

ENDO PHARMACEUTICALS HOLDINGS INC  
Form 10-K  
February 29, 2012  
Table of Contents

**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, 2011

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: 001-15989

**ENDO PHARMACEUTICALS HOLDINGS INC.**

(Exact name of registrant as specified in its charter)

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**13-4022871**  
(I.R.S. Employer  
Identification Number)

**100 Endo Boulevard Chadds Ford, Pennsylvania**  
(Address of Principal Executive Offices)

**19317**  
(Zip Code)

**(Registrant's Telephone Number, Including Area Code): (610) 558-9800**

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

<u>Title of Each Class</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock of \$0.01 par value	The NASDAQ Global Select Market

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

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, 2011 was \$4,660,596,549 based on a closing sale price of \$40.17 per share as reported on the NASDAQ Global Select Market on June 30, 2011. Shares of the registrant's common stock held by each officer and director and each beneficial owner of 10% or more of the outstanding common stock 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 shares of non-voting common stock authorized or outstanding.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of February 17, 2012: 116,708,557

**Documents Incorporated by Reference**

## Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

Portions of the registrant's proxy statement to be filed with the SEC pursuant to Regulation 14A in connection with the registrant's 2012 Annual Meeting of Stockholders, 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, 2011.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**INDEX TO FORM 10-K**

**FOR THE YEAR ENDED DECEMBER 31, 2011**

<u>Forward-Looking Statements</u>	1
<b><u>PART I</u></b>	2
Item 1 <u>Business</u>	2
Item 1A <u>Risk Factors</u>	36
Item 1B <u>Unresolved Staff Comments</u>	74
Item 2 <u>Properties</u>	75
Item 3 <u>Legal Proceedings</u>	76
Item 4 <u>Mine Safety Disclosures</u>	76
<b><u>PART II</u></b>	76
Item 5 <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	76
Item 6 <u>Selected Financial Data</u>	78
Item 7 <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	79
Item 7A <u>Quantitative and Qualitative Disclosures about Market Risk</u>	144
Item 8 <u>Financial Statements and Supplementary Data</u>	145
Item 9 <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	145
Item 9A <u>Controls and Procedures</u>	145
Item 9B <u>Other Information</u>	147
<b><u>PART III</u></b>	147
Item 10 <u>Directors, Executive Officers and Corporate Governance</u>	147
Item 11 <u>Executive Compensation</u>	147
Item 12 <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	148
Item 13 <u>Certain Relationships and Related Transactions, and Director Independence</u>	148
Item 14 <u>Principal Accountant Fees and Services</u>	148
<b><u>PART IV</u></b>	148
Item 15 <u>Exhibits, Financial Statement Schedules</u>	148
<u>Signatures</u>	150
Certifications	
Exhibit Index	

**Table of Contents**

**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 the 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 Item 1A under the caption Risk Factors in this document, 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. You are advised to consult any further disclosures we make on related subjects in our reports filed with the Securities and Exchange Commission (SEC). Also note that, in 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.

---

**Table of Contents**

**PART I**

**Item 1. Business Overview**

Endo Pharmaceuticals Holdings Inc., which we refer to as Endo, we, us, or the Company, is a U.S. based, specialty healthcare solutions company focused on branded and generic pharmaceuticals, devices and services. We have redefined our position in the healthcare marketplace by anticipating and embracing the evolution of health decisions based on the need for high-quality and cost-effective care. We aim to be the premier partner to healthcare professionals and payment providers, delivering an innovative suite of complementary branded and generic drugs, devices, services and clinical data to meet the needs of patients in areas such as pain management, urology, oncology and endocrinology.

In June 2011, we acquired American Medical Systems Holdings, Inc. (AMS), a leading provider of devices and therapies for treating male and female pelvic health conditions. The acquisition of AMS strengthens our leading core urology franchise and expands our presence in the medical devices market. In November 2010, we acquired Generics International (US Parent), Inc. (doing business as Qualitest Pharmaceuticals, which we refer to herein as Qualitest), a leading U.S. based privately-held generics company and currently the sixth largest U.S. generics company, as measured by prescriptions filled during 2011. Qualitest is focused on cost-competitive, high-quality manufactured products with cost advantages or with high barriers to entry. In September 2010, we acquired our partner on Opana<sup>®</sup> ER, Penwest Pharmaceuticals Co. (Penwest), a drug delivery company focused on applying its drug delivery technologies and drug formulation expertise to the formulation of its collaborators product candidates under licensing collaborations. In July 2010, we acquired HealthTronics, Inc. (HealthTronics), a provider of healthcare services and manufacturer of certain related medical devices, primarily for the urology community. In February 2009, we completed our acquisition of Indevus Pharmaceuticals, Inc. (now, Endo Pharmaceuticals Solutions Inc., which we refer to herein as Indevus), a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology, endocrinology and oncology. As a combined company, we expect to deliver more comprehensive healthcare solutions across our diversified businesses in four key segments, Branded Pharmaceuticals, Generics, Devices and Services in key therapeutic areas including pain and urology.

We have a portfolio of branded pharmaceuticals that includes established brand names such as Lidoderm<sup>®</sup>, Opana<sup>®</sup> ER, Voltaren<sup>®</sup> Gel, Percocet<sup>®</sup>, Frova<sup>®</sup>, Supprelin<sup>®</sup> LA, Vantas<sup>®</sup>, Valstar<sup>®</sup> and Fortesta<sup>®</sup> Gel. Branded products comprised approximately 61% of our total revenues in 2011. Our non-branded generic portfolio, which accounted for 21% of total revenues in 2011, currently consists of products primarily focused in pain management. We generally focus on selective generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. Device revenue accounted for 11% of total revenues in 2011 and our services segment accounted for the remaining 2011 revenue. We generated total revenues of \$2.73 billion for the year ended December 31, 2011.

Financial information presented herein reflects the operating results of Indevus from February 23, 2009, HealthTronics from July 2, 2010, Penwest from September 20, 2010, Qualitest from November 30, 2010 and AMS from June 18, 2011.

On a continuous basis, we evaluate and, where appropriate, pursue acquisition opportunities. In particular, we look to continue to enhance our product line by acquiring or licensing rights to additional products and compounds and therefore regularly evaluate 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.

Our wholly-owned subsidiary, Endo Pharmaceuticals Inc. (EPI), commenced operations in 1997 by acquiring certain pharmaceutical products, related rights and assets of The DuPont Merck Pharmaceutical

## **Table of Contents**

Company, which subsequently became DuPont Pharmaceuticals Company and was thereafter purchased by the Bristol-Myers Squibb Pharma Company in 2001. EPI was formed by certain members of the then-existing management of DuPont Merck and an affiliate of Kelso & Company who were also parties to the purchase agreement under which we acquired these initial assets.

We were incorporated in Delaware as a holding company on November 18, 1997 and have our principal executive offices at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317 (telephone number: (610) 558-9800).

### **Our Strategy**

Our core strategy is to continue to build a healthcare solutions company to improve outcomes for patients, providers, and payers and respond to changing economics. We strive to enable better care by redefining healthcare value. The execution of our strategy will enable us to be the premier partner to healthcare professionals and payment providers, delivering an innovative suite of complementary branded and generic drugs, devices, services and clinical data to meet the needs of patients in areas such as pain management, urology, oncology and endocrinology.

Over the past three years, we have evolved from a product-driven pharmaceutical company to a healthcare solutions provider with an integrated business model that includes both branded and generic prescription drugs, medical devices and healthcare services. Our diversified business across therapeutic areas with a core focus in pain management and urology enables us to strengthen our partnerships with patients, providers, and payers by offering multiple products and platforms to deliver healthcare solutions. For example, our recent acquisitions have had or are expected to have the following results:

In February 2009, we acquired Indevus, which helped us expand beyond our legacy pain management business and secured a position in urology;

In July 2010, we acquired HealthTronics, which gave us an established presence in the healthcare services space and added critical mass in urology;

In September 2010, we acquired Penwest, which strengthened our pain management franchise by enhancing flexibility around our product Opana® ER;

In November 2010, we acquired Qualitest, which enhanced our solutions platform with the addition of a comprehensive generics business, adding critical mass to our existing generics business while also strengthening our pain management franchise offerings. The combined generics business has approximately 50 abbreviated new drug applications (ANDAs) under active FDA review in multiple therapeutic areas, including pain management, urology, central nervous system (CNS) disorders, immunosuppression, oncology, women's health and hypertension, among others; and

In June 2011, we acquired AMS, which furthered Endo's evolution from a pharmaceutical product-driven company to a healthcare solutions provider, strengthened our core urology franchise and expanded our presence in the medical devices market.

We believe that recent healthcare reform in the U.S. places a premium on providing cost-effective healthcare solutions like those we offer. Applying the technology platforms of our recent acquisitions to Endo's already substantial business holds the potential for significant advantages in the new healthcare environment that will enhance our product offerings and accelerate growth.

See Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report on Form 10-K for further discussion.

## **Table of Contents**

### **Our Competitive Strengths**

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

***Proactive anticipation of the evolution of healthcare delivery in the U.S. by diversifying our business away from that of a product-driven pharmaceutical company to that of a healthcare solutions provider.*** In light of the evolving healthcare industry, we have executed a number of corporate acquisitions in 2010 and 2011 to diversify our business and become a healthcare solutions provider with an integrated business model that includes both branded and generic prescription drugs, as well as medical devices and healthcare services. This diversification will enable us to provide customers with quality outcomes and economic value and offer unique solutions along targeted disease care pathways. As a result of recent strategic actions combined with strategic investments in our core business, we have redefined our position in the healthcare marketplace and successfully reduced the revenue concentration of Lidoderm®. Lidoderm® contributed approximately 30% of our business revenue in 2011, compared to 46% and 52% in 2010 and 2009, respectively. Our acquisitions of AMS, Qualitest and HealthTronics have also contributed to our diversification. The acquisition of Qualitest has enabled us to gain critical mass in our generics business. Through HealthTronics and AMS, we provide healthcare services and manufacture medical devices, primarily for the urology community.

***Established portfolio of branded products.*** We have assembled a portfolio of branded prescription products to treat and manage pain. In addition, as a result of our acquisition of Indevus, we have added several branded products to treat conditions in urology and endocrinology. Our branded products include: Lidoderm®, Opana® ER, Voltaren® Gel, Percocet®, Frova®, Supprelin® LA, Vantas®, Valstar® and Fortesta® Gel. For a more detailed description of each of our products, see Product Overview.

***Focused pipeline.*** As a result of our focused research and development efforts, we believe we have a promising development pipeline and are well-positioned to capitalize on our core development products. Currently, our core development pipeline consists of one NDA filed with the FDA and two products in Phase III trials. We have also initiated development efforts for medical devices and have multiple programs at concept and development stages across urology, uro-oncology, endocrinology and urogynecology. For a more detailed description of our development pipeline, see Select Products in Development.

***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. We are continuously seeking opportunities that deepen our presence in the pain management area as well as in the areas of oncology, urology and endocrinology. We will continue to capitalize on our core expertise with analgesics and expand our abilities to both capture earlier-stage opportunities and pursue other therapeutic areas. Through our acquisition of AMS, we have expanded our expertise in the development of medical devices. Through our Qualitest business, we have increased our efforts to seek out and develop generic products with complex formulations and high barriers to entry. We continue to invest in research and development because we believe it is critical to our long-term competitiveness. At December 31, 2011, our research and development and regulatory affairs staff consisted of 445 employees, based primarily in Westbury, New York, Minnetonka, Minnesota, San Jose, California, Huntsville, Alabama, and at our corporate headquarters in Chadds Ford, Pennsylvania. Our research and development expenses, including upfront and milestone payments were \$182.3 million in 2011, \$144.5 million in 2010 and \$185.3 million in 2009.

We have assembled an experienced and multi-disciplined research and development team of scientists and technicians with drug discovery and development expertise, medical device design and development expertise, and broad experience in working with the FDA. To supplement our internal efforts, we engage the services of various independent research organizations, physicians and hospitals to conduct and coordinate our preclinical and clinical studies to establish the safety and effectiveness of new products.

***Targeted national sales and marketing infrastructure.*** We market our branded products directly to physicians through a sales force of over 1,000 employees in the pharmaceutical products, devices and services



## **Table of Contents**

markets. This sales force consists of 450 Endo pharmaceutical sales representatives and 228 sales contracted representatives focusing primarily on pain products, 79 Endo sales representatives focusing primarily on bladder and prostate cancer products, 35 Endo medical center representatives focusing on the treatment of central precocious puberty and 27 Endo account executives focusing on managed markets customers. We also have 361 sales representatives focusing primarily on devices and 39 on services. We market our products and services to primary care physicians and specialty physicians, including those specializing in pain management, orthopedics, neurology, rheumatology, surgery, anesthesiology, urology and pediatric endocrinology. Our sales forces also target retail pharmacies and other healthcare professionals throughout the U.S. We distribute our products principally through independent wholesale distributors, but we also sell directly to retailers, clinics, government agencies, doctors and retail and specialty pharmacies. Our marketing policy is designed to assure that products and relevant, appropriate medical information are immediately available to physicians, pharmacies, hospitals, public and private payers, and appropriate healthcare professionals throughout the U.S. 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.

***Expanding focus on generic products.*** Our generics business has approximately 50 ANDAs under active FDA review in multiple therapeutic areas, including pain management, urology, CNS disorders, immunosuppression, oncology, women's health and hypertension, among others. We develop generic products including those that involve significant barriers to entry such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. 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. Our generics business is focused in categories where there are fewer challenges from low-cost operators in markets such as China and India, with approximately 36% of our product portfolio being comprised of controlled substances, which cannot be manufactured off-shore and imported into the U.S. In addition, approximately 15% of our product portfolio is made up of liquids, which are uneconomical to ship into the U.S. We expect to continue to improve our overall profitability by optimizing our portfolio for high volume and growth while strengthening our U.S. generics competitive position, product pipeline, portfolio and capabilities.

***Manufacturing and distributing medical devices.*** Through our AMS subsidiary, we manufacture medical devices for various pelvic health disorders. Specifically, the AMS business includes a diverse product portfolio that treats men's incontinence, erectile dysfunction, benign prostatic hyperplasia (BPH), women's incontinence and pelvic floor repair. These devices strengthen our leading core urology franchise, where we remain focused on expanding the markets for our products because the portion of afflicted patients seeking treatment remains relatively low. When patients seek treatment, they generally begin with options that will be as minimally invasive as possible, such as pharmaceutical therapies. Also, when patients initially seek treatment, their first physician contact is usually with a general practitioner and not with a surgical specialist. If less invasive options have proven unsuccessful, patients and their physicians may consider surgery as a solution. Sales of these products benefit from an aging population with a desire to maintain a high quality of life, the expanding availability of safe and effective treatments, minimally invasive solutions and increasing patient and physician awareness of these treatments.

***Providing healthcare services.*** Through our HealthTronics subsidiaries, we provide healthcare services and manufacture certain related medical devices, primarily for the urology community. Specifically, the HealthTronics business and applicable services include lithotripsy services, a medical procedure where a device called a lithotripter transmits high energy shockwaves through the body to break up kidney stones, prostate treatment services for benign and cancerous conditions of the prostate, laboratory services, known as anatomical pathology services, for urologists, electronic medical records services and medical products manufacturing, sales, and maintenance.

***Strong balance sheet and significant cash flow.*** We have historically generated significant cash flow from operating activities due to a unique combination of strong brand equity, attractive margins and low capital

## **Table of Contents**

expenditures. For the year ended December 31, 2011, we generated \$702.1 million of cash from operations. We expect that sales of our currently marketed products, devices and services will allow us to continue to generate significant cash flow from operations in the future. We maintain a strong balance sheet with moderate leverage levels and ample liquidity, which gives us flexibility to make strategic investments in our business. As of December 31, 2011, we had \$566.7 million of cash and marketable securities, up to \$500 million of availability under the Revolving Credit Facility, and availability of up to \$500 million of additional revolving or term loan commitments.

***Experienced and dedicated management team.*** Our senior management team has a proven track record of building businesses through internal growth as well as through licensing and acquisitions. Their expertise has contributed to our success in identifying, consummating and integrating such acquisitions. Members of our management team have consummated five significant acquisitions since 2009 (AMS, Qualitest, Penwest, HealthTronics and Indevus) and have received FDA approval on more than twenty new products and product line extensions since 1997. As a result of several successful product launches and our strategic acquisitions, we have grown our total revenues from \$108 million in 1998 to over \$2.7 billion in 2011.

## **Our Areas of Focus**

### ***Pain Management Market***

According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled \$23.9 billion in 2011. This represents an approximate 7% compounded annual growth rate since 2007. Our primary area of focus within this market is analgesics and, specifically, opioid analgesics. In 2011, analgesics were the third most prescribed medication in the U.S. with nearly 312 million prescriptions written for this classification.

Opioid analgesics is a segment that comprised approximately 78% of the analgesic prescriptions for 2011 and represented almost 53% of the overall U.S. pain management market. Total U.S. sales for the opioid analgesic segment were \$8.4 billion in 2011, representing a compounded annual growth rate of 5% since 2007. With the launch of Voltaren® Gel in 2008, Endo gained presence in the osteoarthritis market competing in the analgesic non-narcotic and anti-arthritis classes which together had over 191 million prescriptions written in 2011, representing 41% of the U.S. pain management market. The U.S. sales for the analgesic non-narcotic and anti-arthritis markets were \$15.5 billion with a compound annual growth rate of 8% since 2007.

Opioid analgesic products are used primarily for the treatment of pain associated with orthopedic fractures and sprains, post herpetic-neuralgia, back injuries, migraines, joint diseases, cancer and various surgical procedures.

The growth in this segment has been primarily attributable to:

increasing physician recognition of the need and patient demand for effective treatment of pain;

aging population (according to the U.S. Census Bureau, from 2000 to 2010 the population aged 65 and older reached 40 million people, representing 15% growth over this period);

introduction of new and reformulated branded products; and

increasing incidence of chronic pain conditions, such as cancer, arthritis and low back pain.

### ***Urology, Endocrinology and Oncology Markets***

Through our acquisition of Indevus as well as other business development activities, Endo entered the urology, endocrinology and oncology markets, specifically the prostate cancer therapeutic area with Vantas®, the bladder oncology space with Valstar® and Urocidin™, and the central precocious puberty therapeutic area with



## **Table of Contents**

Supprelin® LA. With our early 2011 launch of Fortesta® Gel, which was approved by the FDA in December 2010 for the treatment of hypogonadism, we entered the testosterone replacement therapy (TRT) market. We anticipate increasing our presence in this market through our development product Aveed™. As a result of our acquisition of HealthTronics, we now offer a full suite of urology products and services with the addition of lithotripsy, BPH and prostate cancer therapies, as well as anatomical pathology services for the detection and diagnosis of cancer and other conditions from our HealthTronics subsidiary. As a result of our acquisition of AMS, we now offer a broad array of medical devices which deliver innovative medical technology solutions to physicians treating male incontinence, erectile dysfunction, female incontinence, pelvic floor repair and BPH.

### *Central Precocious Puberty (CPP)*

In a recent study, the incidence of CPP reported from national registries in the European Union subdivided by gender and age at diagnosis was approximately 1 per 10,000 in girls who were younger than 4 years, thereafter gradually rising to 8 per 10,000 for girls aged 5 to 9 years. The incidence in boys younger than 8 years was approximately 1 per 10,000. Recent market research indicates that girls in the U.S. are physically maturing at an earlier age than they did 30 years ago, and the number of girls diagnosed with precocious puberty is on the rise. In the U.S., 6,000 patients are estimated to have CPP with approximately 2,000 diagnosed annually. CPP is treated by pediatric endocrinologists in the U.S. where there are approximately 790 practicing pediatric endocrinologists. In 2011, the market for drugs to treat CPP, reported by IMS Health NSP, was approximately \$125 million in the U.S.

### *Prostate cancer*

Prostate cancer is the most common cancer for men and the second leading cause of cancer deaths in men. According to the American Cancer Society, every year approximately 240,000 men in the U.S. are diagnosed with prostate cancer and 30,000 die from this disease.

### *Bladder cancer*

There are more than 500,000 people in the U.S. alive with a history of bladder cancer, which is the third most common cancer among men and the eleventh most common among women in the U.S. The American Cancer Society estimated approximately 73,510 new cases of bladder cancer and 14,880 deaths from this disease in the U.S. in 2011. The 2012 estimate is expected to be similar. Rates of bladder cancer are expected to increase due to the aging population; nearly 90% of cases of bladder cancer are diagnosed in people age 55 or older. The number of patients in the total non-invasive bladder cancer population will thus increase due to the rising incidence as well as high recurrence rates, leading to a substantial prevalent population.

### *BCG-refractory CIS bladder cancer*

CIS of the urinary bladder is a rare form of bladder cancer, affecting about 10 of every 100 patients diagnosed with bladder cancer. Standard treatment of CIS of the urinary bladder is transurethral resection of the

## **Table of Contents**

bladder tumor, followed by one or two courses of immunotherapy with the vaccine BCG. About 50 percent of patients will become refractory to BCG therapy. Valstar® intravesical therapy is the only FDA-approved treatment of carcinoma in situ of the urinary bladder in patients who are refractory to BCG immunotherapy when cystectomy or bladder removal is not an option.

### *Testosterone replacement overview*

In the U.S. alone, it is estimated that 13.8 million men have low testosterone levels; however, only about 9% are currently being treated. 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 have dramatically increased, from approximately \$552 million in 2006 to over \$1.6 billion in 2011, representing a compounded annual growth rate of 24% since 2006.

### *Male incontinence*

We estimate over 50 million men worldwide suffer from urinary incontinence, the involuntary release of urine from the body. Male incontinence may be managed with a catheter and leg bag to collect urine, or with pads and diapers to absorb the leaks. These measures are far from ideal, as they come with recurring replacement product costs, the potential for infection, embarrassing leaks and odor, a significantly diminished quality of life, and may even result in the need for managed care.

### *Erectile dysfunction*

Erectile dysfunction is the inability to achieve or maintain an erection sufficient for sexual intercourse. It is most often caused by vascular disease, complications from diabetes, or prostate surgery which can damage both nerves and arteries necessary for erectile function. This disease can also be caused by spinal cord injury, and may have a psychogenic component. We estimate that erectile dysfunction may affect over 400 million men and their partners around the world. The primary treatment for erectile dysfunction is the class of drugs referred to as PDE-5 inhibitors. Approximately 30 percent of patients using these drugs do not have a positive response. If such drugs are not effective, the patient may elect to have an implant of one of our penile prosthesis products, which provide consistent, reliable solutions.

### *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). While stress incontinence is generally caused by a weakening of the pelvic floor and resultant hypermobility of the urethra, 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. Incontinence may be treated through exercises to strengthen pelvic floor muscles, or through the injection of collagen or some other bulking agent into the wall of the urethra or bladder neck to narrow the passage. Surgical solutions are generally recommended only when these other therapies are not effective. 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.

### *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

## **Table of Contents**

transvaginal surgeries. We estimate over 400,000 procedures are performed annually around the world to repair some form of pelvic floor prolapse in women. These procedures have historically been performed through the use of suture and graft materials designed for other surgical applications. We offer less invasive solutions for pelvic floor repair.

### *BPH therapy*

Our products can be used to relieve restrictions on the normal flow of urine from the bladder caused by bladder obstructions, generally the result of BPH or bulbar urethral strictures. Symptoms of BPH include increased urination frequency, sudden urges to urinate, and weak urine flow. More than 70 percent of men over age 60 have some symptoms of BPH. Prior to the development of less invasive therapies, the conventional treatment for those experiencing a physical obstruction of the prostatic urethra was a surgical removal of the prostatic tissue performed under general anesthesia, known as a transurethral resection of the prostate (TURP). We offer men an alternative to a TURP, using laser therapy designed to reduce the comorbidities associated with TURP. This laser system has paved the way for creating a new standard of care in the treatment of BPH.

For those men not yet to the point of urethral obstruction, but for whom symptomatic relief is desired, a less-invasive tissue ablation technique can be performed in a physician's office using microwave energy delivered to the prostate. The market for an office-based therapy for BPH has remained relatively flat, at approximately 100,000 men treated annually, partially due to the continued adoption of laser delivered BPH treatments.

### *Medical Services Markets*

Through our HealthTronics business, we provide services in the following areas:

#### *Lithotripsy services*

We provide lithotripsy services, which is a medical procedure where a device called a lithotripter transmits high energy shockwaves through the body to break up kidney stones. Our lithotripsy services are provided principally through limited partnerships and other entities that we manage, which use lithotripters. In 2011, physicians who are affiliated with us used our lithotripters to perform approximately 50,000 procedures in the U.S. As the general partner of limited partnerships or the manager of other types of entities, we also provide services relating to operating our lithotripters, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting with payors, hospitals, and surgery centers.

#### *Prostate treatment services*

We provide treatments for benign and cancerous conditions of the prostate. In treating benign prostate disease, we deploy three technologies: (1) photo-selective vaporization of the prostate (PVP), (2) trans-urethral needle ablation (TUNA), and (3) trans-urethral microwave therapy (TUMT) in certain partnerships. All three technologies apply an energy source which reduces the size of the prostate gland. For treating prostate and other cancers, we use a procedure called cryosurgery, a process which uses lethal ice to destroy tissue such as tumors for therapeutic purposes. We also manufacture both the medical devices and related consumables utilized in cryosurgery operations, and also provide cryosurgery treatments. Our prostate treatment services are provided principally by us using equipment that we lease from limited partnerships and other entities that we manage. We also provide services relating to operating the equipment, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting.

#### *Anatomical pathology services*

We provide anatomical pathology services primarily to the urology community. We have one pathology lab located in Georgia, HealthTronics Laboratory Solutions that provides laboratory detection and diagnosis services to urologists throughout the U.S. In addition we manage pathology laboratories for physician practice groups

**Table of Contents**

located in Texas, Florida and Pennsylvania. Through HealthTronics Laboratory Solutions, we also provide administrative services to in-office pathology labs for practice groups and provide pathology services to physicians and practice groups with our lab equipment and personnel at our HealthTronics Laboratory Solutions laboratory sites.

*Medical products manufacturing, sales and maintenance*

We manufacture and sell medical devices focused on minimally invasive technologies for tissue and tumor ablation through cryoablation, which is the use of lethal ice to destroy tissue, such as tumors, for therapeutic purposes. We develop and manufacture these devices for the treatment of prostate and renal cancers and we believe that our proprietary technologies have broad applications across a number of markets, including the ablation of tumors in the lung and liver and palliative intervention (treatment of pain associated with metastases). We also manufacture the related spare parts and consumables for these devices. We also sell and maintain lithotripters and related spare parts and consumables.

*Information Technology Solutions*

In the second half of 2011, as part of our effort to increase and broaden the relationships within the urology community, we acquired two electronic medical records software companies, Intuitive Medical Software, LLC and meridianEMR, Inc., which provide electronic medical records for urologists. Together, these acquisitions provide access to approximately 1,850 urologists using data platforms that will enhance service offerings in urology practice management.

**Products Overview***Branded Pharmaceuticals*

The following table summarizes select products in our branded portfolio:

<b>Branded Pharmaceuticals</b>	<b>Active Ingredient(s)</b>	<b>Status</b>
Lidoderm®	lidocaine 5%	Marketed
Opana® ER(1)	oxymorphone hydrochloride	Marketed
Opana®	oxymorphone hydrochloride	Marketed
Percocet®	oxycodone hydrochloride and acetaminophen	Marketed
Voltaren® Gel(2)	diclofenac sodium topical gel 1%	Marketed
Frova®(3)	frovatriptan succinate	Marketed
Supprelin® LA	histrelin acetate	Marketed
Vantas®	histrelin acetate	Marketed
Valstar®	valrubicin	Marketed
Fortesta® Gel(4)	2% testosterone	Marketed

- (1) Licensed marketing and development rights from Grünenthal GMBH.
- (2) Licensed marketing rights from Novartis Consumer Health, Inc.
- (3) Licensed marketing rights from Vernalis Development Limited.
- (4) Licensed marketing and development rights from Strakan International Limited.

**Lidoderm®.** Lidoderm® (lidocaine patch 5%) was launched in September 1999. A topical patch product containing lidocaine, Lidoderm® was the first 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). Lidoderm® is also currently protected by Orange Book-listed patents for, among other things, a method of treating post-herpetic neuralgia and the composition of the lidocaine-containing patch. The last of these patents is set to expire in 2015. In 2011, 2010 and 2009, Lidoderm® net sales were \$825.2 million, \$782.6 million and \$763.7 million, respectively. Lidoderm® accounted for approximately 30% of our 2011 total revenues.

---

**Table of Contents**

**Opana® ER and Opana®.** Opana® ER and Opana® were launched during the second half of 2006 and have shown steady prescription growth trends since their launch. Opana® ER is indicated for the relief of moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time. Opana® ER represents the first drug in which oxymorphone is available in an oral, extended-release formulation and is available in 5 mg, 10 mg, 20 mg, 30 mg and 40 mg tablets. Opana® (oxymorphone hydrochloride) Tablets CII (the immediate-release version) is indicated for the relief of moderate-to-severe acute pain where the use of an opioid is appropriate and is available in 5mg and 10mg tablets. Opana® ER and Opana® net sales were \$400.8 million, \$299.1 million and \$230.6 million in 2011, 2010 and 2009, respectively. Opana® ER and Opana® accounted for approximately 15% of our 2011 total revenues. In December 2011, the FDA approved a new formulation of Opana® ER designed to be crush-resistant, which will continue to be called Opana® ER (oxymorphone hydrochloride) Extended-Release Tablets CII. This new formulation of Opana® ER will have the same dosage strengths, color and packaging and similar tablet size. Endo anticipates transitioning to the new formulation in the first half of 2012.

**Voltaren® Gel.** We launched Voltaren® Gel (diclofenac sodium topical gel 1%) in March 2008 upon closing of the license and supply agreement with Novartis AG and Novartis Consumer Health, Inc. Voltaren® Gel received regulatory approval in October 2007 from the FDA, becoming the first topical prescription treatment for use in treating pain associated with osteoarthritis and the first new product approved in the U.S. for osteoarthritis since 2001. Voltaren® Gel was granted marketing exclusivity in the U.S. as a prescription medicine until October 2010. It is 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. In 2011, 2010 and 2009, net sales of Voltaren® Gel were \$142.7 million, \$104.9 million and \$78.9 million, respectively. Voltaren® Gel accounted for approximately 5% of our 2011 total revenues.

**Percocet®.** Launched in 1976, Percocet® (oxycodone hydrochloride and acetaminophen USP) Tablets CII is approved for the treatment of moderate-to-moderately severe pain. The Percocet® family of products had net sales of \$104.6 million, \$121.3 million and \$127.1 million in the years 2011, 2010 and 2009, respectively. The Percocet® franchise accounted for approximately 4% of our 2011 total revenues.

**Frova®.** We began shipping Frova® (frovatriptan succinate) Tablets upon closing of the license agreement with Vernalis in mid-August 2004. Frova® is indicated for the acute treatment of migraine headaches in adults. We believe that Frova® has differentiating features from other migraine products, including the longest half-life in the triptan class and a very low reported migraine recurrence rate in its clinical program. In 2011, 2010 and 2009, Frova® net sales were \$58.2 million, \$59.3 million, and \$57.9 million, respectively.

**Supprelin® LA.** Supprelin® LA (histrelin acetate) 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 central precocious puberty (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. In 2011, 2010 and 2009, Supprelin® LA net sales were \$50.1 million, \$46.9 million, and \$27.8 million, respectively.

**Valstar®.** Valstar® (valrubicin) 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. Valstar®, originally approved by the FDA in 1998, was withdrawn from the market in 2002 due to a manufacturing problem involving impurity issues in the original formulation and was placed on the FDA Drug Shortages List. In April 2007, the Company



## **Table of Contents**

submitted a supplemental new drug application (sNDA) to the FDA seeking approval to reintroduce Valstar<sup>®</sup> and in February 2009, the FDA approved this sNDA. In September 2009, we launched Valstar<sup>®</sup>. Net sales of Valstar<sup>®</sup> were \$21.5 million, \$14.1 million and \$3.4 million in 2011, 2010 and 2009, respectively.

**Vantas<sup>®</sup>.** Vantas<sup>®</sup> (histrelin acetate) was launched in the U.S. in November 2004. Vantas<sup>®</sup> 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. We are party to a License, Supply and Distribution Agreement with Orion Corporation (Orion) granting Orion the rights to market Vantas<sup>®</sup> throughout Europe as well as certain other countries. Vantas<sup>®</sup> is also approved in Thailand, Singapore, Malaysia, and Argentina. Net sales of Vantas<sup>®</sup> were \$19.0 million, \$17.0 million and \$20.0 million in 2011, 2010, and 2009, respectively, primarily in the U.S.

**Fortesta<sup>®</sup> Gel.** Fortesta<sup>®</sup> 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<sup>®</sup> Gel in the U.S. On July 1, 2010, we submitted a complete response to the FDA following our receipt of a complete response letter in October 2009 from the FDA regarding the NDA for Fortesta<sup>®</sup> Gel. Fortesta<sup>®</sup> Gel was approved by the FDA in December of 2010. We launched Fortesta<sup>®</sup> Gel in the first quarter of 2011. Net sales of Fortesta<sup>®</sup> Gel were \$14.9 million in 2011.

**Hydrogel Polymer Implant.** The hydrogel polymer implant is a subcutaneous, retrievable, non-biodegradable, hydrogel reservoir drug delivery device designed to provide sustained release of a broad spectrum of drugs continuously, at constant, predetermined rates. This technology serves as the basis for two of our currently marketed products: Vantas<sup>®</sup> and Supprelin<sup>®</sup> LA.

The hydrogel polymer implant is the only soft, flexible, reservoir-based drug delivery system available for parenteral administration. Our implant is designed for easy, in-office physician insertion under local anesthesia. The hydrogel polymer compositions possess flexible, tissue-like characteristics providing excellent biocompatibility and patient comfort. The hydrogel polymer implant delivers drugs at zero-order kinetics and the duration of delivery can be predetermined over a range of times.

**Other.** The balance of our other branded portfolio consists of a number of products, none of which accounted for more than 1% of our total revenues in 2011.

**Table of Contents****Generics**

The following table summarizes select products in our generics portfolio:

<b>Generics</b>	<b>Active Ingredient(s)</b>	<b>Status</b>
Endocet®	oxycodone hydrochloride and acetaminophen	Marketed
Morphine Sulfate ER	morphine sulfate	Marketed
Hydrocodone and acetaminophen	hydrocodone and acetaminophen	Marketed
Oxycodone and acetaminophen	oxycodone and acetaminophen	Marketed
Carisoprodol	carisoprodol	Marketed
Hydrocortisone	hydrocortisone	Marketed
Promethazine	promethazine	Marketed
Multi Vitamins	multi vitamins	Marketed
Acetaminophen and codeine	acetaminophen and codeine	Marketed
Spirolactone	spironolactone	Marketed
Butalbital, acetaminophen, and caffeine	butalbital, acetaminophen, and caffeine	Marketed
Methocarbamol	methocarbamol	Marketed
Oxybutynin	oxybutynin	Marketed
Lactulose	lactulose	Marketed
Methylprednisolone	methylprednisolone	Marketed
Perphenazine	perphenazine	Marketed
Lisinopril	lisinopril	Marketed

When a branded pharmaceutical product is no longer protected by any relevant patents, normally as a result of a patent's expiration, or by other, non-patent market exclusivity, third parties have an opportunity to introduce generic counterparts to such branded product. Generic pharmaceutical products are therapeutically equivalent to their brand-name counterparts and are generally sold at prices significantly less than the branded product. Accordingly, generic pharmaceuticals may provide a safe, effective and cost-effective alternative to users of branded products.

Our generic products are sold across multiple therapeutic categories, with pain management being the largest, and in various dosage forms including solids, semi-solids and liquids. Generic products that represented 1% or more of our consolidated total revenues in 2011 included: 1) Endocet® and 2) hydrocodone and acetaminophen, which each accounted for approximately 3% our 2011 revenues, and 3) morphine sulfate ER, which accounted for approximately 1%.

**Devices**

The following table summarizes select products in our devices portfolio:

<b>Medical Devices</b>	<b>Therapy/Condition</b>	<b>Status</b>
AMS 700 MS™ Series; CX™, CXR™ and LGX™ three-piece inflatable penile prostheses	Erectile dysfunction	Marketed
AMS 800® artificial urinary sphincter	Moderate to severe male stress urinary incontinence	Marketed
GreenLight HPS™ High Performance System	Mild to severe symptoms of BPH	Marketed
Elevate™ Anterior and Posterior	Apical and posterior pelvic floor repair	Marketed
Monarc® subfascial hammock	Female stress urinary incontinence	Marketed

Through our AMS subsidiary, we offer a diverse product portfolio that treats men's and women's pelvic health conditions, including:

---

## **Table of Contents**

**AMS 700 MS™ Series.** The AMS 700 MS™ Series are market leading penile implants to treat erectile dysfunction, which is the inability to achieve or maintain an erection sufficient for sexual intercourse. This service contains a complete range of more naturally functioning inflatable prostheses than earlier generations of the product and is distinguished from other penile implants with the use of the InhibiZone® antibiotic coating. InhibiZone® is intended to reduce the rate of revision surgery due to surgical infections and this claim was approved by the FDA in July 2009. AMS 700 MS™ revenue since our June 2011 acquisition of AMS accounted for approximately 2% of our total revenues for 2011.

**AMS 800® Artificial Urinary Sphincter.** The AMS 800® artificial urinary sphincter is designed for the treatment of moderate to severe male urinary incontinence, the involuntary release of urine from the body. It includes an inflatable urethral cuff to restrict flow through the urethra and a control pump that allows the patient to discreetly open the cuff when he wishes to urinate. AMS 800® revenue since our June 2011 acquisition of AMS accounted for approximately 2% of our total revenues for 2011.

**GreenLight™ HPS Laser System.** The GreenLight™ HPS laser system is used to relieve restrictions on the normal flow of urine from the bladder caused by bladder obstructions, generally the result of BPH or bulbar urethral strictures. This therapy offers men experiencing a physical obstruction of the prostatic urethra an alternative to TURP. The GreenLight™ photovaporization of the prostate is designed to reduce the comorbidities associated with TURP. The GreenLight™ XPS and MoXy™ Liquid Cooled Fiber system provide shorter treatment times with similar long-term results compared to other laser systems. The GreenLight™ laser system offers an optimal laser beam that balances vaporization of tissue with coagulation to prevent blood loss and provides enhanced surgical control compared to other laser systems. The GreenLight™ laser and fiber system revenue since our June 2011 acquisition of AMS accounted for approximately 2% of our total revenues for 2011.

**Elevate™ Anterior and Posterior Pelvic Floor Repair System.** AMS 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. Elevate® revenue since our June 2011 acquisition of AMS accounted for approximately 1% of our total revenues for 2011.

**Monarc® Subfascial Hammock.** The Monarc® 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 foramin. Revenue from Monarc® since our June 2011 acquisition of AMS accounted for approximately 1% of our total revenues for 2011.

## **Select Products in Development**

### ***Branded Pharmaceuticals***

Our pipeline portfolio contains products and product candidates that have differentiating features for multiple therapeutic areas, including pain, oncology, urology and endocrinology. The Company's most promising pipeline products are as follows:

**Aveed™.** Aveed™ is a novel, long-acting injectable testosterone preparation for the treatment of male hypogonadism. Male hypogonadism is an increasingly recognized medical condition characterized by a reduced or absent secretion of testosterone from the testes. Reduced testosterone levels can lead to health problems and significantly impair quality of life. Common effects of hypogonadism include decreased sexual desire, erectile dysfunction, muscle loss and weakness, depression, and an increased risk of osteoporosis. If approved, Aveed™ would be the first long-acting injectable testosterone preparation available in the U.S. in the growing market for testosterone replacement therapies. The U.S. rights to Aveed™ were acquired from Schering AG, Germany, in

## **Table of Contents**

July 2005. Although not yet approved in the U.S., Aveed™ is approved in and currently marketed in Europe and a number of other countries. In May 2010, a new patent covering Aveed™ was issued by the U.S. Patent and Trademark Office. The patent's expiration date is March 14, 2027.

On December 2, 2009, we received a complete response letter from the FDA regarding Aveed™. In 2010 and 2011, the Company met with the FDA to discuss the existing clinical data provided to the FDA as well as the potential path-forward. The Company is evaluating how best to address the concerns of the FDA and intends to have future dialogue with the agency regarding a possible regulatory pathway and is preparing a complete response.

**BEMA® Buprenorphine.** In January 2012, the Company signed a worldwide license and development agreement with BioDelivery Sciences International, Inc. (BioDelivery) for the exclusive rights to develop and commercialize BEMA® Buprenorphine. BEMA® Buprenorphine is a transmucosal form of buprenorphine, a partial mu-opiate receptor agonist, which incorporates a bioerodible mucoadhesive (BEMA®) technology. BEMA® Buprenorphine is currently in phase III trials for the treatment of moderate to severe chronic pain.

**Urocidin™.** Urocidin™ is a patented formulation of Mycobacterial Cell Wall-DNA Complex (MCC) developed by Bioniche Life Sciences Inc. (Bioniche) for the treatment of non-muscle-invasive bladder cancer that is currently undergoing Phase III clinical testing.

In July 2009, the Company entered into a License, Development and Supply Agreement with Bioniche, whereby the Company licensed from Bioniche the exclusive rights to develop and market Urocidin™ in the U.S. with an option for global rights. We exercised our option for global rights in the first quarter of 2010.

**Other.** We also have other products, including certain undisclosed products in our therapeutic areas of interest in early stages of development.

We cannot predict when or if any of these products will be approved by the FDA.

### ***Generics***

Our generics pipeline portfolio contains products and product candidates for multiple therapeutic areas, including pain, oncology, urology and endocrinology. Our generics business has a number of products at various stages of development, including approximately 50 abbreviated new drug applications (ANDAs) under active FDA review.

We cannot predict when or if any of these products will be approved by the FDA.

