or consulting services. It is reasonable for a company to rely on healthcare professionals' judgment regarding how to implement these requirements regarding disclosure and subsequent interactions with the committees on which they are members.

PhRMA

Pharmaceutical Research and Manufacturers of America

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Revised July 2008

SCHEDULE 3.8  
NOVARTIS AG MSL GUIDANCE DOCUMENT

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**THE FOLLOWING FIVE PAGES HAVE BEEN OMITTED AND FILED SEPARATELY WITH THE  
U.S. SECURITIES AND EXCHANGE COMMISSION PURSUANT TO A  
REQUEST FOR CONFIDENTIAL TREATMENT.**

SCHEDULE 4.3  
LICENSED PRODUCTS SPECIFICATIONS

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SCHEDULE 4.7(A)  
CERTIFICATE OF ANALYSIS

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SCHEDULE 4.11(A)  
PRICING

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REQUEST FOR CONFIDENTIAL TREATMENT.**

**INDEMNIFICATION AGREEMENT**

This Indemnification Agreement (this “Agreement”) is made as of \_\_\_\_\_, 2015 by and between Endo Health Solutions Inc., a Delaware corporation (“EHSI”), and \_\_\_\_\_ (“Indemnitee”). This Agreement supersedes and replaces any and all previous agreements between EHSI and Indemnitee covering the subject matter of this Agreement.

**RECITALS**

WHEREAS, it is essential to Endo International plc, a public limited company incorporated in Ireland and the ultimate parent of EHSI (the “Company”), to retain and attract as directors and officers the most capable persons available;

WHEREAS, capable persons have become more reluctant to serve publicly-held corporations as directors, officers or in other capacities unless they are provided with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the Company;

WHEREAS, Indemnitee is a director of the Company’s Board of Directors (the “Board”) and/or an officer of the Company;

WHEREAS, both EHSI and Indemnitee recognize the increased risk of litigation and other claims being asserted against directors and officers of publicly-held corporations in today’s environment and the need for substantial protection against personal liability in order to enhance Indemnitee’s continued service to the Company in an effective manner;

WHEREAS, the Company has determined that its inability to retain and attract as directors and officers the most capable persons would be detrimental to the interests of the Company, and that the Company therefore should seek to assure such persons that indemnification and insurance coverage will be available in the future;

WHEREAS, the Company’s Memorandum and Articles of Association (collectively, the “Charter Documents”) require the Company to indemnify its directors and officers to the extent provided therein, and Indemnitee serves as a director and/or officer of the Company, in part, in reliance on such provisions in the Charter Documents;

WHEREAS, in recognition of Indemnitee’s need for substantial protection against personal liability in order to enhance Indemnitee’s continued service to the Company in an effective manner and Indemnitee’s reliance on the Charter Documents, and in part to provide Indemnitee with specific contractual assurance that the protection promised by the Charter Documents and available to directors under the laws of the State of Delaware will be available to Indemnitee (regardless of, among other things, any amendment to or revocation of the applicable provisions of the Charter Documents or any change in the composition of the governing bodies of the Company or any acquisition transaction relating to the Company), the Company wishes EHSI to provide in this Agreement for the indemnification of and the advancing of Expenses (as defined below) to Indemnitee to the fullest extent (whether partial or complete) permitted by the

laws of the State of Delaware and as set forth in this Agreement, and, to the extent insurance is maintained, for the continued coverage of Indemnatee under the directors' and officers' liability insurance policy of the Company; and

WHEREAS, the indirect parent of EHSI, Endo Designated Activity Company, a private limited company incorporated in Ireland, has directed EHSI to enter into this Agreement.

NOW, THEREFORE, in consideration of the premises and the covenants contained herein, and of Indemnatee continuing to serve the Company, EHSI and Indemnatee do hereby covenant and agree as follows:

Section 1. Definitions. As used in this Agreement:

(a) "Corporate Status" shall mean the status of a person who is or was a director, officer, employee, trustee, agent or fiduciary of the Company or of any other corporation, limited liability company, partnership or joint venture, trust, employee benefit plan or other enterprise which such person is or was serving at the request of the Company.

(b) "Change in Control" shall be deemed to occur if and when: (i) any person (including as such term is used in Sections 13(d) and 14(d)(2) of the 1934 Act (as defined below)) is or becomes the "beneficial owner" (as defined in Rule 13d-3 under the 1934 Act (as defined below)), directly or indirectly, of securities representing 25% or more of the combined voting power of the Company's then outstanding securities (not including in the securities beneficially owned by such person any securities acquired directly from the Company), other than a trustee or other fiduciary holding securities under an employee benefit plan of the Company, a corporation owned directly or indirectly by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company, or any Person who becomes such a beneficial owner in connection with a transaction described in clause (A) of paragraph (iii) below; or (ii) during any period of two consecutive years, individuals who at the beginning of such period constitute the Board and any new director whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds (2/3) of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or (iii) the Company's shareholders approve a business combination other than a business combination, (A) which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) at least 50% of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation, or (B) effected to implement a recapitalization of the Company (or similar transaction) in which no person is or becomes the "beneficial owner," directly or indirectly, of securities representing 25% or more of the combined voting power of the Company's then outstanding securities (not including in the securities beneficially owned by such person any securities acquired directly from the Company); or (iv) the Company's shareholders approve a sale or disposition of all or substantially all of the Company's assets (in one transaction or a series of transactions) or a plan or partial or complete liquidation, other than a sale or disposition by the Company of all or

substantially all of the Company's assets to an entity at least 75% of the combined voting power of the voting securities of which are owned by persons in substantially the same proportions as their ownership of the Company immediately prior to such sale or disposition. "1934 Act" means the Securities and Exchange Act of 1934, as amended, including the rules and regulations promulgated thereunder.

(c) "Disinterested Director" shall mean a director of the Company who is not and was not a party to the Proceeding (as defined below) in respect of which indemnification is sought by Indemnitee.

(d) "Enterprise" shall mean the Company and any other corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise of which Indemnitee is or was serving at the request of the Company as a director, officer, employee, trustee, agent or fiduciary.

(e) "Expenses" shall mean all expenses and liabilities, including judgments, fines, penalties, interest, amounts paid in settlement with the approval of the Company, reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, any federal, state, local, foreign or other taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, penalties arising from breaches of Part 4 of Title I of ERISA and related taxes under the United States Internal Revenue Code of 1986, as amended, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness in, or otherwise participating in, a Proceeding. Expenses also shall include (i) Expenses incurred in connection with any appeal resulting from any Proceeding, including without limitation the premium, security for, and other costs relating to any cost bond, supersedeas bond, or other appeal bond or its equivalent, and (ii) Expenses incurred by Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement, by litigation or otherwise. The parties agree that for the purposes of any advancement of Expenses for which Indemnitee has made written demand to the Company in accordance with this Agreement, all Expenses included in such demand that are certified by affidavit of Indemnitee's counsel as being reasonable shall be presumed conclusively to be reasonable.

(f) "Independent Counsel" shall mean a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past three (3) years has been, retained to represent: (i) the Company, EHSI or Indemnitee in any matter material to either such party (other than with respect to matters concerning Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company, EHSI or Indemnitee in an action to determine Indemnitee's rights under this Agreement. EHSI agrees to pay the reasonable fees and

expenses of the Independent Counsel and to fully indemnify such counsel against any and all expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(g) "Proceeding" shall mean any threatened, asserted, pending or completed action, suit, arbitration, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought in the right of the Company or otherwise and whether of a civil, criminal, administrative legislative, or investigative (formal or informal) nature, including any appeal therefrom, in which Indemnitee was, is or will be involved as a party, potential party, non-party witness or otherwise by reason of the fact that Indemnitee is or was a director, officer, employee, trustee, agent or fiduciary of an Enterprise, or by reason of anything done or not done by Indemnitee in any such capacity, by reason of any action taken by him/her or of any action on his/her part while acting pursuant to his/her Corporate Status, in each case whether or not serving in such capacity at the time any liability or Expense is incurred for which indemnification, reimbursement, or advancement of Expenses can be provided under this Agreement. If Indemnitee reasonably believes in good faith that a given situation may lead to or culminate in the institution of a Proceeding, such situation shall be considered a Proceeding under this paragraph.

(h) "Reviewing Party" shall mean any appropriate person or body consisting of a member or members of the Board or any other person or body appointed by the Board who is not a party to the particular Proceeding for which Indemnitee is seeking indemnification, or Independent Counsel.

Section 2. Indemnity in Third-Party Proceedings. EHSI shall indemnify Indemnitee in accordance with the provisions of this Section 2 if Indemnitee was, is, or is threatened to be made, a party to, a witness or other participant in any Proceeding, other than a Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 2, Indemnitee shall be indemnified to the fullest extent permitted by the laws of the State of Delaware, as soon as practicable but in any event no later than thirty (30) days after written demand is presented to the Company, against all Expenses (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses) actually and reasonably incurred by Indemnitee or on his/her behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he/she reasonably believed to be in or not opposed to the best interests of the Company and, in the case of a criminal proceeding had no reasonable cause to believe that his/her conduct was unlawful. No change in applicable law shall have the effect of reducing the benefits available to Indemnitee hereunder.

Section 3. Indemnity in Proceedings by or in the Right of the Company. EHSI shall indemnify Indemnitee in accordance with the provisions of this Section 3 if Indemnitee was, is, or is threatened to be made, a party to, a witness or other participant in any Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 3, Indemnitee shall be indemnified to the fullest extent permitted by the laws of the State of Delaware, as soon as practicable but in any event no later than thirty (30) days after written

demand is presented to the Company, against all Expenses actually and reasonably incurred by him/her or on his/her behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he/she reasonably believed to be in or not opposed to the best interests of the Company. No indemnification for Expenses shall be made under this Section 3 in respect of any claim, issue or matter as to which Indemnitee shall have been finally adjudged by a court to be liable to the Company, unless and only to the extent that the Delaware Court of Chancery or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, Indemnitee is entitled to indemnification. No change in applicable law shall have the effect of reducing the benefits available to Indemnitee hereunder.

Section 4. Indemnification for Expenses of a Party Who is Wholly or Partly Successful. Notwithstanding any other provisions of this Agreement, to the fullest extent permitted by the laws of the State of Delaware and to the extent that Indemnitee is a party to (or a participant in) and is successful, on the merits or otherwise, in any Proceeding or in defense of any claim, issue or matter therein, in whole or in part, EHSI shall indemnify Indemnitee against all Expenses actually and reasonably incurred by him/her in connection therewith. If Indemnitee is entitled under any provision of this Agreement to indemnification by EHSI for some or a portion of the Expenses, EHSI shall indemnify Indemnitee for the portion thereof to which Indemnitee is entitled. For purposes of this Section 4 and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

Section 5. Indemnification For Expenses of a Witness. Notwithstanding any other provision of this Agreement, to the fullest extent permitted by the laws of the State of Delaware and to the extent that Indemnitee is, by reason of his/her Corporate Status, a witness or otherwise asked to participate in any Proceeding to which Indemnitee is not a party, he/she shall be indemnified against all Expenses actually and reasonably incurred by him/her or on his/her behalf in connection therewith.

Section 6. Exclusions. Notwithstanding any provision in this Agreement, EHSI shall not be obligated under this Agreement to make any indemnity in connection with any claim made against Indemnitee:

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision in the Charter Documents, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision. In the event that such actual payment is made under any insurance policy or indemnity provision after EHSI has made an indemnity payment under this Agreement, Indemnitee shall promptly reimburse EHSI for such indemnity in the amount of such payment; or

(b) for (i) an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the 1934 Act or similar provisions of state statutory law or common law, or (ii) any reimbursement of the Company by Indemnitee of any bonus or other incentive-based or equity-

based compensation or of any profits realized by Indemnitee from the sale of securities of the Company, as required in each case under the 1934 Act (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”), or the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act); or

(c) in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees or other indemnitees, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation, (ii) the Proceeding is for enforcement of this Agreement (to the extent that Indemnitee prevails), or (iii) EHSI provides the indemnification, in its sole discretion, pursuant to the powers vested in EHSI under the laws of the State of Delaware; or

(d) for which the Reviewing Party shall have determined (in a written opinion, in any case in which the Independent Counsel is involved) that Indemnitee would not be permitted to be indemnified under the laws of the State of Delaware; provided, however, Indemnitee shall have the right to commence litigation in any court in the States of Pennsylvania or Delaware having subject matter jurisdiction thereof and in which venue is proper seeking an initial determination by the court or challenging any such determination by the Reviewing Party or any aspect thereof, including the legal or factual bases thereof, and EHSI hereby consents to service of process and to appear in any such proceeding. Any determination by the Reviewing Party otherwise shall be conclusive and binding on EHSI and Indemnitee. If Indemnitee commences legal proceedings in a court of competent jurisdiction to secure a determination that Indemnitee should be indemnified under the laws of the State of Delaware, any determination made by the Reviewing Party that Indemnitee is not entitled to be indemnified under the laws of the State of Delaware shall not be binding until a final judicial determination is made (as to which all rights of appeal therefrom have been exhausted or lapsed) that Indemnitee is not entitled to be so indemnified under the laws of the State of Delaware.