### ***Devices***

Our Devices segment maintains a robust portfolio of products and product candidates in development, with differentiating features for our areas of focus in pelvic health. Current development products showing significant promise include enhancements to our minimally invasive sling for mild to moderate incontinence in men, a urology drug delivery device, an adjustable tensioning sling for female incontinence, a phosphorylcholine coated device for pelvic floor repair and a fecal incontinence device. We also have other products, including certain undisclosed products in our therapeutic areas of interest in early stages of development.

We cannot predict when or if any of these products will be approved by the FDA.

### **Competition**

#### ***Branded Pharmaceuticals***

The pharmaceutical industry is highly competitive. Our products compete with products manufactured by many other companies in highly competitive markets throughout the U.S. Our competitors vary depending upon

## **Table of Contents**

therapeutic and product categories. Competitors include many of the major brand name and generic manufacturers of pharmaceuticals, especially those doing business in the U.S. In the market for branded pharmaceuticals, our competitors, including Abbott Laboratories, Johnson & Johnson, Pfizer, Inc., Purdue Pharma, L.P., Allergan, Inc. and Watson Pharmaceuticals Inc., vary depending on product category, dosage strength and drug-delivery systems.

We compete principally through our targeted product development and acquisition and in-licensing strategies. 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 continually to 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.

On October 17, 2006, we became aware that, in response to an independent inquiry, the FDA's Office of Generic Drugs (OGD) had proposed that a study of blood levels of lidocaine should be used as the key measure in proving bioequivalence of a generic version of Lidoderm®. On December 19, 2006, we submitted a Citizen Petition with the U.S. Food and Drug Administration requesting that the FDA apply existing bioequivalence regulations to any ANDA seeking regulatory approval of a generic drug product that references Lidoderm®. The petition emphasizes that the proposed new standard deviates from applicable regulations and OGD's past practices, both of which contemplate demonstration of bioequivalence for a topically acting product like Lidoderm® through a comparative clinical efficacy study. We believe blood levels of the active ingredient, lidocaine, cannot be used as the key measure in proving bioequivalence. To appropriately assess the efficacy and safety of any generic version of Lidoderm®, we believe that it is critical that the FDA require any ANDA satisfy the regulations by following these additional criteria to those that FDA has proposed by (1) conducting comparative clinical studies demonstrating identical safety and efficacy between the generic version and Lidoderm®, and (2) for an applicant relying on Lidoderm® as its Reference Listed Drug, to show that its product produces the same local analgesic effect as Lidoderm® without producing a complete sensory block, in order to assure that the generic product has the same labeling, efficacy and safety profile as Lidoderm®. On August 30, 2007, we submitted an amended Citizen Petition to the FDA requesting that the agency withdraw the bioequivalence recommendations, convene a joint meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) and Advisory Committee for Pharmaceutical Science (ACPS) to discuss development of the appropriate method(s) for demonstrating bioequivalence for patch dosage forms with local routes of administration, decline to approve or stay the approval of any ANDA or 505(b)(2) application referencing Lidoderm® that does not contain studies with clinical safety and efficacy endpoints that demonstrate bioequivalence to Lidoderm® and if the FDA contemplates an alternative to bioequivalence studies with clinical endpoints for Lidoderm®, only develop such method through a valid public process, with input from FDA

## **Table of Contents**

advisory committees, including DODAC and ACPS. Other than an acknowledgement of receipt, we have received no response from FDA to either the initial Citizen Petition or the amended Citizen Petition.

The Company is aware of certain competitive activities involving Lidoderm<sup>®</sup>, Opana<sup>®</sup> ER and Frova<sup>®</sup>. For a full description of these competitive activities, including the litigation related to Paragraph IV filings, see Note 14. Commitments and Contingencies-Legal Proceeding in the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

### ***Generics***

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 Pharmaceuticals Industries Ltd, Watson Pharmaceuticals, Mylan Technologies Inc., and Sandoz, Inc., vary depending on product category and dosage strength.

We believe that our competitive advantages include our ability to continually introduce new generic equivalents for brand-name drug products, our quality and cost-effective production, our customer service and the breadth of our generic product line.

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. This has resulted in 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 are typically sold at higher selling prices. As competition from other generic products increases, selling prices for all participants typically decline. 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 relationships. New drugs and future developments in improved and/or advanced drug delivery technologies or other therapeutic techniques may provide therapeutic or cost advantages to competing products.

### ***Devices***

Competition in the medical device industry is intense and characterized by extensive research efforts and rapid technological progress. The primary competitive factors include clinical outcomes, distribution capabilities, and price relative to (1) competitive technologies and (2) reimbursements to physicians and hospitals for their services. With certain of our products, our competitors may have greater resources with which to develop and market products, broader distribution resources, and economies of scale which we do not have.

The competitive advantage of our AMS subsidiary is driven by its focus on the pelvic health market and our ability to develop new products and innovative procedures, obtain regulatory clearance, ensure regulatory compliance, protect our intellectual property, protect the proprietary technology of our products and manufacturing processes and maintain and develop preference for our products among physicians and patients. All of these abilities require recruiting, retaining, and developing skilled and dedicated employees, training physicians and maintaining and developing excellent relationships with physicians and suppliers.

### ***Services***

The lithotripsy services market is highly fragmented and competitive. We compete with other companies, private facilities and medical centers that offer lithotripsy machines and services, including smaller regional and

**Table of Contents**

local lithotripsy service providers. Additionally, while we believe that lithotripsy has emerged as the superior treatment for kidney stone disease, we also compete with hospitals, clinics and individual medical practitioners that offer alternative treatments for kidney stones.

The prostate treatment services market is also highly fragmented and competitive. We compete with other companies, private facilities and medical centers that offer prostate treatment equipment and services, including smaller regional and local service providers.

Competition in our lab business is also intense. We compete with national, regional and local anatomical pathology labs. Certain of our lab competitors have significantly greater resources than us and some have nationally-recognized reputations. In addition, regional and local labs may have regionally-recognized reputations, pre-established long-term relationships with physicians and practice groups whereby the physicians and practice groups are comfortable with the level of expertise of the labs and therefore place a high value on the relationships.

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

	2011	2010	2009
Cardinal Health, Inc.	25%	33%	35%
McKesson Corporation	24%	28%	29%
AmerisourceBergen Corporation	13%	15%	16%

Revenues from these customers are included within our Branded Pharmaceuticals and Generics 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 what are referred to as distribution service agreements 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. To date we have entered into six such agreements.

None of our devices or services customers or distributors accounted for ten percent or more of our total revenues during 2011, 2010 or 2009.

**Table of Contents****Patents, Trademarks, Licenses and Proprietary Property**

As of February 17, 2012, we held approximately: 417 U.S. issued patents, 390 U.S. patent applications pending, 717 foreign issued patents, and 516 foreign patent applications pending. In addition, as of February 17, 2012, we have licenses for approximately 72 U.S. issued patents, 35 U.S. patent applications pending, 152 foreign issued patents and 226 foreign patent applications pending. The following table sets forth information as of February 17, 2012 regarding each of our currently held material patents:

<b>Patent No.</b>	<b>Patent Expiration*</b>	<b>Relevant Product</b>	<b>Ownership</b>	<b>Jurisdiction Where Granted</b>
5,464,864	November 7, 2015	Frova <sup>®</sup>	Exclusive License	USA
5,616,603	April 1, 2014	Frova <sup>®</sup>	Exclusive License	USA
5,637,611	June 10, 2014	Frova <sup>®</sup>	Exclusive License	USA
5,827,871	October 27, 2015	Frova <sup>®</sup>	Exclusive License	USA
5,962,501	December 16, 2013	Frova <sup>®</sup>	Exclusive License	USA
5,411,738	May 2, 2012	Lidoderm <sup>®</sup>	Exclusive License	USA
5,601,838	May 2, 2012	Lidoderm <sup>®</sup>	Exclusive License	USA
5,827,529	October 27, 2015	Lidoderm <sup>®</sup>	Exclusive License	USA
5,741,510	March 30, 2014	Lidoderm <sup>®</sup>	Exclusive License	USA
5,662,933	September 9, 2013	Opana <sup>®</sup> ER	Owned	USA
5,958,456	September 9, 2013	Opana <sup>®</sup> ER	Owned	USA
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	August 5, 2024	Opana <sup>®</sup> ER	Exclusive License	USA
2131647	September 8, 2014	Opana <sup>®</sup> ER	Owned	Canada
2208230	November 4, 2016	Opana <sup>®</sup> ER	Owned	Canada
2251816	April 18, 2017	Opana <sup>®</sup> ER	Owned	Canada
8,062,652	June 16, 2026	Supprelin <sup>®</sup> LA	Owned	USA
8,062,209	December 2, 2023	AMS 700 <sup>®</sup>	Owned	USA
7,946,975	February 21, 2030	AMS 700 <sup>®</sup>	Owned	USA
6,554,824	July 24, 2021	GreenLight <sup>™</sup> Laser	Owned	USA
6,986,764	July 24, 2021	GreenLight <sup>™</sup> Laser	Owned	USA
7,070,556	November 9, 2023	Monarc <sup>®</sup>	Owned	USA
7,347,812	March 17, 2026	Monarc <sup>®</sup>	Owned	USA
7,988,615	November 9, 2023	Monarc <sup>®</sup>	Owned	USA
6,911,003	January 23, 2023	Monarc <sup>®</sup>	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 proceedings declared by the United States 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 the patents, if issued, would 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.



## **Table of Contents**

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 7. License and Collaboration Agreements in the Consolidated Financial Statements included in Part IV Item 15 of this Annual Report on Form 10-K. 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-Legal Proceedings in the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

## **Governmental Regulation**

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 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, refusal of the government to enter into supply contracts or to approve NDAs and ANDAs, civil penalties and criminal prosecution.

FDA approval is typically required before each dosage form or strength of any new drug can be marketed. Applications for FDA approval to market a drug must contain information relating to efficacy, safety, toxicity, pharmacokinetics, product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling, and quality control. The FDA also has the authority to require post-approval testing after marketing has begun and to suspend or revoke previously granted drug approvals. Product development and approval within this regulatory framework requires many years and involves the expenditure of substantial resources.

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. Some new or evolving review standards or conditions for approval 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 recently 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.

## **Table of Contents**

More stringent controls of the levels of these impurities have been required and may continue to be required for FDA approval of products containing these impurities. Also, labeling revisions, formulation or manufacturing changes and/or product modifications may be necessary 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.

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, 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, additional record keeping and expanded documentation of the properties of certain products and scientific substantiation. Such changes, or new legislation, could have a material adverse effect on our business, financial condition, results of operations and cash flows. In December 2003, Congress passed measures intended to speed the process by which generic versions of brand name drugs are introduced to the market. Among other things, these measures are intended to limit regulatory delays of generic drug applications and penalize companies that reach agreements with makers of brand name drugs to delay the introduction of generic versions. These changes could result in increased generic competition for our branded and generic products and could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, on September 27, 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007 (FDAAA) that re-authorized requirements for testing drug products in children, where appropriate, and included new requirements for post-approval studies or clinical trials of drugs that are known to or that signal the potential to pose serious safety risks, and authority to require risk evaluation and mitigation strategies, or REMS to ensure that the benefits of a drug outweigh the risks of the drug, all of which may increase the time and cost necessary for new drug development as well as the cost of maintaining regulatory compliance for a marketed product.

The evolving and complex nature of 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 ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

### ***NDA / BLA Process***

FDA approval is typically required before any new drug can be marketed. A New Drug Application (NDA) or Biologics License Application (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, or 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, or 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, or GCP, 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



## Table of Contents

(cGMP) regulations, and to ensure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;

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, which frequently begins with the initial introduction of the compound into healthy human subjects prior to introduction into patients, involves testing the product for safety, adverse effects, dosage, tolerance, absorption, metabolism, excretion and other elements of clinical pharmacology.

Phase II typically involves studies in 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 to further evaluate clinical safety and efficacy 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. In some cases, the FDA allows a company to rely on data developed in foreign countries or previously published data, which eliminates the need to independently repeat some or all of the studies.

On January 4, 2011, the FDA published a final rule to amend its regulations that govern the informed consent process for clinical trials of products regulated by the FDA. The final rule requires that all informed consent documents for applicable drug and medical device clinical trials initiated on or after March 7, 2012, inform individual clinical trial subjects that a description of the clinical trial in which they are participating will be published in the National Institutes of Health/National Library of Medicine clinicaltrials.gov website. The rule became effective March 7, 2011; however the FDA has stated that it will not enforce the rule's requirements until March 7, 2012. We anticipate that we will incur increased costs associated with the transition to and compliance with these new requirements in our clinical trial programs.

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. The process of completing clinical trials for a new drug may take many years and require the expenditures of substantial resources. Preparing an NDA, BLA or marketing authorization application involves considerable data collection, verification, analysis and expense, and there can be no assurance that approval from the FDA or any other health authority will be granted on a timely basis, if at all. The approval process is affected by a number of factors, primarily the risks and benefits demonstrated in clinical trials as well as the severity of the disease and the availability of alternative treatments. The FDA may deny an NDA or BLA, or foreign government health authorities may deny a marketing authorization application, if the applicable regulatory criteria are not satisfied, or such authorities may require additional testing or information.

As a condition of approval, the FDA or foreign regulatory authorities may require further studies, including Phase IV post-marketing studies to provide additional data. For some drugs, the FDA may require a REMS, which could include medication guides, physician communication plans, or restrictions on distribution and use, such as limitations on who may prescribe the drug or where it may be dispensed or administered. In September 2007, Congress passed legislation authorizing FDA to require companies to undertake such studies to assess the risks of drugs known or signaling potential to have serious safety issues. Other post-marketing studies could be used to gain approval for the use of a product as a treatment for clinical indications other than those for which the

## **Table of Contents**

product was initially tested. Also, the FDA or foreign government regulatory authorities require post-marketing reporting to monitor the adverse effects of drugs. Results of post-marketing programs may limit or expand the further marketing of the products.

On January 30, 2007, the FDA announced a drug safety initiative to implement a number of proposals made by the Institute of Medicine in a September 2006 report. As part of this program, the FDA has begun publishing a newsletter that contains non-confidential, non-proprietary information regarding post-marketing review of new drug products. Additionally, in 2005, the FDA created a Drug Safety Oversight Board to provide oversight and advice to the Center for Drug Evaluation and Research Director on the management of important drug safety issues and to manage the dissemination of certain safety information through FDA's Web site to healthcare professionals and patients.

On February 6, 2009, the FDA sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a REMS to address whether the benefits of these products continue to outweigh the risks. The FDA has authority to require a REMS under the FDAAA when necessary to ensure that the benefits of a drug outweigh the risks. The affected opioid drugs include brand name and generic products. Three products sold by Endo were included in the list of affected opioid drugs: Opana® ER, morphine sulfate ER and oxycodone ER. We cannot determine what may be required by the FDA in connection with a REMS for these products, but intend to comply with any enacted requirements. For example, on December 9, 2011, the FDA approved our interim REMS for Opana® ER, while a class-wide REMS is being developed by an Industry Working Group. Changes could, among other things, require different labeling, monitoring of patients or physicians, education programs for patients or physicians, or curtailment of supplies or limitations on distribution. These changes, or others required by the FDA, could have an adverse effect on the sales, gross margins and marketing costs of these products.

On January 14, 2011, the FDA announced in the Federal Register that it was taking steps to reduce the maximum amount of acetaminophen in prescription drug products, to help reduce or prevent the risk of liver injury from an unintentional overdose of acetaminophen. A variety of combination drug products include acetaminophen, such as those that contain the opioids oxycodone hydrochloride or hydrocodone bitartrate and acetaminophen, among others. Under additional authority granted to the FDA by the FDAAA, the FDA notified holders of approved NDAs and ANDAs that they would be required to modify the labeling of prescription acetaminophen drug products to reflect new safety information about acetaminophen and liver toxicity. The FDA also announced that it was asking product sponsors to limit the maximum strength of acetaminophen per unit of the combination drug products to 325 mg over a three-year phase-out period. At the end of that period, the FDA could seek to withdraw those products that contain more than 325 mg of acetaminophen from the market. Among the products impacted by the FDA's action are three Endo combination drug pain relief products: Percocet®, Endocet® and Zydone®. These regulatory changes, or others required by the FDA, could have an adverse effect on our business, financial condition, results of operations, and cash flows.

Finally, the FDA is developing guidance for the industry on how to test, detect and prevent safety problems during drug development, including tests that would identify preclinical biomarkers of toxicity. Because these initiatives and other similar initiatives are still being developed, it is unclear what impact, if any, they may have on our ability to obtain approval of new drugs or on our sales of existing products.

In addition to these initiatives, the Prescription Drug User Fee Act (PDUFA) was reauthorized on September 27, 2007 through passage of the FDAAA. In connection with that reauthorization legislation, Congress enacted new measures authorizing FDA to require companies to undertake post-approval testing of products to assess known or signaled potential serious safety risks and to make labeling changes to address safety risks. The legislation also re-authorized FDA to require testing of drug products in children where appropriate, and provided additional incentives to companies that agree to undertake such testing in connection with a new NDA as part of the Best Pharmaceuticals for Children Act (BPCA). The legislation also contained provisions to expedite new drug development, and collect data and results from clinical trials of drug products more readily available via a registry managed by the National Institutes of Health. These provisions, depending on how they

## **Table of Contents**

are and continue to be implemented by the FDA, could impact our ability to market existing and new products. The PDUFA and the Medical Device User Fee and Modernization Act (MDUFMA) are each due to be reauthorized for 2012, the ultimate terms of which may contain additional provisions and measures impacting our ability to market existing and new products.

Section 505(b)(2) of the Federal Food Drug and Cosmetic Act provides a procedure for an applicant to seek approval of a drug product for which safety and/or efficacy has been established through preclinical and clinical data that the applicant does not have proprietary rights to use. Under that section, despite not having a right of reference, an applicant can cite to studies containing such clinical data to prove safety or efficacy, along with any additional clinical data necessary to support the application. Section 505(b)(2) NDAs are subject to patent certification and notification requirements that are similar to those that are required for ANDAs (refer to next section). Approval of Section 505(b)(2) NDAs, like ANDAs, also may be delayed by market exclusivity that covers the reference product. However, despite the similarities, Section 505(b)(2) applications are not permitted when an applicant could submit and obtain approval of an ANDA.

### ***ANDA Process***

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 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 regarded as therapeutically equivalent, meaning that a pharmacist can substitute the product for the reference-listed drug. There are other or additional measures the FDA may rely upon to determine bioequivalence in locally acting products, which could include comparative clinical efficacy trials. In May 2007, the FDA began posting to its website, bioequivalence recommendations for individual products in order to provide guidance to generic manufacturers on the specific method of demonstrating bioequivalence.

An ANDA also may 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. For example, the FDA has authorized the substitution of acetaminophen for aspirin in certain combination drug products and switching the drug from a capsule to tablet form. Bioequivalence data may be required, if applicable, as in the case of a tablet in place of a capsule, although the two products would not be rated as therapeutically equivalent, meaning that a pharmacist cannot automatically substitute the product for the reference-listed drug. Congress re-authorized pediatric testing legislation in September 2007 which may continue to affect pharmaceutical firms' ability to file ANDAs via the suitability petition route. In addition, under that same legislation, ANDA applicants are required to implement a REMS in connection with obtaining approval of their products, when the reference-listed drug has an approved REMS.

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. For example, under the Best Pharmaceuticals for Children Act, if a manufacturer receives and accepts a written request from the FDA to conduct studies on the safety and efficacy of its product in children, the exclusivity of a product is extended by six months past the patent or regulatory expiration date if the manufacturer completes and submits the results of the studies, a so-called pediatric extension.

The Generic Drug Enforcement Act of 1992, or Generic Act, allows the FDA to impose permissive or mandatory debarment and other penalties on individuals and companies that commit certain illegal acts relating

## **Table of Contents**

to the drug approval process. In some situations, the Generic Act authorizes the FDA to not accept or review applications for a period of time from a company or an individual that has committed certain violations. It also authorizes the temporary denial of approval of applications during the investigation of certain violations that could lead to debarment and also, in more limited circumstances, authorizes the suspension of the distribution of approved drugs by the affected company. Lastly, the Generic Act allows for civil penalties and withdrawal of previously approved applications. We believe neither we nor any of our employees have ever been subject to debarment.

### ***Patent and Non-Patent Exclusivity Periods***

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 relies 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 bases 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 a 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, or the 2003 Medicare Act, with accompanying amendments to the Hatch Waxman Act (The 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. If the listed drug is a new chemical entity, in certain circumstances, the FDA may not approve any application for five years; if it is not a new chemical entity, the FDA may not approve a competitive application for three years. Certain additional periods of exclusivity may be available if the listed drug is indicated for use in a rare disease or condition or is studied for pediatric indications.

### ***Medical Device Regulation***

Numerous governmental authorities, principally the FDA and comparable foreign regulatory agencies, regulate the development, testing, manufacturing, labeling, marketing, and distribution of our medical devices. In Europe and certain other countries, we comply with the European Union Directives for Medical Devices and certify our compliance with the CE Mark. In other countries outside the U.S., we comply with appropriate local registration and authorization. In the U.S., under the FDCA, medical devices, such as those manufactured by AMS and HealthTronics 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 ensure safety and effectiveness. Class I includes devices with the least risk and Class III includes those with the greatest risk. 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 Regulation, 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

## **Table of Contents**

general controls and may also be subject to other special controls as deemed necessary by the FDA to ensure 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.

HealthTronics currently markets Class I and Class II medical devices, and AMS currently markets Class I, II and III medical devices. If a device is classified as Class I or II, and if it is not 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. By regulation, the FDA is required to clear a 510(k) within 90 days of submission of the application. As a practical matter, clearance often takes longer, particularly if a clinical trial is required. A successful 510(k) submission results in FDA permission to market the new device.

Class III devices are approved through a Premarket Approval Application, or 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. On January 3, 2012, the FDA ordered manufacturers of transvaginal surgical mesh used for pelvic organ prolapse and of single incision mini-slings for urinary incontinence, such as AMS to conduct post-market safety studies and to monitor adverse event rates relating to the use of these products. These class-wide post-market study orders apply to eighteen AMS pelvic floor repair and mini-sling products. AMS is in the process of complying with these orders. In its orders, the FDA also noted that it is still considering the recommendation of an advisory committee on September 9, 2011, that urogynecological surgical mesh for transvaginal repair of pelvic organ prolapse be reclassified from Class II to Class III.

The FDA has broad post-market regulatory and enforcement powers with respect to medical devices, similar to those for pharmaceutical products. Failure to comply with the applicable U.S. medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, consent decrees, civil money penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA's refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product applications, and criminal prosecution.

On January 19, 2011, the FDA's Center for Devices and Radiological Health (CDRH) unveiled a plan of 25 action items it intends to implement during 2011 relating to the 510(k) premarket notification process for bringing medical devices to market. Among the actions the FDA indicated it plans to take are to issue guidance documents to clarify when clinical data should be submitted in support of a premarket notification submission, to clarify the review of submissions that use multiple predicates in a premarket notification submission, to clarify when modifications to a device require a new 510(k), and other guidance documents. The plan includes other intended measures such as streamlining the review of innovative lower-risk products through the de novo review process, and establishing a Center Science Council of senior FDA experts to enhance science-based decision-making in 510(k) reviews. The FDA announced that it intends to refer to the Institute of Medicine (IOM) for further review and consider other significant actions, such as whether or not to define the scope and grounds for the exercise of authority to partially or fully rescind a 510(k) marketing clearance, to clarify and consolidate the concepts of indications for use and intended use, to clarify when a device should no longer be available as a predicate to support a showing of substantial equivalence, whether to develop guidance on a new class of devices, called class IIb, for which additional data would be necessary to support a 510(k) determination.

On July 29, 2011, the IOM released its report, which recommended that the FDA move towards replacing the current 510(k) review process, which is based on substantial equivalence determinations, with a new integrated premarket and post-market regulatory framework that provides a reasonable assurance of safety and



## **Table of Contents**

efficacy. The IOM also recommended that the FDA prioritize enhancement of its post-market surveillance program. The IOM also stated that it was unable to study fully the seven specific actions referred to it by the FDA because the requests came at the end of its review. While the FDA has not acted on the IOM recommendation to replace the 510(k) substantial equivalence framework, it has, as of December 27, 2011, issued updated or new draft guidance on when device modification require a new 510(k), on its evaluation of substantial equivalence in premarket notification 510(k) submissions, including with regard to multiple predicate devices, and on its decisions on whether and how to approve a device clinical study, among other draft guidance.

The extent and how the FDA will implement some or all of its planned action items and draft guidance is unknown at this time. If implemented, these actions could have a significant effect on the cost of applying for and maintaining applications under the 510(k) clearance mechanism, and on the criteria required for achieving clearance for additional uses of existing devices or new 510(k) devices.

### ***Quality Assurance Requirements***

The FDA enforces regulations to ensure 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 current good manufacturing practices, or cGMP. The cGMP regulations the FDA enforces are comprehensive and cover all aspects of manufacturing operations, from receipt of raw materials to finished product distribution, insofar as they bear upon whether drugs meet all the identity, strength, quality and purity characteristics required of them. The cGMP regulations for devices, called the Quality System Regulation, are also comprehensive and cover all aspects of device manufacture, from pre-production design 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 FFDCA. To assure compliance 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. If the FDA concludes that the facilities to be used do not or did not meet cGMP, good laboratory practices or GLP or good clinical practices or GCP requirements, it will not approve the application. Corrective actions to remedy the deficiencies must be performed and are usually verified in a subsequent inspection. In addition, manufacturers of both pharmaceutical products and active pharmaceutical ingredients, or APIs, used to formulate the drug also ordinarily undergo a pre-approval inspection, although the inspection can be waived when the manufacturer has had a passing cGMP inspection in the immediate past. 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 their cGMP status. 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, usually after conferring with the FDA. In respect to domestic establishments, the FDA could initiate product seizures or request or in some instances require product recalls and seek to enjoin 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.

On January 9, 2012, we announced that, as a result of a temporary shutdown by Novartis Consumer Health Division of its manufacturing facility in Lincoln, Nebraska to facilitate certain manufacturing process improvements, there would be a short-term supply constraint for our Opana® ER product, which is manufactured

## **Table of Contents**

by Novartis. To the best of our knowledge, these manufacturing improvements are intended to address the possibility of packaging errors that could potentially result in product mix-ups. We are working collaboratively with the FDA to minimize supply disruptions and are expediting the production of our recently approved formulation of Opana® ER, designed to be crush-resistant, at a third-party manufacturing facility managed by our development partner, Grünenthal. Also, as a result of the temporary Novartis facility shutdown, we will begin production of our Voltaren® Gel product at an alternative Novartis manufacturing source to begin during early second quarter 2012 and, as a result, we expect short-term disruption for patients of this product. We expect certain of our other products will be affected by the temporary Novartis shutdown.

Following a FDA inspection of the manufacturing facility in Huntsville, Alabama, our subsidiary, Qualitest, received a Form 483 Notice of Inspectional Observations dated December 7, 2011, listing six observations of the inspectors. The observations focused on product and process control procedures, product release specifications and building maintenance. A comprehensive response was provided to the FDA on December 28, 2011, addressing the issues in each of the observations, corrective actions, and remediation plans. To date, we have not received a response from the FDA.

### ***Other FDA Matters***

If there are any modifications to an approved drug, including changes in indication, manufacturing process or labeling or a change in a manufacturing facility, an applicant must notify FDA, and in many cases, approval for such changes must be submitted to the FDA. Additionally, the FDA regulates post-approval promotional labeling and advertising activities to assure that such activities are being conducted in conformity with statutory and regulatory requirements. These regulations include standards or restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities and off-label promotion. While physicians may prescribe for off-label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. The FDA has very broad enforcement authority under the FDCA, and failure to abide by these regulations can result in compliance or enforcement action, including the issuance of warning letters directing entities to correct deviations from FDA regulations and civil and criminal investigations and prosecutions. These activities could have a material adverse effect on our business, results of operations, financial condition and cash flows.

### ***Drug Enforcement Administration***

We sell products that are controlled substances as defined in the Controlled Substances Act of 1970 (CSA), which establishes certain security and record keeping requirements administered by the U.S. Drug Enforcement Administration (DEA). The DEA is concerned with the control of registered handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

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, 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. 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.

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

## **Table of Contents**

discretion in whether or not to make such adjustments. Any delay or refusal by the DEA in establishing our quotas, or modification of our quotas, for controlled substances could delay or stop 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.

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. Failure to maintain compliance, particularly as manifested in loss or diversion, 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.

We, and to our knowledge, our third-party API suppliers, dosage form manufacturers, distributors and researchers have necessary registrations, and we believe all registrants operate in conformity with applicable registration requirements.

### ***Clinical Laboratory Improvement Amendments of 1988 and State Regulation***

Since we operate clinical laboratory services as part of our HealthTronics business, we are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), we are required to hold a certificate applicable to the type of work we perform and to comply with certain CLIA-imposed standards. CLIA regulates virtually all clinical laboratories by requiring that they be certified by the federal government and comply with various operational, personnel, facilities administration, quality and proficiency requirements intended to ensure that their clinical laboratory testing services are accurate, reliable and timely. CLIA does not preempt state laws that are more stringent than federal law.

To renew our CLIA certificate, we are subject to survey and inspection every two years to assess compliance with program standards, and may be subject to additional random inspections. Standards for testing under CLIA are based on the level of complexity of the tests performed by the laboratory. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. CLIA compliance and certification is also a prerequisite to be eligible to bill for services provided to governmental payor program beneficiaries.

In addition to CLIA requirements, we are subject to various state laws. CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states, including California, have implemented their own more stringent laboratory schemes. State laws may require that laboratory personnel meet certain qualifications, specify certain quality controls, or prescribe record maintenance requirements.

### ***Government Benefit Programs***

Statutory and regulatory requirements for Medicaid, Medicare, Tricare and other government healthcare programs govern provider reimbursement levels, including requiring that all pharmaceutical companies pay rebates to individual states based on a percentage of their net sales arising from Medicaid program-reimbursed products. In addition, under a final rule promulgated by the United States Department of Defense on March 17, 2009, and reissued on October 15, 2010 with an effective date of December 27, 2010, payments made to retail pharmacies under the Tricare Retail Pharmacy Program for prescriptions filled on or after January 28, 2008 are

## **Table of Contents**

subject to certain price ceilings. Under the final rule and as a condition for placement on the Uniform Formulary, manufacturers are required, among other things, to make refunds for prescriptions filled beginning on January 28, 2008 and extending to future periods based on the newly applicable price limits. Though we have requested a waiver to be exempt from such refunds for the period January 28, 2008 through May 25, 2009, based upon our belief that the Department of Defense is not likely to prevail in court with its interpretation that such refunds are owed, it remains uncertain whether the amounts would be payable. 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 such measures or their impact on our profitability and cash flows. These efforts could, however, have material consequences for the pharmaceutical industry as a whole and consequently, also for the Company.

From time to time, legislative changes are made to government healthcare programs that impact our business. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003 created a new prescription drug coverage program for people with Medicare through a new system of private market drug benefit plans. This law provides a prescription drug benefit to seniors and individuals with disabilities in the Medicare program (Medicare Part D). Congress continues to examine various Medicare policy proposals that may result in a downward pressure on the prices of prescription drugs in the Medicare program.

In addition, in March 2010, President Obama signed into law the U.S. Health Reform Law, which will make major changes to the U.S. healthcare system.

While some provisions of the new healthcare reform law have already taken effect, most of the provisions to expand access to health care coverage will not be implemented until 2014 and beyond. Since implementation is incremental to the enactment date of the law, there are still many challenges and uncertainties ahead. Such a comprehensive reform measure will require expanded implementation efforts on the part of federal and state agencies embarking on rule-making to develop the specific components of their new authority. The Company will monitor closely the implementation and any attempts to repeal, replace, or remove funding of the new health care reform law. This effort will primarily take place on two fronts: 1) in Congress through attempts to pass legislation to overturn all or specific sections of the law and 2) in the Courts through attempts to have the law declared unconstitutional.

The U.S. Supreme Court announced that it will hear the legal challenges to the health care reform law in 2012. The court will consider the constitutionality of the individual mandate, as well as whether the overall health care law can still stand even if the individual mandate is ruled unconstitutional. The Court's decision could significantly impact on the number of Americans who would be afforded access to health care services under the Patient Protection and Affordable Care Act.

Barring a Supreme Court ruling that the Patient Protection and Affordable Care Act is unconstitutional, the passage of the PPACA and the Reconciliation Act will result in a transformation of the delivery and payment for health care services in the U.S. The combination of these measures will expand health insurance coverage to an estimated 32 million Americans. In addition, there are significant health insurance reforms that are expected to improve patients' ability to obtain and maintain health insurance. Such measures include: the elimination of lifetime caps; no rescission of policies; and no denial of coverage due to preexisting conditions. The expansion of healthcare insurance and these additional market reforms should result in greater access to the Company's products.

Our estimate of the overall impact of healthcare reform reflects a number of uncertainties. However, we believe that the impact to our business will be largely attributable to changes in the Medicare Part D Coverage Gap, the imposition of an annual fee on branded prescription pharmaceutical manufacturers, and increased rebates in the Medicaid Fee-For-Service Program and Medicaid Managed Care plans. There are a number of other provisions in the legislation that collectively are expected to have a small impact, including originator average manufacturers price (AMP) for new formulations, and the expansion of 340B pricing to new entities. These various elements of healthcare reform adversely impacted total revenues by approximately \$40 million in 2011 compared to approximately \$20 million in 2010.

## **Table of Contents**

### ***Healthcare Fraud and Abuse Laws***

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry. For example, in the U.S., there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward past purchases or recommendations. Violations of these laws 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 health care programs. These laws also apply to hospitals, physicians and other potential purchasers of our products.

In particular, 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. The term 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, 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. In addition, the recently enacted U.S. Health 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 effective March 23, 2010. 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 U.S. Health Reform Law provides that 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, as virtually any relationship with entities that purchase or refer for our services could implicate the Anti-Kickback Statute.

Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, the OIG issued regulations in July 1991, and periodically since that time, which the OIG refers to as safe harbors. These safe harbor regulations set forth certain provisions which, if met in form and substance, will assure pharmaceutical and medical device companies, healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Additional safe harbor provisions providing similar protections have been published intermittently since 1991. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG or federal prosecutors. Additionally, there are certain statutory exceptions to the federal Anti-Kickback Statute, one or more of which could be used to protect a business arrangement, although we understand that the OIG is of the view that an arrangement that does not meet the requirements of a safe harbor cannot satisfy the corresponding statutory exception, if any, under the federal Anti-Kickback Statute.

Additionally, many states have adopted laws similar to the federal Anti-Kickback Statute. 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, and do not contain identical safe harbors.

Government officials have focused their Anti-Kickback Statute enforcement efforts relating to drug and device manufacturers, including False Claims Act (described below) actions on marketing of healthcare services

## **Table of Contents**

and products, among other activities, and have brought cases against numerous pharmaceutical and medical device companies, and certain sales and marketing personnel for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business or reward past purchases or recommendations.

Another development affecting the healthcare industry is the increased use of the federal civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act's whistleblower or qui tam provisions. The civil False Claims Act imposes 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 alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claim laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program.

When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of \$5,500 to \$11,000 for each separate false claim. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act also has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare reimbursement information when detailing the provider of services, improper promotion of off-label uses (i.e., uses not expressly approved by FDA in a drug's or device's label), misrepresentations with respect to the services rendered and causing improper claims to be submitted for allegedly unapproved drugs or other products. Our activities relating to the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products, the sale and marketing of our products and our service arrangements or data purchases, among other activities, may be subject to scrutiny under these laws. For example, a number of cases brought by local and state government entities are pending that allege generally that our wholly owned subsidiary, EPI, and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid. The cost of defending these cases and any other actions that may be brought under the False Claims Act or a similar state law, as well as any sanctions imposed, could adversely affect our financial performance.

Also, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several new federal crimes, including health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. The false statements statute 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 health care benefits, items or services.

In addition, some states have enacted compliance and reporting requirements aimed at drug and device manufacturers. For example, under California law, pharmaceutical companies must adopt a comprehensive compliance program that is in accordance with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, or the PhRMA Code. The PhRMA Code seeks to promote transparency in relationships between health care professionals and the pharmaceutical industry and to ensure that pharmaceutical marketing activities comport with the highest ethical standards. The PhRMA Code contains strict limitations on certain interactions between health care professionals and the pharmaceutical industry relating to gifts, meals, entertainment and speaker programs, among others. The AdvaMed Code of Ethics on Interactions with Healthcare Professionals contains similar limitations on interactions with health care professionals and the medical device industry. Massachusetts and Vermont require drug and device companies to

## **Table of Contents**

adopt standards that are in some areas more restrictive than the AdvaMed Code or PhRMA Code, imposing additional restrictions on the types of interactions that pharmaceutical and medical device companies or their agents (e.g., sales representatives) may have with health care professionals, including bans or strict limitations on the provision of meals, entertainment, hospitality, travel and lodging expenses, and other financial support, including funding for continuing medical education activities. Some states, including Massachusetts, Vermont and Minnesota, also require public reporting of certain payments to physicians and other health care providers.

The Federal Sunshine Law, which is part of the Affordable Care Act, also imposes federal sunshine provisions, requiring annual reporting beginning in 2013 of various types of payments to physicians and teaching hospitals, beginning with payments made in 2012. On December 19, 2011, the U.S. Centers for Medicare and Medicaid Services (CMS), released a proposed rule to implement the Federal Sunshine Law, which includes a request for comments on the feasibility of this reporting date given that the expected release of the final rule will be during 2012. Accordingly, due to the delayed release of the Proposed Rule, CMS indicated that it will not require the collection of the reporting information until after the final rule issues. This would mean that the 2012 report currently scheduled to be filed in 2013 would likely be for a portion of 2012 unless the final rule provides otherwise.

Finally, our HealthTronics subsidiary is subject to the federal self-referral prohibition commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services (DHS) reimbursed by Medicare if the physician (or a member of the physician's immediate family) has a financial relationship with the entity, unless the relationship meets an exception to the prohibition, and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral. These restrictions generally prohibit us from billing a Medicare patient or any payor, including, without limitation, Medicare, for any DHS furnished by HealthTronics to a Medicare beneficiary, when the physician ordering the DHS, or any member of the physician's immediate family, has an investment interest in, or compensation arrangement with, HealthTronics, unless the arrangement meets an exception to the prohibition. Any person who presents or causes to be presented a claim to the Medicare program in violation of the Stark Law is subject to civil monetary penalties of up to \$15,000 per bill submission, an assessment of up to three times the amount of claims, and possible exclusion from participation in federal governmental payor programs. Many states also have self-referral prohibitions which, unlike the Stark Law, are not limited to Medicare patient referrals. While we have attempted to comply with the Stark Law and similar state laws, it is possible that some of our financial arrangements with physicians could be subject to regulatory scrutiny at some point in the future, and we cannot provide an assurance that we will be found to be in compliance with these laws following any such regulatory review.

### ***Healthcare Privacy and Security Laws***

Our HealthTronics subsidiary is a covered entity subject to the administrative simplification section of HIPAA, the Health Information Technology for Economic and Clinical Health Act (HITECH Act) and their implementing regulations (collectively, the HIPAA Regulations), which establish, among other things, standards for the privacy, security and notification of the security breach of certain individually identifiable health information (protected health information). To the extent that one of our other business units is a business associate because it receives protected health information from a health care provider, health plan or other covered entity to provide a service on behalf of the covered entity, the business unit is also directly subject to the privacy, security and breach notification standards and the HIPAA civil and criminal enforcement scheme. As a business associate of a covered entity, we also have potential contractual liability for privacy, security or breach notification standard violations to the covered entity under a business associate agreement. The HIPAA Regulations also limit our ability to use protected health information for certain marketing initiatives and receive payments from third parties for marketing initiatives involving protected health information. The HITECH Act, adopted in 2009 as part of the American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the HIPAA Regulations and seek attorney's fees and costs associated with pursuing federal civil actions.

## **Table of Contents**

The states also have health information privacy and security laws which may be more restrictive of our uses and disclosures of patient information than the HIPAA Regulations. While we have attempted to comply with the HIPAA Regulations and similar state laws, it is possible that some of our health information management activities could be subject to regulatory scrutiny at some point in the future, and we cannot provide an assurance that we will be found to be in compliance with all of these laws following any such regulatory review.

## **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 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 Annual Report on Form 10-K.

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

We continue to seek to enhance our product line and develop a balanced portfolio of differentiated products through selective 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 under Note 7. License and Collaboration Agreements in the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

## **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, toxic and hazardous substances. Violation of these laws and regulations, which frequently change, can lead to substantial fines and penalties. Some 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 17, 2012, we have 4,566 employees, of which 438 are engaged in research and development and regulatory work, 1,348 in sales and marketing, 270 in quality assurance and 2,510 in general and administrative capacities. Our employees are not represented by unions and we believe that our relations with our employees are good.



**Table of Contents****Executive Officers of the Registrant**

The following table sets forth information as of February 17, 2012 regarding each of our current executive officers:

<b>Name</b>	<b>Age</b>	<b>Position and Offices</b>
David P. Holveck	66	President and Chief Executive Officer and Director
Julie H. McHugh	47	Chief Operating Officer
Alan G. Levin.	49	Executive Vice President, Chief Financial Officer
Ivan P. Gergel, M.D.	51	Executive Vice President, Research and Development and Chief Scientific Officer
Caroline B. Manogue	43	Executive Vice President, Chief Legal Officer and Secretary

**Biographies**

Our executive officers are briefly described below:

DAVID P. HOLVECK, 66, is President, Chief Executive Officer and a Director of Endo. Prior to joining Endo in April 2008, Mr. Holveck was President of Johnson & Johnson Development Corporation and Vice President, Corporate Development of Johnson & Johnson, a diversified healthcare company, since 2004. Mr. Holveck joined Johnson & Johnson as a Company Group Chairman in 1999, following the acquisition of Centocor, Inc., a biotechnology company, by Johnson & Johnson. Mr. Holveck was Chief Executive Officer of Centocor, Inc. at the time of the acquisition. Mr. Holveck joined Centocor in 1983 and progressed through various executive positions. In 1992, he assumed the role of President and Chief Operating Officer and later that year was named President and Chief Executive Officer. Prior to joining Centocor, he had held positions at General Electric Company, Corning Glass Works and Abbott Laboratories. Mr. Holveck is a member of the Board of Trustees for The Fund for West Chester University, as well as the Board of Directors of the Pharmaceutical Research & Manufacturers of America (PhRMA), the University City Science Center and the Kimmel Center.