Section 7. Advances of Expenses.

(a) Notwithstanding any provision of this Agreement to the contrary, EHSI shall advance or reimburse, to the extent not prohibited by law, the Expenses incurred by Indemnitee in connection with any Proceeding (or any part of any Proceeding) (“Advances”). Advances shall be made within twenty-one (21) days after the receipt by the Company of a statement or statements requesting such Advances from time to time, whether prior to or after final disposition of any Proceeding. Advances shall be unsecured and interest free. Advances shall be made without regard to Indemnitee’s ability to repay the Expenses and without regard to Indemnitee’s ultimate entitlement to indemnification under the other provisions of this Agreement. Advances shall also include any and all reasonable Expenses incurred pursuing an action to enforce this right of advancement, including Expenses incurred preparing and forwarding statements to the Company to support the Advances claimed. This Section 7 shall



not apply to any claim made by Indemnitee for which indemnity is excluded pursuant to Section 6.

(b) The obligation of EHSI to make an advancement of Expenses pursuant to Section 7(a) shall be subject to the condition that, if, when and to the extent that the Reviewing Party determines that Indemnitee would not be permitted to be so indemnified under applicable law, EHSI shall be entitled to be reimbursed by Indemnitee (who hereby agrees to reimburse EHSI) for all such amounts paid; provided, however, that if Indemnitee has commenced or thereafter commences legal proceedings in a court of competent jurisdiction to secure a determination that Indemnitee should be indemnified under the laws of the State of Delaware, any determination made by the Reviewing Party that Indemnitee would not be permitted to be indemnified under the laws of the State of Delaware shall not be binding and Indemnitee shall not be required to reimburse EHSI for any Advance until a final judicial determination is made with respect thereto (as to which all rights of appeal therefrom have been exhausted or lapsed). Indemnitee's undertaking to repay such Advances shall be unsecured and interest-free.

Section 8. Procedure for Notification and Defense of Claim.

(a) Indemnitee shall notify the Company in writing of any matter with respect to which Indemnitee intends to seek indemnification or advancement of Expenses hereunder as soon as reasonably practicable following the receipt by Indemnitee of any written notice, summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification or advancement of Expenses covered under this Agreement. The written notification to the Company shall include a description of the nature of the Proceeding, the facts underlying the Proceeding, and documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification. The failure by Indemnitee to notify the Company hereunder will not relieve EHSI from any liability which it may have to Indemnitee hereunder or otherwise than under this Agreement, and any delay in so notifying the Company shall not constitute a waiver by Indemnitee of any rights under this Agreement. The Secretary of the Company shall, promptly upon receipt of such a request for indemnification, advise the Board and EHSI in writing that Indemnitee has requested indemnification.

(b) The Company and EHSI will be entitled to participate in the Proceeding at its own expense.

Section 9. Procedure Upon Application for Indemnification.

(a) Upon written request by Indemnitee for indemnification pursuant to Section 8(a), a determination with respect to Indemnitee's entitlement thereto shall be made by the Reviewing Party, who shall be: (i) if a Change in Control (other than a Change in Control which has been approved by a majority of the Board who were directors immediately prior to such Change in Control) shall have occurred, Independent Counsel, retained pursuant to Section 9(c); or (ii) if a Change in Control shall not have occurred, (A) selected by a majority vote of the

Disinterested Directors, even though less than a quorum of the Board, or (B) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, Independent Counsel, retained by the Company and EHSI (who shall make such determination in the form of a written opinion to the Board, a copy of which shall be delivered to Indemnatee). Indemnatee shall cooperate with the Reviewing Party, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnatee and reasonably necessary to such determination. Any costs or Expenses (including attorneys' fees and disbursements) incurred by Indemnatee in so cooperating with the Reviewing Party shall be borne by EHSI (irrespective of the determination as to Indemnatee's entitlement to indemnification).

(b) In the event that Independent Counsel is retained by the Company and EHSI pursuant to Section 9(a), written notice of the selection shall be provided promptly to Indemnatee. Upon the due commencement of any judicial proceeding pursuant to Section 11(a) of this Agreement, legal counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

(c) EHSI agrees that if there is a Change in Control of the Company (other than a Change in Control which has been approved by a majority of the Board who were directors immediately prior to such Change in Control) then with respect to all matters thereafter arising concerning the rights of Indemnatee to indemnity payments and Advances under this Agreement or any other agreement or the Charter Documents now or hereafter in effect relating to any Proceeding, EHSI shall seek legal advice only from Independent Counsel selected by Indemnatee and approved by the Company (which approval shall not be unreasonably withheld). Such Independent Counsel, among other things, shall render its written opinion to the Company, EHSI and Indemnatee as to whether and to what extent Indemnatee would be permitted to be indemnified under the laws of the State of Delaware. EHSI agrees to pay the reasonable fees of the Independent Counsel and to indemnify fully such Independent Counsel against any and all expenses (including attorneys' fees), claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

Section 10. Presumptions and Effect of Certain Proceedings.

(a) In making a determination with respect to entitlement to indemnification hereunder, the Reviewing Party shall, to the fullest extent not prohibited by the laws of the State of Delaware, presume that Indemnatee is entitled to indemnification under this Agreement if Indemnatee has submitted a request for indemnification in accordance with Section 8(a) of this Agreement, and EHSI shall, to the fullest extent not prohibited by the laws of the State of Delaware, have the burden of proof to overcome that presumption in connection with the making by any person, persons or entity of any determination contrary to that presumption.

(b) Subject to Section 11(d), if the Reviewing Party shall not have made a determination within sixty (60) days after receipt by the Company of the request thereof, the requisite determination of entitlement to indemnification shall, to the fullest extent not prohibited by the laws of the State of Delaware, be deemed to have been made and Indemnatee shall be

entitled to such indemnification, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under the laws of the State of Delaware; provided, however, that such 60-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 10(b) shall not apply if the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 9(a) of this Agreement.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, shall not (except as otherwise expressly provided in this Agreement) adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not meet any particular standard of conduct, act in good faith and in a manner which he/she reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that his/her conduct was unlawful.

(d) Actions of Others. The knowledge and/or actions, or failure to act, of any director, officer, employee, trustee, agent or fiduciary of the Enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

Section 11. Remedies of Indemnitee.

(a) Subject to Section 11(d), in the event that (i) the advancement of Expenses is not timely made pursuant to Section 7 of this Agreement, (ii) no determination of entitlement to indemnification shall have been made pursuant to Section 9(a) of this Agreement within ninety (90) days after receipt by the Company of the request for indemnification, (iii) the payment of indemnification is not made pursuant to Section 2 or 3 within thirty (30) days after receipt by the Company of a written request thereof, or (iv) EHSI or any other person takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or Proceeding designed to deny, or to recover from, Indemnitee the benefits provided or intended to be provided to Indemnitee hereunder, Indemnitee shall be entitled to an adjudication by a court of his/her entitlement to such indemnification or advancement of Expenses.

(b) Any judicial proceeding commenced pursuant to this Section 11 shall be conducted in all respects as a de novo trial on the merits and EHSI shall have the burden of proving that Indemnitee is not entitled to indemnification or advancement of Expenses.

(c) If a determination shall have been made that Indemnitee is entitled to indemnification, EHSI shall be bound by such determination in any judicial proceeding commenced pursuant to this Section 11, absent (i) a misstatement by Indemnitee of a material

fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement of Indemnitee to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.

Section 12. Non-exclusivity; Insurance; Subrogation; Other Payments.

(a) The rights of indemnification and to receive advancement of Expenses as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Charter Documents, any agreement, a vote of stockholders or a resolution of the Board, or otherwise. To the extent that a change in the laws of the State of Delaware, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Charter Documents and this Agreement, it is the intent of the parties hereto that Indemnitee shall, by this Agreement, enjoy the greater benefits so afforded by such change. To the extent that there is a conflict or inconsistency between the terms of this Agreement and the Charter Documents, it is the intent of the parties hereto that Indemnitee shall enjoy the greater benefits regardless of whether contained herein or in the Charter Documents. No amendment or alteration of the Charter Documents or any other agreement shall adversely affect the rights provided to Indemnitee under this Agreement.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents of the Enterprise, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any such director, officer, employee or agent under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms hereof, the Company has director and officer liability insurance in effect, the Company shall give prompt notice of such claim or of the commencement of a Proceeding, as the case may be, to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies.

(c) In the event of any payment under this Agreement, EHSI shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable EHSI to bring suit to enforce such rights. EHSI shall pay or reimburse all expenses actually and reasonably incurred by Indemnitee in connection with such subrogation.

(d) EHSI's obligation to indemnify or advance Expenses hereunder to Indemnitee who is or was serving at the request of the Company as a director, officer, employee, trustee, agent or fiduciary of any Enterprise shall be reduced by any amount Indemnitee has

actually received as indemnification or advancement of Expenses from such other corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of Expenses from such other corporation, limited liability company, partnership, joint venture, trust or other enterprise.

Section 13. Actions of the Company. To the extent that this Agreement contemplates actions to be taken by the Company or EHSI, any officer engaging in such actions shall not be a party to the Proceeding in respect of which indemnification is sought.

Section 14. Duration of Agreement. This Agreement shall continue until and terminate upon the later of: (a) ten (10) years after the date that Indemnitee shall have ceased to serve as a director or an officer of the Company or in other Corporate Status due to service as a director or an officer of the Company or (b) one (1) year after the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification or advancement of Expenses hereunder and of any proceeding commenced by Indemnitee pursuant to Section 11 of this Agreement relating thereto. This Agreement shall be binding upon EHSI and its successors and assigns, and EHSI agrees to assign this Agreement to any purchaser of substantially all of the assets and to secure the agreement of such purchaser to assume this Agreement. This Agreement shall inure to the benefit of Indemnitee and his/her heirs, executors and administrators.

Section 15. Reliance as Safe Harbor. Indemnitee shall be entitled to indemnification for any action or omission to act undertaken (a) in good faith reliance upon the records of the Company, including its financial statements, or upon information, opinions, reports or statements furnished to Indemnitee by the officers or employees of the Company or any of its subsidiaries in the course of their duties, or by committees of the Board, or by any other person as to matters Indemnitee reasonably believes are within such other person's professional or expert competence, or (b) on behalf of the Company in furtherance of the interests of the Company in good faith in reliance upon, and in accordance with, the advice of legal counsel or accountants, provided such legal counsel or accountants were selected with reasonable care by or on behalf of the Company. In addition, the knowledge and/or actions, or failures to act, of any director, officer, agent or employee of the Company shall not be imputed to Indemnitee for purposes of determining the right to indemnity hereunder.

Section 16. Severability. If any provision or provisions of this Agreement shall be held to be invalid, void, illegal or otherwise unenforceable for any reason whatsoever, by a court of competent jurisdiction: (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal, void or otherwise unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent permitted by law; (b) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement shall be construed so as to give effect to the intent manifested thereby.

Section 17. Merger. This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof; provided, however, that this Agreement is a supplement to and in furtherance of the Charter Documents and the laws of the State of Delaware, and shall not be deemed a substitute thereof, nor to diminish or abrogate any rights of Indemnitee thereunder.

Section 18. Modification and Waiver. No supplement, modification or amendment of this Agreement shall be binding unless executed in writing by both of the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions hereof (whether or not similar) nor shall such waiver constitute a continuing waiver. In the event EHSI or any of its subsidiaries enters into an indemnification agreement with another director, officer, employee, trustee, agent or fiduciary of the Company or any of its subsidiaries containing a term or terms more favorable to Indemnitee than the terms contained herein (as determined by Indemnitee), Indemnitee shall be afforded the benefit of such more favorable term or terms and such more favorable term or terms shall be deemed incorporated by reference herein as if set forth in full herein. As promptly as practicable following the execution by EHSI or the relevant subsidiary of each indemnity agreement with any such other director, officer, employee, trustee, agent or fiduciary (i) EHSI shall send a copy of the indemnity agreement to Indemnitee, and (ii) if requested by Indemnitee, EHSI shall prepare, execute and deliver to Indemnitee an amendment to this Agreement containing such more favorable term or terms.