JULIE H. MCHUGH, 47, is Chief Operating Officer of Endo Pharmaceuticals. Prior to joining Endo, Ms. McHugh was the CEO of Nora Therapeutics, Inc., a venture capital-backed biotech company focused on the treatment of infertility disorders. Prior to joining Nora Therapeutics, she was Company Group Chairman for Johnson & Johnson's Worldwide Virology Business Unit, which included oversight of a R&D portfolio including compounds for HIV, Hepatitis C, and Tuberculosis. Prior to her role as Company Group Chairman, Ms. McHugh was President of Centocor, Inc. a J&J subsidiary. Ms. McHugh received a Bachelor of Science degree from Pennsylvania State University and her masters of business administration degree from St. Joseph's University. She currently serves on the Board of Directors of ViroPharma Inc., the Board of Directors of the Biotechnology Organization (BIO), the Board of Directors of the New England Healthcare Institute (NEHI), the Board of Visitors for the Smeal College of Business of the Pennsylvania State University, and the Board of Directors for the Nathaniel Adamczyk Foundation. She is a past Chairman of the Board of Directors of the Pennsylvania Biotechnology Industry Organization.

ALAN G. LEVIN, 49, was appointed Executive Vice President and Chief Financial Officer in June 2009. Prior to joining Endo, Mr. Levin worked with Texas Pacific Group, a leading private equity firm, and one of their start-up investments in Emerging Markets. Before that, he was Senior Vice President & Chief Financial Officer of Pfizer, Inc. where he worked for 20 years in a variety of executive positions of increasing responsibility, including Treasurer and Senior Vice President of Finance & Strategic Management for the company's research and development organization. He received a bachelor's degree from Princeton University and a master's degree from New York University's Stern School of Business. Mr. Levin is a certified public accountant and an Editorial Advisor for the *Journal of Accountancy*. He is a member of the Advisory Board of Celtic Therapeutics, a private equity fund.

---

## **Table of Contents**

IVAN P. GERGEL, M.D., 51, was appointed Executive Vice President, Research & Development and Chief Scientific Officer in April 2008. Prior to joining Endo, Dr. Gergel was Senior Vice President of Scientific Affairs and President of the Forest Research Institute of Forest Laboratories Inc. Prior to that, Dr. Gergel served as Vice President and Chief Medical Officer at Forest and Executive Vice President of the Forest Research Institute. He joined Forest in 1998 as Executive Director of Clinical Research following nine years at SmithKline Beecham, and was named Vice President of Clinical Development and Clinical Affairs in 1999. Dr. Gergel received his M.D. from the Royal Free Medical School of the University of London and an MBA from the Wharton School. Dr. Gergel is a member of the Board of Directors of Pennsylvania BIO, a member of PhRMA's Scientific and Regulatory Executive Committee, as well as a member of the Board of Directors of the PhRMA Foundation.

CAROLINE B. MANOGUE, 43, has served as Endo's Executive Vice President, Chief Legal Officer and Secretary since 2004. Prior to joining Endo in 2000 as Endo's Senior Vice President, General Counsel and Secretary, she practiced law in the New York office of the law firm Skadden, Arps, Slate, Meagher & Flom LLP, where she specialized in mergers & acquisitions, securities and corporate law. At Endo, she is responsible for all aspects of the company's legal function, including securities law, litigation, government affairs, intellectual property and commercial law, as well as overseeing compliance with current laws and existing pharmaceutical company guidelines relating to, among other things, clinical, sales and marketing practices. In her capacity as Secretary, she is responsible for corporate governance matters and reports directly to the Board of Directors. Ms. Manogue received her J.D. from Fordham Law School and her B.A. cum laude from Middlebury College. She is the 2011-2012 Chairperson of the PhRMA Law Section, a member of the Board of Trustees of the Healthcare Institute of New Jersey (HINJ) and a member of HINJ's Finance and Audit Committee.

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*).

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

#### **Risks related to our business**

**We face intense competition, in particular from companies that develop rival products to our branded pharmaceutical products and from companies with which we compete to acquire rights to intellectual property assets.**

The pharmaceutical industry is intensely competitive, and we face competition across the full range of our activities. In addition to product safety, development and efficacy, other competitive factors in the branded pharmaceuticals market include product quality and price, reputation, service and access to scientific and technical information. If we fail to compete successfully in any of these areas, our business, results of operations, financial condition and cash flows could be adversely affected. Our competitors include many of the major brand name and generic manufacturers of pharmaceuticals, especially those doing business in the U.S. In the market for

## Table of Contents

branded pharmaceuticals, our competitors, including Abbott Laboratories, Johnson & Johnson, Pfizer, Inc., Purdue Pharma, L.P., Allergan, Inc. and Watson Pharmaceuticals Inc., vary depending on product category, product dosage strength and drug-delivery systems. It is possible that developments by our competitors will make our products or technologies uncompetitive or obsolete. Because we are smaller than some of our national competitors in the branded pharmaceuticals sector, we may lack the financial and other resources needed to maintain our profit margins and market share in this sector.

The intensely competitive environment of the branded products business requires an ongoing, extensive search for medical and technological innovations and the ability to market products effectively, including the ability to communicate the effectiveness, safety and value of branded products for their intended uses to healthcare professionals in private practice, group practices and managed care organizations. There can be no assurance that we will be able to successfully develop medical or technological innovations or that we will be able to effectively market our existing branded products or new products we develop.

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 to our in-house research and development efforts, we seek to acquire rights to new intellectual property through corporate acquisitions, asset acquisitions, licensing and joint venture arrangements. We compete to acquire the intellectual property assets that we require to continue to develop and broaden our product range. Competitors with greater resources may acquire assets that we seek, and even where we are successful, competition may increase the acquisition price of such assets or prevent us from capitalizing on such acquisitions or licensing opportunities. If we fail to compete successfully, our growth may be limited.

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

Under the Hatch-Waxman Act, the FDA can approve an ANDA for a generic version of a branded drug and what is referred to as a Section 505(b)(2) NDA, for a branded variation of an existing branded drug, without undertaking the full clinical testing necessary to obtain approval to market a new drug. We refer to this process as the ANDA process. In place of such clinical studies, an ANDA applicant usually needs to only submit data demonstrating that its product has the same active ingredient(s) and is bioequivalent to the branded product, in addition to any data necessary to establish that any difference in strength, dosage form, inactive ingredients, or delivery mechanism does not result in different safety or efficacy profiles, as compared to the reference drug.

The Hatch-Waxman Act requires an applicant for a drug that relies, at least in part, on the patent of one of our branded drugs to notify us of their application and potential infringement of our patent rights. Upon receipt of this notice we have 45 days to bring a patent infringement suit in federal district court against the applicant seeking approval of a product covered by one of our patents. If such a suit is commenced, the FDA is generally prohibited from granting approval of the ANDA or Section 505(b)(2) NDA until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in the generic's favor or expiration of the patent(s). If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the standards for approval of ANDAs and Section 505(b)(2) NDAs. Frequently, the unpredictable nature and significant costs of patent litigation leads the parties to settle to remove this uncertainty. Settlement agreements between branded companies and generic applicants may allow, among other things, a generic product to enter the market prior to the expiration of any or all of the applicable patents covering the branded product, either through the introduction of an authorized generic or by providing a license to the applicant for the patents in suit.

---

**Table of Contents**

As previously reported, on January 15, 2010, the Company and the holders of the Lidoderm® NDA and relevant patent, Teikoku Seiyaku Co., Ltd., and Teikoku Pharma USA, Inc. (collectively, Teikoku) received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) (a Paragraph IV Notice) from Watson Laboratories, Inc. (Watson) advising of the filing of an Abbreviated New Drug Application (ANDA) for a generic version of Lidoderm® (lidocaine topical patch 5%). The Paragraph IV Notice refers to U.S. Patent No. 5,827,529, which covers the formulation of Lidoderm®, a topical patch to relieve the pain of post herpetic neuralgia launched in 1999. This patent is listed in the FDA's Orange Book and expires in October 2015. As a result of this Notice, on February 19, 2010, the Company and Teikoku filed a lawsuit against Watson in the United States District Court of the District of Delaware. 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. This lawsuit was recently heard by the United States District Court of the District of Delaware and concluded on February 14, 2012. We are currently waiting for the court's decision. In October 2010, Teikoku Pharma USA listed U.S. Patent No. 5,741,510 in the FDA Orange Book, and this patent expires in March 2014. On June 30, 2011, the Company and Teikoku filed a second lawsuit against Watson in the United States District Court of the District of Delaware alleging infringement of U.S. Patent Nos. 5,741,510, 6,096,333, and 6,096,334 which cover lidocaine patch formulations and manufacturing processes. The trial relating to this lawsuit has not yet been scheduled.

As previously reported, in January 2011, the Company and Teikoku received a Paragraph IV Notice from Mylan Technologies Inc. (Mylan) advising of the filing of an ANDA for a generic version of Lidoderm® (lidocaine topical patch 5%). The Paragraph IV Notice refers to U.S. Patent Nos. 5,827,529 and 5,741,510, which cover the formulation of Lidoderm®. These patents are listed in the FDA's Orange Book and expire in October 2015 and March 2014, respectively. On March 14, 2011, the Company filed a lawsuit against Mylan in the United States District Court for the District of Delaware, claiming that the Paragraph IV Notice served by Mylan failed to comply with the requirements of 21 U.S.C. 355(b)(3)(C)(1) and 21 C.F.R. 214.95(a). In that suit, the Company seeks a declaration that Mylan's Paragraph IV Certification Notice is null, void and without legal effect, and that as a result, Mylan has failed to properly trigger the ANDA litigation process. In the alternative, the Company alleges that Mylan's submission of its ANDA constitutes infringement of the 510 patent under 35 U.S.C. sec. 271(e)(2)(A). The trial relating to this lawsuit has not yet been scheduled.

Litigation is inherently uncertain and we cannot predict the outcome of our cases against Watson and Mylan. If either of these companies wins its respective lawsuit and is able to obtain FDA approval of its product, it may be able to launch its generic version of Lidoderm® prior to the expiration of the applicable patents in 2014 and 2015. Additionally, it is possible that another generic manufacturer may also seek to launch a generic version of Lidoderm® and challenge the applicable patents. For a complete description of the related legal proceeding see Note 14. Commitments and Contingencies-Legal Proceedings.

Notwithstanding the foregoing patent litigations, even if Watson, Mylan or any other generic manufacturer were to overcome the 510 and 529 patents, no generic version of Lidoderm® can be marketed without the approval of the FDA of the respective ANDA for a generic version of Lidoderm®. In December 2006, the Division of Bioequivalence, Office of Generic Drugs, Center for Drug Evaluation and Research, or OGD, issued draft guidance making recommendations regarding establishing bioequivalence with our patent-protected product, Lidoderm® (lidocaine topical patch 5%), pursuant to which a party could seek ANDA approval of a generic version of that product. In that draft guidance, OGD has recommended a bioequivalence study characterizing the pharmacokinetic profile of lidocaine as well as a skin irritation/sensitization study of any lidocaine-containing patch formulation. This recommendation deviates from our understanding of the applicable regulations and of OGD's past practices, which, for a topically acting product such as Lidoderm®, would require demonstration of bioequivalence through a comparative clinical equivalency study rather than through a pharmacokinetic study.

On December 19, 2006, we submitted a Citizen Petition to the FDA requesting that the FDA apply existing bioequivalence regulations to any ANDA seeking regulatory approval of a generic drug product that references Lidoderm®. We submitted an amendment to that filing in August 2007 in order to provide additional data. Our

## Table of Contents

Citizen Petition emphasizes that the FDA's recommendation deviates from applicable regulations and OGD's past practices, both of which contemplate demonstration of bioequivalence for a topically acting product like Lidoderm® through a comparative clinical efficacy study. We believe blood levels of the active ingredient, lidocaine, cannot properly be used as the key measure in proving bioequivalence. To appropriately assess the efficacy and safety of any generic version of Lidoderm®, and to assure that the generic product has the same labeling, efficacy and safety profile as Lidoderm®, we believe that it is critical that the FDA require any ANDA applicant relying on Lidoderm® as its reference listed drug satisfy the regulations by conducting comparative clinical studies demonstrating (1) bioequivalence between the generic version and Lidoderm®, and (2) that the generic version produces the same local analgesic effect as Lidoderm® without producing a complete sensory block. The FDA has not acted on our Citizen Petition, and it is unclear whether or not the FDA will agree with our position. In addition to this Petition, on September 28, 2007, we filed comments with the FDA regarding the draft guidance through which we reiterated our position as set forth in the Citizen Petition, referencing the Citizen Petition and supporting data. The draft guidance remains available and has not been updated or revised since being issued.

Endo intends, and has been advised by Teikoku that it also intends, to vigorously defend our intellectual property rights in Lidoderm® and to pursue all available legal, business and regulatory avenues in defense of Lidoderm®, including enforcement of the product's intellectual property rights and approved labeling. However, there can be no assurance that our defense will be successful, and any defense may result in significant expense and divert management's attention from our business. Additionally, we cannot predict or determine the timing or outcome of the Paragraph IV litigation discussed above but will explore all options as appropriate in the best interests of the Company.

Lidoderm® accounted for 30% of our revenues in 2011, 46% in 2010 and 52% in 2009. Although we currently anticipate that Lidoderm® will represent a decreasing percentage of our annual sales without taking into account any potential future business development transactions, it will still represent a significant percentage of our revenues. Furthermore, if a generic version of Lidoderm® were introduced into the market before 2015, our revenues from Lidoderm® would decrease significantly and could have a material adverse effect on our business, results of operations, financial condition and cash flows as well as our stock price.

### **Patent litigation, which is often time-consuming and expensive, could have a material adverse effect on our business, results of operations, financial condition and cash flows.**

The discovery, trial and appeals process in patent litigation can take several years. Regardless of FDA approval, should we commence a lawsuit against a third party for patent infringement or should there be a lawsuit commenced against us with respect to any alleged patent infringement by us, whether because of the filing of an ANDA or otherwise, the time and cost of such litigation as well as the ultimate outcome of such litigation, if commenced, whether or not we are successful, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

**Table of Contents****Most of our total revenues come from a small number of products.**

The following table provides a breakdown of our revenues for the years ended December 31 (dollars in thousands):

	2011		2010		2009	
	\$	%	\$	%	\$	%
Lidoderm®	825,181	30	782,609	46	\$ 763,698	52
Opana® ER	384,339	14	239,864	14	171,979	12
Voltaren® Gel	142,701	5	104,941	6	78,868	5
Percocet®	104,600	4	121,347	7	127,090	9
Frova®	58,180	2	59,299	3	57,924	4
Supprelin® LA	50,115	2	46,910	3	27,822	2
Other brands	92,651	3	112,602	7	108,729	7
Total Branded Pharmaceuticals*	1,657,767	61	1,467,572	86	1,336,110	91
Total Generics	566,854	21	146,513	9	124,731	9
Total Devices revenue	300,299	11				
Total Services revenue	205,201	8	102,144	6		
Total revenues*	2,730,121	100	1,716,229	100	\$ 1,460,841	100

\* Percentages may not add due to rounding.

If we are unable to continue to market any of our products, if any of them were to lose market share, for example, as the result of the entry of new competitors, particularly companies producing generic versions of branded drugs, or if the prices of any of these products were to decline significantly, our total revenues, profitability and cash flows would be materially adversely affected.

**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 patent protection relating to the technologies, processes and products we are currently developing and those we 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 assure 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 or his or her employer may have rights in the invention. We cannot assure 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, or PTO, by analogous foreign offices or in legal proceedings. Moreover, we believe that obtaining foreign patents may be more difficult than obtaining domestic patents because of differences in patent laws and, accordingly, our patent position may be stronger in the U.S. than abroad. Foreign patents may be more difficult to protect and enforce and/or the remedies available may be less extensive than in the U.S. Various countries limit the subject matter that can be patented and limit the ability of a patent owner to enforce patents in the medical field. This may limit our ability to obtain or utilize certain of our patents internationally. Because unissued U.S. patent applications are typically not published 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 that we were the first creator of the inventions covered by our pending patent applications or the first to file patent applications on those inventions. Several drug companies and research and academic institutions have developed technologies, filed patent applications or received patents for technologies that may be related to our business. Others may file patent applications and may receive patents that may conflict

## **Table of Contents**

with patents or patent applications we have obtained or licensed, either by claiming the same methods or compounds or by claiming methods or compounds that could dominate those owned by or licensed to us. We cannot assure you that any of our pending patent applications will be allowed, or, if allowed, whether the scope of the claims allowed will be sufficient to protect our products. Litigation to establish the validity of patents, to defend against patent infringement claims of others and to assert patent infringement claims against others can be expensive and time-consuming even if the outcome is favorable to us. If the outcome is unfavorable to us, this could have a material adverse effect on our business. We have taken and may, in the future, take steps to enhance our patent protection, but we cannot assure you that these steps will be successful or that, if unsuccessful, our patent protection will be adequate.

We also rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We attempt to protect our proprietary technology in large part by confidentiality agreements with our employees, consultants and other contractors. We cannot assure you, however, that these agreements will not be breached, that we would have adequate remedies for any breach, that these agreements will be enforceable, or that competitors will not gain access to, or independently discover, our trade secrets. We cannot assure you that others will not independently develop substantially equivalent proprietary information or be issued patents that may prevent the sale of our products or know-how or require licensing and the payment of significant fees or royalties by us in order to produce our products. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. Moreover, we cannot assure you that our technology does not infringe upon any valid claims of patents that other parties own.

We license certain of our material technology and trademarks from third parties, including patents related to Lidoderm® from Teikoku and Hind Health Care, Inc (Hind). We cannot guarantee that such licenses will be renewed at the expiration of their term, if subject to renewal, or that the licensors will not exercise termination rights in connection with those licenses. The loss of any of our material licenses may have a material adverse effect on our business.

In the future, if we were found to be infringing on a patent owned by a third party, we might have to seek a license from such third party to use the patented technology. We cannot assure you that, if required, we would be able to obtain such a license on terms acceptable to us, if at all. If a third party brought a legal action against us or our licensors, we could incur substantial costs in defending ourselves, and we cannot assure you that such an action would be resolved in our favor. If such a dispute were to be resolved against us, we could be subject to significant damages, and the testing, manufacture or sale of one or more of our technologies or proposed products, if developed, could be enjoined.

We cannot assure you as to the degree of protection any patents will afford, whether the PTO will issue patents or whether we will be able to avoid violating or infringing upon patents issued to others or that others will not manufacture and distribute our patented products upon expiration of the applicable patents. Though we enter into confidentiality agreements and non-compete agreements, these agreements may be of limited effectiveness, and therefore it may be difficult for us to protect our trade secrets.

**We may incur significant liability if it is determined that we are promoting or have in the past promoted the off-label use of drugs or medical devices.**

Companies may not promote drugs or medical devices for off-label uses that is, uses that are not described in the product's labeling and that differ from those that were approved or cleared by the FDA. Under what is known as the practice of medicine, physicians and other healthcare practitioners may prescribe drug products and use medical devices for off-label or unapproved uses, and such uses are common across some medical specialties. Although the FDA does not regulate a physician's choice of medications, treatments or product uses, the Federal Food, Drug and Cosmetic Act, or FFDCA, and FDA regulations significantly restrict permissible communications on the subject of off-label uses of drug products and medical devices by pharmaceutical and medical device companies. The FDA, the Federal Trade Commission, or the FTC, the Office

## **Table of Contents**

of Inspector General of the Department of Health and Human Services, or the OIG, the Department of Justice, or the DOJ, and various state Attorneys General actively enforce laws and regulations that prohibit the promotion of off-label uses. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil fines, criminal fines and penalties, civil damages and exclusion from federal funded healthcare programs such as Medicare and Medicaid as well as potential liability under the federal False Claims Act. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payors or other persons allegedly harmed by such conduct.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA's regulations and judicial case law allow companies to engage in some forms of truthful, non-misleading, and non-promotional speech concerning the off-label uses of their products. The Company has endeavored to establish and implement extensive compliance programs in order to instruct employees on complying with the relevant advertising and promotion legal requirements. Nonetheless, the FDA, OIG, the DOJ and/or the state Attorneys General may take the position that the Company is not in compliance with such requirements, and, if such non-compliance is proven, we may be subject to significant liability, including administrative, civil and criminal penalties and fines. In addition, our management's attention could be diverted from our business operations and our reputation could be damaged.

In January 2007 and April 2011, we received subpoenas issued by the OIG, and the DOJ, respectively. The subpoenas request documents relating to Lidoderm® (lidocaine patch 5%) focused primarily on the sale, marketing and promotion of Lidoderm®. We are cooperating with the government in responding to the subpoenas. At this time, we cannot predict or determine the outcome of the government's investigation or reasonably estimate the amount or range of amounts of fines or penalties that might result from a settlement or an adverse outcome from this investigation. However, should the government choose to initiate action against us, we could face substantial penalties, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

**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, 2011 and 2010, goodwill and other intangibles comprised approximately 69% and 57%, respectively, of our total assets. This provisional measurement of goodwill and other intangibles is subject to change and such changes could be significant. 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.

Events giving rise to impairment of goodwill or other intangible assets are an inherent risk in the pharmaceutical and medical device industries and 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 may incur liability if our support of continuing medical or health education programs and/or product promotions are determined, or are perceived, to be inconsistent with regulatory requirements.**

Product promotion educational activities, support of continuing medical education programs, and other interactions with health care professionals must be conducted in a manner consistent with the FDA regulations and the Anti-Kickback Statute (described below). Although we endeavor to follow the applicable requirements, should it be determined that we have not appropriately followed the requirements, the government may initiate an action against us which may result in significant liability, including administrative, civil and criminal sanctions. Such penalties could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, management's attention could be diverted and our reputation could be damaged.



## **Table of Contents**

### **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. Specifically, the federal Anti-Kickback Statute 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 a federal healthcare program such as the Medicare and Medicaid programs. Due to recent legislative changes, violations of the Anti-Kickback Statute also carry potential federal False Claims Act liability. Because of the sweeping language of the federal Anti-Kickback Statute, many potentially beneficial business arrangements would be prohibited if the statute were strictly applied. To avoid this outcome, the United States Department of Health and Human Services' Office of Inspector General has published regulations known as safe harbors that identify exceptions or exemptions to the statute's prohibitions. Arrangements that do not fit within the safe harbors are not automatically deemed to be illegal, but must be evaluated on a case-by-case basis for compliance with the statute. Additionally, many states have adopted laws similar to the federal Anti-Kickback Statute. 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, and do not contain identical safe harbors.

Also, our HealthTronics subsidiary is subject to the federal self-referral prohibition commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services (DHS), reimbursed by Medicare if the physician (or a member of the physician's immediate family) has a financial relationship with the entity, unless the relationship meets an exception to the prohibition, and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral. These restrictions generally prohibit us from billing a Medicare patient or any payor, including, without limitation, Medicare, for any DHS furnished by HealthTronics to a Medicare beneficiary, when the physician ordering the DHS, or any member of the physician's immediate family, has an investment interest in, or compensation arrangement with HealthTronics, unless the arrangement meets an exception to the prohibition. Any person who presents or causes to be presented a claim to the Medicare program in violation of the Stark Law is subject to civil monetary penalties of up to \$15,000 per bill submission, an assessment of up to three times the amount claimed, and possible exclusion from participation in federal governmental payor programs. Many states also have self-referral prohibitions which, unlike the Stark Law, are not limited to Medicare patient referrals. While we have attempted to comply with the Stark Law and similar state laws, it is possible that some of our financial arrangements with physicians could be subject to regulatory scrutiny at some point in the future, and we cannot assure you that we will be found to be in compliance with these laws following any such regulatory review.

We seek to comply with these laws and to fit our relationships with customers and other referral sources within one of the defined safe harbors. We are unaware of any violations of these laws. However, due to the breadth of the statutory provisions and the absence of uniform guidance in the form of regulations or court decisions, there can be no assurance that our practices will not be challenged under anti-kickback or similar laws. Violations of such restrictions may be punishable by civil and/or criminal sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from participation in U.S. federal and state healthcare programs (including Medicaid and Medicare). Any liability from such a violation could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In addition, the FDA has the authority to regulate the claims we make in marketing our prescription drug and medical device products to ensure that such claims are true, not misleading, supported by scientific evidence and consistent with the product's approved or cleared labeling. Failure to comply with FDA requirements in this regard could result in, among other things, suspensions or withdrawal of approvals, product seizures, injunctions against the manufacture, holding, distribution, marketing and sale of a product, and civil and criminal sanctions.

## Table of Contents

Also, the federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to, or the knowing use of false statements to obtain payment from, the government. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act. Private whistleblower plaintiffs and federal and state authorities recently have brought actions against drug and device manufacturers alleging that the manufacturers' activities constituted causing healthcare providers to submit false claims, alleging that the manufacturers themselves made false or misleading statements to the federal government, alleging that the manufacturers improperly promoted their products for off-label uses not approved by the FDA, or offered inducements to referral sources that are prohibited by the federal Anti-Kickback Statute, and alleging that the manufacturers caused improper claims to be submitted for allegedly unapproved drugs or other products. To the extent we become the subject of any such investigations or litigation, it could be time-consuming and costly to us and could have a material adverse effect on our business. In addition, if our activities are found to violate federal or state False Claims Act statutes, it could have a material adverse effect on our business, financial conditions, results of operations and cash flows.

**Many of our core products contain narcotic ingredients. As a result of reports of misuse or abuse of prescription narcotics, the sale of such drugs may be subject to new regulation, including the development and implementation of REMS, which may prove difficult or expensive to comply with, and we and other pharmaceutical companies may face lawsuits.**

Many of our core products contain narcotic ingredients. Misuse or abuse of such drugs can lead to physical or other harm. For example, in the past, reportedly widespread misuse or abuse of OxyContin<sup>®</sup>, a product of Purdue Pharma L.P., or Purdue, containing the narcotic oxycodone, resulted in the strengthening of warnings on its labeling. In addition, we believe that Purdue, the manufacturer of OxyContin<sup>®</sup>, faces or did face numerous lawsuits, including class action lawsuits, related to OxyContin<sup>®</sup> misuse or abuse. We may be subject to litigation similar to the OxyContin<sup>®</sup> suits related to any narcotic-containing product that we market.

The FDA or the U.S. Drug Enforcement Administration, referred to herein as the DEA, may impose new regulations concerning the manufacture, storage, transportation and sale of prescription narcotics. Such regulations may include new labeling requirements, the development and implementation of formal Risk Evaluation and Mitigation Strategy, or REMS, restrictions on prescription and sale of these products and mandatory reformulation of our products in order to make abuse more difficult. On September 27, 2007, Congress passed legislation authorizing the FDA to require companies to undertake post-approval studies in order to assess known or signaled potential serious safety risks and to make any labeling changes necessary to address safety risks. Congress also empowered the FDA to require companies to formulate REMS to ensure a drug's benefits outweigh its risks. On April 19, 2011, the FDA issued letters to manufacturers of long-acting and extended-release opioid drug products requiring them to develop and submit to the FDA a post-market REMS plan to ensure 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. We received a REMS notification letter from the FDA to develop the REMS education and training program for prescribers for our Opana<sup>®</sup> ER, morphine sulfate ER, and oxycodone ER drug products. On December 9, 2011, the FDA approved our interim REMS for Opana<sup>®</sup> ER, while a class-wide REMS is being developed by an Industry Working Group. 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 health care practitioners who request 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.

## Table of Contents

**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.**

Federal and state governmental authorities in the U.S., principally 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.

With respect to pharmaceutical products, the submission of an 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 typically takes many years, varies substantially based upon the type, complexity and novelty of the pharmaceutical product, and the application process is subject to uncertainty. The NDA approval process for a new product varies in time, generally requiring a minimum of 10 months, 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. The FDA also requires companies to undertake post-approval surveillance regarding their drug products and to report adverse events.

With respect to medical devices, such as those manufactured by HealthTronics and AMS, 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 FFDCa, or premarket approval, or 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 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. HealthTronics' currently commercialized products have received premarket clearance under Section 510(k) of the FFDCa. AMS' currently commercialized products have received premarket clearance or PMA from the FDA under Section 510(k) or 515 of the FFDCa.

The FDA also has authority under the FFDCa to require a manufacturer to conduct post-market surveillance of a Class II or Class III device.

On October 20, 2008, the FDA issued a 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, 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 this July 2011 update, the FDA maintained that adverse events are not rare, as previously reported, and 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. FDA also convened an advisory panel which met on September 8-9, 2011 to further address the safety and effectiveness of

## **Table of Contents**

transvaginal surgical mesh used to treat POP and SUI. At the conclusion of the meetings, the advisory panel recommended reclassifying transvaginal mesh products used to treat POP to Class III devices (premarket approval) and recommended that manufacturers of these products be required to conduct additional post-market surveillance studies. The advisory panel recommended that transvaginal surgical mesh products used to treat SUI remain as Class II devices. Regarding retropubic and transobturator (TOT) slings, the advisory panel recommended that no additional post-market surveillance studies are necessary. Regarding mini-slings, the advisory panel recommended premarket study for new devices and additional post-market surveillance studies. The advisory panel's recommendations are now under consideration by FDA.

On January 3, 2012, the FDA ordered manufacturers of transvaginal surgical mesh used for pelvic organ prolapse and of single incision mini-slings for urinary incontinence, such as AMS, to conduct post-market safety studies and to monitor adverse event rates relating to the use of these products. These class-wide post-market study orders apply to eighteen AMS pelvic floor repair and mini-sling products. AMS is in the process of complying with these orders. In its order, the FDA also noted that it is still considering the recommendation of an advisory committee, made on September 9, 2011, that urogynecological surgical mesh for transvaginal repair of pelvic organ prolapse be reclassified from Class II to Class III.

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.

As part of its on-going quality program, AMS is engaged in a review of its quality systems, including its process validation procedures for many of its products, and is implementing a variety of enhancements to such systems, controls and procedures. In particular, because certain of AMS's products are legacy products that have been in use for 15 to 20 years, they may require enhancements of AMS's procedures, including additional remedial efforts, which could result in added costs.

We cannot assure you that the FDA or other regulatory agencies will approve or clear for marketing any products developed by us, on a timely basis, if at all, or, if granted, that approval will not entail limiting the indicated uses for which we may market the product, which could limit the potential market for any of these products.

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. For example, on January 19, 2011, the FDA's Center for Devices and Radiological Health, or CDRH, unveiled a plan of twenty-five action items it intends to implement during 2011 relating to the 510(k) premarket notification process for bringing medical devices to market. Among the actions the FDA plans to take are to issue guidance documents to clarify when clinical data should be submitted in support of a premarket notification submission, to clarify the review of submissions that use multiple predicates in a premarket notification submission, to clarify when modifications to a device require a new 510(k) determination, and other guidance documents. The FDA announced that it intends to refer to the Institute of Medicine, or IOM, for further review and consideration of other potential significant actions, such as whether or not to define the scope and grounds for the exercise of authority to partially or fully rescind a 510(k) marketing clearance, to clarify and consolidate the concepts of indications for use and intended use, to clarify when a device should no longer be available as a predicate to support a showing of substantial equivalence, whether to develop guidance on a new class of devices, called class IIb, for which additional data would be necessary to support a 510(k) determination.

## **Table of Contents**

On July 29, 2011, the IOM released its report, which recommended that the FDA move towards replacing the current 510(k) review process, which is based on substantial equivalence determinations, with a new integrated premarket and post-market regulatory framework that provides a reasonable assurance of safety and efficacy. The IOM also recommended that the FDA prioritize enhancement of its post-market surveillance program. The IOM also stated that it was unable to study fully the seven specific actions referred to it by the FDA because the requests came at the end of its review. While the FDA has not acted on the IOM recommendation to replace the 510(k) substantial equivalence framework, it has, as of December 27, 2011, issued updated or new draft guidance on when device modification require a new 510(k), on its evaluation of substantial equivalence in premarket notification 510(k) submissions, including with regard to multiple predicates, and on its decisions on whether and how to approve a device clinical study, among other draft guidance.

The extent to which and how the FDA will implement some or all of its planned action items and draft guidance is unknown at this time. If implemented, these actions could have a significant effect on the cost of applying for and maintaining applications under the 510(k) clearance mechanism, and on the criteria required for achieving clearance for additional uses of existing devices or new 510(k) devices. Further, some new or evolving 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 recently 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.

More stringent controls of the levels of these impurities have been required and may continue to be required for FDA approval of products containing these impurities. Also, labeling revisions, formulation or manufacturing changes and/or product modifications may be necessary 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.

In addition, on September 27, 2007, through passage of the Food and Drug Administration Amendments Act of 2007, or FDAAA, Congress passed legislation authorizing the FDA to require companies to undertake additional post-approval studies in order to assess known or signaled potential serious safety risks and to make any labeling changes necessary to address safety risks. Congress also empowered the FDA to require companies to formulate REMS to ensure a drug's benefits outweigh its risks.

The FDA's exercise of its authority under the FDCA could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved products. Foreign regulatory agencies often have similar authority and may impose comparable costs. Post-marketing studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our products. Further, 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. Likewise, manufacturing issues or problems at a supplier or third party manufacturer of our products could have an adverse effect on sales of our products, and could lead to product recalls or product shortages. Furthermore, new data and information, including information about product misuse at the user level, may lead government agencies, professional

## **Table of Contents**

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 assure that marketed products are safe, effective and consistently of uniform, high quality. The DEA administers registration, drug allotment and accountability systems to assure 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 the facilities, processes and procedures used to manufacture and market pharmaceutical and medical 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 current good manufacturing practices (cGMP), regulations enforced by the FDA. Compliance with cGMP regulations requires the dedication of substantial resources and requires significant expenditures. The FDA periodically inspects both our third party and owned manufacturing facilities and procedures to assure compliance. The FDA may cause a suspension or withdrawal of product approvals if regulatory standards are not maintained. In the event an approved manufacturing facility for a particular drug 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.

On May 17, 2010, our subsidiary, HealthTronics, received a warning letter from the FDA in connection with an FDA inspection of Endocare, a subsidiary of HealthTronics, conducted in November 2009. The warning letter alleges instances of deficiencies relating to medical device reporting, or MDR, complaint handling and corrective and preventative action procedures, design control, and failure to seek FDA clearance of a design change. On June 15, 2010, HealthTronics provided a detailed response to the warning letter, including a description of its comprehensive corrective action plan to address the FDA's concerns. On August 25, 2010, the FDA issued a reply to HealthTronics indicating that, with the exception of the remaining close-out of a corrective action and preventative action, or CAPA, review, its responses and corrective action plan appear to be adequate and will be verified at future inspections. On November 1, 2010, after ongoing updates and discussions with the FDA, HealthTronics reported that it had completed the remaining CAPA review, and was implementing corrective action to address and close-out the CAPA. On July 25, 2011, HealthTronics sent a final update letter to the FDA informing the FDA that HealthTronics has resolved all open concerns and requesting the FDA to provide a close-out letter to the May 17, 2010 warning letter. In December 2011, HealthTronics received such close-out letter from the FDA.

The FDA is authorized to perform inspections under the FFDCIA. During inspections of factory or manufacturing facilities, the FDA utilizes a Form FDA 483 to document and communicate observations made during inspections. The observations made on the Form 483 are not final and are not a finding as to whether the specific facility in question is compliant. Our Qualitest subsidiary operates two main manufacturing facilities, one site is located in Huntsville, Alabama and the second site is located in Charlotte, North Carolina. Both sites have been inspected by the FDA.

Following a FDA inspection of the manufacturing facility in Huntsville, Alabama, our subsidiary, Qualitest, received a Form 483 Notice of Inspectional Observations dated December 7, 2011, listing six observations of the inspectors. The observations focused on product and process control procedures, product release specifications and building maintenance. A comprehensive response was provided to the FDA on December 28, 2011, addressing the issues in each of the observations, corrective actions, and remediation plans. To date, we have not received a response from the FDA.

## **Table of Contents**

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. Failure to comply with applicable legal requirements subjects the Qualitest facilities to possible legal or regulatory action, including shutdown, which may adversely affect their ability to supply us with product. Were we not able to manufacture products at the Qualitest facilities because of regulatory, business or any other reasons, the manufacture and marketing of these products would be interrupted. 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 and, as a result, our procurement quota may not be sufficient to meet commercial demand or complete clinical trials.

We cannot determine what effect changes in regulations or legal interpretations 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.

### **Implementation by the FDA of certain specific public advisory committee recommendations regarding acetaminophen use in both over-the-counter and prescription products could have an adverse material impact on our net sales of Percocet® and Endocet®.**

The FDA held a public advisory committee meeting in June 2009 to discuss acetaminophen use in both over-the-counter and prescription products, the potential for liver injury, and potential interventions to reduce the incidence of liver injury. The panel's recommendations included the banning of certain prescription painkillers which combine acetaminophen with an opiate narcotic, and lowering the maximum dose of over-the-counter painkillers containing acetaminophen. These recommendations were made following the release in May 2009 of a FDA report that found severe liver damage, and even death, can result from a lack of consumer awareness that acetaminophen can cause such injury. These recommendations were advisory in nature and the FDA was not bound to follow these recommendations.

On January 14, 2011, the FDA announced in the Federal Register that it was taking 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. A variety of prescription combination drug products include acetaminophen, such as those that contain the opioids oxycodone hydrochloride or hydrocodone bitartrate and acetaminophen, among others. Specifically, the FDA announced that it was asking product sponsors to limit the maximum strength of acetaminophen per dosage unit of the prescription combination drug products to 325 mg over a three-year phase-out period. At the end of that period, the FDA could seek to withdraw those prescription combination drug products that contain more than 325 mg of acetaminophen from the market, citing its authority to initiate withdrawal proceedings under the FDCA. Among the products impacted by the FDA's action are three Endo combination drug pain relief products: Percocet®, Endocet® and Zydone®; and the Qualitest combination drug pain relief products: butalbital/acetaminophen/caffeine, hydrocodone/acetaminophen and oxycodone/acetaminophen. In addition, under additional authority granted to the FDA by the FDAAA, the FDA notified holders of approved NDAs and ANDAs that they would be required to modify the labeling of prescription acetaminophen drug products to include a Boxed Warning to include new safety information about acetaminophen and liver toxicity, and a Warning on the potential for allergic reactions. These regulatory changes, or others required by the FDA, could have an adverse effect on our business, financial condition, results of operations, and cash flows.

## **Table of Contents**

**Timing and results of clinical trials to demonstrate the safety and efficacy of products as well as the FDA's approval of products are uncertain.**

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.

The rate of patient enrollment sometimes delays completion of clinical studies. 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. Delays in planned patient enrollment can result in increased development costs and delays in regulatory approval. In addition, we rely on collaboration partners that may control or make changes in trial protocol and design enhancements that may also delay clinical trials. Product supplies may be delayed or be insufficient to treat the patients participating in the clinical trials, or manufacturers or suppliers may not meet the requirements of the FDA or foreign regulatory authorities, such as those relating to cGMP. We also may experience delays in obtaining, or we may not obtain, required initial and continuing approval of our clinical trials from institutional review boards. We cannot assure you that we will not experience delays or undesired results in these or any other of our clinical trials.

We cannot assure you that the FDA or foreign regulatory agencies will approve, clear for marketing or certify any products developed by us, on a timely basis, if at all, or, if granted, 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.

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 these trials would prevent us from obtaining required regulatory approvals.

**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 the purchase of assets, joint ventures and licenses or by acquiring other companies. However, we cannot assure 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, and we may have to compete for acquisition candidates.

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.



## Table of Contents

Acquisitions, such as the recent Indevus, HealthTronics, Penwest, Qualitest and AMS acquisitions may expose us to additional risks and may have a material adverse effect on our profitability and cash flows. Any acquisitions we make may:

fail to accomplish our strategic objectives;

not be successfully combined with our operations;

not perform as expected; and

expose us to cross border risks.

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.

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.

**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, and these new products must meet regulatory standards and receive requisite regulatory approvals. Products we are currently developing may or may not receive the regulatory approvals necessary for us to market them. Furthermore, the development and commercialization process is time-consuming and costly, and we cannot assure you that any of our products, if and when developed and approved, can be successfully commercialized. Some of our collaboration partners may decide to make substantial changes to a product's formulation or design, may experience financial difficulties or have limited financial resources, any of which 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, possibly, additional costs in developing and marketing that product.

We conduct research and development primarily to enable us to manufacture and market FDA-approved pharmaceuticals and devices in accordance with FDA regulations. Much of our drug development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology. Typically, research expenses related to the development of innovative compounds and the filing of NDAs for these products are significantly greater than those expenses associated with ANDAs for 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 our industry, particularly with respect to new drugs, our research and development expenditures may not result in the successful introduction of FDA approved new pharmaceutical products. Also, after we submit an NDA or ANDA, the FDA may require that we conduct additional studies, including, depending on the product, studies to assess the product's interaction with alcohol, and as a result, we may be unable to reasonably predict the total research and development costs to develop a particular product. Indeed, on September 27, 2007, Congress passed legislation authorizing the FDA to require companies to undertake post-approval studies in order to assess known or signaled potential serious safety risks and to make any labeling changes necessary to address safety risks. Congress also empowered the FDA to require companies to formulate REMS to ensure a drug's benefits outweigh its risks.

## **Table of Contents**

### **Our generics business faces intense competition from brand-name companies that sell or license their own generic versions of our generic products or seek to delay the introduction of our generic products.**

Brand-name pharmaceutical companies have taken aggressive steps to thwart competition from generic equivalents of their brand-name products. In particular, brand-name companies sell directly to the generics market or license their products for sale to the generics market through licensing arrangements or strategic alliances with generic pharmaceutical companies (so-called authorized generics). While there have been legislative proposals by members of Congress to limit the use of authorized generics, no significant regulatory approvals are currently required for a brand-name manufacturer to sell directly or through a third party to the generic market. Brand-name manufacturers do not currently face any other significant barriers to entry into such market. The introductions of these so-called authorized generics have had and may continue to have an adverse effect by reducing our generics market share and adversely affecting our profitability and cash flows.

In addition, brand-name companies continually seek new ways to delay generic introduction and decrease the impact of generic competition, such as filing new patents on drugs whose original patent protection is about to expire; filing an increasing number of patents that are more complex and costly to challenge; filing suits for patent infringement that automatically delay approval by the FDA; developing patented controlled release or other next generation products, which often reduces the demand for the generic version of the existing product for which we may be seeking approval; changing product claims and product labeling; developing and marketing as over-the-counter products those branded products that are about to face generic competition; or filing Citizens Petitions with the FDA seeking restraints on our products or seeking to prevent them from coming to market. These strategies may increase the costs and risks associated with our efforts to introduce generic products and may delay or prevent such introduction altogether.

### **Our revenues and profits from generic pharmaceutical products typically decline as a result of intense competition from other pharmaceutical companies.**

Our generic products compete with branded products and with generic versions made by or for other manufacturers, such as Mallinckrodt Inc., Teva Pharmaceuticals Industries Ltd and Watson Pharmaceuticals, Inc. Net selling prices of generic drugs typically decline, often dramatically, as additional generic pharmaceutical companies, both domestic and foreign, receive approvals and enter the market for a given generic product and competition intensifies. When additional versions of one of our generic products enter the market, we generally lose market share and our selling prices and margins on that product decline. Because we are smaller than many of our full-line competitors in the generic pharmaceutical products sector, we may lack the financial and other resources needed to maintain our profit margins and market share in this sector. Our ability to sustain our sales and profitability on any generic product over time is affected by the number of new companies selling such product and the timing of their approvals.

### **If the efforts of manufacturers of branded pharmaceuticals to use litigation and legislative and regulatory means to limit the use of generics and certain other products are successful, sales of our generic products may suffer.**

Pharmaceutical companies that produce patented brand products can employ a range of legal and regulatory strategies to delay the introduction of competing generics and other products to which we do not have a right of reference to all necessary preclinical and clinical data. Opposing such efforts or litigation actions can be costly and time-consuming and result in delays in the introduction of our products.

The products for which we are developing generic versions may be claimed by their manufacturer to be protected by one or more patents. If we file an ANDA to seek FDA approval of our generic version of such a drug, we are required to certify that any patent or patents listed as covering the approved listed drug are invalid, unenforceable or will not be infringed by our generic version. Similar certification requirements apply to new drug applications filed under Section 505(b)(2) of the FDCA, where we rely on information to which we do not have a right of reference. Once the FDA accepts our ANDA or Section 505(b)(2) NDA, we are required to notify

## **Table of Contents**

the brand manufacturer of this fact. The brand manufacturer then has 45 days from the receipt of the notice in which to file a suit for patent infringement. If it does so, the FDA is generally prevented from granting approval of the ANDA or Section 505(b)(2) NDA until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in the generic's favor or expiration of the patent(s).

### **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 potential liability risks that arise from the testing, manufacturing, marketing and sale of our products. In addition to direct expenditures for damages, settlement and defense costs, there is a possibility of adverse publicity as a result of product liability claims. Product liability is a significant commercial risk for us. Some plaintiffs have received substantial damage awards in some jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. 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, which would also result in adverse publicity as well as in costs connected to the recall and loss of revenue.

We acquired Qualitest, and Qualitest and, in certain cases, we or certain of our subsidiaries, along with several other pharmaceutical manufacturers, have been named as defendants in a number of cases filed in various state and federal courts that allege plaintiffs experienced injuries as a result of using the prescription medicine metoclopramide. Many of these cases are in the discovery phase of the litigation. Qualitest and, in certain cases, the Company and certain of our other subsidiaries are also named as defendants in cases that have been filed in various state and federal courts that allege plaintiffs experienced injuries as a result of using prescription medications containing propoxyphene, which has been manufactured and marketed by Qualitest as well as other manufacturers. We may be subject to liabilities arising out of these cases, and are responsible for the cost of managing these cases. We intend to contest all of these cases vigorously. Additional litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions with respect to metoclopramide, propoxyphene-containing prescription medications or other products in the future. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us and/or Qualitest. Subject to certain terms and conditions, we will be indemnified by the former owners of Qualitest with respect to, among other things, metoclopramide and propoxyphene litigation arising out of the sales of the product by Qualitest between January 1, 2006 and November 30, 2010, the date on which the acquisition was completed, subject to an overall liability cap of \$100 million for all claims arising out of or related to the acquisition, including the claims described above.

Also, Qualitest and, in certain cases, the Company or certain of our subsidiaries, have been named as defendants in lawsuits that were filed after the recent recall of several lots of Qualitest's oral contraceptive products in which the plaintiffs seek out-of-pocket losses, medical expenses, and other damages associated with the alleged failure of these products. Three of these lawsuits seek certification of a nationwide class of all patients who used the recalled products. We may be subject to liabilities arising out of these cases, and are responsible for the cost of managing these cases. We intend to contest all of these cases vigorously. Additional litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions.

AMS and, in certain cases, the Company or certain of its 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 POP and SUI. Plaintiffs in these suits allege various personal injuries including chronic pain, incontinence and inability to control bowel function, and permanent deformities. On February 7, 2012, the United States Judicial Panel on Multidistrict Litigation issued an order to consolidate and transfer certain of these claims filed against AMS in various federal courts to the Southern District of West Virginia as MDL 2325. We may be subject to liabilities arising out of these cases, and are responsible for the cost of managing these cases. We intend to contest all of these cases vigorously. However, there can be no assurance that our defense will be successful, and any defense may result in significant expense and divert management's

## **Table of Contents**

attention from our business. Additionally, we cannot predict or determine the timing or outcome of this litigation but will explore all options as appropriate in the best interests of the Company. Additional litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions in the future. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us and/or AMS.

We cannot assure 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. If any claim is brought against us, regardless of the success or failure of the claim, we cannot assure 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. Additionally, we may be limited by the surviving insurance policies of our recently acquired subsidiaries.

### **Mesh litigation and FDA actions in connection with surgical mesh may adversely affect sales of our female incontinence and pelvic floor repair products.**

On October 20, 2008, the FDA issued a Public Health Notification regarding potential complications associated with transvaginal placement of surgical mesh to treat POP and 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, 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 this July 2011 update, the FDA maintained that adverse events are not rare, as previously reported, and 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.

FDA also convened an advisory panel which met on September 8-9, 2011 to further address the safety and effectiveness of transvaginal surgical mesh used to treat POP and SUI. At the conclusion of the meetings, the advisory panel recommended reclassifying transvaginal mesh products used to treat POP to Class III devices (premarket approval) and recommended that manufacturers of these products be required to conduct additional post-market surveillance studies. The advisory panel recommended that transvaginal surgical mesh products used to treat SUI remain as Class II devices. Regarding retropubic and transobturator (TOT) slings, the advisory panel recommended that no additional post-market surveillance studies are necessary. Regarding mini-slings, the advisory panel recommended premarket study for new devices and additional post-market surveillance studies. The advisory panel's recommendations are now under consideration by FDA.

On January 3, 2012, the FDA ordered manufacturers of transvaginal surgical mesh used for pelvic organ prolapse and of single incision mini-slings for urinary incontinence, such as AMS, to conduct post-market safety studies and to monitor adverse event rates relating to the use of these products. These class-wide post-market study orders apply to eighteen AMS pelvic floor repair and mini-sling products. AMS is in the process of complying with these orders. In its order, the FDA also noted that it is still considering the recommendation of an advisory committee, made on September 9, 2011, that urogynecological surgical mesh for transvaginal repair of pelvic organ prolapse be reclassified from Class II to Class III.

We cannot predict the extent to which these developments could result in a decrease in the number of surgical procedures using surgical mesh. A decrease in the number of surgical procedures using surgical mesh may adversely affect sales of our female incontinence and pelvic floor repair products.

---

**Table of Contents**

**We may incur liabilities as the result of over-time cases which, if ultimately determined adverse to the industry, could have a material adverse effect on our business, financial condition, results of operations and cash flows.**

A number of pharmaceutical companies are defendants in litigation brought by their own current and former pharmaceutical sales representatives, alleging that the companies violated wage and hour laws by misclassifying the sales representatives as exempt employees, and by failing to pay overtime compensation. We are subject to one such case, *Susan S. Quinn, on behalf of herself and all others similarly situated v. Endo Pharmaceuticals Inc.*, which was conditionally certified as an opt-in class action on June 1, 2011, and is currently pending in the United States District Court for the District of Massachusetts. The case has been stayed pending resolution of the *Christopher v. SmithKline Beecham Corporation* matter currently before the Supreme Court. We may in the future be the subject of similar cases. Depending on developments in this ongoing and any future litigation, there is a possibility that we will suffer an adverse decision or verdicts of substantial amounts, or that we will enter into monetary settlements. Any unfavorable outcome as a result of such litigation could have a material adverse effect on our business, financial condition, results of operations and cash flows.

**The availability of third party reimbursement for our products is uncertain, and 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, private health insurers and others. We cannot be certain that, over time, third party payment for our products will be adequate for us to maintain price levels sufficient for realization of an appropriate return on our investment. Government payors, 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.

Examples of some of the major government healthcare programs include Medicare and Medicaid. The Medicare Prescription Drug Improvement and Modernization Act of 2003, or the Medicare Modernization Act, created a new prescription drug coverage program for people with Medicare through a new system of private market insurance providers beginning in January 2006, or Part D. Although the new Part D benefit resulted in Medicare coverage for outpatient drugs previously not covered by Medicare, the new benefit has resulted in an increased use of formularies (listings of prescription drugs approved for use) such that, in the event a Medicare beneficiary's medications are not listed on the applicable formulary, such Medicare beneficiary may not receive reimbursement for such medications. Moreover, once these formularies are established, a Medicare Part D plan is not obligated to pay for drugs omitted from a formulary, unless the beneficiary receives an exception, and the cost of these non-covered drugs will not be counted towards the annual out-of-pocket beneficiary deductible established by the Medicare Modernization Act. Also, formularies may have tiers where cost-sharing varies depending on the tier to which a particular drug is assigned. Further, since 2006, private insurance policies that supplement Medicare coverage, known as Medigap policies, no longer may include prescription drug coverage and therefore cannot be used to cover the cost of off-formulary medications. Our product mix is shifting towards products for aging demographics and, as a result, over time we will become increasingly dependent on Medicare. If our products are or become excluded from Part D plan formularies, or are placed on formulary tiers that require significant beneficiary cost-sharing, demand for our products might decrease and we may be forced to lower prices for our products, which may adversely affect our business, financial condition, results of operations and cash flows.

From time to time, state Medicaid programs review our products to assess whether such products should be subject to a prior authorization process, which processes vary state-by-state but generally require physicians prescribing the products to answer several questions prior to the product being dispensed. The institution of a

---

**Table of Contents**

prior authorization process may adversely impact the sales of the related product in the state and depending on the state, may adversely affect our business and results of operations. On February 20, 2008, in connection with its Clinical Drug Review Program, the Pharmacy and Therapeutics Committee of the New York State Department of Health reviewed our product Lidoderm® and recommended that it be subject to a prior authorization process. As a result, on July 31, 2008, the New York State Department of Health placed Lidoderm® in its Clinical Drug Review Program, which is a specific program within its prior authorization program. There can be no assurance that such a process, or the implementation thereof, in New York State or elsewhere would not have a material adverse effect on our business, financial condition, results of operations and cash flows.

If government and commercial third party payers do not provide adequate coverage and reimbursement levels for users of our products, the market acceptance of these products could be adversely affected. In addition, the following factors could significantly influence the purchase of pharmaceutical products, which would result in lower prices and a reduced demand for our products that might force us to reduce the price of these products to remain competitive:

the trend toward managed healthcare in the U.S.;

the growth of organizations such as HMOs and managed care organizations;

legislative proposals to reform healthcare and government insurance programs; and

price controls and non-reimbursement of new and highly priced medicines for which the economic therapeutic rationales are not established.

In February, 2009, President Obama signed into law the American Recovery and Reinvestment Act of 2009, which appropriates \$1.1 billion to fund comparative effectiveness research, or CER, relating to healthcare treatments. In March 2010, the President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, which we collectively refer to as the U.S. Health Reform Law, which, among other things, created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct CER. Although the concept of CER now has significant momentum, numerous unresolved and potentially contentious issues remain, and stakeholders are following implementation of these new laws closely. Depending on how CER is implemented, CER could possibly present regulatory and reimbursement issues under certain circumstances. For additional discussion of the U.S. Health Reform Law, see While healthcare reform may increase the number of patients who have insurance coverage for our products, its cost containment measures may adversely affect reimbursement for our products.

**Third party payors could refuse to reimburse healthcare providers for use of HealthTronics and AMS's current or future service offerings or products, which could negatively impact our business, results of operations, financial condition and cash flows.**

Third party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of medical procedures and treatments, particularly for elective procedures, which would include a number of AMS's product offerings. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare 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. AMS has experienced lower procedure volume levels, particularly in Europe, as a result of recent austerity measures or budget reduction measures adopted by certain European countries in response to growing budget deficits and volatile economic conditions and may experience lower levels of reimbursement with respect to AMS's products in the future as a result. In the U.S., lithotripsy treatments offered by HealthTronics are reimbursed under various federal and state programs, including Medicare and Medicaid, as well as under private healthcare programs, primarily at fixed rates. Governmental programs are subject to statutory and regulatory changes, administrative rulings, interpretations of

## Table of Contents

policy and governmental funding restrictions, and private programs are subject to policy changes and commercial considerations, all of which may have the effect of decreasing program payments, increasing costs or requiring HealthTronics and AMS to modify the way in which they operate their businesses.

**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 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 in return for the purchase of our products. Sanctions for violating these laws include criminal penalties and civil sanctions and possible exclusion from the Medicare, Medicaid, and other government healthcare programs. 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.

We also 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, fraudulent, or for an item or service that was not provided as claimed. 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 healthcare companies, which do not require proof of a specific intent to defraud the government, may result in payment of fines and/or administrative exclusion from the Medicare, Medicaid, and/or other government healthcare programs.

We are subject to provisions 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 on a periodic basis to allow for accurate determination of rebates owed under the Medicaid Drug Rebate Agreement, ceiling prices under the 340B program and certain other government pricing arrangements, and reimbursement rates for certain drugs paid under Medicare Part B.

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 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 these 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 as we recently did with a number of New York counties. 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.

Government regulations regarding price reporting and rebate payment obligations are complex, and we are continually evaluating the methods that we use to calculate and report the amounts owed by us with respect to Medicaid and other government pricing programs. The federal Medicaid Drug Rebate Program, for example, requires that we make quarterly rebate payments to all states that offer a non-managed care-based Medicaid pharmacy benefit to their eligible citizens. Our calculations of these rebate payments are subject to review and

**Table of Contents**

challenge by various government agencies and authorities and it is possible that any such review could result either in material changes to the method used for calculating the amounts owed to the pertinent government agency (or agencies), or to the amounts themselves. In addition, because the methods for calculating reported prices are not fully specified in regulations or sub-regulatory guidance documents, our processes for these calculations and our judgments supporting these calculations involve, and will continue to involve, subjective decisions. Further, these calculations are subject to the risk of errors. As noted above, any governmental agency that commences an action, if successful, could impose, based on a claim of violation of the federal False Claims Act or similar state laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from participation in federal healthcare programs (including Medicaid and Medicare). Some of the applicable laws impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments, or even in the absence of such ambiguity, a governmental authority may take a position contrary to a position we have taken, may demand payments for rebates owed based upon the government's pricing determinations, and may seek to impose civil and/or criminal sanctions. If such events occurred, any such governmental penalties, sanctions or retrospective revisions to payments already made could have a material adverse effect on our business, financial position, results of operations and cash flows, and could cause the market value of our common stock to decline.

**Once approved, there is no guarantee that the market will accept our future products, and regulatory requirements could limit the commercial usage of our products.**

Even if we obtain regulatory approvals, uncertainty exists as to whether the market will accept our products. A number of factors may limit the market acceptance of our products, including the timing of regulatory approvals and market entry relative to competitive products, the availability of alternative products, the price of our products relative to alternative products, the availability of third party reimbursement and the extent of marketing efforts by third party distributors or agents that we retain. We cannot assure you that our products will receive market acceptance in a commercially viable period of time, if at all. We cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position, results of operations and cash flows may be materially adversely affected, and the market value of our common stock could decline. In addition, many of our products contain narcotic ingredients that carry stringent record keeping obligations, strict storage requirements and other limitations on these products' availability, which could limit the commercial usage of these products.

**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. Total revenues from customers who accounted for 10% or more of our total revenues during the years ended December 31 are as follows:

	2011	2010	2009
Cardinal Health, Inc.	25%	33%	35%
McKesson Corporation	24%	28%	29%
AmerisourceBergen Corporation	13%	15%	16%

Revenues from these customers are included within our Branded Pharmaceuticals and Generics 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.



## Table of Contents

**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, including Teikoku, our sole source of Lidoderm®.**

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 is our sole source of our new formulation of Opana® ER, designed to be crush-resistant. 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 most of our products are manufactured by third parties, we have a limited ability to control the manufacturing process or costs related to this 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 which would have a material adverse impact on our business, results of operations, financial condition and cash flows. For example, in December 2011, Novartis Consumer Health, Inc.'s Lincoln, Nebraska manufacturing facility was temporarily shut down to facilitate its implementation of certain manufacturing process improvements. These improvements are intended to address the possibility of rare instances of errors in the packaging of the tablets, potentially resulting in product mix-ups. The temporary supply disruption is not related to the efficacy or safety of Endo's products. As a result, there will be a short-term supply constraint of Opana® ER and certain other Endo analgesic products manufactured at this facility, including Opana®, Voltaren® Gel, oxymorphone hydrochloride, Percocet®, Percodan®, Endocet®, Endodan®, morphine sulfate ER and Zydone®. Additionally, if any facility that manufactures our products experiences a natural disaster such as the recent earthquakes in Japan or the recent tornados in Alabama, 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.

We have entered into minimum purchase requirement contracts with some of our third party manufacturers. In May 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc., or Novartis, pursuant to which Novartis has agreed to manufacture certain of our commercial products in addition to products in development. On February 23, 2011, we gave notice to Novartis Consumer Health, Inc. that we would terminate this agreement effective February 2014. As of December 31, 2011, we are required to purchase a minimum of approximately \$11.2 million of product from Novartis Consumer Health, Inc. per year, or pro rata portion thereof, until the effective date of the termination of the agreement.

We also have a long-term contract with Teikoku Seiyaku Co., Ltd., under which Teikoku manufactures Lidoderm® at its Japanese facility for commercial sale by us in the U.S. We agreed to purchase a minimum number of patches per year from Teikoku through 2012, representing the noncancelable portion of the Teikoku agreement. Teikoku has agreed to fix the supply price of Lidoderm® for a period of time after which the price will be adjusted at future set dates based on a price index defined in the Teikoku agreement. Since future price changes are unknown, we have used prices currently existing under the Teikoku agreement, and estimated our minimum purchase requirement to be approximately \$34.0 million per year through 2012. The minimum purchase requirement shall remain in effect subsequent to 2012, except that we have the right to terminate the Teikoku agreement after 2012 if we fail to meet the annual minimum requirement.

## Table of Contents

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 the other steps necessary 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, an obligation which 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 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.

For example, our subsidiary AMS currently relies on single- or sole-source suppliers for certain raw materials and certain components used in its male prostheses, many of its female products, its GreenLight™ laser systems, and for the TherMatrx® disposables. These sources of supply could encounter manufacturing difficulties or may unilaterally decide to stop supplying AMS because of product liability concerns or other factors. We and AMS cannot be certain that we would be able to timely or cost-effectively replace any of these sources upon any disruption due to the need to qualify alternate designs or sources. Any interruption or failure by these sources to supply raw materials or components to AMS could have a material adverse effect on sales of AMS's products.

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.

**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.**

In November 2010, we acquired Qualitest's pharmaceutical manufacturing facilities located in Huntsville, Alabama and Charlotte, North Carolina. The Qualitest facilities currently manufacture many of the Qualitest products that we acquired. In connection with the AMS acquisition, we acquired AMS's manufacturing facilities in Minnesota and California, where many of AMS's products are made. Because the manufacture of pharmaceutical products and medical devices requires precise and reliable controls, and due to significant compliance obligations imposed by laws and regulations, we may face delays in qualifying the Qualitest facilities or the AMS manufacturing facilities for the manufacture of new products or for other products that are currently manufactured for us by third parties.

## **Table of Contents**

If our manufacturing facilities fail to comply with regulatory requirements or encounter other manufacturing difficulties, it could adversely affect their ability to supply products to us. All facilities and manufacturing processes used for the manufacture of pharmaceutical products and medical devices must be operated in conformity with cGMP and, in the case of controlled substances, DEA regulations. Compliance with the FDA's cGMP and DEA requirements applies to both drug products seeking regulatory approval and to approved drug products. In complying with cGMP requirements, pharmaceutical manufacturing facilities must continually expend significant time, money and effort in production, record-keeping and quality assurance and control so that their products meet applicable specifications and other requirements for product safety, efficacy and quality. Failure to comply with applicable legal requirements subjects our manufacturing facilities to possible legal or regulatory action, including shutdown, which may adversely affect their ability to supply us with 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.

### **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, 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, as well as the production of these products and, 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 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, although the DEA has substantial discretion in whether or not to make such adjustments. 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.

### **We invest in securities that are subject to market risk and the recent issues in the financial markets could adversely affect the value of our assets.**

At December 31, 2011, \$18.8 million of our marketable securities portfolio was invested in AAA rated investments in auction-rate debt securities. Auction-rate securities are long-term variable rate bonds tied to short-term interest rates. After the initial issuance of the securities, the interest rate on the securities is reset periodically, at intervals established at the time of issuance (e.g., every seven, twenty-eight, or thirty-five days; every six months; etc.). In an active market, auction-rate securities are bought and sold at each reset date through a competitive bidding process, often referred to as a "Dutch auction". Auctions are successful when the supply and demand of securities are in balance. Financial institutions brokering the auctions would also participate in the auctions to balance the supply and demand. Beginning in the second half of 2007, auctions began to fail for specific securities and in mid-February 2008 auction failures became common, prompting market participants, including financial institutions, to cease or limit their exposure to the auction-rate market. Given the current liquidity conditions in the global credit markets, the auction-rate securities market has become inactive. Consequently, our auction-rate securities are currently illiquid through the normal auction process.

## **Table of Contents**

The underlying assets of our auction-rate securities are student loans. The student loans are insured by the Federal Family Education Loan Program (FFELP).

Throughout 2011, the auction-rate securities market has continued to be inactive. If credit and capital markets deteriorate further or we experience any additional ratings downgrades on any investments in our portfolio (including on our auction-rate securities), we may incur additional impairments in future periods, which could negatively affect our financial condition, cash flow or reported earnings.

Any of these events could materially affect our results of operations and our financial condition. In the event we need to access these funds, we could be required to sell these securities at an amount below our original purchase value. Although, based on our ability to access our cash and cash equivalents and our other liquid investments as well as our expected operating cash flows, we do not expect to be required to sell these securities at a loss, there can be no assurance that we will not have to sell these securities at a loss. In addition, volatility and disruption of the capital and credit markets in the U.S. may affect our access to capital and increase our cost of capital in general.

### **Sales of our products may be adversely affected by the consolidation of the wholesale drug distribution and retail pharmacy industries, a trend which may continue.**

The network through which we sell our products has undergone significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of large retail drug store chains. As a result, 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. We expect that consolidation of drug wholesalers and retailers will place competitive pressures on drug manufacturers, including us. If we lose any of these customer accounts, or if our relationship with them were to deteriorate, our business could also be materially and adversely affected. Orders for our products may increase or decrease depending on the inventory levels held by our major customers. Significant increases and decreases in orders from our major customers could cause our operating results to vary significantly from quarter to quarter.

Retail availability of our products is greatly affected by the inventory levels our customers hold. We monitor wholesaler inventory of our products using a combination of methods, including tracking prescriptions filled at the pharmacy level to determine inventory amounts the wholesalers have sold to their customers. Pursuant to distribution service agreements with six of our significant wholesale customers, we receive inventory level reports. For other wholesalers where we do not receive inventory level reports, however, our estimates of wholesaler inventories may differ significantly from actual inventory levels. Significant differences between actual and estimated inventory levels may result in excessive inventory production, inadequate supplies of products in distribution channels, insufficient or excess product available at the retail level, and unexpected increases or decreases in orders from our major customers. Forward buying by wholesalers, for example, may result in significant and unexpected changes in customer orders from quarter to quarter. These changes may cause our revenues to fluctuate significantly from quarter to quarter, and in some cases may cause our operating results for a particular quarter to be below our expectations or internal projections. If our financial results are below expectations for a particular period, the market price of our securities may drop significantly.

### **We may not be able to maintain our current insurance policies covering our business, assets, directors and officers and product liability claims and we may not be able to obtain new policies in the future.**

Property, product liability, directors and officers and general liability insurance represent significant costs to us. Since the events of September 11, 2001, and due to an increased focus on corporate governance in the U.S., and product liability lawsuits related to pharmaceuticals and medical devices, liability and other types of insurance have, in some instances, become more difficult and costly to obtain. As we continue to expand our portfolio of available products, we may experience an increase in the number of product liability claims against us. Moreover, we may be subject to claims that are not covered by insurance. In addition, products for which we

## **Table of Contents**

currently have coverage may be excluded from coverage in the future. Certain claims may be subject to our self-insured retention, exceed our policy limits or relate to damages that are not covered by our policy. In addition, product liability coverage for certain pharmaceutical entities is becoming more expensive and increasingly difficult to obtain and, as a result, we may not be able to obtain the type and amount of coverage we desire or to maintain our current coverage. Unanticipated additional insurance costs could have a material adverse effect on our results of operations and cash flows. There can be no assurance that we will be able to maintain our existing insurance policies or obtain new policies in meaningful amounts or at a reasonable cost. Any failure to obtain or maintain any necessary insurance coverage could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors will remain highly dependent, in large part, upon our ability to attract and retain qualified scientific, technical and commercial personnel. The loss of key scientific, technical and commercial personnel or the failure to recruit additional key scientific, technical and commercial personnel could have a material adverse effect on our business. While we have consulting agreements with certain key individuals and institutions and have employment agreements with our key executives, we cannot assure 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 assure you that we will be able to continue to attract and retain the qualified personnel necessary for the development of our business.

### **Our revenues and operating results may fluctuate in future periods and we may fail to meet expectations, which may cause the value of our securities to decline.**

Our quarterly operating results are difficult to predict and may fluctuate significantly from period to period. Accordingly, one cannot predict our quarterly financial results based on our full-year financial guidance. We cannot predict with certainty the timing or level of sales of our products in the future. If our quarterly sales or operating results fall below the expectations of investors or securities analysts, the value of our securities could decline substantially. Our operating results may fluctuate due to various factors including those set forth above. As a result of these factors, we believe that period-to-period comparisons of our operating results are not a good indication of our future performance.

### **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 healthcare companies in general have been highly volatile and may continue to be highly volatile in the future. For example, in 2011, our stock traded between \$26.02 and \$44.53 per share. The following factors, in addition to other risk factors described in this section, may cause the market value of our securities to fluctuate:

FDA approval or disapproval of any of the drug applications we have submitted;

the success or failure of our clinical trials;

new data or new analyses of older data that raises potential safety or effectiveness issues concerning our approved products;

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, such as Lidoderm®;

developments concerning our or others' proprietary rights, including patents;



## Table of Contents

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;

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;

litigation; and

economic and other external factors, including disasters and other crises.

### **Our operations could be disrupted if our information systems fail or if we are unsuccessful in implementing necessary upgrades.**

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. 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 publication of negative results of studies or clinical trials on pharmaceutical industry products may adversely impact our sales revenue.**

From time to time, studies or clinical trials on various aspects of pharmaceutical products are conducted by academics or others, including government agencies. The results of these studies or trials, when published, may have a dramatic effect on the market for the pharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our products compete could adversely affect our sales, the prescription trends for our products and the reputation of our products. In the event of the publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our products compete, our business, financial condition, results of operations and cash flows could be materially adversely affected. In addition, on September 27, 2007, Congress enacted requirements for the reporting of clinical trial information by expanding the type of clinical trials for which a sponsor or investigator of a drug, medical device or biological product clinical trial must register and provide results to the National Institutes of Health (NIH) for inclusion in the publicly-available Clinical Trial Registry database of clinical trials. It is unclear what impact the publication of clinical research data will have for our products.

### **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. We intend to seek approval of and market certain of our products outside of the U.S. To market our products in the European Union and other foreign jurisdictions, we must obtain separate regulatory authorization and comply with numerous and varying regulatory requirements. Approval of a product by the comparable regulatory authorities of foreign countries must still 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 approval may differ from that required to obtain FDA approval. The foreign regulatory approval process includes all of the risks associated with obtaining FDA approval set forth herein and approval by the FDA does not ensure approval by the regulatory authorities of any other country, nor does the approval by foreign regulatory authorities in one country ensure approval by regulatory authorities in other foreign countries or the FDA. If we fail to comply with these regulatory requirements or obtain and maintain required approvals, our target market will be reduced and our ability to generate revenue from abroad will be adversely affected.





---

**Table of Contents**

**If the indemnitors default on their obligations, the outcome of the Redux litigation could materially harm us.**

On September 15, 1997, Indevus (then known as Interneuron Pharmaceuticals, Inc.) announced a market withdrawal of its first commercial prescription product, the anti-obesity medication Redux (dexfenfluramine hydrochloride capsules C-IV), which had been launched in June 1996 by its licensee, American Home Products Corporation, which became Wyeth and was later acquired by Pfizer. The withdrawal of Redux was based on a preliminary analysis by the FDA of potential abnormal echocardiogram findings associated with certain patients taking Redux or the combination of fenfluramine with phentermine. Following the withdrawal, Indevus was named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions, some of which purport to be class actions, in federal and state courts relating to the use of Redux and other weight loss drugs. The existence of such litigation may materially adversely affect our business. In addition, although we are unable to predict the outcome of any such litigation, if successful uninsured or insufficiently insured claims, or if a successful indemnification claim, were made against us, our business, financial condition and results of operations could be materially adversely affected. In addition, the uncertainties associated with these legal actions may have an adverse effect on the market price of our common stock and on our ability to obtain product liability insurance for other products at costs acceptable to us, or at all, which may materially adversely affect our business, financial condition and results of operations.

On May 30, 2001, Indevus (then known as Interneuron Pharmaceuticals, Inc.) entered into an Indemnity and Release Agreement with Wyeth (then known as American Home Products Corporation and referred to herein as Wyeth), which provides for indemnification of Redux-related claims brought by plaintiffs who initially opted out of Wyeth's national class action settlement of diet drug litigation and by those claimants who allege primary pulmonary hypertension. This agreement also provides for funding of all defense costs related to all Redux-related claims and provides for Wyeth to fund certain additional insurance coverage to supplement the Company's existing product liability insurance. However, there can be no assurance that uninsured or insufficiently insured Redux-related claims or Redux-related claims for which we are not otherwise indemnified or covered under the indemnity and release agreement will not have a material adverse effect on our future business, results of operations or financial condition or that the potential of any such claims would not adversely affect our ability to obtain sufficient financing to fund operations. Additionally, there is no assurance that as indemnitor, Wyeth will remain solvent and able to respond to all claims covered by the indemnity and release agreement. We are unable to predict whether the existence of such litigation may adversely affect our business.

Pursuant to agreements we have with Les Laboratoires Servier, from whom Indevus in-licensed rights to Redux, Boehringer Ingelheim Pharmaceuticals, Inc., which assembled Redux, and other parties, we may be required to indemnify such parties for Redux-related liabilities. We are unable to predict whether such indemnification obligations, if they arise, may adversely affect our business.

**Agreements between branded pharmaceutical companies and generic pharmaceutical companies are facing increased government scrutiny in both 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 generics business 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 FTC and the Antitrust Division of the Department of Justice for review. The FTC has publicly stated that, in its view, some of these settlement agreements violate the antitrust laws and has brought actions against some 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. Any adverse outcome of these actions or investigations could have a significant adverse effect on our business, financial condition and results of operations. In addition, some members of Congress have proposed legislation that would limit the types of

## Table of Contents

settlement agreements generic manufacturers can enter into with brand companies. The impact of such pending litigation and legislative proposals is uncertain and could adversely affect our business, financial condition and results of operations.

### **While healthcare reform may increase the number of patients who have insurance coverage for our products, its cost containment measures may adversely affect reimbursement for our products.**

In March 2010, the U.S. Health Reform Law was enacted in the U.S. This legislation has both current and longer-term impacts on us, as discussed below.

The provisions of the U.S. Health Reform Law are effective on various dates over the next several years. The principal provisions affecting us provide for the following:

an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively (effective January 1, 2010);

extension of Medicaid prescription drug rebates to drugs dispensed to enrollees in certain Medicaid managed care organizations (effective March 23, 2010);

an increase in the additional Medicaid rebates for new formulations of oral solid dosage forms of innovator drugs;

the revision of the average manufacturer price, or AMP, definition to remove the retail pharmacy class of trade (effective October 1, 2010);

expansion of the types of institutions eligible for the Section 340B discounts for outpatient drugs provided to hospitals meeting the qualification criteria under Section 340B of the Public Health Service Act of 1944 (effective January 1, 2010) (340B Pricing);

a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition of the manufacturer's outpatient drugs to be covered under Medicare Part D (effective January 1, 2011);

an annual fee payable to the federal government (which is not deductible for U.S. income tax purposes) based on our prior-calendar-year share relative to other companies of branded prescription drug sales to specified government programs (effective January 1, 2011, with the total fee to be paid each year by the pharmaceutical industry increasing annually through 2019);

a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the U.S., with limited exceptions (effective January 1, 2013);

new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting any transfer of value made or distributed to physicians and teaching hospitals and reporting any investment interests held by physicians and their immediate family members during each calendar year (beginning in 2012, with reporting starting in 2013);

## Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

a new requirement to annually report drug samples that manufacturers and distributors provide to physicians (effective April 1, 2012);

creation of the Independent Payment Advisory Board which will have authority to recommend certain changes to the Medicare program that could result in reduced payments for items and services (recommendations could have the effect of law even if Congress does not act on the recommendations, and the implementation of changes based upon Independent Payment Advisory Board recommendations may affect payments beginning in 2015); and

establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending, (beginning January 1, 2011).

## **Table of Contents**

A number of the provisions of the U.S. Health Reform Law may adversely affect reimbursement for our products. Additionally, the best price requirements with respect to Medicaid rebates have traditionally been a significant consideration with respect to the level of rebates in our Medicare and commercial contracting. The U.S. Health Reform Law's effects on rebate amounts could adversely impact our future results of operations.

Over the next few years, regulations and guidance implementing the U.S. Health Reform Law as well as additional healthcare reform proposals may have a financial impact on the Company. In addition, the U.S. Health Reform Law requires that, except in certain circumstances, individuals must obtain health insurance beginning in 2014, and it also provides for an expansion of Medicaid coverage in 2014. It is expected that, as a result of these provisions, there will be a substantial increase in the number of Americans with health insurance beginning in 2014, a significant portion of whom will be eligible for Medicaid. We anticipate that this will increase demand for pharmaceutical products overall. However, in view of the many uncertainties, including but not limited to pending litigation challenging the new law and changes in the partisan composition of Congress, we are unable at this time to determine whether and to what extent sales of our prescription pharmaceutical products in the U.S. will be impacted.

### **We may not be able to realize all of the anticipated benefits of our acquisitions of HealthTronics, Penwest, Qualitest and AMS.**

The success of our recent acquisitions of HealthTronics, Penwest, Qualitest and AMS will depend, in large part, on our ability to realize the anticipated benefits and expand our business from integrating aspects of the operations of Endo with aspects of the operations of HealthTronics, Penwest, Qualitest and AMS. If we are not able to successfully integrate certain aspects of the companies we recently acquired, the anticipated benefits of the applicable acquisition may not be realized fully or at all or may take longer to realize than expected.

### **Our Consolidated Financial Statements may be impacted in future periods based on the accuracy of our valuations of each of our acquired businesses.**

Accounting for our acquisitions involves complex and subjective valuations of the assets, liabilities, and noncontrolling interests of the acquired entities, which will be recorded in the Company's Consolidated Financial Statements pursuant to the general accounting rules applicable for business combinations. Differences between the inputs and assumptions used in the valuations and actual results could have a material effect on our Consolidated Financial Statements in future periods.

### **If HealthTronics is not able to establish or maintain relationships with physicians and hospitals, its ability to successfully commercialize current or future service offerings will be materially harmed.**

HealthTronics is dependent on healthcare providers in two respects. First, if physicians and hospitals and other healthcare facilities, which HealthTronics refers to as Customers, determine that HealthTronics' services are not of sufficiently high quality or reliability, or if its Customers determine that its services are not cost-effective, they will not utilize HealthTronics' services. In addition, any change in the rates of or conditions for reimbursement could substantially reduce (1) the number of procedures for which HealthTronics or its Customers can obtain reimbursement or (2) the amounts reimbursed to HealthTronics or its Customers for services provided by HealthTronics. If third-party payors reduce the amount of their payments to Customers, HealthTronics Customers may seek to reduce their payments to HealthTronics or seek an alternate supplier of services. Because unfavorable reimbursement policies have constricted and may continue to constrict the profit margins of the hospitals and other healthcare facilities which HealthTronics bills directly, HealthTronics may need to lower fees to retain existing customers and attract new ones. These reductions could have a significant adverse effect on revenues and financial results of HealthTronics by decreasing demand for its services or creating downward pricing pressure. Second, physicians generally own equity interests in the HealthTronics' partnerships. HealthTronics provides a variety of services to the partnerships and, in general, manages the partnerships' day-to-day affairs. HealthTronics operations could become disrupted, and financial results adversely affected, if

## **Table of Contents**

these physician partners became dissatisfied with HealthTronics' services, if these physician partners believe that its competitors or other persons provide higher quality services or a more cost-beneficial model or service, or if HealthTronics became involved in disputes with its partners.

### **Our sales may be adversely affected if physicians do not recommend, endorse or accept AMS' products.**

We rely upon physicians to recommend, endorse and accept its products. Many of AMS' products are based on new treatment methods. Acceptance of AMS' products is dependent on educating the medical community as to the distinctive characteristics, perceived benefits, clinical efficacy, and cost-effectiveness of our products, including those of AMS, compared to competitive products, and on training physicians in the proper application of our products. We believe AMS' products address major market opportunities, but if we are unsuccessful in educating physicians about the benefits of AMS' products, or such products are identified in regulatory agency public health communications, our sales and earnings could be adversely affected.

### **We are subject to health information privacy and security standards that include penalties for noncompliance.**

The administrative simplification section of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, collectively HIPAA, impose stringent requirements on covered entities (healthcare providers, health plans and healthcare clearinghouses) to safeguard the privacy and security of individually-identifiable health information. Certain of our operations are subject to these requirements, and we believe that we are in compliance with the applicable standards. Penalties for noncompliance with these rules include both criminal and civil penalties. In addition, the Health Information Technology for Economic and Clinical Health Act (included in the American Recovery and Reinvestment Act of 2009) and its implementing regulations, collectively HITECH, expanded federal health information privacy and security protections. Among other things, HITECH makes certain of HIPAA's privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also set forth new notification requirements for certain breaches, increased the civil penalties that may be imposed against covered entities, business associates and possibly other persons for HIPAA violations, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions.

### **New and proposed federal and state laws and regulatory initiatives relating to various initiatives in healthcare reform (such as improving privacy and the security of patient information and combating healthcare fraud) could require us to expend substantial sums to appropriately respond to and comply with this broad variety of legislation (such as acquiring and implementing new information systems for privacy and security protection), which could negatively impact our business, results of operations, financial condition and cash flows.**

Recent legislative and regulatory initiatives at the state and federal levels address concerns about the privacy and security of health information. HITECH expands the health information privacy and security protections under HIPAA and imposes new obligations to notify individuals and the United States Department of Health and Human Services Office for Civil Rights, or OCR, of breaches of certain unsecured health information. We do not yet know the total financial or other impact of these laws and regulations on us. Continuing compliance with these laws and regulations may require us to spend substantial sums, including, but not limited to, purchasing new information technology, which could negatively impact financial results. Additionally, if we fail to comply with the HIPAA privacy, security and breach notification standards, we could suffer civil penalties of up to \$1,500,000 per calendar year for violations of an identical standard and criminal penalties of up to \$250,000 and 10 years in prison for offenses committed with the intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain or malicious harm. In addition, healthcare providers will continue to remain subject to any state laws that are more restrictive than the federal privacy regulations. These privacy laws vary by state and could impose additional penalties.

## **Table of Contents**

The provisions of HIPAA criminalize situations that previously were handled exclusively civilly through repayments of overpayments, offsets and fines by creating new federal healthcare fraud crimes. Further, as with the federal laws, general state criminal laws may be used to prosecute healthcare fraud and abuse. We believe that our business arrangements and practices comply with existing healthcare fraud and abuse laws. However, a violation could subject us to penalties, fines and/or possible exclusion from Medicare or Medicaid. Such sanctions could significantly reduce our financial results.

Future healthcare legislation and regulation or other changes in the administration of or interpretation of existing legislation or regulations regarding governmental healthcare programs could have an adverse effect on our business and the results of our operations.

### **We may be required to modify HealthTronics agreements, operations, marketing and expansion strategies in response to changes in the statutory and regulatory environment.**

We regularly monitor developments in statutes and regulations relating to our business. See the risk described under the caption We are subject to various regulations pertaining to the marketing of our products and services. We may be required to modify our agreements, operations, marketing and expansion strategies from time to time in response to changes in the statutory and regulatory environment. We carefully structure all of our and HealthTronics agreements, operations, marketing and strategies, although we can provide no assurance that these arrangements will not be challenged successfully.

### **HealthTronics and AMS could be adversely affected by special risks and requirements related to their medical products manufacturing businesses.**

HealthTronics and AMS are subject to various risks and requirements associated with being medical equipment manufacturers, 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 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 HealthTronics or AMS's products, sales may be adversely affected;

potential product liability claims for any defective goods that are distributed; and

the need for research and development expenditures to develop or enhance products and compete in the equipment markets.