Section 19. Notices. All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed to have been duly given if (a) delivered by hand and receipted for by the party to whom said notice or other communication shall have been directed, (b) mailed by certified or registered mail, with postage prepaid, on the third business day after the date on which it is so mailed, (c) mailed by reputable overnight courier and receipted for by the party to whom said notice or other communication shall have been directed or (d) sent by facsimile transmission, with receipt of oral confirmation that such transmission has been received, for each party, at the address indicated on the signature page of this Agreement, or at such other address as each party shall provide to the other party.

Section 20. Applicable Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws and/or rules. EHSI and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement may be brought in the Chancery Court of the State of Delaware (the "Delaware Court"), or in any other state or federal court in the United States of America with subject matter and personal jurisdiction, but not in any court in any other country, (ii) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court, and (iii) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum.

Section 21. Period of Limitations. No legal action shall be brought and no cause of action shall be asserted by or in the right of EHSI against Indemnatee, Indemnatee's spouse, heirs, executors or personal or legal representatives after the expiration of two (2) years from the date of accrual of such cause of action, and any claim or cause of action of EHSI shall be extinguished and deemed released unless asserted by the timely filing of a legal action within such two-year period; provided, however, that if any shorter period of limitations is otherwise applicable to any such cause of action such shorter period shall govern.

Section 22. Identical Counterparts. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement.

Section 23. Headings. The headings contained in this Agreement are inserted for convenience only and shall not be deemed to affect construction of this Agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed as of the day and year first above written.

ENDO HEALTH SOLUTIONS INC.

INDEMNITEE

By:

/s/Matthew J. Maletta

Name: Matthew J. Maletta  
Title: EVP, CLO & Secretary  
Address: 1400 Atwater Drive  
Malvern, PA 19355

\_\_\_\_\_  
Name:  
Title: Director  
Address:



## ENDO HEALTH SOLUTIONS INC.

## EXECUTIVE EMPLOYMENT AGREEMENT

THIS AGREEMENT (this "Agreement") is hereby entered into as of the 28th day of February, 2016, by and between Endo Health Solutions Inc. (the "Company"), a wholly-owned subsidiary of Endo International plc ("Endo"), and Rajiv De Silva ("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 March 18, 2016 (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 and Chief Executive Officer of Endo and shall be assigned with the customary duties and responsibilities of such position. In addition, as of the Effective Date, Executive shall serve as member of the board of directors of Endo (the "Board"). For as long as Executive is the Chief Executive Officer of Endo, Endo shall nominate Executive for re-election to the Board. At the time of Executive's termination of employment with the Company for any reason, Executive shall resign from the Board and the board of directors of any of Endo's affiliates. Executive shall not receive any compensation in addition to the compensation described in Sections 3 and 4 of this Agreement for serving as a director of Endo or as a director or officer of any of Endo's affiliates, but shall be covered under the indemnification and directors' and officers' liability insurance provisions of Section 14(d) for any such services.
  - (b) Executive shall report directly to the Board. 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 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.

### 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 \$1,155,000 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"), 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, beginning with the 2016 fiscal year, Executive shall be eligible to receive a target annual cash bonus of 125% 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 (at a level commensurate with his position as Chief Executive Officer, as compared to other senior executives of the Company), which may be subject to the achievement of certain performance targets set by the Committee. 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 (including travel in first-class) 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 at the Company's headquarters, 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; vacation must be taken at such time or times as approved by the Board; 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.

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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 three months or more under an accident and health plan covering employees of the Company. 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) and as evidenced by a resolution adopted by two-thirds of the independent members of the Board. "Cause" shall mean, for purposes of this Agreement: (a) the continued failure by Executive substantially to perform Executive's duties under this Agreement (other than any such failure resulting from Disability or other illness), (b) Executive makes, or is found to have made, a false certification relating to the Company's financial statements, (c) the criminal felony indictment of Executive by a court of competent jurisdiction, (d) the engagement by Executive in misconduct that has caused, or in the good faith judgment of the Board may cause if not discontinued, material harm (financial or otherwise) to the Company or any of its affiliates, such harm to include, without limitation, (i) the disclosure of material secret or Confidential Information (as defined in Section 10



(d) of the Company or any of its affiliates, (ii) 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 (iii) 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, (e) the debarment of Executive by the FDA, or (f) the continued material breach by Executive of this Agreement. For purposes of this definition, Cause shall not exist unless written demand is delivered by the Board to Executive which specifically identifies the conduct, events or circumstances that may provide grounds for Cause in reasonable detail within ninety (90) calendar days of the Company’s knowledge of such conduct, events or circumstances. During the thirty (30) day period after receipt of such demand, Executive shall have an opportunity to cure or remedy such conduct, events or circumstances and present his case to the full Board (with the assistance of counsel chosen by Executive) before any termination for Cause is finalized by a vote by at least two-thirds of the independent members of the Board at a meeting of the Board called and held for such purpose. References to the Company in subsections (a) through (f) 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.
- (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 (as defined in Section 7 below) 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: (i) a diminution in Executive’s Base Salary, Target Bonus (provided that in no event shall a failure to earn a bonus equal or in excess of the Target Bonus by reason of failure to achieve applicable performance goals be deemed Good Reason) or a material diminution in benefits; (ii) a material, adverse change to Executive’s position, duties or responsibilities without Executive’s express written consent; (iii) any change in reporting structure such that Executive is required to report to someone other than the Board; (iv) any material breach by the Company of its obligations under this



Agreement (including the material failure to pay any amounts due hereunder when due or the failure of the Company to abide by the requirements of Section 14(a)(i) below with respect to successors or permitted assigns); 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;

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(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, 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 terms no less favorable to Executive and 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, 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 Other Than in Connection with a Change in Control. 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, in either case other than where such termination would entitle Executive to the benefits provided in Section 8(e) of this Agreement, then, subject to Section 14(f) 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 terms no less favorable to Executive and 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, 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) Termination by the Company Without Cause or by Executive for Good Reason Following a Change in Control. 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 within twenty-four (24) months following a Change in Control, then, in lieu of the amounts due under Section 8(d) above and subject to Section 14(f) of this Agreement, Executive shall be entitled to the benefits provided in this Section 8(e):
- (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 three (3)



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 three (3) years following such termination on terms no less favorable to Executive and Executive's dependents (including with respect to payment for the costs thereof) than those in effect immediately prior to such termination, which such three 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.
- (v) For purposes of this Agreement, "Change in Control" shall have the meaning set forth in Endo's 2015 Stock Incentive Plan, as amended from time to time (provided that any such amendment is not adverse to Executive).
- (f) 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), 8(d)(iv), and 8(e)(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.

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- (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) 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 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.

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 twenty-four (24) 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; provided, that the foregoing shall not apply to Executive's head of operations/chief of staff. 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 affiliate's employees or the provision of references shall not constitute a breach of such obligations.

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- (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 twenty-four (24) 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 compete in whole or in part with the products or services (both on 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) For the avoidance of doubt it shall not be a violation of this Section 11(b), for Executive to provide services to 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.

- (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. 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 response to a valid subpoena, court order, regulatory request or other 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, 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. 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, following the second anniversary of 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 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) Fees and Expenses. The Company shall pay reasonable and documented legal fees and related expenses, up to a maximum amount of \$50,000, incurred by Executive in connection with the negotiation of this Agreement and related employment arrangements. Such reimbursement shall be made as soon as practicable, but in no event later than the end of the calendar year following the calendar year in which the expenses were incurred. Executive is responsible for any taxes that may be due based upon the value of the fees and expenses reimbursed by the Company. Executive acknowledges that Executive has had the opportunity to consult with legal counsel of Executive’s choice in connection with the drafting, negotiation and execution of this Agreement and related employment arrangements.
- (c) 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 with a copy to the Chairman of the Committee. 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.

- (d) 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.
- (e) 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.
- (f) Release of Claims. The termination benefits described in Section 8(d) and Section 8(e) 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(d) of this Agreement and provided further that, following a Change in Control, Executive's requirement to deliver a release shall be contingent on the Company delivering to Executive a release of claims in the form of Exhibit A hereto.
- (g) 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.

- (h) Executive Acknowledgement. Executive acknowledges 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.
- (i) 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.
- (j) 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.
- (k) 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.
- (l) 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.

- (m) 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.
- (n) 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.
- (o) 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.
- (p) 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.
- (q) Entire Agreement. This Agreement constitutes the entire agreement between the parties hereto and supersedes all prior agreements, if any, understandings and arrangements, oral or written, between the parties hereto with respect to the subject matter hereof.
- (r) 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/ ROGER H. KIMMEL

Name: Roger H. Kimmel

Title: Chairman of the Board of Directors

**EXECUTIVE**

By: /s/ RAJIV DE SILVA

Name: Rajiv De Silva

Title: President & Chief Executive Officer



## EXHIBIT A

### FORM OF RELEASE AGREEMENT

THIS RELEASE AGREEMENT (the "Release") is made by and between Rajiv De Silva ("Executive") and Endo Health Solutions, Inc. (the "Company").

1. FOR AND IN CONSIDERATION of the payments and benefits provided in Section [8(d)(iii) and (iv)] of the Employment Agreement between Executive and the Company dated as of February 28, 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)(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.

[Upon the Release becoming effective, the Company hereby discharges and generally releases Executive from all claims, causes of action, suits, agreements, and damages which the Company may have now or in the future against Executive for any act, omission or event relating to his employment with the Company or termination of employment therefrom occurring up to and including the date on which the Company signs the Release (excluding any acts or omissions constituting fraud, theft, embezzlement or breach of fiduciary duty by Executive) to the extent that such claim, cause of action, suit, agreement or damages is based on facts, acts, omissions, circumstances or events actually known, or which should have been reasonably known, on the date on which the Company signs the Release by any member of the Board of Directors of the Company.]<sup>1</sup>

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.

<sup>1</sup> Insert upon qualifying termination following a Change in Control.

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.

Dated:

\_\_\_\_\_  
Rajiv De Silva

Dated:

The confidential portions of this exhibit have been filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities and Exchange Act of 1934, as amended. REDACTED PORTIONS OF THIS EXHIBIT ARE MARKED BY AN

\*\*\*.

**FIRST AMENDMENT TO  
SECOND AMENDED AND RESTATED DEVELOPMENT AND LICENSE AGREEMENT**

This **FIRST AMENDMENT TO SECOND AMENDED AND RESTATED DEVELOPMENT AND LICENSE AGREEMENT** dated January \_\_, 2016, with an effective date as of January 1, 2016 (the “First Amendment Effective Date”), is by and between BioSpecifics Technologies Corp., a Delaware corporation (“BTC”), and Endo Global Ventures, a Bermuda unlimited liability company. BTC and Endo shall sometimes be referred to herein collectively as “Parties.”

**RECITALS**

WHEREAS, BTC and Auxilium Pharmaceuticals, Inc. (“Auxilium”) entered into a Second Amended and Restated Development and License Agreement dated August 31, 2011 (the “Agreement”);

Whereas Auxilium assigned the Agreement to Auxilium Be1muda ULC (“Auxilium Bermuda”) on January 20, 2015;

WHEREAS, an affiliate of Endo International plc acquired Auxilium and Auxilium Be1muda on January 29, 2015, and Auxilium Bermuda changed its name to Endo Global Ventures (“Endo”);

WHEREAS, disputes have arisen between BTC and Endo regarding certain payments for Cost of Goods for sales of the Product for the Partner II Territory and the Japan Territory under the Agreement, and

WHEREAS, the Parties now desire to amend the Agreement and resolve the dispute as set forth herein.

**TERMS**

NOW, THEREFORE, for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, BTC and Endo agree as follows:

1. Definitions. Capitalized terms used but not otherwise defined herein, shall have the respective meanings ascribed to terms in the Agreement.
2. All references in the Agreement to Auxilium will be replaced with references to Endo (as defined above).
3. Section 1.7. The Agreement is hereby amended to delete Section 1.7, which defines the term “Auxilium Territory,” and replaced with the following:

“Endo Territory” shall mean the Territory and any other country not included in (1) the Japan Territory or (2) Partner II Territory; provided, however, that, regardless of whether Endo Commercializes the Product in the United States itself or through a Sublicensee, the Endo Territory will always include the United States.
4. Sections 1.55 and 1.57. The Agreement is hereby amended to delete Sections 1.55 and 1.57, which define the terms “Partner” and “Partner Territory,” respectively. Any references in the Agreement to the terms “Partner” and “Partner Territory” are hereby deleted.
5. Section 1.56. The Agreement is hereby amended to delete Section 1.56, which defines the term “Partner II,” and replaced with the following:

“Partner II” shall mean one or more Persons (excluding any Endo Affiliates), from time to time, to whom Endo sublicenses any of the rights granted by BTC hereunder to research, Develop, use, Manufacture, Commercialize, market, sell or distribute the Product in the Field in one or more countries of the Partner II Territory including, but not limited to, Swedish Orphan Biovitrum AB.
6. Section 2.2(c) of the Agreement. Section 2.2(c) of the Agreement is hereby deleted in its entirety and replaced by the following:

(c) Exercise of Options.