### **Our pathology laboratory business is heavily regulated, which poses significant compliance risks for the business and places constraints on business opportunities.**

We are subject to various federal and state laws and regulations. Among the applicable federal laws and regulations are the Stark Law, Anti-Kickback Statute, False Claims Act, and Clinical Laboratory Improvement Amendments, or CLIA, and similar state licensure laws as well as associated regulations and anti-markup regulations, reassignment regulations, and Medicare usual charge regulations. The applicable state laws and regulations include account billing statutes and regulations of various forms (including direct billing, anti-markup, and disclosure statutes and regulations), fee-splitting statutes and regulations, anti-kickback statutes and regulations, self-referral statutes and regulations, lab licensure and certification statutes and regulations, and insurance fraud statutes and regulations. If it is determined that any aspect of our pathology laboratory services



## **Table of Contents**

business model or any specific pathology laboratory services facility or partnership is not in compliance with any of these laws or regulations, this could threaten our ability to carry on aspects of the business model, the business model in its entirety, or activities relating to one or more facilities or partnerships. Noncompliance could also expose the Company to federal or state enforcement actions or other proceedings or private lawsuits or other proceedings against the Company. Our obligation to operate the pathology laboratory services unit within the strictures of various applicable federal and state laws and regulations constrains our ability to implement new strategies for generating business opportunities. In the future, additional laws and regulations may arise at the federal or state level in the pathology laboratory services field that may create additional uncertainty, negatively impact results for this unit, or jeopardize the functioning of aspects of the business model, the business model in its entirety, or specific facilities or partnerships.

### **We are subject to many environmental, health and safety laws and regulations which pose significant compliance risks for the business.**

We are subject to many environmental, health and safety laws and regulations. Compliance with these laws and regulations can be a significant factor in our business, and we have incurred and expect to continue to incur expenditures to maintain compliance. Some of our operations require permits or controls to prevent and limit pollution. Moreover, some or all of the environmental laws and regulations to which we are subject could become more stringent or more stringently enforced in the future. Our failure to comply with applicable environmental laws and regulations and permit requirements could result in civil or criminal fines or penalties or enforcement actions, including regulatory or judicial orders enjoining or curtailing operations or requiring corrective measures, installation of pollution control equipment or remedial actions. Additionally, some environmental laws and regulations impose liability and responsibility on present and former owners, operators or users of facilities and sites for environmental contamination at such facilities and sites without regard to causation or knowledge of contamination. We could incur material liabilities under these and other laws and regulations related to environmental protection and safety.

### **International operations of AMS could expose us to various risks, including risks related to fluctuations in foreign currency exchange rates.**

AMS derives a significant portion of its net sales from operations in international markets. Since our June 2011 acquisition of AMS, 32.6% of our AMS subsidiary's 2011 total revenues were to customers outside the U.S. Some of these sales were to governmental entities and other organizations with extended payment terms. A number of factors, including differing economic conditions, changes in political climate, differing tax structures, changes in diplomatic and trade relationships, and political or economic instability in the countries where AMS does business, could affect payment terms and AMS's 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 Euro, Canadian dollar, Australian dollar, and Great Britain pound. Increases in the value of the foreign currencies relative to the U.S. dollar would positively impact our earnings and decreases in the value of the foreign currencies relative to the U.S. dollar would negatively impact our earnings.

### **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 AMS's 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.



## Table of Contents

In addition, some countries in which AMS sells products are, to some degree, subject to political, economic and/or social instability. AMS's 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 instability or disruptions, including local and regional instability, or disruptions due to natural disasters, such as severe weather and geological events;

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;

scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;

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 and we are experiencing fluidity in regulatory and pricing trends as a result of healthcare reform. Any material decrease in AMS's international sales would adversely impact AMS's results of operations and financial condition.

### **Worldwide economic conditions may adversely affect our business, operating results and financial condition.**

We believe that worldwide economic conditions have resulted and may continue to result in reductions in the procedures using AMS's products. Although a majority of AMS's products are subject to reimbursement from third-party government and non-governmental entities, some procedures that use AMS's products can be deferred by patients. In current economic conditions, patients may not have employer-provided healthcare or be as willing to take time off from work or spend their money on deductibles and co-payments often required in connection with

the procedures that use AMS's products. Beyond patient demand, hospitals and clinics may be less likely to purchase capital equipment in the current economic conditions and credit environment. Economic conditions could also affect the financial strength of AMS's vendors and their ability to fulfill their commitments to AMS, and the financial strength of AMS's customers and its ability to collect accounts receivable. While AMS believes that worldwide economic conditions may have contributed to a softening in AMS's recent revenue growth rates, the specific impact is difficult to measure. We cannot predict how these economic conditions will impact future sales, cost of goods sold, or bad debt expense.

**We have indebtedness which could adversely affect our financial position and prevent us from fulfilling our obligations under such indebtedness.**

We currently have a substantial amount of indebtedness. As of December 31, 2011, we have total debt of approximately \$3.6 billion in aggregate principal amount. This debt primarily consists of \$1.3 billion of senior notes, \$1.9 billion secured term loan indebtedness and \$0.4 billion of convertible senior subordinated notes. As

## Table of Contents

of December 31, 2011, we have availability of \$0.5 billion under our revolving credit facility, not including an up to \$0.5 billion uncommitted expansion option available under our 2011 Credit Facility, subject to satisfaction of certain conditions. We may also incur significant additional indebtedness in the future.

Our substantial indebtedness may:

make it difficult for us to satisfy our financial obligations, including making scheduled principal and interest payments on the notes and our other 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;

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.

**Despite our current level of indebtedness, we may still be able to incur substantially more indebtedness. This could exacerbate the risks associated with our substantial indebtedness.**

We and our subsidiaries may be able to incur substantial additional indebtedness in the future, including potential additional secured indebtedness pursuant to the uncommitted expansion option under our 2011 Credit Facility, subject to satisfaction of certain conditions, and subsidiary indebtedness to which the notes would be effectively subordinated. The terms of the indentures will limit, but not prohibit, us or our subsidiaries from incurring additional indebtedness, but these limits are subject to significant exceptions and do not limit liabilities that do not constitute debt. If we incur any additional indebtedness that ranks equally with the notes and the guarantees, the holders of that indebtedness will be entitled to share ratably with the holders of the notes and the guarantees in any proceeds distributed in connection with any insolvency, liquidation, reorganization, dissolution or other winding-up of us. This may have the effect of reducing the amount of proceeds paid to you. 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.**

The indentures governing the notes and the agreements governing the 2011 Credit Facility and other outstanding indebtedness subject us to various covenants 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;

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

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, including the 2011 Credit Facility and/or the notes.

## **Table of Contents**

**We are a holding company with no direct operations and will depend on the business of our subsidiaries to satisfy our obligations under our indebtedness.**

We are a holding company with no direct operations. Our principal assets are the equity interests we hold in our operating subsidiaries. Our subsidiaries will conduct substantially all of the operations necessary to fund payments on our indebtedness. Our subsidiaries are legally distinct from us and have no obligation to make funds available to us. Our ability to make payments on our indebtedness will depend on our subsidiaries cash flow and their payment of funds to us. Our subsidiaries' ability to make payments to us will depend on:

their earnings;

covenants contained in our debt agreements and the debt agreements of our subsidiaries;

covenants contained in other agreements to which we or our subsidiaries are or may be subject;

business and tax considerations; and

applicable law, including state laws regulating the payment of dividends and distributions.

We cannot assure you that the operating results of our subsidiaries at any given time will be sufficient to make distributions or other payments to us or that any distributions and/or payments will be adequate to pay principal and interest, and any other payments on our indebtedness when due.

**Our variable rate indebtedness exposes us to interest rate risk, which could cause our debt costs to increase significantly.**

A substantial portion of our borrowings under the 2011 Credit Facility are at variable rates of interest, exposing us to interest rate risks. We are exposed to the risk of rising interest rates to the extent that we fund our operations with short-term or variable-rate borrowings. As of December 31, 2011, our total aggregate principal of debt consists of approximately \$1.9 billion of floating-rate debt. Based on this amount, a 1% rise in interest rates would result in approximately \$19 million in incremental annual interest expense. If London Inter-Bank Offer rates (LIBOR) increase in the future, then our floating-rate debt could have a material effect on our interest expense.

**We may be unable to repay or repurchase amounts outstanding on our indebtedness at maturity.**

At maturity, the entire outstanding principal amount of our indebtedness, together with accrued and unpaid interest, will become due and payable. We may not have the funds to fulfill these obligations or the ability to refinance these obligations. If the maturity date occurs at a time when other arrangements prohibit us from repaying our indebtedness, we would try to obtain waivers of such prohibitions from the lenders and holders under those arrangements, or we could attempt to refinance the borrowings that contain the restrictions. If we could not obtain the waivers or refinance these borrowings, we would be unable to repay our indebtedness.

**To service our indebtedness, we will require a significant amount of cash. If we fail to generate sufficient cash flow from future operations, we may have to refinance all or a portion of our indebtedness or seek to obtain additional financing.**

We expect to obtain the funds to pay our expenses and the amounts due under our indebtedness primarily from operations. Our ability to meet our expenses and make these payments thus depends on our future performance, which will be affected by financial, business, economic, competitive, legislative, regulatory and other factors, many of which are beyond our control. Our business may not generate sufficient cash flow from operations in the future and our currently anticipated growth in revenue and cash flow may not be realized, either or both of which could result in our being unable to pay amounts due under our outstanding indebtedness, or to fund other liquidity needs, such as future capital expenditures. If we do not have sufficient cash flow from operations, we may be required to refinance all or part of our then existing indebtedness, sell assets, reduce or



## **Table of Contents**

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. Our ability to restructure or refinance our indebtedness, including the notes, will depend on the condition of the capital markets and our financial condition at such time. Any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. In addition, the terms of existing or future debt agreements, including the indentures governing the notes, may restrict us from adopting any of these alternatives. Any failure to make scheduled payments of interest or principal on our outstanding indebtedness would likely result in a reduction of our credit rating, which could negatively impact our ability to incur additional indebtedness on commercially reasonable terms or at all. The failure to generate sufficient cash flow or to achieve any of these alternatives could materially adversely affect the value of our notes, our business, financial condition and other results of operations, and our ability to pay the amounts due under the notes and our other indebtedness.

**Our failure to comply with the agreements relating to our outstanding indebtedness, including as a result of events beyond our control, could result in an event of default under our outstanding indebtedness that could materially and adversely affect our results of operations and our financial condition.**

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. Upon acceleration of certain of our other indebtedness, holders of the notes could declare all amounts outstanding under the notes immediately due and payable. We cannot assure 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. Further, if we are unable to repay, refinance or restructure our secured debt, the holders of such debt could proceed against the collateral securing that indebtedness. We have pledged substantially all of our assets as collateral under the 2011 Credit Facility. If the lenders under the 2011 Credit Facility accelerate the repayment of borrowings, we may not have sufficient assets to repay the obligations outstanding under the 2011 Credit Facility and our other indebtedness, including the notes. Furthermore, our borrowings under the 2011 Credit Facility are expected to be at variable rates of interest and expose us to interest rate risk. If interest rates increase, our debt service obligations on the variable rate indebtedness would increase even though the amount borrowed remains the same, and our net income would decrease. For a description of our indebtedness, see Note 18. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

**Account data breaches involving customer or patient data stored could adversely affect our reputation and services segment revenues.**

Through our HealthTronics Information Technology Solutions component of our services segment, we store customer and patient data. Breaches of the systems storing such data could lead to reputational damage and claims against us. If we are sued in connection with any material data security breach, we could be involved in protracted litigation. If unsuccessful in defending such lawsuits, we may have to pay damages or change our business practices or pricing structure. In addition, any reputational damage resulting from data breach could decrease the use of our services, which could have a material adverse effect on our service business revenues and future growth prospects of our Services segment.

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

None.

**Table of Contents****Item 2. Properties**

All of our properties are either owned or leased pursuant to operating leases. Our significant properties are as follows:

<b>Property</b>	<b>Location</b>	<b>Purpose</b>	<b>Square Footage</b>	<b>Ownership</b>
<i>Painter s Crossing One Associates, L.P.(1)</i>	Chadds Ford, Pennsylvania	Corporate Headquarters	approximately 47,756 square feet	Leased
<i>Painter s Crossing Two Associates, L.P.(2)</i>	Chadds Ford, Pennsylvania	Corporate Headquarters	approximately 64,424 square feet	Leased
<i>Painter s Crossing Three Associates, L.P.(3)</i>	Chadds Ford, Pennsylvania	Corporate Headquarters	approximately 48,600 square feet	Leased
<i>Brandywine Seven(4)</i>	Chadds Ford, Pennsylvania	Corporate Headquarters	approximately 23,949 square feet	Leased
<i>177 Cantiaque Rock Road LLC(5)</i>	Westbury, New York	Research and Development	approximately 24,190 square feet	Leased
<i>Cedar Brook LP(6)</i>	Cranbury, New Jersey	Distribution / Manufacturing	approximately 51,000 square feet	Leased
<i>HEP Davis Spring, L.P.(7)</i>	Austin, Texas	HealthTronics Headquarters and Manufacturing / Service Center	approximately 67,405 square feet	Leased
<i>Qualitest Building</i>	Huntsville, Alabama	Qualitest Headquarters / Distribution	approximately 280,000 square feet	Owned
<i>Vintage Pharmaceuticals, LLC liquids formulation facility</i>	Huntsville, Alabama	Distribution / Manufacturing / Laboratories	approximately 180,000 square feet	Owned
<i>Vintage Pharmaceuticals, LLC tablets manufacturing facility</i>	Huntsville, Alabama	Distribution / Manufacturing / Laboratories	approximately 309,000 square feet	Owned
<i>Charlotte Building</i>	Charlotte, North Carolina	Distribution / Manufacturing / Laboratories	approximately 60,000 square feet	Owned
<i>Charlotte Warehouse(8)</i>	Charlotte, North Carolina	Distribution	approximately 58,000 square feet	Leased
<i>AMS Corporate Headquarters</i>	Minnetonka, Minnesota	AMS Headquarters / Warehouse / Research and Development / Manufacturing	approximately 230,000 square feet	Owned
<i>Ireland Manufacturing Facility(9)</i>	Westmeath, Ireland	AMS Manufacturing	approximately 33,700 square feet	Leased
<i>San Jose Facilities(10)</i>	San Jose, California	AMS Office / Manufacturing / Research and Development / Warehouse	approximately 68,644 square feet	Leased

- (1) - Lease term ends August, 2013
- (2) - Lease term ends January, 2015
- (3) - Lease term ends March, 2018
- (4) - Lease term ends January, 2015
- (5) - Lease term ends May, 2013
- (6) - Lease term ends March, 2015
- (7) - Lease term ends September, 2015
- (8) - Lease term ends May, 2021
- (9) - Lease term ends February, 2016
- (10) - Lease term ends October, 2016



**Table of Contents**

On October 28, 2011, our subsidiary Endo Pharmaceuticals Inc. entered into a lease agreement with RT/TC Atwater LP, a Delaware limited partnership, for a new corporate headquarters to consist of approximately 300,000 square feet of office space located at 1400 Atwater Boulevard, Malvern, Pennsylvania.

**Item 3. Legal Proceedings**

The disclosures under Note 14. Commitments and Contingencies-Legal Proceedings in the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K are incorporated in this Part I, Item 3 by reference.

**Item 4. Mine Safety Disclosures**

None

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

*Market Information.* Our common stock is traded on the NASDAQ Global Select Market under the symbol ENDP. 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 Common Stock	
	High	Low
Year Ending December 31, 2011		
1st Quarter	\$ 38.51	\$ 32.14
2nd Quarter	\$ 44.53	\$ 36.65
3rd Quarter	\$ 42.09	\$ 26.76
4th Quarter	\$ 36.41	\$ 26.02
Year Ending December 31, 2010		
1st Quarter	\$ 24.85	\$ 19.19
2nd Quarter	\$ 24.29	\$ 19.58
3rd Quarter	\$ 34.26	\$ 21.30
4th Quarter	\$ 38.20	\$ 32.80

*Holders.* As of February 17, 2012, we estimate that there were approximately 55 record holders of our common stock.

*Dividends.* We have never declared or paid any cash dividends on our capital stock. In June 2011, we established a new credit facility with Morgan Stanley Senior Funding, Inc., as administrative agent, Bank of America, N.A., as Syndication Agent, and certain other lenders. We also entered into indentures in June 2011 and November 2010 among the Company, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, which governs the terms of the Company's \$1.3 billion aggregate principal amount of senior notes. Subject to certain limitations, we are permitted to pay dividends under the terms of our new credit facility and senior notes.

**Table of Contents**

*Performance Graph.* The following graph provides a comparison of the cumulative total stockholder return on the Company's common stock with that of the cumulative total stockholder return on the (i) NASDAQ Stock Market Index (U.S.) and (ii) the NASDAQ Pharmaceutical Index, commencing on December 31, 2006 and ending December 31, 2011. The graph assumes \$100 invested on December 31, 2006 in the Company's common stock and in each of the comparative indices. Our historic stock price performance is not necessarily indicative of future stock price performance.

	2006	2007	December 31,		2010	2011
			2008	2009		
Endo Pharmaceuticals Holdings Inc.	\$ 100.00	\$ 96.70	\$ 93.84	\$ 74.40	\$ 129.48	\$ 125.20
NASDAQ Composite Index	\$ 100.00	\$ 110.26	\$ 65.65	\$ 95.19	\$ 112.10	\$ 110.81
NASDAQ Pharmaceutical Index	\$ 100.00	\$ 90.99	\$ 84.71	\$ 95.64	\$ 100.10	\$ 110.44

*Recent sales of unregistered securities; Use of proceeds from registered securities.* During the fourth quarter of 2011, the Company did not sell any unregistered securities.

**Table of Contents**

*Purchase of equity securities by the issuer and affiliated purchasers.* The following table reflects purchases of Endo Pharmaceuticals Holdings Inc. common stock by the Company during the three-months ended December 31, 2011:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plan	Approximate Dollar Value of Shares that May Yet be Purchased Under the Plan
October 1, 2011 to October 31, 2011		\$		\$ 231,508,579
November 1, 2011 to November 30, 2011				231,508,579
December 1, 2011 to December 31, 2011				231,508,579
Total		\$		\$ 231,508,579

**Item 6. Selected Financial Data**

The consolidated financial data presented below have been derived from our audited financial statements. The selected historical consolidated financial data presented below should be read in conjunction with Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and Item 8. 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 year amounts have been reclassified to conform to the current year presentation.

	2011	2010	Year Ended December 31,		2007
			2009	2008	
	(dollars in thousands, except per share data)				
<b>Consolidated Statement of Operations Data:</b>					
Total revenues	\$ 2,730,121	\$ 1,716,229	\$ 1,460,841	\$ 1,260,536	\$ 1,085,608
Operating income	508,366	465,366	390,024	387,474	317,226
Income before income tax	351,691	420,698	359,660	391,828	353,250
Consolidated net income	\$ 242,065	\$ 287,020	\$ 266,336	\$ 255,336	\$ 227,440
Less: Net income attributable to noncontrolling interests	54,452	28,014			
Net income attributable to Endo Pharmaceuticals Holdings Inc.	\$ 187,613	\$ 259,006	\$ 266,336	\$ 255,336	\$ 227,440
<b>Basic and Diluted Net Income Per Share Attributable to Endo Pharmaceuticals Holdings Inc.:</b>					
Basic	\$ 1.61	\$ 2.23	\$ 2.27	\$ 2.07	\$ 1.70
Diluted	\$ 1.55	\$ 2.20	\$ 2.27	\$ 2.06	\$ 1.69
Shares used to compute basic net income per share attributable to Endo Pharmaceuticals Holdings Inc.	116,706	116,164	117,112	123,248	133,903
Shares used to compute diluted net income per share attributable to Endo Pharmaceuticals Holdings Inc.	121,178	117,951	117,515	123,720	134,525

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

Cash dividends declared per share	\$	\$	\$	\$	\$
-----------------------------------	----	----	----	----	----

**Table of Contents**

	2011	As of and for the Year Ended December 31,			2007
		2010	2009	2008	
		(dollars in thousands)			
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 547,620	\$ 466,214	\$ 708,462	\$ 775,693	\$ 350,325
Total assets	7,292,583	3,912,389	2,488,803	1,908,733	1,702,638
Long-term debt, less current portion, net	3,424,329	1,045,801	322,534	243,150	
Other long-term obligations, including capitalized leases	706,885	327,431	196,678	71,999	13,390
Total Endo Pharmaceuticals Holdings Inc. stockholders equity	\$ 1,977,690	\$ 1,741,591	\$ 1,497,411	\$ 1,207,111	\$ 1,292,290
Noncontrolling interests	61,901	61,738			
Total stockholders equity	\$ 2,039,591	\$ 1,803,329	\$ 1,497,411	\$ 1,207,111	\$ 1,292,290
<b>Other Financial Data:</b>					
Net cash provided by operating activities	\$ 702,115	\$ 453,646	\$ 295,406	\$ 355,627	\$ 365,742
Net cash (used in) provided by investing activities	(2,374,092)	(896,323)	(245,509)	179,807	(614,528)
Net cash provided by (used in) financing activities	\$ 1,752,681	\$ 200,429	\$ (117,128)	\$ (110,066)	\$ (28,974)

**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 (MD&A) describes the principal factors affecting the results of operations, liquidity and capital resources, and critical accounting estimates at Endo. 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.

**EXECUTIVE SUMMARY****About the Company**

We are a U.S. based, specialty healthcare solutions company with a diversified business model, operating in four key business segments: Branded Pharmaceuticals, Generics, Devices and Services. These segments reflect a 2011 reassessment of our reporting structure, whereby management is better able to assess its prospects and future cash flow potential to ultimately make more informed operating decisions about resource allocation and the enterprise as a whole. We deliver an innovative suite of complementary branded and generic drugs, devices, services and clinical data to meet the needs of patients in areas such as pain management, urology, endocrinology and oncology. We believe that recent healthcare reform in the U.S. places a premium on providing cost-effective healthcare solutions, like those we offer. Over the past two years, we have invested in and reshaped our company through a combination of organic and strategic growth initiatives, creating a company that we believe is positioned to address the changing economics that are driving the transformation of the U.S. healthcare environment.

We believe our diversified business model enables us to strengthen our partnerships with providers, payers and patients by offering multiple products and platforms to deliver healthcare solutions. We have a portfolio of branded pharmaceuticals that includes established brand names such as Lidoderm<sup>®</sup>, Opana<sup>®</sup> ER, Voltaren<sup>®</sup> Gel, Percocet<sup>®</sup>, Frova<sup>®</sup>, Supprelin<sup>®</sup> LA, Vantas<sup>®</sup>, Valstar<sup>®</sup> and Fortesta<sup>®</sup> Gel. Branded products comprised approximately 61% of our revenues in 2011, with 30% of our revenues coming from Lidoderm<sup>®</sup>. Our non-branded generic portfolio, which accounted for 21% of revenues in 2011, currently consists of products primarily focused on pain management. We generally focus on selective generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. Device revenue accounted for 11% of total revenues in 2011 and our services segment accounted for the remaining 2011 revenue.

## **Table of Contents**

### ***2011 A Year in Review***

During 2011, we achieved revenue growth for the thirteenth consecutive year and further diversified our Branded Pharmaceuticals, Generics, Devices, and Services businesses in key therapeutic areas, including pain management and urology. We executed on our growth strategy by acquiring AMS, a market leading provider of medical devices and therapies that help restore pelvic health. Our acquisition of AMS furthers Endo's evolution from a product-driven company to a healthcare solutions provider, strengthens our leading core urology franchise and expands our presence in the medical devices market. During 2011, we acquired two businesses in the healthcare information technology area which will help us leverage our position in the urology space. Additionally, in December 2011, the FDA approved a new formulation of Opana® ER designed to be crush-resistant, which will continue to be called Opana® ER (oxymorphone hydrochloride) Extended-Release Tablets CII with the same dosage strengths, color and packaging and similar tablet size. Endo anticipates transitioning in the first half of 2012 from the original formulation to the new formulation.

Total revenues for the year ended December 31, 2011 were \$2.73 billion, a 59% increase over 2010, with net income of \$187.6 million, or \$1.55 per diluted share, as compared to \$259.0 million or \$2.20 per diluted share in 2010. The increase in revenues was driven by organic growth in our branded pharmaceuticals product portfolio, including Lidoderm®, Opana® ER and Voltaren® Gel, as well as our June 2011 acquisition of AMS, which contributed \$300.3 million to our total 2011 revenue. Also included in 2011 revenue is \$205.2 million, representing the full-year impact of our HealthTronics acquisition, compared to \$102.1 million in 2010, representing the revenues of HealthTronics from July 2, 2010. Qualitest contributed revenue of \$467.1 million in 2011, as compared to \$30.3 million from November 30, 2010 to December 31, 2010.

### ***Business Environment***

The Company conducts its business within the pharmaceutical, devices, and healthcare services industries, which are highly competitive and subject to numerous government regulations. Many competitive factors may significantly affect the Company's sales of its products and services, including 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 and services 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 competition is one of the Company's leading challenges. Similarly, the Company competes with other providers with respect to the devices and services we offer, as well as providers of alternative treatments.

In the pharmaceutical industry, the majority of an innovative product's commercial value is usually realized during the period that the product has market exclusivity. When a product loses exclusivity, it is no longer protected by a patent and is subject to new competing products in the form of generic brands. Upon loss of exclusivity, the Company can lose a major portion of that product's sales in a short period of time. Intellectual property rights have increasingly come under attack in the current healthcare environment. Generic drug firms have filed Abbreviated New Drug Applications (ANDAs) seeking to market generic forms of certain of the Company's key pharmaceutical products, prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in ANDA filings, the generic firms will then introduce generic versions of the product at issue, resulting in the potential for substantial market share and revenue losses for that product. For a complete description of legal proceedings, see Note 14. Commitments and Contingencies-Legal Proceeding in the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

The healthcare industry is subject to various government-imposed regulations authorizing prices or price controls 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. Driven in part by budget concerns,

## **Table of Contents**

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 pricing pressures or 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 a generally downward pressure on prices.

Changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage, as a result of the current global economic downturn may impact the Company's business.

Pharmaceutical production processes are complex, highly regulated and vary widely from product to product. We contract with various third party manufacturers and suppliers to provide us with raw materials used in our products and finished goods. Our most significant agreements are with Novartis Consumer Health, Inc., Teikoku Seiyaku Co., Ltd., Mallinckrodt Inc., Noramco, Inc., Almac Pharma Services and Sharp Corporation. Shifting or adding manufacturing capacity can be a lengthy process that could require significant expenditures and regulatory approvals. 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, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

### *Healthcare Reform*

On March 23, 2010, President Obama signed into law H.R. 3590, the Patient Protection and Affordable Care Act (PPACA), which will make major changes to the U.S. healthcare system. On March 30, 2010, the President signed H.R. 4872, the Health Care and Education Reconciliation Act of 2010 (Reconciliation Act), which included a package of changes to the PPACA, as well as additional elements to reform health care in the U.S.

While some provisions of the new healthcare reform law have already taken effect, most of the provisions to expand access to health care coverage will not be implemented until 2014 and beyond. Since implementation is incremental to the enactment date of the law, there are still many challenges and uncertainties ahead. Such a comprehensive reform measure will require expanded implementation efforts on the part of federal and state agencies embarking on rule-making to develop the specific components of their new authority. The Company will monitor closely the implementation and any attempts to repeal, replace, or remove funding of the new health care reform law. This effort will primarily take place on two fronts: 1) in Congress through attempts to pass legislation to overturn all or specific sections of the law and 2) in the Courts through attempts to have the law declared unconstitutional.

The U.S. Supreme Court announced that it will hear the legal challenges to the health care reform law in 2012. The court will consider the constitutionality of the individual mandate, as well as whether the overall health care law can still stand even if the individual mandate is ruled unconstitutional. The Court's decision could significantly impact on the number of Americans who would be afforded access to health care services under the Patient Protection and Affordable Care Act.

Barring a Supreme Court ruling that the Patient Protection and Affordable Care Act is unconstitutional, the passage of the PPACA and the Reconciliation Act will result in a transformation of the delivery and payment for

## **Table of Contents**

health care services in the U.S. The combination of these measures will expand health insurance coverage to an estimated 32 million Americans. In addition, there are significant health insurance reforms that are expected to improve patients' ability to obtain and maintain health insurance. Such measures include: the elimination of lifetime caps; no rescission of policies; and no denial of coverage due to preexisting conditions. The expansion of healthcare insurance and these additional market reforms should result in greater access to the Company's products.

Our estimate of the overall impact of healthcare reform reflects a number of uncertainties. However, we believe that the impact to our business will be largely attributable to changes in the Medicare Part D Coverage Gap, the imposition of an annual fee on branded prescription pharmaceutical manufacturers, and increased rebates in the Medicaid Fee-For-Service Program and Medicaid Managed Care plans. There are a number of other provisions in the legislation that collectively are expected to have a small impact, including originator average manufacturers price (AMP) for new formulations, and the expansion of 340B pricing to new entities. These various elements of healthcare reform adversely impacted total revenues by approximately \$40 million in 2011 compared to approximately \$20 million in 2010.

In the U.S., the Medicare Prescription Drug Improvement and Modernization Act of 2003 continues to provide an effective prescription drug benefit to seniors and individuals with disabilities in the Medicare program (Medicare Part D). Uncertainty will continue to exist due to Congressional proposals that have the potential to impose new costs and increase pricing pressures on the pharmaceutical industry.

In response to the U.S. debt-ceiling crisis, Congress passed the Budget Control Act of 2011 on August 2, 2011. Within the Act, Congress created the Joint Select Committee on Deficit Reduction (JSC), which was charged with issuing a formal recommendation on how to reduce the federal deficit by \$1.2 to \$1.5 trillion over the next ten years. The Budget Control Act provided that if Congress failed to pass a deficit reduction plan by December 23, 2011, a process of sequestration would occur on January 1, 2013 which will result in across-the-board spending cuts to certain government programs, including Medicare, in order to meet the deficit reduction goal. Since the JSC failed to put forth a proposal and Congress ultimately failed to pass a deficit reduction plan, the sequestration process is scheduled to be triggered in 2013. The automatic spending cuts that would occur as a result of the sequestration process are unpalatable for many lawmakers and Congress may use the 2012 session to consider repealing the cuts by finding savings in other programs, such as Medicaid.

### *Governmental Regulation*

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 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, refusal of the government to enter into supply contracts or to approve NDAs and ANDAs, civil penalties and criminal prosecution.

FDA approval is typically required before each dosage form or strength of any new drug can be marketed. Applications for FDA approval to market a drug must contain information relating to efficacy, safety, toxicity, pharmacokinetics, product formulation, raw material suppliers, stability, manufacturing processes, packaging,

labeling, and quality control. The FDA also has the authority to require post-approval testing after marketing has begun and to suspend or revoke previously granted drug approvals. Product development and approval within this regulatory framework requires many years and involves the expenditure of substantial resources.

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. Some new or evolving review standards or conditions for approval were not applied to many established products currently on the market, including certain opioid products. As a result, the



## **Table of Contents**

FDA does not have as extensive safety databases on these products as on some products developed more recently. Accordingly, we believe the FDA has recently 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.

More stringent controls of the levels of these impurities have been required and may continue to be required for FDA approval of products containing these impurities. Also, labeling revisions, formulation or manufacturing changes and/or product modifications may be necessary 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.

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, 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, additional record keeping and expanded documentation of the properties of certain products and scientific substantiation. Such changes, or new legislation, could have a material adverse effect on our business, financial condition, results of operations and cash flows. In December 2003, Congress passed measures intended to speed the process by which generic versions of brand name drugs are introduced to the market. Among other things, these measures are intended to limit regulatory delays of generic drug applications and penalize companies that reach agreements with makers of brand name drugs to delay the introduction of generic versions. These changes could result in increased generic competition for our branded and generic products and could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, on September 27, 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007 (FDAAA) that re-authorized requirements for testing drug products in children, where appropriate, and included new requirements for post-approval studies or clinical trials of drugs that are known to or that signal the potential to pose serious safety risks, and authority to require risk evaluation and mitigation strategies, or REMS to ensure that the benefits of a drug outweigh the risks of the drug, all of which may increase the time and cost necessary for new drug development as well as the cost of maintaining regulatory compliance for a marketed product.

The evolving and complex nature of 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 ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

### ***Pipeline Developments***

In January 2012, the Company signed a worldwide license and development agreement with BioDelivery Sciences International, Inc. (BioDelivery) for the exclusive rights to develop and commercialize BEMA<sup>®</sup> Buprenorphine, a transmucosal form of buprenorphine which incorporates a bioerodible mucoadhesive

(BEMA<sup>®</sup>) technology and is currently in phase III trials for the treatment of moderate to severe chronic pain. At this time, the Company made an upfront payment to BioDelivery for \$30.0 million, which was expensed as Research and development in the first quarter of 2012.

In December 2011, the FDA approved a new formulation of Opana<sup>®</sup> ER designed to be crush-resistant, which will continue to be called Opana<sup>®</sup> ER with the same dosage strengths, color and packaging and similar tablet size. Endo anticipates transitioning in the first half of 2012 from the original formulation to the new formulation.

## **Table of Contents**

On December 27, 2011 and November 11, 2011, the Company terminated development of pegoclone and the octreotide implant for the treatment of acromegaly, respectively, after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product.

In addition, during the first quarter of 2011, the Company assessed all of its in-process research and development (IPR&D) assets and concluded, separately, to discontinue development of its octreotide implant for the treatment of carcinoid syndrome due to recent market research that indicates certain commercial challenges, including the expected rate of physician acceptance and the expected rate of existing patients willing to switch therapies.

In 2011, we announced topline results from a Phase II study comparing the novel investigational drug axomadol against placebo in the treatment of patients with moderate-to-severe chronic lower back pain. The results indicated that axomadol did not meet predetermined study end points; consequently, we terminated the Grünenthal Axomadol Agreement.

In January 2011, the Company entered into a Discovery, Development and Commercialization Agreement (the 2011 Orion Agreement) with Orion Corporation (Orion) to exclusively co-develop products for the treatment of certain cancers and solid tumors. In January 2011, Endo exercised its option to obtain a license to jointly develop and commercialize Orion's Anti-Androgen program focused on castration-resistant prostate cancer, one of Orion's four contributed research programs, and made a corresponding payment to Orion for \$10 million, which was expensed as Research and development in the first quarter of 2011.

### ***Change in Directors and Executive Officers***

On March 3, 2011, the Registrant increased the size of its Board of Directors from eight to nine and appointed David B. Nash, M.D., M.B.A. to fill this new vacancy. Dr. Nash is the founding dean of the Jefferson School of Population Health, located on the campus of Thomas Jefferson University in Philadelphia, Pennsylvania, having taken that position in 2008. Previously, Dr. Nash was the Chairman of the Department of Health Policy of the Jefferson Medical College from 2003 to 2008. Dr. Nash is internationally recognized for his work in outcomes management, medical staff development and quality-of-care improvement; his publications have appeared in more than 100 articles in major journals. Dr. Nash serves on the Board of Directors of Humana Inc., one of the nation's largest publicly traded health and supplemental benefits companies. Dr. Nash also has served as a member of the Board of Trustees of Catholic Healthcare Partners in Cincinnati, Ohio. The Board believes that Dr. Nash brings a value-added set of attributes that enhance the Company's ability to help people achieve lifelong well-being. Dr. Nash is a widely recognized innovator in an emerging medical discipline that unites population health, health policy, and individual health.

### ***Corporate Headquarters Lease***

On October 28, 2011, our subsidiary Endo Pharmaceuticals Inc. entered into a lease agreement with RT/TC Atwater LP, a Delaware limited partnership, for a new Company headquarters to consist of approximately 300,000 square feet of office space located at 1400 Atwater Boulevard, Malvern, Pennsylvania. The term of this triple net lease is twelve years and includes three renewal options, each for an additional sixty (60)-month period. The lease is expected to commence early 2013 with a monthly lease rate for the initial year of \$0.5 million, increasing by 2.25% each year thereafter. Under the terms of this lease, we will have a continuous and recurring right throughout the initial four (4) years of the lease term to lease up to approximately one hundred fifty thousand (150,000) additional square feet. We are responsible for all tenant improvement costs, less a tenant improvement allowance of \$45 per square foot.

## **RESULTS OF OPERATIONS**

The Company reported net income attributable to Endo Pharmaceuticals Holdings Inc. for 2011 of \$187.6 million or \$1.55 per diluted share on total revenues of \$2.73 billion compared with net income of \$259.0 million or \$2.20 per diluted share on total revenues of \$1.72 billion for 2010.

**Table of Contents****Consolidated Results Review****Year Ended December 31, 2011 Compared to the Year Ended December 31, 2010****Revenues**

Total revenues in 2011 increased 59% to \$2.73 billion from \$1.72 billion in the comparable 2010 period. This increase in revenues is primarily driven by our recent acquisition of AMS, from which we derived \$300.3 million in revenue, plus the full-year impact from our 2010 acquisitions, including \$467.1 million in revenues from Qualitest and \$205.2 million in revenues from HealthTronics. The remaining increase in total revenue was driven by organic growth in our branded pharmaceuticals product portfolio including Lidoderm<sup>®</sup>, Opana<sup>®</sup> ER and Voltaren<sup>®</sup> Gel. Sales growth of our branded pharmaceuticals was essentially volume driven.

The following table provides a breakdown of our revenues for the years ended December 31 (dollars in thousands). We have retrospectively revised the segment presentation for all periods presented reflecting the change from three to four reportable segments.

	2011		2010	
	\$	%	\$	%
Lidoderm <sup>®</sup>	825,181	30	782,609	46
Opana <sup>®</sup> ER	384,339	14	239,864	14
Voltaren <sup>®</sup> Gel	142,701	5	104,941	6
Percocet <sup>®</sup>	104,600	4	121,347	7
Frova <sup>®</sup>	58,180	2	59,299	3
Supprelin <sup>®</sup> LA	50,115	2	46,910	3
Other brands	92,651	3	112,602	7
<b>Total Branded Pharmaceuticals*</b>	<b>1,657,767</b>	<b>61</b>	<b>1,467,572</b>	<b>86</b>
<b>Total Generics</b>	<b>566,854</b>	<b>21</b>	<b>146,513</b>	<b>9</b>
<b>Total Devices revenue</b>	<b>300,299</b>	<b>11</b>		
<b>Total Services revenue</b>	<b>205,201</b>	<b>8</b>	<b>102,144</b>	<b>6</b>
<b>Total revenues*</b>	<b>2,730,121</b>	<b>100</b>	<b>1,716,229</b>	<b>100</b>

\* Percentages may not add due to rounding.

*Lidoderm<sup>®</sup>*. Net sales of Lidoderm<sup>®</sup> in 2011 increased by \$42.6 million or 5% to \$825.2 million from \$782.6 million in 2010. The growth in net sales is primarily attributable to increased volumes in 2011. In addition, we were required to pay Hind royalties based on net sales of Lidoderm<sup>®</sup> until this obligation expired on November 23, 2011. Hind royalties were recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm<sup>®</sup>. Due to the expiration of this obligation, these royalties decreased from \$86.8 million in 2010 to \$77.9 million in 2011, which had a favorable impact to 2011 net sales of \$8.9 million. Lidoderm<sup>®</sup> had solid performance this year and continues to generate strong cash flow that we can use to invest in our business to continue to further diversify our revenue base.

*Opana<sup>®</sup> ER*. Net sales of Opana<sup>®</sup> ER in 2011 increased by 60% or \$144.5 million to \$384.3 million from \$239.9 million in 2010. The growth in net sales is primarily attributable to continued prescription and market share growth of the product, as we continue to drive our promotional efforts through physician targeting. In addition, our strategy to contract with managed care organizations has resulted in increases in volume as we have broadened our access for the brand. In December 2011, Novartis Consumer Health, Inc.'s Lincoln, Nebraska manufacturing facility was temporarily shut down to facilitate its implementation of certain manufacturing process improvements. These improvements are intended to address the possibility of rare instances of errors in the packaging of the tablets, potentially resulting in product mix-ups. The temporary supply disruption is not related to the efficacy or safety of Endo's products. As a result, there will be a short-term supply constraint on Opana<sup>®</sup> ER in early 2012, while we begin production of the new formulation of Opana<sup>®</sup> ER, designed to be



---

**Table of Contents**

crush-resistant, at a third party manufacturing facility managed by Endo's development partner, Grünenthal. The Company estimates that this facility will achieve scale and start to fully supply market demand by late March or early April 2012.

*Voltaren® Gel.* Net sales of Voltaren® Gel in 2011 increased by \$37.8 million or 36% to \$142.7 million from \$104.9 million in 2010. The increase was driven by volume. The Company launched Voltaren® Gel in March 2008 and we believe the growth of Voltaren® Gel since its launch is driven by the product's proven clinical efficacy combined with our continued promotional activities aimed at increasing product awareness in the target audience. As a result of the temporary shut-down of the Novartis Consumer Health Lincoln, Nebraska manufacturing facility, there will be a short-term supply constraint of Voltaren® Gel. Endo will begin production of Voltaren® Gel at an alternative Novartis Consumer Health, Inc. manufacturing source. The precise timing of the initial resupply date remains somewhat uncertain; however, at this point, we expect resupply to begin during early second quarter and to reach commercial scale by the end of second quarter 2012. We would expect to return to promotional activities at that time.

*Percocet®.* Net sales of Percocet® in 2011 decreased by \$16.7 million or 14% to \$104.6 million from \$121.3 million in 2010. The decrease is primarily attributable to decreased volumes during 2011 as compared to 2010.

*Frova®.* Net sales of Frova® in 2011 decreased by \$1.1 million or 2% to \$58.2 million from \$59.3 million in 2010. The decrease in net sales is primarily attributable to reduced volumes during 2011 as compared to 2010, partially offset by price increases.

*Supprelin® LA.* Net sales of Supprelin® LA in 2011 increased by \$3.2 million or 7% to \$50.1 million from \$46.9 million in 2010. This increase was driven primarily by volume growth during 2011, resulting primarily from an increase in new patient starts and a growing base of continued care patients. We believe this growth is largely due to a strong base of national opinion leader support and ongoing efforts to streamline the treatment initiation process.