(i) Exercise Period; Exercise of Option. The period during which Endo may exercise an Additional Indication Option (the "Exercise Period") shall commence on the date on which BTC submits a Phase II Clinical Trial report to Endo for the Product for such Additional Indication and ends one hundred and twenty (120) days thereafter. BTC shall provide Endo with a copy of a Phase II Clinical Trial report and any additional data or results in its control. Endo may exercise the Additional Indication Option at any time during the Exercise Period by delivering to BTC a written notice of exercise with regard to such Additional Indication (each, an "Exercised Indication") that sets forth the effective date of the exercise (the "Exercised Indication Date"), which must be within the Exercise Period. Upon receipt, BTC shall counter-sign the exercise notice which shall then be appended to and incorporated by reference into this Agreement effective the Exercised Indication Date.

(ii) Early Exercise Option. In the event Endo desires to exercise its Additional Indication Option at any stage of development activity prior to the submission of a Phase II Clinical Trials report (each, an "Early Exercised Indication"), Endo shall deliver to BTC a written notice of Early Exercised Indication with regard to such Additional Indication. Such notice shall be subject to the written consent of BTC, which consent shall not be unreasonably withheld. Such notice shall set forth the Exercised Indication Date, and, upon receipt of the written consent of BTC, shall be appended to and incorporated by reference into this Agreement.

7. Section 7.2(a) of the Agreement. Section 7.2(a) of the Agreement is hereby deleted in its entirety and replaced by the following:

(a) In addition to the royalty payments to be made to BTC under Section 7.1,

- (i) Endo shall pay to BTC an amount equal to a \*\*\* (\*\*\*)% mark-up of Cost of Goods in respect of any sale of Product in the Field in the Endo Territory.



- (ii) The Parties hereby agree that in consideration for the following one-time payments, and as settlement for any disputes in connection to Cost of Goods payments pursuant to the Agreement, there shall be no further payments for Cost of Goods for sales of the Product payable by Endo to BTC for the Partner II Territory or Japan Territory. Therefore, within ten (10) days of the last signature date below, Endo shall pay to BTC as follows:

(A) Eight Million US Dollars (\$8,000,000) for any mark-up on Costs of Goods for sales of Product for any Exercised Indication currently marketed (i.e., XIAFLEX/XIAPEX for Dupuytren' s contracture and Peyronie' s Disease) by Paitner II and the Japan Partner; and

(B) Two Hundred Fifty Thousand US Dollars (\$250,000) for any mark-up on Cost of Goods for sales of Product for any other present or future Exercised Indication that may be sublicensed in the Partner II Territory and Japan Territory.

8. Section 7.4(a) of the Agreement. Section 7.4(a) of the Agreement is hereby deleted in its entirety and replaced by the following:

(a) Upon Exercise of Option.

(i) Within ten (10) Business Days of the inclusion of an Exercised Indication in the Field in accordance with Section 2.2(c)(i), Endo shall make a one-time license fee payment to BTC on a per Indication basis in the amount of \*\*\*.

(ii) Within ten (10) Business Days of the inclusion of an Exercised Indication in the Field in accordance with Section 2.2(c)(ii), Endo shall make a one-time license fee payment to BTC on a per Indication basis in the amount of Five Hundred Thousand US dollars (\$500,000).

9. Section 13.4 of the Agreement. Section 13.4 of the Agreement is deleted in its entirety and replaced by the following:

All communications between the Parties with respect to any of the provisions of this Agreement will be sent to the addresses set out below, or to other addresses as designated by one Party to the other by notice pursuant hereto, by internationally recognized courier or by prepaid certified, air mail (which shall be deemed received by the other Party on the seventh business day following deposit in the mails), or by facsimile transmission or other electronic means of communication (which shall be deemed received when transmitted), with confirmation by letter given by the close of business on or before the next following business day:

If to BTC, at:

Biospecifics Technologies Corp. 35 Wilbur Street  
Lynbrook, New York 11563  
Attn: Thomas Wegman, President

with a copy to:

Morgan Lewis & Bockius LLP One Federal Street  
Boston, MA 02110  
Attn: Carl A. Valenstein, Partner

If to Endo at:

Endo Global Ventures 1400 Atwater Drive

Malvern, PA 19355

Attention: Chief Legal Officer Facsimile: 484-713-5204

Email: [LegalNotices@endo.com](mailto:LegalNotices@endo.com)

For purposes of Section 11.3, from time-to-time, Endo shall provide appropriate contact information for each Partner IL

10. Releases. In consideration for the above, BTC, on its behalf, its successors, assigns and Affiliates, whether past, present or future, hereby releases and forever discharges Endo and its successors, assigns, and Affiliates, from any and all claims, demands, actions, suits or causes of action, known or unknown, arising under the Agreement for mark-up on Cost of Goods payments for the Partner II Territory and the Japan Territory. In consideration for the above, Endo, on its behalf, its successors, assigns and Affiliates, whether past, present or future, hereby releases and forever discharges BTC and its successors, assigns, and Affiliates, from any and all claims, demands, actions, suits or causes of action, known or unknown, arising under the Agreement for mark-up on Cost of Goods payments for the Partner II Territory and the Japan Territory.
11. Amendment. Except to the extent amended hereby, the provisions of the Agreement shall remain unmodified, and the Agreement, as amended by this Amendment shall remain in full force and effect in accordance with its terms.
12. Governing Law. This Amendment shall be governed by and construed in accordance with the law of the State of New York, without regard to the conflicts of law rules of such state.
13. Counterparts. This Amendment may be executed simultaneously in counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

CONFIDENTIAL

ETC-Endo First Amendment to Second Amended and Restated License Agreement

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date last written below.

BIOSPECIFICS TECHNOLOGIES CORP.

/s/Thomas Wegman

Name: Thomas Wegman

Title: President

Date: 1/24/16

ENDO GLOBAL VENTURES

/s/James Bodi

Name: James Bodi for and on behalf of Appleby Directors I (Bermuda) LTD.

Title: Director of Endo Global Ventures

Date: 1 February 2016

CONFIDENTIAL

BTC-Endo First Amendment to Second Amended and Restated License Agreement

## SUBSIDIARIES OF THE REGISTRANT

The following is a list of subsidiaries of the Company as of December 31, 2015, omitting some subsidiaries which, considered in the aggregate, would not constitute a significant subsidiary.

Subsidiary	Jurisdiction of Incorporation or Organization	Ownership by Endo International plc
Astora Women's Health Technologies	Ireland	Indirect
Endo DAC	Ireland	Direct
Endo Finance II Limited	Ireland	Indirect
Endo Finance III Limited	Ireland	Indirect
Endo Finance IV Limited	Ireland	Indirect
Endo Finance Limited	Ireland	Indirect
Endo Ireland Finance Limited	Ireland	Indirect
Endo Management Limited	Ireland	Indirect
Endo TopFin Limited	Ireland	Indirect
Endo Ventures Limited	Ireland	Indirect
Hawk Acquisition Ireland Limited	Ireland	Indirect
Paladin Labs Europe Limited	Ireland	Indirect
Endo Bermuda Finance Limited	Bermuda	Indirect
Endo Global Ventures	Bermuda	Indirect
Endo Ventures Bermuda Limited	Bermuda	Indirect
Paladin Labs Canadian Holding Inc.	Canada	Indirect
Paladin Labs Inc.	Canada	Indirect
Endo Ventures Cyprus Limited	Cyprus	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 US Holdings Luxembourg I S.a r.l.	Luxembourg	Indirect
Endo US Holdings Luxembourg II S.a r.l.	Luxembourg	Indirect
Grupo Farmaceutico Somar, S.A. de C.V.	Mexico	Indirect
Laboratorios Paladin S.A. de C.V.	Mexico	Indirect
Serral, S.A. de C.V.	Mexico	Indirect
Somar Humana, S.A. de C.V.	Mexico	Indirect
Endo Netherlands B.V.	Netherlands	Indirect
Litha Healthcare Group Limited	South Africa	Indirect
Actient Therapeutics, LLC	Delaware	Indirect
Anchen Incorporated	Delaware	Indirect
Anchen Pharmaceuticals, Inc.	California	Indirect
Astora Holdings, LLC	Delaware	Indirect
Astora Women's Health Holdings, LLC	Delaware	Indirect
Astora Women's Health, LLC	Delaware	Indirect
Auxilium Pharmaceuticals, Inc.	Delaware	Indirect
Auxilium US Holdings, LLC	Delaware	Indirect
DAVA Pharmaceuticals, Inc.	Delaware	Indirect
Endo Finance LLC	Delaware	Indirect
Endo Finco Inc.	Delaware	Indirect
Endo Health Solutions Inc.	Delaware	Indirect
Endo LLC	Delaware	Indirect
Endo Pharmaceuticals Inc.	Delaware	Indirect
Endo Pharmaceuticals Solutions Inc.	Delaware	Indirect
Endo Pharmaceuticals Valera, Inc.	Delaware	Indirect
Endo U.S. Inc.	Delaware	Indirect
Generics Bidco I, LLC	Delaware	Indirect

<b>Subsidiary</b>	<b>Jurisdiction of Incorporation or Organization</b>	<b>Ownership by Endo International plc</b>
Generics Bidco II, LLC	Delaware	Indirect
Generics International (US Holdco), Inc.	Delaware	Indirect
Generics International (US Midco), Inc.	Delaware	Indirect
Generics International (US Parent), Inc.	Delaware	Indirect
Generics International (US), Inc.	Delaware	Indirect
JHP Acquisition LLC	Delaware	Indirect
JHP Group Holdings, Inc.	Delaware	Indirect
Ledgemont Royalty Sub LLC	Delaware	Indirect
Par, Inc.	Delaware	Indirect
Par Pharmaceutical Companies, Inc.	Delaware	Indirect
Par Pharmaceutical, Inc.	Delaware	Indirect
Par Sterile Products, LLC	Delaware	Indirect
Vintage Pharmaceuticals, LLC	Delaware	Indirect

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) and Form S-3 (No. 333-204657) of Endo International plc of our report dated February 29, 2016 relating to the financial statements, 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 29, 2016

## CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-194253 and 333-204958 on Form S-8, and No. 333-204657 on Form S-3 of Endo International plc of our report dated February 28, 2014 (June 2, 2015 as to the effects of the discontinued operations discussed in Note 3), relating to the consolidated financial statements, comprised of the consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for the year ended December 31, 2013, and the consolidated financial statement schedule for the year ended December 31, 2013, of Endo Health Solutions Inc. (now known as Endo International plc) and subsidiaries, appearing in this Annual Report on Form 10-K of Endo International plc for the year ended December 31, 2015.

/s/ DELOITTE & TOUCHE LLP

Philadelphia, Pennsylvania  
February 29, 2016



## POWER OF ATTORNEY

Each of the undersigned, hereby constitutes and appoints each of Rajiv De Silva, Suketu P. Upadhyay, Matthew J. Maletta and Orla Dunlea 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Roger H. Kimmel</u> Roger H. Kimmel	Chairman and Director	February 23, 2016
<u>/s/ Shane M. Cooke</u> Shane M. Cooke	Director	February 23, 2016
<u>/s/ Arthur J. Higgins</u> Arthur J. Higgins	Director	February 23, 2016
<u>/s/ Nancy J. Hutson, Ph.D.</u> Nancy J. Hutson, Ph.D.	Director	February 23, 2016
<u>/s/ Michael Hyatt</u> Michael Hyatt	Director	February 23, 2016
<u>/s/ William P. Montague</u> William P. Montague	Director	February 23, 2016
<u>/s/ Jill D. Smith</u> Jill D. Smith	Director	February 23, 2016
<u>/s/ William F. Spengler</u> William F. Spengler	Director	February 23, 2016

CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002

I, Rajiv De Silva, 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/ RAJIV DE SILVA

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Rajiv De Silva

President and Chief Executive Officer  
(Principal Executive Officer)

Date: February 29, 2016

CERTIFICATION OF CHIEF FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002

I, Suketu P. Upadhyay, 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/ SUKETU P. UPADHYAY

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Suketu P. Upadhyay

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

Date: February 29, 2016

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, Rajiv De Silva, 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, 2015 (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/ RAJIV DE SILVA

Name: Rajiv De Silva  
Title: President and Chief Executive Officer  
(Principal Executive Officer)

Date: February 29, 2016

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.

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, Suketu P. Upadhyay, 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, 2015 (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/ SUKETU P. UPADHYAY

Name: Suketu P. Upadhyay  
Title: Executive Vice President, Chief Financial Officer  
(Principal Financial Officer)

Date: February 29, 2016

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.