*Other brands.* Net sales of our other branded products in 2011 decreased by \$20.0 million or 18% to \$92.7 million from \$112.6 million in 2010. This decrease is primarily attributable to decreased sales of Opana® as demand continues to shift from Opana® to Opana® ER. This decrease was partially offset by the 2011 launch of Fortesta® Gel, which contributed \$14.9 million of net sales in 2011 as well as increased sales of both Vantas® and Valstar®.

*Generics.* Net sales of our generic products in 2011 increased by \$420.3 million or 287% to \$566.9 million from \$146.5 million in 2010. This increase was primarily driven by our acquisition of Qualitest on November 30, 2010. Qualitest products contributed \$446.2 million of net sales of generic products in 2011, compared with \$30.3 million in 2010.

*Devices.* Revenues from our devices business in 2011 were \$300.3 million and were primarily attributable to sales of products from our AMS subsidiary, which we acquired in June 2011. AMS products that represented approximately 1% or more of our consolidated total revenues in 2011 included the AMS 700® series of inflatable prostheses, the AMS 800® artificial urinary sphincter, the GreenLight™ laser therapy products used to treat BPH, the Monarc® subfascial hammock and the Elevate™ anterior pelvic floor repair system.

*Services.* Revenues from our services business in 2011 increased by \$103.1 million to \$205.2 million from \$102.1 million in 2010. This increase was driven by the full-year impact of HealthTronics, which contributed six months of revenue in 2010 compared to a full year of revenue in 2011. The \$205.2 million consisted primarily of lithotripsy fees of \$110.2 million, cryosurgery treatment fees of \$26.0 million and other service revenues from our HealthTronics business.

**Table of Contents****Gross Margin, Costs and Expenses**

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

	2011		2010	
	\$	% of revenues	\$	% of revenues
Cost of revenues	1,065,208	39	504,757	29
Selling, general and administrative	824,534	30	547,605	32
Research and development	182,286	7	144,525	8
Asset impairment charges	116,089	4	35,000	2
Acquisition-related items, net	33,638	1	18,976	1
Total costs and expenses*	2,221,755	81	1,250,863	73

\* Percentages may not add due to rounding.

**Costs of Revenues and Gross Profit Margin**

Costs of revenues in 2011 increased by \$560.5 million or 111%, to \$1,065.2 million from \$504.8 million in 2010, primarily due to the acquisition of AMS in June 2011 and a full year of activity from our 2010 acquisitions. Gross profit margins were 61% in 2011 compared with 71% in 2010. The reduction in gross profit margin in 2011 is primarily due to our 2010 acquisitions, which contributed a lower gross profit margin percentage than Endo's legacy products. Costs of revenues have also been unfavorably impacted by the increased amortization expense resulting from the intangible assets recognized as part of our recent acquisitions. Amortization expense in Costs of revenues was \$185.5 million, \$84.0 million and \$62.9 million in 2011, 2010 and 2009, respectively. Beginning in November 2011, the Teikoku royalty based on net sales of Lidoderm® is also included in Costs of revenues. These decreases in gross profit margin were partially offset by the elimination of the royalty obligation related to net sales of Opana® ER in September 2010, subsequent to our acquisition of Penwest.

**Selling, General and Administrative Expenses**

Selling, general and administrative expenses in 2011 increased by 51% to \$824.5 million from \$547.6 million in 2010. The increase in Selling, general and administrative expenses is primarily attributable to our second half 2010 acquisitions and our June 2011 acquisition of AMS, which, on a combined basis, contributed approximately \$250.4 million of Selling, general and administrative expense during 2011 compared with \$24.7 million during 2010. The increase was also partially driven by certain separation costs and other integration initiatives associated with our acquisitions totaling \$21.8 million during 2011. The remaining increase is primarily attributable to the overall growth of our business and the related increases in costs. Selling, general and administrative expenses as a percentage of revenue decreased to 30% in 2011 from 32% in 2010.

**Research and Development Expenses**

Research and development expenses in 2011 increased by 26% to \$182.3 million from \$144.5 million in 2010. This increase is primarily driven by the addition of AMS's and Qualitest's research and development portfolios to our existing programs, the progress of our branded pharmaceutical portfolio's development, and the expansion of our efforts in the pharmaceutical discovery and device research and development areas.

We invest in research and development because we believe it is important to our long-term competitiveness. As a percent of revenues, R&D expense was approximately 7%, 8% and 13% in 2011, 2010 and 2009, respectively. The variation in R&D expense as a percent of revenues is primarily due to upfront and milestone payments to third party collaborative partners included in R&D expense totaling \$19.1 million or 1% of revenue, \$23.9 or 1% of revenue million and \$77.1 million or 5% of revenue in 2011, 2010 and 2009, respectively. In addition to upfront and milestone payments, total research and development 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. Research and development spending also includes enterprise-wide costs which support



## **Table of Contents**

our overall research and development infrastructure. These enterprise-wide costs are not allocated by product or to specific R&D projects. Unallocated enterprise-wide R&D costs were \$63.5 million, \$57.3 million and \$40.1 million in 2011, 2010 and 2009, respectively.

We continually evaluate our portfolio of R&D assets to appropriately balance our early-stage and late-stage programs in order to support future growth of the Company. With the addition of Qualitest in November 2010, the Company's pharmaceutical R&D programs now include projects in a diversified set of therapeutics areas, including pain management, urology, central nervous system (CNS) disorders, and immunosuppression, oncology, women's health and hypertension markets, among others.

We manage our pharmaceutical R&D programs on a portfolio basis, investing resources in each stage of research and development from early discovery through late-stage development. These stages include: (1) early-stage projects consisting of assets in both preclinical and Phase I programs; (2) middle-stage projects consisting of assets in Phase II programs, and (3) late-stage projects consisting of assets in Phases III programs, assets in which an NDA is currently pending approval, or on-market assets in post marketing Phase IV programs.

We consider our branded R&D programs in Phase III, or late-stage development, to be our significant R&D programs as they could potentially have an impact on our near-term revenue and earnings. As of December 31, 2011, our late-stage branded pharmaceutical programs, excluding on-market assets, include Avedd™, BEMA® Buprenorphine and Urocidin™.

The Company's pharmaceutical research and development efforts are also focused on the goal of developing a balanced, diversified portfolio of innovative and clinically differentiated generic products across a wide range of therapeutic areas. We generally focus on selective generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. 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. For the years ended December 31, 2011, 2010 and 2009, the Company's direct R&D expense related to generics was \$29.1 million, \$17.5 million and \$24.2 million, respectively.

FDA approval of an abbreviated new drug application (ANDA) is required before a generic equivalent of an existing or reference-listed drug can be marketed. As of December 31, 2011, we have approximately 50 ANDAs under active FDA review in multiple therapeutic areas. 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.

We are also committed to developing new products and improving our current products in our medical device business to provide physicians and patients with better clinical outcomes through less invasive and more efficiently delivered therapies. Most of these R&D activities are conducted in our Minnesota and California facilities, although we also work with physicians, research hospitals, and universities around the world. Many of the ideas for new and improved products come from a global network of leading physicians who also work with us in evaluating new concepts and in conducting clinical trials to gain regulatory approvals. We conduct applied research in areas that we think will likely lead to product commercialization activities. This research is often done at a technology platform level such that the science can be utilized to develop a number of different products. The development process for any new product can range from months to several years, primarily depending on the regulatory pathway required for approval.

Our product development engineers work closely with their marketing partners to identify important needs in the urology, gynecology, urogynecology and colorectal markets. The team then analyzes the opportunities to optimize the value of the product development portfolio. Our product development teams continue to improve our current product lines and develop new products to increase our market share and also expand the markets we serve. In addition, we believe our clinical data will continue to drive market expansion for our therapies and demonstrates our technology leadership position.



**Table of Contents**

The following table presents the composition of our total R&D expense as of December 31, 2011 and, for our branded pharmaceuticals R&D portfolio, the number of projects by stage of development:

	Research and Development Expense (in thousands)			Number of Projects at December 31, 2011			
	2011	2010	2009	Preclinical and Phase I	Phase II	Phase III(1)	Phase IV
Early-stage	\$ 26,638	\$ 22,872	\$ 9,418	12			
Middle-stage	11,697	13,373	50,729				
Late-stage	21,447	33,485	60,779			2	4
Sub-Total *	\$ 59,782	\$ 69,730	\$ 120,926				
Generics portfolio *	29,121	17,452	24,242				
Devices portfolio *	29,850						
Enterprise-wide unallocated R&D costs	63,533	57,343	40,149				
Total R&D expense	\$ 182,286	144,525	185,317				

\* Excludes all costs not allocated to specific products and R&D projects.

(1) Includes projects for which an NDA has been filed with the FDA.

These amounts are not necessarily indicative of our future R&D spend or our future R&D focus. Over time, our R&D spend among categories is unpredictable. We continually evaluate each product under development in an effort to allocate R&D dollars efficiently to projects we believe to be in the best interests of the Company based on, among other factors, the performance of such products in preclinical and/or clinical trials, our expectations regarding the potential future regulatory approval of the product and our view of the potential commercial viability of the product in light of market conditions.

R&D expenses, in total dollars, are expected to increase as a result of our recent strategic acquisitions and the expansion of our efforts in the pharmaceutical discovery and device R&D areas. As we continue to execute on our strategy of being a healthcare solutions provider with an integrated business model that includes branded and generic prescription drugs, medical devices and healthcare services, the composition of research and development expense may change reflecting our focus on these multiple products and platforms.

**Asset Impairment Charges**

In May 2010, Teva Pharmaceutical Industries Ltd. terminated the pargolone development and licensing arrangement with the Company upon the completion of the Phase IIb study. As a result, the Company concluded that there was a decline in the fair value of the corresponding indefinite-lived intangible asset. Accordingly, we recorded a \$13.0 million impairment charge during the year ended December 31, 2010.

As part of our 2010 annual review of all IPR&D assets, we conducted an in-depth review of both octreotide indications. This review covered a number of factors including the market potential of each product given its stage of development, taking into account, among other things, issues of safety and efficacy, product profile, competitiveness of the marketplace, the proprietary position of the product and its potential profitability. Our 2010 review resulted in no impact to the carrying value of our octreotide acromegaly intangible asset. However, the analysis identified certain commercial challenges with respect to the octreotide carcinoid syndrome intangible asset including the expected rate of physician acceptance and the expected rate of existing patients willing to switch therapies. Upon analyzing the Company's research and development priorities, available resources for current and future projects, and the commercial potential for octreotide carcinoid syndrome, the Company decided to discontinue development of octreotide for the treatment of carcinoid syndrome. As a result of the above developments, the Company recorded a pre-tax non-cash impairment charge of \$22.0 million in 2010 to write-off, in its entirety, the octreotide carcinoid syndrome intangible asset.



**Table of Contents**

In September 2011, the Company recorded a pre-tax non-cash impairment charge of \$22.7 million to completely impair its cost method investment in a privately-held company focused on the development of an innovative treatment for certain types of cancer. This impairment was recorded due to the negative clinical trial results related to this company's lead asset.

On November 11, 2011, the Company decided to terminate development of its octreotide implant for the treatment of acromegaly and, on December 27, 2011, terminated its pagoclone development program after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the products. Accordingly, we recorded pre-tax non-cash impairment charges of \$8.0 million and \$9.0 million, respectively, in 2011 to completely write-off the remaining pagoclone intangible asset and the octreotide acromegaly intangible asset.

As part of our 2011 annual review of all IPR&D assets, we conducted an in-depth review of one of the lead IPR&D assets we acquired from Qualitest. This review covered a number of factors including the market potential of this product given its stage of development, taking into account, among other things, issues of safety and efficacy, product profile, competitiveness of the marketplace, the proprietary position of the product and its potential profitability. As part of this review, the Company also considered a deficiency received from the FDA on an ANDA submission for this asset, which was received during the fourth quarter of 2011. As a result of the 2011 review as well as the regulatory challenges and changes in the development timeline resulting from the FDA's request, the Company terminated its development of this asset. In addition, as a result changes in market conditions since the acquisition date, there has been a significant deterioration in the commercial potential for this product. Accordingly, we recorded a pre-tax non-cash impairment charge of \$71.0 million in 2011 to write off the intangible asset in its entirety.

Our remaining 2011 asset impairment charges of \$5.4 million were related to various other long-lived assets for which we determined the carrying amount was not fully recoverable.

***Acquisition-Related Items, net***

Acquisition-related items, net in 2011 were \$33.6 million of expense compared to \$19.0 million of expense in 2010. Acquisition-related items, net in 2011 primarily consisted of transaction fees of \$41.0 million, including legal, separation, integration, and other expenses for our recent acquisitions, partially offset by a favorable change in the fair value of the acquisition-related contingent consideration of \$7.4 million, which was recorded as a gain. The change in the fair value of the acquisition-related contingent consideration primarily reflects changes to our present value assumptions associated with our valuation models. This compares to 2010 transaction fees of \$70.4 million, including legal, separation, integration, and other expenses for our 2010 acquisitions, partially offset by a favorable change in the fair value of the acquisition-related contingent consideration of \$51.4 million, which was recorded as a gain. The 2010 and 2011 change in the fair value of the acquisition-related contingent consideration was primarily due to management's assessment that it would not be obligated to make contingent consideration payments related to octreotide.

***Interest Expense, net***

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

	2011	2010
Interest expense	\$ 148,623	\$ 47,956
Interest income	(599)	(1,355)
Interest expense, net	\$ 148,024	\$ 46,601

**Table of Contents**

Interest expense in 2011 was \$148.6 million compared with \$48.0 million in 2010. The increase in interest expense was primarily attributable to increases to our average total indebtedness in 2011 compared to 2010. In 2011, we incurred \$66.6 million of interest expense on our \$1.3 billion of senior notes, of which \$400.0 million originated in November 2010 and the remaining \$900.0 million in June 2011. This compares to \$3.1 million of senior note interest in 2010. Our 2011 interest expense related to our credit facilities was \$51.3 million compared to \$5.4 million in 2010. This increase was largely attributable to the 2011 Credit Facility entered into in June 2011, which provided \$2.2 billion of term loan indebtedness compared to \$400.0 million of term loan indebtedness at December 31, 2010. These increases were partially offset by reduced interest expense on our Non-recourse Notes, which incurred \$7.3 million of interest expense in 2010 until they were retired in the third quarter of 2010.

Interest income decreased to \$0.6 million in 2011 compared to \$1.4 million in 2010. This decrease is a result of the fluctuations in the amount of cash invested in interest-bearing accounts, including our money market funds and auction-rate securities, as well as the yields on those investments.

***Loss (Gain) on Extinguishment of Debt***

In June 2011, we terminated the 2010 Credit Facility and established the 2011 Credit Facility. Unamortized financing costs associated with the prior credit facilities totaled approximately \$14.7 million on June 17, 2011. In accordance with the applicable accounting guidance for debt modifications and extinguishments, approximately \$8.5 million of this amount was written off and is included in the Condensed Consolidated Statements of Operations as a Loss on extinguishment of debt.

In September 2011 and December 2011, we made prepayments of \$135.0 million and \$125.0 million, respectively, on our Term Loan B Facility. In accordance with the applicable accounting guidance for debt modifications and extinguishments, approximately \$3.4 million of the remaining unamortized financing costs were written off in connection with our 2011 prepayments and included in the Consolidated Statements of Operations as a Loss on extinguishment of debt.

***Other Income, net***

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

	2011	2010
Gain on trading securities	\$	\$ (15,420)
Loss on auction-rate securities rights		15,659
Other income	(3,268)	(2,172)
Other income, net	\$ (3,268)	\$ (1,933)

During 2010, the value of our trading auction-rate securities increased by \$15.4 million. The increases in fair value were more than offset by losses recorded as a result of decreases in the fair value of our auction-rate securities rights totaling \$15.7 million. As all auction-rate securities rights were exercised and all trading auction-rate securities were sold on June 30, 2010, there were no subsequent changes to their respective fair values.

***Income Tax***

Income tax expense in 2011 decreased 18% from 2010 to \$109.6 million. This fluctuation is due to a \$69.0 million decrease in income before income tax and the decrease in our effective income tax rate to 31.2% from 31.8% in 2010. The decrease in the effective income tax rate is primarily due to an increase in non-taxable income attributable to non-controlling interests in the current period as compared to the comparable 2010 period, the release of reserves related to uncertain tax positions due to statute of limitations expirations and audit settlements, an increase in the Domestic Production Activities deduction, and a decrease in transactions costs

**Table of Contents**

from acquisitions in the current period as compared to the comparable 2010 period. This decrease was partially offset by a lower benefit from non-taxable reductions in the fair value of contingent consideration in the current period as compared to the comparable 2010 period, the establishment of a valuation allowance in the current period against an anticipated capital loss on our cost method investment in a privately-held company and a charge for the non-deductible Branded Prescription Drug fee enacted in 2011.

***Net income attributable to noncontrolling interests***

As a result of our July 2010 acquisition of HealthTronics, we own interests in various partnerships and limited liability corporations (LLCs) where we, as the general partner or managing member, exercise effective control. Accordingly, we consolidate various entities where we do not own 100% of the entity in accordance with the accounting consolidation principles. Net income attributable to noncontrolling interests relates to the portion of the net income of these partnerships and LLCs not attributable, directly or indirectly, to our ownership interests. Net income attributable to noncontrolling interest increased to \$54.5 million in 2011 from \$28.0 million in 2010 due to the results of our HealthTronics subsidiary, which contributed six months of results in 2010 compared to a full year in 2011.

***2012 Outlook***

We estimate that our 2012 total revenues will be between \$3.15 billion and \$3.30 billion. Our estimate is based on the continued growth of both our generic and branded product portfolios, driven by ongoing prescription demand for our key inline products, including Lidoderm®, Opana® ER, and Voltaren® Gel, and the full-year effect of the AMS acquisition. We currently expect the effects of the temporary supply constraints linked to the Novartis facility shutdown to have a disproportionate effect on first quarter revenues. We believe our estimate contemplates a range of outcomes related to certain assumptions, including recovery from the Novartis supply disruption and the recent procedural volume pressures in the AMS Women's Health business. Cost of revenues as a percent of total revenues is expected to increase when compared to 2011. This increase is expected due to a full year of amortization expense associated with the intangible assets acquired with AMS as well as growth in lower margin generic and branded pharmaceutical products in 2012, partially offset by a full year's revenues from the AMS acquisition. Selling, general and administrative expenses, as a percentage of revenues, are expected to decline in 2012, relative to 2011, reflecting new approaches to customer segmentation and marketing, annualized effects of the prior year's cost reduction efforts and forecasted synergies associated with our AMS acquisition. Absolute selling, general and administrative expenses, however, will increase, reflecting the full year effects of our acquisitions. As well, we will continue to provide promotional support behind our key on-market products. Research and development expenses are expected to increase due to the addition of AMS's research and development portfolio to our existing programs, the progress of our branded pharmaceutical portfolio's development, as well as the expansion of our efforts in the pharmaceutical discovery and device research and development areas. Of course, there can be no assurance that the Company will achieve these results.

***Year Ended December 31, 2010 Compared to the Year Ended December 31, 2009******Revenues***

Total revenues in 2010 increased 17% to \$1.72 billion from \$1.46 billion in the comparable 2009 period. This increase in revenues is primarily driven by organic growth in our branded pharmaceuticals product portfolio, including Lidoderm®, Opana® ER and Voltaren® Gel, as well as our 2010 acquisitions, including \$102.1 million in revenues from HealthTronics and \$30.3 million in revenues from Qualitest. Lastly, included in 2010 are the revenues from the products we acquired, including Supprelin® LA and other brands, resulting from our acquisition of Indevus. The full year of revenues from these products in 2010 compares to a partial year in 2009 as the revenue from Indevus was included from February 23, 2009 through December 31, 2009. For the year-ended December 31, 2010, sales growth was essentially volume driven, while price fluctuations had no material impact.

**Table of Contents**

The following table provides a breakdown of our revenues for the years ended December 31 (dollars in thousands):

	2010		2009	
	\$	%	\$	%
Lidoderm®	782,609	46	\$ 763,698	52
Opana® ER	239,864	14	171,979	12
Voltaren® Gel	104,941	6	78,868	5
Percocet®	121,347	7	127,090	9
Frova®	59,299	3	57,924	4
Supprelin® LA	46,910	3	27,822	2
Other brands	112,602	7	108,729	7
<b>Total Branded Pharmaceuticals*</b>	<b>1,467,572</b>	<b>86</b>	<b>1,336,110</b>	<b>91</b>
<b>Total Generics</b>	<b>146,513</b>	<b>9</b>	<b>124,731</b>	<b>9</b>
<b>Total Devices</b>				
<b>Total Services revenue</b>	<b>102,144</b>	<b>6</b>		
<b>Total revenues*</b>	<b>1,716,229</b>	<b>100</b>	<b>\$ 1,460,841</b>	<b>100</b>

\* Percentages may not add due to rounding.

*Lidoderm®*. Net sales of Lidoderm® in 2010 increased by \$18.9 million or 2% to \$782.6 million from \$763.7 million in 2009. The growth of this product has slowed, in recent years, as it matures and competition in the topical pain market increases. Notwithstanding, the product has had a solid performance this year and continues to generate strong cash flow that we can use to invest in our business to continue to further diversify our revenue base.

*Opana® ER*. Net sales of Opana® ER in 2010 increased by 39% or \$67.9 million to \$239.9 million from \$172.0 million in 2009. The growth in net sales is primarily attributable to continued prescription and market share growth of the product. In addition, our strategy to effectively contract with managed care organizations has resulted in increases in volume as we have broadened our access for the brand.

*Voltaren® Gel*. Net sales of Voltaren® Gel in 2010 increased by \$26.1 million or 33% to \$104.9 million from \$78.9 million in 2009. The increase was driven by volume. The Company launched Voltaren® Gel in March 2008. We believe the growth of Voltaren® Gel since its launch is driven by improved formulary positioning with MCOs, and the product's proven clinical efficacy combined with our continued promotional activities aimed at increasing product awareness in the target audience. We believe we are establishing a strong position in the osteoarthritis market with Voltaren® Gel.

*Percocet®*. Net sales of Percocet® in 2010 decreased by \$5.7 million or 5% to \$121.3 million from \$127.1 million in 2009. The decrease is primarily attributable to decreased volumes during 2010 as compared to 2009, partially offset by price increases.

*Frova®*. Net sales of Frova® in 2010 increased by \$1.4 million or 2% to \$59.3 million from \$57.9 million in 2009. The growth in net sales is primarily attributable to price increases, partially offset by decreases in volume.

*Supprelin® LA*. Net sales of Supprelin® LA during 2010 increased by \$19.1 million or 69% from the comparable 2009 period. This increase was driven primarily by volume growth in 2010, as well as a full twelve months of activity in 2010 compared to a partial period in 2009. In 2010, volume growth was driven primarily by an increase in new patient starts and a growing base of continued care patients. We believe this growth is largely due to a strong base of national opinion leader support and ongoing efforts to streamline the treatment initiation process.

**Table of Contents**

*Other brands.* Net sales of our other branded products in 2010 increased by \$3.9 million or 4% to \$112.6 million from \$108.7 million in 2009. This increase is primarily attributable to a full year of royalty revenue from Sanctura<sup>®</sup> and Sanctura XR<sup>®</sup> compared to approximately ten months in 2009.

*Generics.* Net sales of our generic products in 2010 increased by \$21.8 million or 17% to \$146.5 million from \$124.7 million in 2009. This increase was primarily driven by our acquisition of Qualitest on November 30, 2010, which contributed \$30.3 million of net sales of generic products in 2010. This increase was partially offset by a shortage of other competing generic opioids in the market during the first half of 2009, which was an anomaly and did not recur to the same extent during 2010.

*Service revenues.* Service revenues were \$102.1 million during 2010. This amount consists of revenues from the acquisition of HealthTronics.

**Gross Margin, Costs and Expenses**

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

	2010		2009	
	\$	% of revenues	\$	% of revenues
Cost of revenues	504,757	29	375,058	26
Selling, general and administrative	547,605	32	534,523	37
Research and development	144,525	8	185,317	13
Asset impairment charges	35,000	2	69,000	5
Acquisition-related items, net	18,976	1	(93,081)	(6)
Total costs and expenses*	1,250,863	73	1,070,817	73

\* Percentages may not add due to rounding.

**Costs of Revenues and Gross Profit Margin**

Costs of revenues in 2010 increased by \$129.7 million or 35%, to \$504.8 million from \$375.1 million in 2009, primarily due to increased revenues in 2010. Gross profit margins were 71% in 2010 compared with 74% in 2009. The reduction in gross profit margin in 2010 is primarily due to the acquisitions of HealthTronics and Qualitest, which have contributed a lower gross profit margin percentage than Endo's branded pharmaceuticals net sales relative to total revenues. Gross profit margin has also been unfavorably impacted by the increased amortization expense in 2010 compared to the 2009 period as a result of our recent acquisitions, including a full twelve months of amortization on the acquired Indevus intangible assets. Lastly, gross profit margin was negatively impacted by the increase in royalty expense recorded on net sales of Opana<sup>®</sup> ER during 2010 compared to 2009, as a result of the expiration of the 50% royalty holiday during the three months ended March 31, 2010, partially offset by the elimination of this royalty obligation in the latter portion of the year, subsequent to our acquisition of Penwest. This royalty, however, was no longer payable beginning on September 20, 2010 as a result of the acquisition of Penwest.

**Selling, General and Administrative Expenses**

Selling, general and administrative expenses in 2010 increased by 2% to \$547.6 million from \$534.5 million in 2009. The increase in Selling, general and administrative expenses for 2010 compared to 2009 is primarily attributable to increased expenses as a result of our acquisitions of HealthTronics, Qualitest, and Penwest of \$24.7 million as well as \$10.1 million of certain costs incurred in connection with continued efforts to enhance the cost structure of the Company, and \$6.7 million in start-up costs associated with our contract sales organization. These amounts were partially offset by a reduction in Selling, general and administrative expenses

**Table of Contents**

from Indevus in 2010 compared to 2009 resulting from further integration of Indevus into our operations during 2010, the favorable impact of certain cost reduction initiatives, and the timing of certain sales and marketing programs.

***Research and Development Expenses***

Research and development expenses in 2010 decreased by 22% to \$144.5 million from \$185.3 million in 2009. This decrease is primarily a result of lower upfront and milestone payments in 2010, as compared to 2009.

***Asset Impairment Charges***

In May 2010, Teva Pharmaceutical Industries Ltd. terminated the pargoclone development and licensing arrangement with the Company upon the completion of the Phase IIb study. As a result, the Company concluded that there was a decline in the fair value of the corresponding indefinite-lived intangible asset. Accordingly, we recorded a \$13.0 million impairment charge in 2010. As part of our annual review of all IPR&D assets, we conducted an in-depth review of both octreotide indications. This review covered a number of factors including the market potential of each product given its stage of development, taking into account, among other things, issues of safety and efficacy, product profile, competitiveness of the marketplace, the proprietary position of the product and its potential profitability. Our review resulted in no impact to the carrying value of our octreotide acromegaly intangible asset. However, the analysis identified certain commercial challenges with respect to the octreotide carcinoid syndrome intangible asset including the expected rate of physician acceptance and the expected rate of existing patients willing to switch therapies. Upon analyzing the Company's research and development priorities, available resources for current and future projects, and the commercial potential for octreotide carcinoid syndrome, the Company has decided to discontinue development of octreotide for the treatment of carcinoid syndrome. As a result of the above developments, the Company recorded a pre-tax non-cash impairment charge of \$22.0 million in 2010, to write-off, in its entirety, the octreotide carcinoid syndrome intangible asset.

This compares to a \$65.0 million impairment charge relating to the write-down of our Aveed™ indefinite-lived intangible asset and a \$4.0 million write-off of our Pro2000 indefinite-lived intangible asset in 2009. However, due to the unsuccessful Phase III clinical trials for Pro2000, which were completed in December of 2009, the Company concluded there was no further value or alternative use associated with this indefinite-lived asset. As a result of the FDA's response letter received in December of 2009, the Company reassessed the fair value of our Aveed™ indefinite-lived intangible asset and concluded that the asset was impaired due to a change in probability of approval, relative timing of commercialization and the changes to the targeted population of eligible recipients. The extent of the impairment was partially offset due to the Company being notified that the U.S. patent office had issued a Notice of Allowance on a patent covering the Aveed™ formulation. The patent should expire no earlier than late 2025.

***Acquisition-Related Items, net***

Acquisition-related items, net in 2010 were \$19.0 million in expense compared to \$93.1 million of income in 2009. Acquisition-related items, net in 2010 primarily consisted of transaction fees of \$70.4 million, including legal, separation, integration, and other expenses for our 2010 acquisitions, partially offset by favorable changes in the fair value of the acquisition-related contingent consideration of \$51.4 million, which was recorded as a gain. The change in the fair value of the acquisition-related contingent consideration was primarily due to management's current assessment that it will not be obligated to make contingent consideration payments based on the anticipated timeline for the NDA filing and FDA approval of octreotide for the treatment of acromegaly. This compares to \$93.1 million in income in 2009, in which we incurred \$35.0 million of acquisition-related costs which were attributable to transaction fees, professional service fees, employee retention and separation arrangements and other costs related to the Indevus acquisition. These costs were more than offset by favorable changes in the fair value of the acquisition-related contingent consideration which resulted in a gain of \$128.1 million during the year ended December 31, 2009.



**Table of Contents****Interest Expense (Income), net**

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

	2010	2009
Interest expense	\$ 47,956	\$ 41,247
Interest income	(1,355)	(3,529)
Interest expense, net	\$ 46,601	\$ 37,718

Interest expense in 2010 was \$48.0 million compared with \$41.2 million for the comparable period in 2009. This increase is primarily due to \$8.5 million of interest expense resulting from the \$800.0 million of indebtedness the Company incurred in November of 2010. Interest income decreased to \$1.4 million in 2010 compared to \$3.5 million in 2009. This decrease is a result of the fluctuations in the amount of cash invested in interest-bearing accounts, including our money market funds and auction-rate securities, as well as the yields on those investments.

**Loss (Gain) on Extinguishment of Debt**

As a result of the cash tender offer for any and all outstanding Non-recourse notes, which closed in September 2009, the Company accepted for payment and purchased Non-recourse notes at a purchase price of \$1,000 per \$1,000 principal amount, for a total amount of approximately \$48 million (excluding accrued and unpaid interest up to, but not including, the payment date for the Notes, fees and other expenses in connection with the tender offer). The aggregate principal amount of Non-recourse notes purchased represents approximately 46% of the \$105 million aggregate principal amount of Non-recourse notes that were outstanding prior to the tender offer closing. Accordingly, the Company recorded a \$4.0 million gain on the extinguishment of debt, net of transaction costs. The gain was calculated as the difference between the aggregate amount paid to purchase the Non-recourse notes and their carrying amount.

**Other Income, net**

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

	2010	2009
Gain on trading securities	(15,420)	(15,222)
Loss on auction-rate securities rights	15,659	11,662
Other (income) expense	(2,172)	231
Other income, net	\$ (1,933)	\$ (3,329)

During 2010, the value of our trading auction-rate securities increased by \$15.4 million. The increase in fair value was more than offset by losses recorded as a result of decreases in the fair value of our auction-rate securities rights totaling \$15.7 million. These changes were primarily a result of the Company exercising the auction-rate securities rights in the second quarter of 2010 and liquidating our outstanding UBS AG (UBS) auction-rate security portfolio at par value. During 2009, the value of our trading auction-rate securities increased by \$15.2 million, which was partially offset by losses recorded as a result of decreases in the fair value of our auction-rate securities rights totaling \$11.7 million.

**Income Tax**

Income tax expense in 2010 increased by 43% to \$133.7 million from \$93.3 million in 2009. The increase in income tax expense is due to the increase in income before income tax as compared to 2009, as well as the increase in our effective income tax rate to 31.8% from 25.9% in 2009. The increase in the effective income tax rate is primarily the result of a smaller favorable impact related to changes in the fair value of acquisition related



## **Table of Contents**

contingent consideration of \$15.7 million in 2010, compared to \$40.5 million in 2009. These impacts resulted from non-taxable reductions in the fair value of contingent consideration of \$44.8 million in 2010, compared to \$115.7 million in 2009. The increase in rate was also impacted by an increase in non-deductible transaction costs, which unfavorably impacted 2010 income tax expense by \$9.6 million, compared to \$3.3 million in 2009. These increases were partially offset by the impact of the noncontrolling interests in our consolidated limited partnerships and limited liability companies assumed with the HealthTronics acquisition, as they are not taxable to Endo and favorably impacted 2010 income tax expense by \$9.8 million.

## **Business Segment Results Review**

In the fourth quarter of 2011, as a result of our strategic planning process, the Company's executive leadership team reorganized the manner in which it views our various business activities. Management's intention was to better understand the entity's performance, better assess its prospects and future cash flow potential and ultimately make more informed operating decisions about resource allocation and the enterprise as a whole. Based on this change, we reassessed our reporting structure under the applicable accounting guidance and determined that the Company now has four reportable segments. We have retrospectively revised the segment presentation for all periods presented reflecting the change from three to four reportable segments. This change in our segments has no impact on the Company's consolidated financial statements for all years presented.

The four reportable business segments in which the Company now operates include: (1) Branded Pharmaceuticals, (2) Generics, (3) Devices and (4) Services. Each segment derives revenue from the sales or licensing of their respective products or services and is discussed below.

### ***Branded Pharmaceuticals***

This group of products includes a variety of branded prescription products related to treating and managing pain as well as our urology, endocrinology and oncology products. The marketed products that are included in this operating segment include Lidoderm®, Opana® ER, Percocet®, Voltaren® Gel, Frova®, Supprelin® LA, Vantas®, Valstar® and Fortesta® Gel.

### ***Generics***

This segment is comprised of our legacy Endo non-branded generic portfolio and the portfolio from our recently acquired Qualitest business. Our generics business has historically focused on selective generics related to pain that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. With the addition of Qualitest, the segment's product offerings now include products in the pain management, urology, central nervous system (CNS) disorders, immunosuppression, oncology, women's health and hypertension markets, among others.

### ***Devices***

The Devices segment currently focuses on providing technology solutions to physicians treating men's and women's pelvic health conditions and operates in the following business lines: men's health, women's health, and BPH therapy. These business lines are discussed in greater detail within Note 5. Acquisitions in the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K. We distribute devices through our direct sales force and independent sales representatives in the U.S., Canada, Australia, Brazil and Western Europe. Additionally, we distribute devices through foreign independent distributors, primarily in Europe, Asia, and South America, who then sell the products to medical institutions. None of our devices or services customers or distributors accounted for ten percent or more of our total revenues during 2011, 2010 or 2009. Foreign subsidiary sales are predominantly to customers in Western Europe, Canada, Australia and Brazil.

## **Table of Contents**

### *Services*

The Services segment provides urological services, products and support systems to urologists, hospitals, surgery centers and clinics across the U.S. These services are sold through the following business lines: lithotripsy services, prostate treatment services, anatomical pathology services, medical products manufacturing, sales and maintenance and electronic medical records services. These business lines are discussed in greater detail within Note 5. Acquisitions in the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

We evaluate segment performance based on each segment's adjusted income (loss) before income tax, a financial measure not determined in accordance with U.S. generally accepted accounting principles (GAAP). We define adjusted income (loss) before income tax as income (loss) before income tax before certain upfront and milestone payments to partners, acquisition-related items, net, cost reduction initiatives, impairments of long-lived assets, amortization of intangible assets related to marketed products and customer relationships, inventory step-up recorded as part of our acquisitions, non-cash interest expense, and certain other items that the Company believes do not reflect its core operating performance.

Certain corporate general and administrative expenses are not allocated and are therefore included within Corporate unallocated. We calculate consolidated adjusted income (loss) before income tax by adding the adjusted income (loss) before income tax of each of our reportable segments to corporate unallocated adjusted income (loss) before income tax.

We refer to adjusted income (loss) 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 its 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 by us 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 financial reporting at this time. Further, we believe that adjusted income (loss) before income tax may be useful to investors as we are aware that certain of our significant stockholders utilize adjusted income (loss) before income tax to evaluate our financial performance. Finally, adjusted income (loss) before income tax is utilized in the calculation of adjusted diluted net income per share, which is used by the Compensation Committee of Endo'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) before income tax. Other companies in our industry may define adjusted income (loss) before income tax differently than we do. As a result, it may be difficult to use adjusted income (loss) 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) 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 consolidated adjusted income (loss) before income tax to our consolidated income before income tax, which is determined in accordance with U.S. GAAP and included in our Consolidated Statements of Operations in our Consolidated Financial Statements included in this Annual Report on Form 10-K.

**Table of Contents****Year Ended December 31, 2011 Compared to the Year Ended December 31, 2010****Revenues**

The following table displays our revenue by reportable segment for 2011 and 2010 (in thousands):

	2011	2010
Branded Pharmaceuticals	\$ 1,657,767	\$ 1,467,572
Generics	566,854	146,513
Devices(1)	300,299	
Services	205,201	102,144
<b>Total consolidated revenues to external customers</b>	<b>\$ 2,730,121</b>	<b>\$ 1,716,229</b>

(1) The following table displays our devices revenue by geography (in thousands). International revenues were not material to any of our other segments for any of the years presented.

	2011	2010
<b>Devices:</b>		
United States	\$ 202,462	\$
International	97,837	
<b>Total devices revenues</b>	<b>\$ 300,299</b>	<b>\$</b>

*Branded Pharmaceuticals.* Net sales during 2011 increased 13% to \$1,657.8 million from \$1,467.6 million in 2010. This increase was primarily driven by increased revenues from Opana<sup>®</sup> ER, Lidoderm<sup>®</sup> and Voltaren<sup>®</sup> Gel, partially offset by decreased revenues from Percocet<sup>®</sup> and certain other brands.

*Generics.* Net sales of our generic products in 2011 increased by \$420.3 million or 287% to \$566.9 million from \$146.5 million in 2010. This increase was primarily driven by our acquisition of Qualitest on November 30, 2010. Qualitest products contributed \$446.2 million of net sales of generic products in 2011, compared with \$30.3 million in 2010.

*Devices.* Revenues from our devices business in 2011 were \$300.3 million and were primarily attributable to sales of products from our AMS subsidiary, which we acquired in June 2011. AMS products that represented approximately 1% or more of our consolidated total revenues in 2011 included the AMS 700<sup>®</sup> series of inflatable prostheses, the AMS 800<sup>®</sup> artificial urinary sphincter, the GreenLight<sup>™</sup> laser therapy products used to treat BPH, the Monarc<sup>®</sup> subfascial hammock and the Elevate<sup>™</sup> anterior pelvic floor repair system.

*Services.* Revenues from our services business in 2011 increased by \$103.1 million to \$205.2 million from \$102.1 million in 2010. This increase was driven by the full-year impact of HealthTronics, which contributed six months of revenue in 2010 compared to a full year of revenue in 2011. The \$205.2 million consisted primarily of lithotripsy fees of \$110.2 million, cryosurgery treatment fees of \$26.0 million and other service revenues from our HealthTronics business.

**Adjusted income (loss) before income tax**

The following table displays our adjusted income (loss) before income tax by reportable segment and for 2011 and 2010 (in thousands):

2011	2010
------	------

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

Branded Pharmaceuticals	\$ 890,951	\$ 757,453
Generics	107,204	24,722
Devices	82,418	
Services	68,769	35,538
Corporate unallocated	(318,100)	(194,459)
Total consolidated adjusted income before income tax	\$ 831,242	\$ 623,254

**Table of Contents**

*Branded Pharmaceuticals.* Adjusted income before income tax during 2011 increased 18% to \$891.0 million from \$757.5 million in 2010. This increase was primarily driven by increased revenues from our Branded Pharmaceuticals segment as well as the decrease in the royalty expense to Penwest from \$29.8 million during 2010 to zero during 2011. This royalty was eliminated upon our acquisition of Penwest in the third quarter of 2010.

*Generics.* Adjusted income before income tax during 2011 increased 334% to \$107.2 million from \$24.7 million in 2010. This increase was primarily driven by increased revenues from our Qualitest acquisition as well as decreased research and development expense as a percentage of revenues.

*Devices.* Adjusted income before income tax during 2011 was \$82.4 million and was attributable to our AMS subsidiary, which we acquired in June 2011.

*Services.* Adjusted income before income tax during 2011 was \$68.8 million compared to \$35.5 million in 2010. This increase was driven by our acquisition of HealthTronics, which contributed six months of results in 2010 compared to a full year in 2011.

*Corporate unallocated.* Corporate unallocated adjusted loss before income tax during 2011 increased 64% to \$318.1 million from \$194.5 million in 2010, which is primarily attributable to the overall growth of our business and the related increase in corporate costs, including increases in net interest expense of \$101.4 million.

*Reconciliation to GAAP.* The table below provides reconciliations of our consolidated adjusted income (loss) before income tax to our consolidated income before income tax, which is determined in accordance with U.S. GAAP, for the years ended December 31, 2011 and 2010 (in thousands):

	Twelve Months Ended December 31,	
	2011	2010
Total consolidated adjusted income before income tax	\$ 831,242	\$ 623,254
Upfront and milestone payments to partners	(28,098)	(23,850)
Acquisition-related items, net	(33,638)	(18,976)
Cost reduction initiatives	(21,821)	(17,245)
Asset impairment charges	(116,089)	(35,000)
Amortization of intangible assets related to marketed products and customer relationships	(190,969)	(83,974)
Inventory step-up	(49,438)	(6,289)
Non-cash interest expense	(18,952)	(16,983)
Loss on extinguishment of debt, net	(11,919)	
Accrual for unfavorable court decision for litigation	(11,263)	
Other income (expense), net	2,636	(239)
Total consolidated income before income tax	\$ 351,691	\$ 420,698

**Year Ended December 31, 2010 Compared to the Year Ended December 31, 2009****Revenues**

The following table displays our revenue by reportable segment for 2010 and 2009 (in thousands):

	2010	2009
Branded Pharmaceuticals	\$ 1,467,572	\$ 1,336,110
Generics	146,513	124,731
Devices		
Services	102,144	

Total revenues	\$ 1,716,229	\$ 1,460,841
----------------	--------------	--------------



**Table of Contents**

*Branded Pharmaceuticals.* Net sales during 2010 increased 10% to \$1,467.6 million from \$1,336.1 million in 2009. This increase was primarily driven by increased revenues of Lidoderm®, Opana® ER and Opana® and Voltaren® Gel. Also, included in the 2010 amount are the full-year revenues from the products we acquired, including Supprelin® LA and other brands, from Indevus. This compares to a partial year in 2009 as the revenue from Indevus products was included from February 23, 2009 through December 31, 2009.

*Generics.* Net sales during 2010 increased 17% to \$146.5 million from \$124.7 million in 2009. This increase was primarily driven by our acquisition of Qualitest in November 2010, which contributed \$30.3 million of net sales to our Generics segment in 2010. This increase was partially offset by a shortage of other competing generic opioids in the market during the first half of 2009, which was an anomaly and did not recur to the same extent during 2010.

*Services.* Revenue during 2010 was \$102.1 million. This amount consists of revenues from the acquisition of HealthTronics in July 2010.

**Adjusted income (loss) before income tax**

The following table displays our adjusted income (loss) before income tax by reportable segment and for 2010 and 2009 (in thousands):

	<b>2010</b>	<b>2009</b>
Branded Pharmaceuticals	\$ 757,453	\$ 642,997
Generics	24,722	28,557
Devices		
Services	35,538	
Corporate unallocated	(194,459)	(174,994)
Total consolidated adjusted income before income tax	\$ 623,254	\$ 496,560

*Branded Pharmaceuticals.* Adjusted income (loss) before income tax during 2010 increased 18% to \$757.5 million from \$643.0 million in 2009. This increase was primarily driven by increased revenues from our Branded Pharmaceuticals segment as well as decreases in operating expenses as a result of companywide cost reduction initiatives, particularly related to sales and marketing.

*Generics.* Adjusted income (loss) before income tax during 2010 decreased 13% to \$24.7 million from \$28.6 million in 2009. This decrease was primarily driven by the operating expenses related to our acquisition of Qualitest in November 2010, as well as investments that the company is making in the legacy Endo generics portfolio. These amounts were partially offset by increased revenues from our Generics business in 2010 compared to 2009.

*Services.* Adjusted income (loss) before income tax during 2010 was \$35.5 million. This amount consists of the operating results of HealthTronics, which we acquired in July 2010.

*Corporate unallocated.* Corporate unallocated adjusted loss before income tax during 2010 increased 11% to \$194.5 million from \$175.0 million in 2009. Corporate unallocated adjusted loss before income tax as a percent of consolidated total revenues decreased to 11.3% in 2010 compared to 12.0% in 2009. These fluctuations were primarily driven by the continued growth of the business in 2010, partially offset by the favorable impact of companywide cost reduction initiatives.

**Table of Contents**

*Reconciliation to GAAP.* The table below provides reconciliations of our consolidated adjusted income (loss) before income tax to our consolidated income before income tax, which is determined in accordance with U.S. GAAP, for the years ended December 31, 2010 and 2009 (in thousands):

	Twelve Months Ended December 31,	
	2010	2009
Total consolidated adjusted income before income tax	\$ 623,254	\$ 496,560
Upfront and milestone payments to partners	(23,850)	(77,099)
Acquisition-related items, net	(18,976)	93,081
Cost reduction initiatives	(17,245)	(2,549)
Asset impairment charges	(35,000)	(69,000)
Amortization of intangible assets related to marketed products and customer relationships	(83,974)	(62,931)
Inventory step-up	(6,289)	(11,268)
Non-cash interest expense	(16,983)	(14,719)
Gain on extinguishment of debt, net		4,025
Other (expense) income, net	(239)	3,560
<b>Total consolidated income before income tax</b>	<b>\$ 420,698</b>	<b>\$ 359,660</b>

**LIQUIDITY AND CAPITAL RESOURCES**

Our principal source of liquidity is cash generated from operations. Our principal liquidity requirements are for working capital for operations, licenses, milestone payments, capital expenditures and debt service payments. The Company continues to maintain a sufficient level of working capital, which was approximately \$666.3 million at December 31, 2011 compared to \$623.7 million and \$808.4 million at December 31, 2010 and 2009, respectively. Historically, we have generated positive cash flow from operating activities and have had broad access to financial markets that provide liquidity. Cash, cash equivalents and current marketable securities were approximately \$547.6 million at December 31, 2011 compared to \$466.2 million and \$733.7 million at December 31, 2010 and 2009, respectively. Cash and cash equivalents at December 31, 2011, 2010 and 2009 primarily consisted of bank deposits, time deposits and money market funds.

In 2012, we expect that sales of our currently marketed branded and generic products as well as our devices and our services will allow us to continue to generate positive cash flow from operations. We expect cash generated from operations together with our cash, cash equivalents and current marketable securities to be sufficient to cover cash needs for working capital, general corporate expenses, the payment of contractual obligations, including scheduled principal and interest payments on our outstanding borrowings, capital expenditures, common stock repurchases, if any, and any regulatory and/or sales milestones that may become due.

Beyond 2012, we expect cash generated from operations together with our cash, cash equivalents and marketable securities to continue to be sufficient to cover cash needs for working capital and general corporate purposes, certain acquisitions of other businesses, including the potential payments of up to approximately \$336.5 million in contingent cash consideration payments related to our acquisitions of Indevus and Qualitest, products, product rights, or technologies, the payment of contractual obligations, including principal and interest payments on our indebtedness and our Revolving Credit Facility (defined below), and certain minimum royalties due to Novartis and the regulatory 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. Any of the above could adversely affect our future cash flows. We may need to obtain additional funding for future strategic 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.

---

**Table of Contents**

We may also elect to incur additional debt or issue equity or convertible securities to finance ongoing operations, acquisitions or to meet our other liquidity needs. 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.

A description of our current debt agreements is below.

**Credit Facility.** On June 17, 2011, the Company terminated its existing credit facility and established a \$1,500 million, five-year senior secured term loan facility (the Term Loan A Facility), a \$700 million, seven-year senior secured term loan facility (the Term Loan B Facility, and, together with the Term Loan A Facility, the Term Loan Facilities), and a \$500 million, five-year senior secured revolving credit facility (the 2011 Revolving Credit Facility and, together with the Term Loan Facilities, the 2011 Credit Facility) with Morgan Stanley Senior Funding, Inc., as administrative agent, Bank of America, N.A., as Syndication Agent, and certain other lenders. The 2011 Credit Facility was established primarily to finance our acquisition of AMS and is available for working capital, general corporate purposes and lines of credit. The agreement governing the 2011 Credit Facility (the 2011 Credit Agreement) also permits up to \$500 million of additional revolving or term loan commitments from one or more of the existing lenders or other lenders with the consent of Morgan Stanley Senior Funding, Inc. (the administrative agent) without the need for consent from any of the existing lenders under the 2011 Credit Facility.

The obligations of the Company under the 2011 Credit Facility are guaranteed by certain of the Company's domestic subsidiaries and are secured by substantially all of the assets of the Company and the subsidiary guarantors. The 2011 Credit Facility contains certain usual and customary covenants, including, but not limited to covenants to maintain maximum leverage and minimum interest coverage ratios. Borrowings under the 2011 Credit Facility bear interest at an amount equal to a rate calculated based on the type of borrowing and the Company's Leverage Ratio. For term A loans and revolving loans (other than Swing Line Loans), the Company is permitted to elect to pay interest based on an adjusted LIBOR rate plus between 1.75% and 2.50% or an Alternate Base Rate (as defined in the 2011 Credit Agreement) plus between 0.75% and 1.50%. For term B loans, the Company may elect to pay interest based on an adjusted LIBOR rate plus 3.00% or an Alternate Base Rate plus 2.00%. The Company will pay a commitment fee of between 37.5 to 50 basis points, payable quarterly, on the average daily unused amount of the Revolving Credit Facility.

In September 2011 and December 2011, we made prepayments of \$135.0 million and \$125.0 million, respectively, on our Term Loan B Facility. Pursuant to our rights under the 2011 Credit Agreement, we elected to apply a portion of the September 2011 prepayment against all remaining contractual payments such that we had no remaining principal payment obligations until the maturity of the Term Loan B Facility on June 17, 2018.

**7.00% Senior Notes Senior Notes due 2019.** On June 8, 2011, we entered into an indenture among the Company, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, which governs the terms of the Company's \$500.0 million aggregate principal amount of 7.00% Senior Notes due 2019 (the 2019 Notes). The 2019 Notes were issued in a private offering exempt from the registration requirements of the Securities Act of 1933, as amended (the Securities Act) to qualified institutional buyers in accordance with Rule 144A and to persons outside of the U.S. pursuant to Regulation S under the Securities Act. The 2019 Notes are senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain of the Company's domestic subsidiaries. The Company used the net proceeds of the 2019 Notes offering to partially finance the acquisition of AMS, and to pay related fees and expenses.

The 2019 Notes bear interest at a rate of 7.00% per year, accruing from June 8, 2011. Interest on the 2019 Notes is payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2012. The 2019 Notes will mature on July 15, 2019, subject to earlier repurchase or redemption in accordance with the terms of the indenture governing the 2019 Notes. The indenture governing the 2019 Notes contains covenants

## Table of Contents

that, among other things, restrict the Company's ability and the ability of certain of its restricted subsidiaries to incur certain additional indebtedness and issue preferred stock; make certain dividends, distributions, investments and other restricted payments; sell certain assets; agree to any restrictions on the ability of restricted subsidiaries to make payments to the Company; create certain liens; enter into transactions with affiliates; designate subsidiaries as unrestricted subsidiaries; and consolidate, merge or sell substantially all of the Company's assets. 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 2019 Notes receiving investment grade credit ratings.

**7.00% Senior Notes Senior Notes due 2020.** On November 23, 2010, we entered into an indenture among the Company, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, which governs the terms of the Company's \$400.0 million aggregate principal amount of 7.00% Senior Notes due 2020 (the 2020 Notes). The 2020 Notes were issued in a private offering exempt from the registration requirements of the Securities Act of 1933, as amended (the Securities Act) to qualified institutional buyers in accordance with Rule 144A and to persons outside of the U.S. pursuant to Regulation S under the Securities Act. The 2020 Notes are senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain of the Company's domestic subsidiaries. The Company used the net proceeds of the 2020 Notes offering to partially finance the acquisition of Qualitest, and to pay related fees and expenses.

The 2020 Notes bear interest at a rate of 7.00% per year, accruing from November 23, 2010. Interest on the 2020 Notes is payable semiannually in arrears on June 15 and December 15 of each year, beginning on June 15, 2011. The 2020 Notes will mature on December 15, 2020, subject to earlier repurchase or redemption in accordance with the terms of the indenture governing the 2020 Notes. The indenture governing the 2020 Notes contains covenants that, among other things, restrict the Company's ability and the ability of certain of its restricted subsidiaries to incur certain additional indebtedness and issue preferred stock; make certain dividends, distributions, investments and other restricted payments; sell certain assets; agree to any restrictions on the ability of restricted subsidiaries to make payments to the Company; create certain liens; enter into transactions with affiliates; designate subsidiaries as unrestricted subsidiaries; and consolidate, merge or sell substantially all of the Company's assets. 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 2020 Notes receiving investment grade credit ratings.

**7.25% Senior Notes Senior Notes due 2022.** On June 8, 2011, we entered into an indenture among the Company, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, which governs the terms of the Company's \$400.0 million aggregate principal amount of 7.25% Senior Notes due 2022 (the 2022 Notes). The 2022 Notes were issued in a private offering exempt from the registration requirements of the Securities Act of 1933, as amended (the Securities Act) to qualified institutional buyers in accordance with Rule 144A and to persons outside of the U.S. pursuant to Regulation S under the Securities Act. The 2022 Notes are senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain of the Company's domestic subsidiaries. The Company used the net proceeds of the 2022 Notes offering to partially finance the acquisition of AMS, and to pay related fees and expenses.

The 2022 Notes bear interest at a rate of 7.25% per year, accruing from June 8, 2011. Interest on the 2022 Notes is payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2012. The 2022 Notes will mature on January 15, 2022, subject to earlier repurchase or redemption in accordance with the terms of the indenture governing the 2022 Notes. The indenture governing the 2022 Notes contains covenants that, among other things, restrict the Company's ability and the ability of certain of its restricted subsidiaries to incur certain additional indebtedness and issue preferred stock; make certain dividends, distributions, investments and other restricted payments; sell certain assets; agree to any restrictions on the ability of restricted subsidiaries to make payments to the Company; create certain liens; enter into transactions with affiliates; designate subsidiaries as unrestricted subsidiaries; and consolidate, merge or sell substantially all of the Company's assets. 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 2022 Notes receiving investment grade credit ratings.

## Table of Contents

**2011 Exchange Offer.** On October 14, 2011, the Company filed a Form S-4 Registration Statement with the Securities and Exchange Commission. On October 31, 2011, it filed a prospectus pursuant to Rule 424(b)(3). Pursuant to both filings, the Company offered to exchange the 2019 Notes, 2020 Notes and 2022 Notes for a like principal amount of new notes having identical terms that have been registered under the Securities Act of 1933, as amended. On November 30, 2011, 100% of the 2019 Notes, 2020 Notes and 2022 Notes had been properly tendered in the exchange offer and not withdrawn.

**1.75% Convertible Senior Subordinated Notes due 2015.** As discussed in Note 18. Debt, in the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K, in April 2008, we issued \$379.5 million in aggregate principal amount of 1.75% Convertible Senior Subordinated Notes due April 15, 2015 (the Convertible Notes) in a private offering for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended.

Holders of the Convertible Notes may convert their notes based on a conversion rate of 34.2466 shares of our common stock per \$1,000 principal amount of notes (the equivalent of \$29.20 per share), subject to adjustment upon certain events, only under the following circumstances as described in the indenture for the Convertible Notes: (1) during specified periods, if the price of our common stock reaches specified thresholds; (2) if the trading price of the Convertible Notes is below a specified threshold; (3) at any time after October 15, 2014; or (4) upon the occurrence of certain corporate transactions. We will be permitted to deliver cash, shares of Endo common stock or a combination of cash and shares, at our election, to satisfy any future conversions of the notes. It is our current intention to settle the principal amount of any conversion consideration in cash.

The Convertible Notes are only included in the dilutive net income per share calculation using the treasury stock method during periods in which the average market price of our common stock was above the applicable conversion price of the Convertible Notes, or \$29.20 per share. 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 stock during the period, and included that number in the total diluted shares outstanding for the period.

We have entered into convertible note hedge and warrant agreements that, in combination, have the economic effect of reducing the dilutive impact of the Convertible Notes. However, we separately analyze 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 are excluded because their impact would be anti-dilutive. The treasury stock method is applied when the warrants are in-the-money with the proceeds from the exercise of the warrant used to repurchase shares based on the average stock price in the calculation of diluted weighted average shares. Until the warrants are in-the-money, they have no impact to the diluted weighted average share calculation. The total number of shares that could potentially be included if the warrants were exercised is approximately 13 million.

**Table of Contents**

The following table provides the range of shares that would be included in the dilutive net income per share calculation for the Convertible Notes and warrants based on share price sensitivity (in thousands except per share data):

	Three months ended March 31, 2011				Three months ended June 30, 2011			
	-5%	Actual	+5%	+10%	-5%	Actual	+5%	+10%
Average market price of Endo common stock:	\$ 33.20	\$ 34.95	\$ 36.70	\$ 38.45	\$ 38.13	\$ 40.14	\$ 42.15	\$ 44.15
<i>Impact on dilutive shares:</i>								
Convertible Notes	1,566	2,138	2,656	3,127	3,044	3,543	3,993	4,401
Warrants						46	663	1,222
	1,566	2,138(1)	2,656	3,127	3,044	3,589(1)	4,656	5,623

  

	Three months ended September 30, 2011				Three months ended December 31, 2011			
	-5%	Actual	+5%	+10%	-5%	Actual	+5%	+10%
Average market price of Endo common stock:	\$ 32.05	\$ 33.74	\$ 35.43	\$ 37.11	\$ 30.53	\$ 32.14	\$ 33.75	\$ 35.35
<i>Impact on dilutive shares:</i>								
Convertible Notes	1,156	1,750	2,285	2,770	566	1,187	1,752	2,261
Warrants								
	1,156	1,750(1)	2,285	2,770	566	1,187(1)	1,752	2,261

(1) Amount included in total diluted shares outstanding of 120.8 million, 122.7 million, 120.8 million and 120.4 million for the respective three month periods ended March 31, 2011, June 30, 2011, September 30, 2011 and December 31, 2011.

In accordance with applicable guidance, we calculate our year-to-date basic and diluted shares outstanding using an average of each quarter's basic and diluted share amounts. Accordingly, the actual dilutive impact of our Convertible Notes and warrants for the year ended December 31, 2011 was 2.2 million shares.

**3.25% Convertible AMS Notes Due 2036 and 4.00% Convertible AMS Notes Due 2041.** As a result of our acquisition of AMS, the Company assumed AMS's 3.25% Convertible Notes due 2036 (the 2036 Notes) and 4.00% Convertible Notes due 2041 (the 2041 Notes and, together with the 2036 Notes, the AMS Notes). In accordance with the indentures governing the AMS Notes, the AMS Notes were immediately convertible upon the closing of Endo's acquisition of AMS. From the AMS Acquisition Date until the make whole premium on the 2036 Notes expired on August 9, 2011, we paid \$95.7 million to redeem \$61.4 million of the 2036 Notes at a stated premium of 1.5571. From the AMS Acquisition Date until the make whole premium on the 2041 Notes expired on August 1, 2011, we paid \$423.4 million to redeem \$249.9 million of the 2041 Notes at a stated premium of 1.6940. Our obligation remaining related to the AMS Notes is less than \$1.0 million at December 31, 2011, excluding accrued interest.

**Share Repurchase Program.** Pursuant to our previously announced \$750 million share repurchase plan, we may, from time to time, seek to repurchase our equity in open market purchases, privately-negotiated transactions, accelerated stock repurchase transactions or otherwise. This program does not obligate Endo to acquire any particular amount of common stock. Repurchase activity, if any, will depend on factors such as levels of cash generation from operations, cash requirements for investment in the Company's business, timing and extent of future business development activity, repayment of future debt, if any, current stock price, market conditions and other factors. The share repurchase program may be suspended, modified or discontinued at any time. As a result of a two-year extension approved by the Board of Directors in February 2012, the share repurchase plan is set to expire in April 2014. Pursuant to the existing share repurchase program, we purchased approximately 0.9 million shares of our common stock during 2011 totaling \$34.7 million and approximately 2.5 million shares of our common stock during 2010 totaling \$59.0 million.



**Table of Contents**

**Employee Stock Purchase Plan.** At our Annual Meeting of Stockholders held in May of 2011, our shareholders approved the Endo Pharmaceuticals Holdings Inc. Employee Stock Purchase Plan (the ESPP). The 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 percent of their eligible compensation, subject to certain limitations, to purchase shares of common stock at 85 percent of the lower of the closing price of Endo common stock 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 share of our common stock on the first day of the offering period, subject to certain adjustments. Compensation expense will be calculated in accordance with the applicable accounting guidance and will be 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 one percent 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 of Stock 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.

The ESPP became effective on May 25, 2011 when approved by the Company's stockholders, with the plan commencing on January 1, 2012. Accordingly, there was no impact to our Consolidated Financial Statements in 2011.

**Marketable Securities.** Beginning in 2008 and continuing through 2011, the securities and credit markets have been experiencing severe volatility and disturbance, increasing risk with respect to certain of our financial assets. As a result of our auction-rate securities rights agreement with UBS (described in more detail below), we have been able to minimize our credit risk losses. On June 30, 2010, we were able to exercise our auction-rate securities rights (the Rights), described below, with UBS and liquidate our remaining UBS auction-rate security portfolio at par value. At December 31, 2011 and 2010, \$18.8 million of our marketable securities portfolio was invested in auction-rate debt securities with ratings of AAA. Our investment policy seeks to preserve the value of capital, consistent with maximizing return on the Company's investment, while maintaining adequate liquidity and security. This policy specifically prohibits the investment in auction-rate securities as well as the investment in any security that is below investment grade. However, such restrictions were implemented on a prospective basis and did not impact the Company's ability to continue to hold the auction-rate securities it was invested in when the amended investment policy was adopted.

The underlying assets of our auction-rate securities are student loans. Student loans are insured by the Federal Family Education Loan Program, or FFELP. As of December 31, 2011, the yields on our long-term auction-rate securities were 0.24%. These yields represent the predetermined maximum reset rates that occur upon auction failures according to the specific terms within each security's prospectus. Total interest recognized on our auction-rate securities during 2011, 2010 and 2009 was less than \$0.1 million, \$0.7 million and \$2.4 million, respectively. The issuers have been making interest payments promptly.

The Company determined that an income approach (present value technique) that maximizes the use of observable market inputs is the preferred approach to measuring the fair value of our securities. Specifically, the Company used the discount rate adjustment technique to determine an indication of fair value.

To calculate a price for our auction-rate securities, the Company calculates duration to maturity, coupon rates, market required rates of return (discount rate) and a discount for lack of liquidity in the following manner:

The Company identifies the duration to maturity of the auction-rate securities as the time at which principal is available to the investor. This can occur because the auction-rate security is paying a coupon that is above the required rate of return, and the Company treats the security as being called. It can also occur because the market has returned to normal and the Company treats the auctions as



**Table of Contents**

having recommenced. Lastly, and most frequently, the Company treats the principal as being returned as prepayment occurs and at the maturity of the security. The initial life used for each remaining security, representing time to maturity, was eight years as of December 31, 2011 and December 31, 2010.

The Company calculates coupon rates based on estimated relationships between the maximum coupon rate (the coupon rate in event of a failure) and market interest rates. The representative coupon rate was 3.61% on December 31, 2011 and 5.10% at December 31, 2010. The Company calculates appropriate discount rates for securities that include base interest rates, index spreads over the base rate, and security-specific spreads. These spreads include the possibility of changes in credit risk over time. The spread over the base rate applied to our securities was 204 basis points at December 31, 2011 and 218 basis points at December 31, 2010.

The Company believes that a market participant would require an adjustment to the required rate of return to adjust for the lack of liquidity. We do not believe it is unreasonable to assume a 150 basis points adjustment to the required rate of return and a term of either three, four or five years to adjust for this lack of liquidity. The increase in the required rate of return decreases the prices of the securities. However, the assumption of a three, four or five-year term shortens the times to maturity and increases the prices of the securities. The Company has evaluated the impact of applying each term and the reasonableness of the range indicated by the results. The Company chose to use a four-year term to adjust for the lack of liquidity as we believe it is the point within the range that is most representative of fair value. The Company's conclusion is based in part on the fact that the fair values indicated by the results are reasonable in relation to each other given the nature of the securities and current market conditions.

At December 31, 2011, the fair value of our auction-rate securities, as determined by applying the above described discount rate adjustment technique, was approximately \$17.5 million, representing a 7%, or \$1.3 million discount from their original purchase price or par value. This compares to approximately \$17.3 million, representing an 8%, or \$1.5 million discount from their original purchase price or par value at December 31, 2010. Had the Company chosen to apply a three or five year term with respect to the liquidity adjustment at December 31, 2011, the resultant fair values would have been \$17.2 million and \$17.8 million, respectively. We believe we have appropriately reflected our best estimate of the assumptions that market participants would use in pricing the assets in a current transaction to sell the asset at the measurement date.

Given the uncertainty in the auction-rate securities market, the Company cannot predict when future auctions related to our existing auction-rate securities portfolio will be successful. However, we do not employ an asset management strategy or tax planning strategy that would require us to sell any of our existing securities at a loss. Furthermore, there have been no adverse changes in our business or industry that could require us to sell the securities at a loss in order to meet working capital requirements.

At December 31, 2011 and December 31, 2010, the fair value of our auction-rate securities rights was zero.

**Working Capital.** Working capital increased to \$666.3 million as of December 31, 2011 from \$623.7 million as of December 31, 2010. The components of our working capital for the years ended December 31, are below (in thousands):

	2011	2010	2009
Total current assets	\$ 1,788,096	\$ 1,359,534	\$ 1,280,581
Less: Total current liabilities	(1,121,778)	(735,828)	(472,180)
Working capital	\$ 666,318	\$ 623,706	\$ 808,401

**Table of Contents**

Working capital increased slightly from 2010 to 2011 primarily as a result of the current assets and liabilities assumed in connection with our second quarter 2011 acquisition of AMS and the net cash retained from our 2011 financings to acquire AMS. These amounts were partially offset by the use of cash to prepay \$260.0 million of our Term Loan indebtedness.

Working capital decreased from 2009 to 2010 primarily as a result of expenditures for our acquisitions of HealthTronics, Penwest, and Qualitest. The acquisitions were further offset by the operating results of HealthTronics, Penwest, and Qualitest, and the sale of \$230.3 million of auction-rate debt securities, \$205.0 million of which were non-current assets as of December 31, 2009.

The following table summarizes our statement of cash flows and liquidity (dollars in thousands):

	2011	2010	2009
Net cash flow provided by (used in):			
Operating activities	\$ 702,115	\$ 453,646	\$ 295,406
Investing activities	(2,374,092)	(896,323)	(245,509)
Financing activities	1,752,681	200,429	(117,128)
Effect of foreign exchange rate	702		
Net (decrease) increase in cash and cash equivalents	81,406	(242,248)	(67,231)
Cash and cash equivalents, beginning of period	466,214	708,462	775,693
Cash and cash equivalents, end of period	\$ 547,620	\$ 466,214	\$ 708,462

Current ratio	1.6:1	1.8:1	2.7:1
Days sales outstanding	45	46	43

**Net Cash Provided by Operating Activities.** Net cash provided by operating activities was \$702.1 million for the year ended December 31, 2011, a 55% increase from 2010. Net cash provided by operating activities was \$453.6 million for the year ended December 31, 2010, a 54% increase from the comparable 2009 period. Significant components of our operating cash flows for the years ended December 31, are as follows (in thousands):

	2011	2010	2009
<b>Cash Flow Data-Operating Activities:</b>			
Net income	\$ 242,065	\$ 287,020	\$ 266,336
Depreciation and amortization	237,414	108,404	80,381
Stock-based compensation	46,013	22,909	19,593
Change in fair value of acquisition-related contingent consideration	(7,363)	(51,420)	(128,090)
Asset impairment charges	116,089	35,000	69,000
Loss on auction-rate securities rights		15,659	11,662
Unrealized gain on trading securities		(15,420)	(15,222)
Loss (gain) on extinguishment of debt	11,919		(4,025)
Changes in assets and liabilities which provided cash	99,581	43,672	12,428
Other, net	(43,603)	7,822	(16,657)
Net cash provided by operating activities	\$ 702,115	\$ 453,646	\$ 295,406

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. Operating cash flow is derived by adjusting net income for noncontrolling interests, non-cash operating items, gains and losses attributed to investing and financing activities and changes in operating assets and liabilities resulting from timing differences between the receipts and payments of cash and when the transactions are recognized in our results of operations. As a result, changes in cash from operating activities reflect, among other things, the timing of cash collections from



## Table of Contents

customers, payments to suppliers, managed care organizations and government agencies, collaborative partners, employees, and tax payments in the ordinary course of business. Our operating cash flow benefited from a full year of cash from operations from our Qualitest acquisition and from a partial year of cash generated from AMS operations. In addition, net cash provided by operations was higher due in part to timing and an increasing lag in payments to managed care organizations attributed to government agencies' administrative delays.

**Net Cash (Used in) Investing Activities.** Net cash used in investing activities was \$2,374.1 million for the year ended December 31, 2011 compared to \$896.3 million and \$245.5 million for the years ended December 31, 2010 and 2009, respectively.

The increase in cash used in investing activities in 2011 compared to 2010 is primarily related to net cash paid for the acquisition of AMS of \$2.4 billion in 2011 compared to \$1.1 billion in 2010. Additionally, sales of trading securities and other investments in 2011 totaled \$85.0 million in 2011 compared to \$231.1 million in 2010.

The increase in cash used in investing activities in 2010 compared to 2009 is primarily related to cash consideration paid for the acquisitions of HealthTronics, Penwest, and Qualitest of \$1,105.0 million, net of cash acquired, compared to \$250.4 million of cash used for the Indevus transaction in 2009. The 2010 amounts were offset slightly due to the proceeds received of \$231.1 million for sales of our auction-rate and available for sale securities compared to \$23.8 million in 2009.

**Net Cash Provided by (Used in) Financing Activities.** Net cash provided by financing activities was \$1,752.7 million in 2011 compared to \$200.4 million in 2010 and \$117.1 million used in financing activities in 2009.

The increase in cash provided by financing activities from 2010 to 2011 is primarily a result of our new borrowings during 2011 of \$3,018.0 million, which is net of debt issuance costs of \$82.5 million, partially offset by payments on our Term Loan Facilities of \$689.9 million and the AMS Notes of \$519.0 million.

The change from 2009 to 2010 is primarily a result of the Company's issuance of \$786.6 million of new indebtedness, net of debt issuance and transactions costs. The 2010 cash inflow was partially offset by \$59.0 million related to share repurchases, \$61.6 million in payments to redeem the remaining Non-recourse notes, a \$40.2 million payment in July of 2010 to retire the HealthTronics senior credit facility, and a \$406.8 million payment in November 2010 to retire Qualitest's debt then outstanding under its senior credit facility as well as the associated interest rate swap. Additionally, during 2010, the exercise of equity awards provided \$20.9 million of cash flows from financing activities compared to \$8.0 million in 2009.

**Research and Development.** Over the past few years, we have incurred significant expenditures related to conducting clinical studies to develop new pharmaceutical products and exploring the value of our existing products in treating disorders beyond those currently approved in their respective labels. We may seek to mitigate the risk in, and expense of, our research and development programs by entering into collaborative arrangements with third parties. However, we intend to retain a portion of the commercial rights to these programs and, as a result, we still expect to spend significant funds on our share of the cost of these programs, including the costs of research, preclinical development, clinical research and manufacturing.

We expect to continue to incur significant levels of research and development expenditures as we focus on the development and advancement of our product and services pipeline. There can be no assurance that results of any ongoing or future preclinical or clinical trials related to these projects will be successful, that additional trials will not be required, that any drug or product under development will receive FDA approval in a timely manner or at all, or that such drug or product could be successfully manufactured in accordance with U.S. current Good Manufacturing Practices or successfully marketed in a timely manner, or at all, or that we will have sufficient funds to develop or commercialize any of our products.

**Table of Contents**

***Manufacturing, Supply and Other Service Agreements.*** We contract with various third-party manufacturers and suppliers to provide us with raw materials used in our products, finished goods and certain services. Our most significant agreements are with Novartis Consumer Health, Inc., Novartis AG, Teikoku Seiyaku Co., Ltd., Mallinckrodt Inc., Noramco, Inc., Sharp Corporation, and Ventiv Commercial Services, LLC. As a result of a temporary shutdown by Novartis Consumer Health Division of its manufacturing facility which manufactures Opana® ER, among other products, we are expediting the production of our recently approved formulation of Opana® ER, designed to be crush-resistant, at a manufacturing facility managed by our development partner, Grünenthal. 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, it could have a material adverse effect on our business, financial condition, results of operations and cash flows. For a complete description of commitments under 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 Annual Report on Form 10-K.

***License and Collaboration Agreements.*** We have agreed to certain contingent payments in certain of our license, collaboration and other agreements. Payments under these agreements generally become due and payable only upon the achievement of certain developmental, regulatory, commercial and/or other milestones. Due to the fact that it is uncertain if and when these milestones will be achieved, such contingencies have not been recorded in our Consolidated Balance Sheets and are not reflected in the expected cash requirements for Contractual Obligations table below. In addition, under certain arrangements, we 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. For a complete description of our contingent payments involving our license and collaboration agreements, see Note 7. License and Collaboration Agreements and Note 14. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

***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 stock 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.

***AMS***

On June 17, 2011 (the AMS Acquisition Date), the Company completed its acquisition of all outstanding shares of common stock of AMS for approximately \$2.4 billion in aggregate consideration, including \$70.8 million related to existing AMS stock-based compensation awards and certain other amounts, at which time AMS became a wholly-owned subsidiary of the Company. AMS's shares were purchased at a price of \$30.00 per share.

AMS is a worldwide developer and provider of technology solutions to physicians treating men's and women's pelvic health conditions. The AMS business and applicable services include:

***Men's Health.***

AMS supplies surgical solutions for the treatment of male urinary incontinence, the involuntary release of urine from the body. The fully implantable AMS 800® system includes an inflatable urethral cuff to restrict flow through the urethra and a control pump that allows the patient to discreetly open the cuff when he wishes to urinate. Since 2000, AMS has also been selling the InVance® sling system, a less-invasive procedure for men with moderate incontinence, and in 2007, AMS released the Advance® sling system for the treatment of mild to

---

## **Table of Contents**

moderate stress urinary incontinence. AMS also offers the UroLume® endoprosthesis stent as a less invasive procedure for patients who may not be good surgical candidates, as well as for men suffering from bulbar urethral strictures.

AMS also supplies penile implants to treat erectile dysfunction, the inability to achieve or maintain an erection sufficient for sexual intercourse, with a series of semi-rigid malleable prostheses and a complete range of more naturally functioning inflatable prostheses, including the AMS 700® MS. AMS has refined its implants over the years with improvements to the AMS 700® series of inflatable prostheses, including the AMS 700 LGX® and the MS Pump®. Another key factor that distinguishes AMS's products is the use of the InhibiZon® antibiotic coating, which received FDA approval in July 2009 for AMS's product claim that InhibiZon® reduces the rate of revision surgery due to surgical infections.

### *Women's Health.*

AMS offers a broad range of systems, led by Monarc® and MiniArc®, 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. Monarc® incorporates unique helical needles to place a self-fixating, sub-fascial hammock through the obturator foramin. AMS's MiniArc® Single-Incision Sling for stress incontinence was released in 2007 and requires just one incision to surgically place a small sling under the urethra, which minimizes tissue disruption and potential for blood loss, thereby allowing the procedure to be done with less anesthesia on an outpatient basis. In 2010, AMS launched the MiniArc Precise™, which is designed to enhance the ease and accuracy of placement of the MiniArc® device.

AMS also offers solutions for pelvic floor prolapse and other pelvic floor disorders, which may be caused by pregnancy, labor, and childbirth. In 2008, AMS introduced the Elevate® transvaginal pelvic floor repair system, with no external incisions. Using an anatomically designed needle and self-fixating tips, Elevate® allows for safe, simple and precise mesh placement through a single vaginal incision. The posterior system was launched in 2008 and the anterior system was launched in 2009.

### *BPH Therapy.*

AMS's products can be used to relieve restrictions on the normal flow of urine from the bladder caused by bladder obstructions, generally the result of BPH or bulbar urethral strictures. AMS offers men experiencing a physical obstruction of the prostatic urethra an alternative to a TURP, with the GreenLight™ photovaporization of the prostate. This laser therapy is designed to reduce the comorbidities associated with TURP. AMS's GreenLight™ XPS and MoXy™ Liquid Cooled Fiber provide shorter treatment times with similar long-term results compared to other laser systems. The GreenLight™ laser system offers an optimal laser beam that balances vaporization of tissue with coagulation to prevent blood loss and providing enhanced surgical control compared to other laser systems. AMS also offers the StoneLight® laser and SureFlex™ fiber optics for the treatment of urinary stones. StoneLight® is a lightweight and portable 15-watt holmium laser that offers the right amount of power to effectively fragment most urinary stones. The SureFlex™ fiber optic line is engineered to deliver more energy safely and effectively, even under maximum scope deflection, for high performance holmium laser lithotripsy.

AMS's TherMatrx® product is designed for those men not yet to the point of urethral obstruction, but for whom symptomatic relief is desired. It is a less-invasive tissue ablation technique that can be performed in a physician's office using microwave energy delivered to the prostate.

The acquisition of AMS furthers Endo's evolution from a pharmaceutical product-driven company to a healthcare solutions provider, strengthens our leading core urology franchise and expands our presence in the medical devices market. We believe the combination of AMS with Endo's existing platform will provide additional cost-effective solutions across the entire urology spectrum.

**Table of Contents**

The operating results of AMS from and including June 18, 2011 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheet as of December 31, 2011 reflects the acquisition of AMS.

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

	June 17, 2011 (As initially reported)	Measurement period adjustments	June 17, 2011 (As adjusted)
Cash and cash equivalents	\$ 47,289	\$	\$ 47,289
Commercial paper	71,000		71,000
Accounts receivable	73,868		73,868
Other receivables	791	(161)	630
Inventories	75,525	(156)	75,369
Prepaid expenses and other current assets	7,133		7,133
Income taxes receivable	11,179	(1,712)	9,467
Deferred income taxes	15,360	(820)	14,540
Property, plant and equipment	57,372	(959)	56,413
Other intangible assets	1,390,000	(130,000)	1,260,000
Other assets	4,581		4,581
<b>Total identifiable assets</b>	<b>\$ 1,754,098</b>	<b>\$ (133,808)</b>	<b>\$ 1,620,290</b>
Accounts payable	\$ 9,437	\$ 890	\$ 10,327
Accrued expenses	45,648	187	45,835
Deferred income taxes	507,019	(90,384)	416,635
Long-term debt	520,012	363	520,375
Other liabilities	23,578		23,578
<b>Total liabilities assumed</b>	<b>\$ 1,105,694</b>	<b>\$ (88,944)</b>	<b>\$ 1,016,750</b>
<b>Net identifiable assets acquired</b>	<b>\$ 648,404</b>	<b>\$ (44,864)</b>	<b>\$ 603,540</b>
Goodwill	\$ 1,752,427	\$ 44,009	\$ 1,796,436
<b>Net assets acquired</b>	<b>\$ 2,400,831</b>	<b>\$ (855)</b>	<b>\$ 2,399,976</b>

The above estimated fair values of assets acquired and liabilities assumed are provisional and are based on the information that was available as of the AMS Acquisition Date to estimate the fair value of assets acquired and liabilities assumed. The Company believes that information provides a reasonable basis for estimating the fair values but the Company is waiting for additional information necessary to finalize those amounts, particularly with respect to the estimated fair value of intangible assets, property, plant and equipment, contingent assets and liabilities, and deferred income taxes. Thus, the provisional measurements of fair value reflected are subject to change. Such changes could be significant. The Company expects to finalize the valuation and complete the purchase price allocation as soon as practicable but no later than one year from the AMS Acquisition Date. Measurement period adjustments relate primarily to revisions in estimated cash flows for certain products after obtaining additional information regarding facts and circumstances existing as of the AMS Acquisition Date.

**Table of Contents**

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

	Valuation (in millions)	Amortization Period (in years)
<b>Customer Relationships:</b>		
Men's Health	\$ 97.0	17
Women's Health	37.0	15
BPH	26.0	13
Total	\$ 160.0	16
<b>Developed Technology:</b>		
Men's Health	\$ 690.0	18
Women's Health	150.0	9
BPH	161.0	18
Total	\$ 1,001.0	16
<b>Tradename:</b>		
AMS	\$ 45.0	30
GreenLight	12.0	15
Total	\$ 57.0	27
<b>In Process Research &amp; Development:</b>		
Oracle	\$ 12.0	n/a
Genesis	14.0	n/a
TOPAS	8.0	n/a
Other	8.0	n/a
Total	\$ 42.0	n/a
Total other intangible assets	\$ 1,260.0	n/a

The fair value of the developed technology, IPR&D and customer relationship 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 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 fair value of the AMS and GreenLight tradenames were estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to license the AMS or GreenLight tradename. Thus, we derived the hypothetical royalty income from the projected revenues of AMS and GreenLight products, respectively. Cash flows were assumed to extend through the remaining economic useful life of each class of intangible asset.

The \$1,796.4 million of goodwill has been assigned to our Devices segment. The goodwill recognized is attributable primarily to strategic and synergistic opportunities across the entire urology spectrum, expected corporate synergies, the assembled workforce of AMS and other factors. Approximately \$14.5 million of goodwill is expected to be deductible for income tax purposes.

Deferred tax assets of \$14.5 million are related primarily to federal net operating loss and credit carryforwards of AMS and its subsidiaries. Deferred tax liabilities of \$416.6 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.





**Table of Contents**

The Company recognized \$28.8 million of AMS acquisition-related costs that were expensed during 2011. These costs are included in Acquisition-related items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	<b>Acquisition-related Costs</b>	
	<b>Year Ended</b>	
	<b>December 31, 2011</b>	
Bank fees	\$	16,070
Legal, separation, integration, and other costs		12,684
<b>Total</b>	<b>\$</b>	<b>28,754</b>

The amounts of revenue and net loss of AMS included in the Company's Consolidated Statements of Operations from and including June 18, 2011 to December 31, 2011 are as follows (in thousands, except per share data):

	<b>Revenue and Income</b>	
	<b>included in the</b>	
	<b>Consolidated</b>	
	<b>Statements of</b>	
	<b>Operations from</b>	
	<b>and including June 18,</b>	
	<b>2011 to December 31, 2011</b>	
Revenue	\$	300,299
Net loss attributable to Endo Pharmaceuticals Holdings Inc.	\$	(329)
Basic and diluted net loss per share	\$	

The following supplemental pro forma information presents the financial results as if the acquisition of AMS had occurred on January 1, 2010 for the years ended December 31, 2011 and 2010. 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, 2010, nor are they indicative of any future results.

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>Pro forma consolidated results (in thousands, except per share data):</b>		
Revenue	\$ 2,968,497	\$ 2,259,104
Net income attributable to Endo Pharmaceuticals Holdings Inc.	\$ 214,487	\$ 199,776
Basic net income per share	\$ 1.84	\$ 1.72
Diluted net income per share	\$ 1.77	\$ 1.69

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of AMS to reflect factually supportable adjustments that give effect to events that are directly attributable to the AMS Acquisition, including the borrowing under the 2011 Credit Facility, 2019 Notes, and 2022 Notes as well as the additional depreciation and amortization that would have been charged assuming the fair value adjustments primarily to property, plant and equipment, inventory, and intangible assets, had been applied on January 1, 2010, together with the consequential tax effects.

**Qualitest**

On November 30, 2010 (the Qualitest Acquisition Date), Endo completed its acquisition of all of the issued and outstanding capital stock of Generics International (US Parent), Inc. (Qualitest) from an affiliate of Apax Partners, L.P. for approximately \$770.0 million. In addition, Endo

paid \$406.8 million to retire Qualitest's outstanding debt and related interest rate swap on November 30, 2010. In connection with the Qualitest

**Table of Contents**

acquisition, \$108 million of the purchase price was placed into two separate escrow accounts. One of the escrow accounts was \$8 million, some of which was used to fund working capital adjustments, as defined in the Qualitest Stock Purchase Agreement. This escrow was settled during the third quarter of 2011. There is also a \$100 million escrow account that will be used to fund all claims arising out of or related to the Qualitest acquisition.

In connection with the \$100 million escrow account, to the extent that we are able to realize tax benefits for costs that are funded by the escrow account, we will be required to share these tax benefits with Apax.

Qualitest is a manufacturer and distributor of generic drugs and over-the-counter pharmaceuticals throughout the U.S. Qualitest's product portfolio is comprised of 175 product families in various forms including tablets, capsules, creams, ointments, suppositories, and liquids. This acquisition has enabled us to gain critical mass in our generics business while strengthening our pain portfolio through a larger breadth of product offerings.

The operating results of Qualitest from November 30, 2010 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheet as of December 31, 2010 reflects the acquisition of Qualitest, effective November 30, 2010, the date the Company obtained control of Qualitest.

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

	November 30, 2010 (As initially reported)	Measurement period adjustments	November 30, 2010 (As adjusted)
Cash and cash equivalents	\$ 21,828	\$	\$ 21,828
Accounts receivable	93,228		93,228
Other receivables	1,483		1,483
Inventories	95,000		95,000
Prepaid expenses and other current assets	2,023	(122)	1,901
Deferred income taxes	63,509	7,531	71,040
Property, Plant and equipment	135,807		135,807
Other intangible assets	843,000	(7,000)	836,000
<b>Total identifiable assets</b>	<b>\$ 1,255,878</b>	<b>\$ 409</b>	<b>\$ 1,256,287</b>
Accounts payable	\$ 27,422	\$ (1)	\$ 27,421
Accrued expenses	55,210	4,141	59,351
Deferred income taxes	207,733	(412)	207,321
Long-term debt	406,758		406,758
Other liabilities	9,370	117	9,487
<b>Total liabilities assumed</b>	<b>\$ 706,493</b>	<b>\$ 3,845</b>	<b>\$ 710,338</b>
Net identifiable assets acquired	\$ 549,385	\$ (3,436)	\$ 545,949
Goodwill	\$ 219,986	\$ 4,112	\$ 224,098
<b>Net assets acquired</b>	<b>\$ 769,371</b>	<b>\$ 676</b>	<b>\$ 770,047</b>

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the Qualitest Acquisition Date. As of December 31, 2011, our measurement period adjustments are complete.

**Table of Contents**

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>		
Hydrocodone and acetaminophen	\$ 119.0	17
Oxycodone and acetaminophen	30.0	17
Promethazine	46.0	16
Isosorbide Mononitrate ER	42.0	16
Multi Vitamins	38.0	16
Trazodone	17.0	16
Butalbital, acetaminophen, and caffeine	25.0	16
Triprevifem	16.0	13
Spironolactone	13.0	17
Hydrocortisone	34.0	16
Hydrochlorothiazide	16.0	16
Controlled Substances	52.0	16
Oral Contraceptives	8.0	13
Others	162.0	17
Total	\$ 618.0	16
<b>In Process Research &amp; Development:</b>		
Generics portfolio with anticipated 2011 launch	\$ 63.0	n/a
Generics portfolio with anticipated 2012 launch	30.0	n/a
Generics portfolio with anticipated 2013 launch	17.0	n/a
Generics portfolio with anticipated 2014 launch(1)	88.0	n/a
Total	\$ 198.0	n/a
<b>Tradename:</b>		
Qualitest tradename	\$ 20.0	15
Total	\$ 20.0	15
Total other intangible assets	\$ 836.0	n/a

(1) During the fourth quarter of 2011, the Company received a deficiency from the FDA on an ANDA submission for one of its lead assets in this portfolio. Subsequently, in early 2012, the Company terminated its development program for this asset as a result of the regulatory challenges and changes in the development timeline resulting from the FDA's request. In addition, as a result changes in market conditions since the acquisition date, there has been a significant deterioration in the commercial potential for this product. Accordingly, we recorded a pre-tax non-cash impairment charge of \$71.0 million in 2011 to write off the intangible asset in its entirety, which was assigned to our generics segment and recorded in the Asset impairment charges line of our Consolidated Statements of Operations.

The fair value of the developed technology assets and IPR&D assets were estimated using an 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 probability-weighted cash flows discounted at rates 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. Cash flows were generally assumed to extend through the economic useful life of the developed technology, IPR&D asset or tradename. The fair value of the Qualitest tradename was estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to license the Qualitest tradename. Thus, we derived the hypothetical royalty income from the projected revenues

of Qualitest.

**Table of Contents**

The \$224.1 million of goodwill was assigned to our Generics segment. The goodwill recognized is attributable primarily to expected purchasing, manufacturing and distribution synergies as well as its assembled workforce. Approximately \$170.4 million of goodwill is expected to be deductible for income tax purposes.

Deferred tax assets of \$71.0 million are related primarily to federal and state net operating loss and credit carryforwards of Qualitest and its subsidiaries. Deferred tax liabilities of \$207.3 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

The Company recognized \$8.0 million and \$38.8 million of Qualitest acquisition-related items, net that were expensed during 2011 and 2010, respectively. These amounts are included in Acquisition-related items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	Acquisition-related Costs Year Ended December 31,	
	2011	2010
Bank fees	\$	\$ 14,215
Legal, separation, integration, and other costs	8,284	24,572
Changes in fair value of acquisition-related contingent consideration	(313)	
Total	\$ 7,971	\$ 38,787

The amounts of revenue and net loss of Qualitest included in the Company's Consolidated Statements of Operations for the year ended December 31, 2010 are as follows (dollars in thousands, except per share data):

	Revenue and Net Loss included in the Consolidated Statements of Operations from November 30, 2010 to December 31, 2010
Revenue	\$ 30,323
Net loss	\$ (3,056)
Basic and diluted loss per share	\$ (0.03)

The following supplemental pro forma information presents the financial results as if the acquisition of Qualitest had occurred on January 1, 2010 for the year ended December 31, 2010. 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, 2010, nor are they indicative of any future results.

	Year Ended December 31, 2010
<b>Pro forma consolidated results (in thousands, except per share data):</b>	
Revenue	\$ 2,038,761
Net income attributable to Endo Pharmaceuticals Holdings Inc.	\$ 243,710
Basic net income per share	\$ 2.10
Diluted net income per share	\$ 2.07

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of Qualitest to reflect the additional depreciation and amortization that would have been charged assuming the fair value adjustments primarily to property, plant and

equipment and intangible assets, had been applied on January 1, 2010, together with the consequential tax effects.



**Table of Contents*****Penwest Pharmaceuticals Co.***

On September 20, 2010 (the Penwest Acquisition Date), the Company completed its tender offer for the outstanding shares of common stock of Penwest and on November 4, 2010, we closed this acquisition for approximately \$171.8 million in aggregate cash consideration, at which time Penwest became our wholly-owned subsidiary. On August 22, 2011, Penwest was merged into Endo Pharmaceuticals Inc., at which time Penwest ceased its existence as a separate legal entity.

This transaction contributes to Endo's core pain management franchise and permits us to maximize the value of our oxymorphone franchise.

The operating results of Penwest from September 20, 2010 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheets as of December 31, 2010 reflects the acquisition of Penwest, effective September 20, 2010, the date the Company obtained control of Penwest.

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

	<b>September 20, 2010</b>
Cash and cash equivalents	\$ 22,343
Marketable securities	800
Accounts receivable	10,866
Other receivables	131
Inventories	407
Prepaid expenses and other current assets	493
Deferred income taxes	29,765
Property, plant and equipment	915
Other intangible assets	111,200
Other assets	2,104
<b>Total identifiable assets</b>	<b>\$ 179,024</b>
Accounts payable	\$ 229
Income taxes payable	160
Penwest shareholder liability	
Accrued expenses	1,542
Deferred income taxes	40,168
Other liabilities	4,520
<b>Total liabilities assumed</b>	<b>\$ 46,619</b>
<b>Net identifiable assets acquired</b>	<b>\$ 132,405</b>
Goodwill	\$ 39,361
<b>Net assets acquired</b>	<b>\$ 171,766</b>

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the Penwest Acquisition Date. As of December 31, 2011, our measurement period adjustments are complete.

**Table of Contents**

The valuation of the intangible assets acquired and related amortization periods are as follows (in millions):

	Valuation	Amortization Period (in years)
<b>In Process Research &amp; Development:</b>		
Otsuka	\$ 5.5	n/a
A0001(1)	1.6	n/a
Total	\$ 7.1	n/a
<b>Developed Technology:</b>		
Opana <sup>®</sup> ER	\$ 104.1	10
Total	\$ 104.1	10
Total other intangible assets	\$ 111.2	n/a

- (1) The Company terminated Penwest's A0001 development program after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, we recorded a pre-tax non-cash impairment charges of \$1.6 million in 2011 to completely write-off the A0001 intangible asset, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our Consolidated Statements of Operations.

The fair values of the IPR&D assets and developed technology asset were estimated using an income approach. To calculate fair value, the Company used probability-weighted cash flows discounted at rates considered appropriate given the inherent risks associated with the asset. The Company believes that the level and timing of cash flows appropriately reflect market participant assumptions. Cash flows were generally assumed to extend through the economic useful life of our developed technology or IPR&D asset.

The \$39.4 million of goodwill was assigned to our Branded Pharmaceuticals segment. The goodwill recognized is attributable primarily to the control premium associated with our oxymorphone franchise and other factors. None of the goodwill is expected to be deductible for income tax purposes.

Deferred tax assets of \$29.8 million are related primarily to federal net operating loss and credit carryforwards of Penwest. Deferred tax liabilities of \$40.2 million are related primarily to the difference between the book basis and tax basis of the identifiable intangible assets.

The Company recognized \$0.3 million and \$10.7 million of Penwest acquisition-related costs that were expensed during 2011 and 2010, respectively. These costs are included in Acquisition-related items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	Acquisition-related Costs Year Ended December 31,	
	2011	2010
Bank fees	\$	\$ 3,865
Legal, separation, integration, and other costs	259	6,815
Total	\$ 259	\$ 10,680

Due to the pro forma impacts of eliminating the pre-existing intercompany royalties between Penwest and Endo, which were determined to be at fair value, we have not provided supplemental pro forma information as amounts are not material to the Consolidated Statements of Operations.

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

We have also considered the impacts of Penwest, since the date we obtained a majority interest, on our Consolidated Statement of Operations and concluded amounts were not material.

## **Table of Contents**

### ***HealthTronics, Inc.***

On July 2, 2010 (the HealthTronics Acquisition Date), the Company completed its initial tender offer for all outstanding shares of common stock of HealthTronics and obtained effective control of HealthTronics. On July 12, 2010, Endo completed its acquisition of HealthTronics for approximately \$214.8 million in aggregate cash consideration for 100% of the outstanding shares, at which time HealthTronics became a wholly-owned subsidiary of the Company. HealthTronics shares were purchased at a price of \$4.85 per HealthTronics Share. In addition, Endo paid \$40 million to retire HealthTronics debt that had been outstanding under its Senior Credit Facility. As a result of the acquisition, the HealthTronics Senior Credit Facility was terminated.

HealthTronics is a provider of healthcare services and manufacturer of certain related medical devices, primarily for the urology community. The HealthTronics business and applicable services include:

#### *Lithotripsy services.*

HealthTronics provides lithotripsy services, which is a medical procedure where a device called a lithotripter transmits high energy shockwaves through the body to break up kidney stones. Lithotripsy services are provided principally through limited partnerships and other entities that HealthTronics manages, which use lithotripters. In 2011, physician partners used our lithotripters to perform approximately 50,000 procedures in the U.S. While the physicians render medical services, HealthTronics does not. As the general partner of limited partnerships or the manager of other types of entities, HealthTronics also provide services relating to operating its lithotripters, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting with payors, hospitals, and surgery centers.

#### *Prostate treatment services.*

HealthTronics provides treatments for benign and cancerous conditions of the prostate. In treating benign prostate disease, HealthTronics deploys three technologies in a number of its partnerships above: (1) PVP, (2) TUNA, and (3) TUMT. All three technologies apply an energy source which reduces the size of the prostate gland. For treating prostate and other cancers, HealthTronics uses a procedure called cryosurgery, a process which uses lethal ice to destroy tissue such as tumors for therapeutic purposes. In April 2008, HealthTronics acquired Advanced Medical Partners, Inc., which significantly expanded its cryosurgery partnership base. In July 2009, HealthTronics acquired Endocare, Inc., which manufactures both the medical devices and related consumables utilized by its cryosurgery operations and also provides cryosurgery treatments. The prostate treatment services are provided principally by using equipment that HealthTronics leases from limited partnerships and other entities that HealthTronics manages. Benign prostate disease and cryosurgery cancer treatment services are billed in the same manner as its lithotripsy services under either retail or wholesale contracts. HealthTronics also provides services relating to operating the equipment, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting.

#### *Anatomical pathology services.*

HealthTronics provides anatomical pathology services primarily to the urology community. HealthTronics has one pathology lab located in Georgia, which provides laboratory detection and diagnosis services to urologists throughout the U.S. In addition, in July 2008, HealthTronics acquired Uropath LLC, now referred to as HealthTronics Laboratory Solutions, which managed pathology laboratories located at Uropath sites for physician practice groups located in Texas, Florida and Pennsylvania. Through HealthTronics Laboratory Solutions, HealthTronics continues to provide administrative services to in-office pathology labs for practice groups and pathology services to physicians and practice groups with its lab equipment and personnel at the HealthTronics Laboratory Solutions laboratory sites.

#### *Medical products manufacturing, sales and maintenance.*

HealthTronics manufactures and sells medical devices focused on minimally invasive technologies for tissue and tumor ablation through cryoablation, which is the use of lethal ice to destroy tissue, such as tumors, for

**Table of Contents**

therapeutic purposes. HealthTronics develops and manufactures these devices for the treatment of prostate and renal cancers and our proprietary technologies also have applications across a number of additional markets, including the ablation of tumors in the lung, liver metastases and palliative intervention (treatment of pain associated with metastases). HealthTronics manufactures the related spare parts and consumables for these devices. HealthTronics also sells and maintains lithotripters and related spare parts and consumables.

The acquisition of HealthTronics reflects Endo's desire to continue expanding our business beyond pain management into complementary medical areas where HealthTronics can be innovative and competitive. We believe this expansion will enable us to be a provider of multiple healthcare solutions and services that fill critical gaps in patient care.

The operating results of HealthTronics from July 2, 2010 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheets as of December 31, 2010 reflects the acquisition of HealthTronics, effective July 2, 2010, the date the Company obtained control of HealthTronics.

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

	<b>July 2, 2010</b>
Cash and cash equivalents	\$ 6,769
Accounts receivable	33,388
Other receivables	1,006
Inventories	12,399
Prepaid expenses and other current assets	5,204
Deferred income taxes	46,489
Property, plant and equipment	30,687
Other intangible assets	73,124
Other assets	5,210
<b>Total identifiable assets</b>	<b>\$ 214,276</b>
Accounts payable	\$ 3,084
Accrued expenses	20,510
Deferred income taxes	22,376
Long-term debt	43,460
Other liabilities	1,785
<b>Total liabilities assumed</b>	<b>\$ 91,215</b>
<b>Net identifiable assets acquired</b>	<b>\$ 123,061</b>
Noncontrolling interests	\$ (63,227)
Goodwill	\$ 155,009
<b>Net assets acquired</b>	<b>\$ 214,843</b>

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the HealthTronics Acquisition Date. As of December 31, 2011, our measurement period adjustments are complete.

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

<b>Valuation (in millions)</b>	<b>Amortization Period (in years)</b>
------------------------------------	---

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

Endocare Developed Technology	\$	46.3	10
HealthTronics Tradename		14.6	15
Service Contract(1)		12.2	n/a
Total	\$	73.1	n/a

**Table of Contents**

(1) This intangible asset relates to our IGRT business, which was sold in September 2011 for approximately \$13.0 million. Accordingly, the carrying amount of this asset was reduced to zero at the time of sale.

The fair value of the developed technology asset was 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 probability-weighted cash flows discounted at rates 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. Cash flows were assumed to extend through the economic useful life of the purchased technology. The fair value of the HealthTronics Tradename was estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to license the HealthTronics Tradename. Thus, we derived the hypothetical royalty income from the projected revenues of HealthTronics' services.

HealthTronics has investments in partnerships and limited liability companies (LLCs) where we, as the general partner or managing member, exercise effective control. Accordingly, we consolidate various entities where we do not own 100% of the entity in accordance with the accounting consolidation principles. As a result, we are required to fair value the noncontrolling interests as part of our purchase price allocation. To calculate fair value, the Company used historical transactions which represented Level 2 data points within the fair value hierarchy to calculate applicable multiples of each respective noncontrolling interest in the partnerships and LLCs.

The \$155.0 million of goodwill has been assigned to our Services segment. The goodwill recognized is attributable primarily to strategic and synergistic opportunities across the HealthTronics network of urology partnerships, expected corporate synergies, the assembled workforce of HealthTronics and other factors. Approximately \$33.6 million of goodwill is expected to be deductible for income tax purposes.

Deferred tax assets of \$46.5 million are related primarily to federal net operating loss and credit carryforwards of HealthTronics and its subsidiaries. Deferred tax liabilities of \$22.4 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

The Company recognized \$3.7 million and \$20.9 million of HealthTronics acquisition-related costs that were expensed during 2011 and 2010, respectively. These costs are included in Acquisition-related items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	<b>Acquisition-related Costs</b>	
	<b>Year Ended December 31,</b>	
	<b>2011</b>	<b>2010</b>
Bank fees	\$	\$ 2,017
Acceleration of outstanding HealthTronics stock-based compensation		7,924
Legal, separation, integration, and other costs	3,704	10,988
Total	\$ 3,704	\$ 20,929

The amounts of revenue and net loss of HealthTronics included in the Company's Consolidated Statements of Operations for the year ended December 31, 2010 are as follows (dollars in thousands, except per share data):

	<b>Revenue and Net Loss included</b>	
	<b>in the Consolidated</b>	
	<b>Statements</b>	
	<b>of Operations from July 2,</b>	
	<b>2010 to December 31, 2010</b>	
Revenue	\$	102,144
Net loss	\$	(8,098)
Basic and diluted loss per share	\$	(0.07)





**Table of Contents**

The following supplemental pro forma information presents the financial results as if the acquisition of HealthTronics had occurred on January 1, 2010 for the year ended December 31, 2010. 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, 2010, nor are they indicative of any future results.

	Year Ended December 31, 2010
<b>Pro forma consolidated results (in thousands, except per share data):</b>	
Revenue	\$ 1,814,918
Net income attributable to Endo Pharmaceuticals Holdings Inc.	\$ 264,165
Basic net income per share	\$ 2.27
Diluted net income per share	\$ 2.24

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of HealthTronics to reflect the additional depreciation and amortization that would have been charged assuming the fair value adjustments primarily to property, plant and equipment, and intangible assets, had been applied on January 1, 2010, together with the consequential tax effects.

**Indevus**

On February 23, 2009 (the Indevus Acquisition Date), the Company completed its initial tender offer for all outstanding shares of common stock of Indevus. Through purchases in subsequent offering periods, the exercise of a top-up option and a subsequent merger (the Indevus Merger), the Company completed its acquisition of Indevus on March 23, 2009, at which time Indevus became a wholly-owned subsidiary of the Company.

The Indevus shares were purchased at a price of \$4.50 per share, net to the seller in cash, plus contractual rights to receive up to an additional \$3.00 per share in contingent cash consideration payments, pursuant to the terms of the Indevus Agreement and Plan of Merger, dated as of January 5, 2009 (the Indevus Merger Agreement). Accordingly, the Company paid approximately \$368.0 million in aggregate initial cash consideration for the Indevus shares and entered into the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement (each as defined in the Indevus Merger Agreement), providing for the payment of up to an additional \$3.00 per share in contingent cash consideration payments, in accordance with the terms of the initial tender offer.

The total cost to acquire all outstanding Indevus shares pursuant to the initial tender offer and the Indevus Merger Agreement could be up to an additional approximately \$267.0 million, if Endo is obligated to pay the maximum amounts under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement. The fair value of those potential obligations is zero at December 31, 2011.

Indevus was a specialty pharmaceutical company engaged in the acquisition, development, and commercialization of products to treat conditions in urology, endocrinology and oncology. Following the completion of the Indevus Merger, Indevus was renamed Endo Pharmaceuticals Solutions Inc.

Approved products assumed in the acquisition included Sanctura<sup>®</sup> (trospium chloride) and Sanctura XR<sup>®</sup> (trospium chloride extended release capsules) for the treatment of overactive bladder (OAB); Supprelin<sup>®</sup> LA (histrelin acetate) for treating central precocious puberty (CPP); Vantas<sup>®</sup> (histrelin) for the palliative treatment of advanced prostate cancer; Delatestryl<sup>®</sup> (testosterone enanthate) for the treatment of male hypogonadism; Hydron<sup>®</sup> Implant, which is used as a drug delivery device and provides for a sustained release of a broad spectrum of drugs continuously; and Valstar<sup>®</sup> (valrubicin) for therapy of bacillus Calmette-Guerin (BCG)-refractory carcinoma *in situ* (as CIS) of the bladder.

**Table of Contents**

As of December 31, 2011, Aveed<sup>TM</sup> (testosterone undecanoate) represents the primary development product from the Indevus acquisition. Aveed<sup>TM</sup> is expected to be the first long-acting injectable testosterone preparation available in the U.S. for the treatment of male hypogonadism in the growing market for testosterone replacement therapies. Aveed<sup>TM</sup> had historically been referred to as Nebido<sup>®</sup>. On May 6, 2009, we received notice from the FDA that Nebido<sup>®</sup> was unacceptable as a proprietary name for testosterone undecanoate. In August 2009, we received approval from FDA to use the name Aveed<sup>TM</sup>. On May 18, 2010, a new patent covering Aveed<sup>TM</sup> was issued by the U.S. Patent and Trademark Office. The patent's expiration date is March 14, 2027. The Company acquired U.S. rights to Aveed<sup>TM</sup> from Schering AG, Germany, in July 2005. In June 2008, we received an approvable letter from the FDA indicating that the NDA may be approved if the Company is able to adequately respond to certain clinical deficiencies related to the product. In September 2008, agreement was reached with the FDA with regard to the additional data and risk management strategy. In March 2009, the FDA accepted for review the complete response submission to the new drug application for Aveed<sup>TM</sup> intramuscular injection. On December 2, 2009, we received a complete response letter from the FDA regarding Aveed<sup>TM</sup> in response to our March 2009 complete response submission. In the complete response letter, the FDA has requested information from Endo to address the agency's concerns regarding very rare but serious adverse events, including post-injection anaphylactic reaction and pulmonary oily microembolism. The letter also specified that the proposed Risk Evaluation and Mitigation Strategy (REMS) is not sufficient. In 2010 and 2011, we met with the FDA to discuss the existing clinical data provided to the FDA as well as the potential path-forward. The Company is evaluating how best to address the concerns of the FDA and intends to have future dialogue with the agency regarding a possible regulatory pathway and is preparing a complete response. The outcome of future communications with the FDA could have a material impact on (1) management's assessment of the overall probability of approval, (2) the timing of such approval, (3) the targeted indication or patient population and (4) the likelihood of additional clinical trials.

Management believes the Company's acquisition of Indevus is particularly significant because it reflects our commitment to expand our business beyond pain management into complementary medical areas where we believe we can be innovative and competitive. The combined company markets products through its differentially deployed field sales forces and has the capability to develop innovative new therapies using a novel drug delivery technology.

The operating results of Indevus from February 23, 2009 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheet as of December 31, 2009 reflects the acquisition of Indevus, effective February 23, 2009, the date the Company obtained control of Indevus. The acquisition date fair value of the total consideration transferred was \$540.9 million, which consisted of the following (in thousands):

	<b>Fair Value of Consideration Transferred</b>
Cash	\$ 368,034
Contingent consideration	172,860
<b>Total</b>	<b>\$ 540,894</b>

**Table of Contents**

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

	<b>February 23, 2009</b>
Cash and cash equivalents	\$ 117,675
Accounts receivable	14,591
Inventories	17,157
Prepaid and other current assets	8,322
Property, plant and equipment	8,856
Other intangible assets	532,900
Deferred tax assets	167,749
Other non-current assets	1,331
<b>Total identifiable assets</b>	<b>\$ 868,581</b>
Accounts payable	\$ 5,116
Accrued expenses	26,725
Convertible notes	72,512
Non-recourse notes	115,235
Deferred tax liabilities	210,647
Other non-current liabilities	18,907
<b>Total liabilities assumed</b>	<b>449,142</b>
<b>Net identifiable assets acquired</b>	<b>\$ 419,439</b>
Goodwill	\$ 121,455
<b>Net assets acquired</b>	<b>\$ 540,894</b>

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the Indevus Acquisition Date.

Of the \$532.9 million of acquired intangible assets, \$255.9 million was assigned to IPR&D. The remaining \$277.0 million has been assigned to license rights and is subject to a weighted average useful life of approximately 11 years.

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

	<b>Valuation (in millions)</b>	<b>Amortization Period (in years)</b>
<b>In Process Research &amp; Development:</b>		
Valstar <sup>®</sup> (1)	\$ 88.0	n/a
Aveed <sup>™</sup> (2)	100.0	n/a
Octreotide(3)	31.0	n/a
Pagoclone(4)	21.0	n/a
Pro2000(5)	4.0	n/a
Other	11.9	n/a
<b>Total</b>	<b>\$ 255.9</b>	<b>n/a</b>
<b>License Rights:</b>		

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

Hydrogel Polymer	\$ 22.0	10
Vantas <sup>®</sup>	36.0	10
Sanctura <sup>®</sup> Franchise	94.0	12
Supprelin <sup>®</sup> LA	124.0	10
Other	1.0	4
<b>Total</b>	<b>\$ 277.0</b>	<b>11</b>
Total other intangible assets	\$ 532.9	

**Table of Contents**

- (1) The FDA approved the sNDA for Valstar® subsequent to the Indevus Acquisition Date. Therefore, Valstar® was initially classified as IPR&D and subsequently transferred to License Rights upon obtaining FDA approval and is being amortized over a 15 year useful life.
- (2) As a result of the FDA's complete response letter related to our filed NDA, we performed an impairment analysis during the fourth quarter ended December 31, 2009. We concluded there was a decline in the fair value of the indefinite-lived intangible. Accordingly, we recorded a \$65.0 million impairment charge, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our Consolidated Statements of Operations.
- (3) As part of our 2010 annual review of all IPR&D assets, we conducted an in-depth review of both octreotide indications. This review covered a number of factors including the market potential of each product given its stage of development, taking into account, among other things, issues of safety and efficacy, product profile, competitiveness of the marketplace, the proprietary position of the product and its potential profitability. Our 2010 review resulted in no impact to the carrying value of our octreotide acromegaly intangible asset. However, the analysis identified certain commercial challenges with respect to the octreotide carcinoid syndrome intangible asset including the expected rate of physician acceptance and the expected rate of existing patients willing to switch therapies. Upon analyzing the Company's research and development priorities, available resources for current and future projects, and the commercial potential for octreotide carcinoid syndrome, the Company decided to discontinue development of octreotide for the treatment of carcinoid syndrome. As a result of the above developments, the Company recorded a pre-tax non-cash impairment charge of \$22.0 million in 2010 to write-off, in its entirety, the octreotide carcinoid syndrome intangible asset, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our Consolidated Statements of Operations. On November 11, 2011, the Company separately decided to terminate development of the octreotide implant for the treatment of acromegaly after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, we recorded a pre-tax non-cash impairment charge of \$9.0 million in 2011 to completely write-off the octreotide acromegaly intangible asset, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our Consolidated Statements of Operations.
- (4) In May 2010, Teva terminated the development and licensing arrangement with us upon the completion of the Phase IIb study. We concluded there was a decline in the fair value of the indefinite-lived intangible asset. Accordingly, we recorded a \$13.0 million impairment charge, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our Consolidated Statements of Operations. On December 27, 2011, the Company terminated its pagoclone development program after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, we recorded a pre-tax non-cash impairment charges of \$8.0 million in 2011 to completely write-off the pagoclone intangible asset, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our Consolidated Statements of Operations.
- (5) In December 2009, our Phase III clinical trials for Pro2000 provided conclusive results that the drug was not effective. We concluded there was no further value or alternative future uses associated with this indefinite-lived asset. Accordingly, we recorded a \$4.0 million impairment charge to write-off the Pro2000 intangible asset in its entirety, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our Consolidated Statements of Operations.

The fair value of the IPR&D assets and License Rights assets, with the exception of the hydrogel polymer technology, were estimated using an 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 probability-weighted cash flows discounted at rates 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. Cash flows were generally assumed to extend either through or beyond the patent life of each product, depending on the circumstances particular to each product. The fair value of the hydrogel polymer technology was estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to license the technology. The hydrogel polymer technology is currently used in the following products: Vantas® and Supprelin® LA. Thus, we derived the hypothetical royalty income from the projected revenues of those drugs. The fair value of the hydrogel polymer technology also includes an existing royalty payable by the

**Table of Contents**

Company to the certain third party partners based on the net sales derived from drugs that use the hydrogel polymer technology. Discount rates applied to the estimated cash flows for all intangible assets acquired ranged from 13% to 20%, depending on the current stage of development, the overall risk associated with the particular project or product and other market factors. We believe the discount rates used are consistent with those that a market participant would use.

The \$121.5 million of goodwill was assigned to our Branded Pharmaceuticals segment. The goodwill recognized is attributable primarily to the potential additional applications for the hydrogel polymer technology, expected corporate synergies, the assembled workforce of Indevus and other factors. None of the goodwill is expected to be deductible for income tax purposes.

The deferred tax assets of \$167.7 million are related primarily to federal net operating loss and credit carryforwards of Indevus and its subsidiaries. The deferred tax liabilities of \$210.6 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

During the years ended December 31, 2011, 2010 and 2009, we recorded \$7.1 million in income, \$51.4 million in income and \$93.1 million in income for Indevus acquisition-related items, net. These amounts are included Acquisition-related items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	<b>Acquisition-related Costs Year Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
Investment bank fees, includes Endo and Indevus	\$	\$	\$ 13,030
Legal, separation, integration, and other items			21,979
Changes in fair value of acquisition-related contingent consideration	(7,050)	(51,420)	(128,090)
<b>Total</b>	<b>\$ (7,050)</b>	<b>\$ (51,420)</b>	<b>\$ (93,081)</b>

The amounts of revenue and net loss of Indevus included in the Company's Consolidated Statements of Operations for the year ended December 31, 2009 are as follows (dollars in thousands, except per share data):

	<b>February 23, 2009 to December 31, 2009</b>
Revenue	\$ 66,719
Net loss	\$ (107,779)
Basic and diluted loss per share	\$ (0.92)

**Other**

In the second half of 2011, as part of our effort to increase and broaden the relationships within the urology community, we acquired two electronic medical records software companies, Intuitive Medical Software, LLC and meridianEMR, Inc., which individually and combined represent immaterial acquisitions. These acquisitions provide electronic medical records for urologists. Together, these acquisitions provide access to approximately 1,850 urologists using data platforms that will enhance service offerings in urology practice management.

**Legal Proceedings.** We are subject to various patent, product liability, government investigations and other legal proceedings in the ordinary course of business. Contingent 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 a complete description of legal proceedings, see Note 14. Commitments and Contingencies-Legal Proceeding in the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

**Table of Contents**

**Expected Cash Requirements for Contractual Obligations.** The following table presents our expected cash requirements for contractual obligations for each of the following years subsequent to December 31, 2011 (in thousands):

Contractual Obligations	Total	Payment Due by Period					
		2012	2013	2014	2015	2016	Thereafter
Lease obligations(1)	\$ 127,124	\$ 15,412	\$ 26,159	\$ 11,658	\$ 10,095	\$ 7,804	\$ 55,996
Debt related payments(2)	4,743,506	249,897	291,975	306,773	711,696	1,040,505	2,142,660
Minimum purchase commitments to Novartis(3)	24,267	11,200	11,200	1,867			
Minimum purchase commitments to Teikoku(4)	34,000	34,000					
Minimum Voltaren® royalty obligations due to Novartis(5)	45,000	30,000	15,000				
Minimum advertising and promotion spend(6)	9,532	9,532					
Other obligations(7)	48	48					
<b>Total</b>	<b>\$ 4,983,477</b>	<b>\$ 350,089</b>	<b>\$ 344,334</b>	<b>\$ 320,298</b>	<b>\$ 721,791</b>	<b>\$ 1,048,309</b>	<b>\$ 2,198,656</b>

- (1) Includes minimum cash payments related to our leased automobiles, machinery and equipment and facilities, including the corporate headquarters in Malvern, Pennsylvania, which is currently under construction. For the purpose of calculating our annual obligations related to our Malvern, Pennsylvania corporate headquarters lease, we have assumed a lease commencement during the first quarter of 2013. Under the terms of our leases for our current headquarters in Chadds Ford, Pennsylvania, we will be required to pay all future minimum lease payments to the landlord upon vacating the Chadds Ford location. Based on an anticipated move in early 2013, we believe the future minimum lease payments due to our current landlord at that time will be approximately \$12 million, which is reflected in 2013 above. As part of the construction of its new headquarters, the Company intends to pay for approximately \$30 million in tenant improvements during 2012; however, this amount is not reflected above as the Company does not view these payments as legally binding.
- (2) Includes minimum cash payments related to principal and interest, including commitment fees, 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 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) We are party to a long-term manufacturing and development agreement with Novartis Consumer Health, Inc. (Novartis) whereby Novartis has agreed to manufacture certain of our commercial products and products in development. We are required to purchase, on an annual basis or pro rata portion thereof, a minimum amount of product from Novartis until the termination of the agreement in February 2014. The purchase price per product is equal to a predetermined amount per unit, subject to periodic adjustments. Since future price changes are unknown, for purposes of this contractual obligations table, all amounts scheduled above represent the minimum purchase quantities at the price currently existing under the agreement with Novartis. Due to the short-term supply issues at Novartis, we may seek a reduction to these commitments. There can be no guarantee that such a reduction will be successfully achieved.
- (4) On April 24, 2007, we amended our Supply and Manufacturing Agreement with Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc. (collectively, Teikoku) dated as of November 23, 1998, pursuant to which Teikoku manufactures and supplies Lidoderm® (lidocaine patch 5%) (the Product) to Endo. This amendment is referred to as the Amended Agreement. Under the terms of the Amended Agreement, Endo has agreed to purchase a minimum number of Lidoderm® patches per year through 2012, representing the noncancelable portion of the Amended Agreement. The minimum purchase requirement shall remain in effect subsequent to 2012, except that Endo has the right to terminate the Amended Agreement after 2012, if we fail to meet the annual minimum requirement. Teikoku has agreed to fix the supply price of Lidoderm® for a specified period of time after which the price will be adjusted at future dates certain based on a price index defined in the Amended Agreement. Since future price changes are unknown, for purposes of this contractual obligations table, all amounts scheduled above represent the minimum patch quantities at the price currently existing under the Amended Agreement. Effective November 1, 2010, the parties amended the Amended Agreement. Pursuant to this amendment, Teikoku has agreed to supply additional Product at no cost to Endo in each of 2011, 2012 and 2013 in the event Endo's firm orders of Product exceed certain thresholds in those years. We will update the Teikoku purchase commitments upon future price changes made in accordance with the Amended Agreement.

**Table of Contents**

- (5) Under the terms of the five-year Voltaren® Gel Agreement, Endo made an up-front cash payment of \$85 million. 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 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 Voltaren® Gel Agreement, which may be reduced under certain circumstances, including Novartis's failure to supply the Licensed Product. These guaranteed minimum royalties will be creditable against royalty payments on a Voltaren® Gel Agreement year basis such that Endo's obligation with respect to each Voltaren® Gel Agreement year is to pay the greater of (i) royalties payable based on annual net sales of the Licensed Product or (ii) the guaranteed minimum royalty for such Agreement year.
- (6) Under the terms of the five-year Voltaren® Gel Agreement, Endo has agreed to certain minimum advertising and promotional spending, subject to certain thresholds as defined in the Voltaren® Gel Agreement. Subsequent to June 30, 2012, the minimum advertising and promotional spending are determined based on a percentage of net sales of the licensed product. Due to the short-term supply issues at Novartis, we may seek a reduction to these commitments. There can be no guarantee that such a reduction will be successfully achieved.
- (7) This amount is comprised of obligations assumed in connection with our acquisition of Penwest, including costs associated with Penwest's collaborative discovery agreements and certain severance obligations.

In addition, we have agreed to certain contingent payments in certain of our acquisition, 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 Sheet and are not reflected in the table above. In addition, under certain arrangements, we 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.

As of December 31, 2011, our liability for unrecognized tax benefits amounted to \$46.9 million (including interest and penalties). Due to the nature and timing of the ultimate outcome of these uncertain tax positions, we cannot make a reasonably 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, impairment of intangible assets, 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 net sales 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 intend to 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 stockholder value. Through execution of our business strategy we intend to focus on developing new products through both an internal and a virtual research and development organization with greater scientific and clinical capabilities; expanding the Company's product line by acquiring new products and technologies in existing therapeutic and complementary areas; increasing revenues and earnings through sales and marketing programs for our innovative product offerings and effectively using the Company's resources; and providing additional resources to support our generics business.

**Non-U.S. Operations.** Our operations outside of the U.S. were not material during 2011. As a result, fluctuations in foreign currency exchange rates did not have a material effect on our financial statements.



## **Table of Contents**

In general, it is the practice and intention of the Company to reinvest the earnings of its non-U.S. subsidiaries in those operations. As of December 31, 2011, the Company has not made a provision for U.S. or additional foreign withholding taxes on approximately \$89.2 million of the excess of the amount for financial reporting over the tax basis of investments in foreign subsidiaries that are essentially permanent in duration. Generally, such amounts become subject to U.S. taxation upon the remittance of dividends and under certain other circumstances. It is not practicable to estimate the amount of deferred tax liability related to investments in these foreign subsidiaries.

***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.

## **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 marketable securities and other 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 chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and allowances are reasonably determinable, and when collectability is reasonably assured. 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 during the period following launch.

## **Table of Contents**

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. Over the past three 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 six of our wholesaler customers. These agreements, which pertain to branded products only, 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.

Under the DSAs, we received information from our six wholesaler customers about the levels of inventory they held for our branded products as of December 31, 2011. Based on this information, which we have not independently verified, we believe that total branded inventory held at these wholesalers is within normal levels. In addition, we also 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.

### *Devices*

As a result of our acquisition of AMS, we sell products in this segment through a direct sales force. A portion of our revenue is generated from consigned inventory or from inventory with field representatives. For these products, revenue is recognized at the time the product has been used or implanted. For all other transactions, we recognize revenue when title to the goods and risk of loss transfer to our customers providing there are no remaining performance obligations required from us or any matters requiring customer acceptance. In cases where we utilize distributors or ship product directly to the end user, we recognize revenue upon shipment provided all revenue recognition criteria have been met. We record estimated sales returns, discounts and rebates as a reduction of net sales in the period the related revenue is recognized.

We provide incentives to customers, including volume based rebates. Customers are not required to provide documentation that would allow us to reasonably estimate the fair value of the benefit received and we do not receive an identifiable benefit in exchange for the consideration. Accordingly, the incentives are recorded as a reduction of revenue.

Our Devices customers have rights of return for the occasional ordering or shipping error. We maintain an allowance for these returns and reduce reported revenue for expected returns from shipments during each reporting period. This allowance is based on historical and current trends in product returns.

### *Services*

In our Services segment, we recognize revenue generally when services are provided or, in the case of fees for product sales and licensing applications, revenues are generally recognized upon delivery or for licensing fees, when the patient is treated. In our HealthTronics business, revenue is recognized based on the type of product or service sold, as follows:

Fees for urology treatments. A substantial majority of our Services revenues are derived from fees related to lithotripsy treatments performed using our lithotripters. For lithotripsy and prostate treatment services, we, through our partnerships and other entities, facilitate the use of our equipment and provide other support services in connection with these treatments at hospitals and other health care facilities. The professional fee payable to the physician performing the procedure is generally billed and collected by the physician.

**Table of Contents**

Fees for managing the operation of our lithotripters and prostate treatment devices. Through our partnerships and otherwise directly by us, we provide services related to operating our lithotripters and prostate treatment equipment and receive a management fee for performing these services. We recognize revenue for these services as the services are provided.

Fees for maintenance services. We provide equipment maintenance services to our partnerships as well as outside parties. These services are billed either on a time and material basis or at a fixed contractual rate, payable monthly, quarterly, or annually. Revenues from these services are recorded when the related maintenance services are performed.

Fees for equipment sales, consumable sales and licensing applications. We manufacture and sell medical devices focused on minimally invasive technologies for tissue and tumor ablation through cryosurgery, and their related consumables. We also sell and maintain lithotripters and manufacture and sell consumables related to the lithotripters. We distribute the Revolix laser and consumables related to the laser. With respect to some lithotripter sales, in addition to the original sales price, we receive a licensing fee from the buyer of the lithotripter for each patient treated with such lithotripter. In exchange for this licensing fee, we provide the buyer of the lithotripter with certain consumables. All the sales for equipment and consumables are recognized when the related items are delivered. Revenues from licensing fees are recorded when the patient is treated. In some cases, we lease certain equipment to our partnerships as well as third parties. Revenues from these leases are recognized on a monthly basis or as procedures are performed.

Fees for anatomical pathology services. We provide anatomical pathology services primarily to the urology community. Revenues from these services are recorded when the related laboratory procedures are performed.

***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.

**Table of Contents**

The following table presents the activity and ending balances for our product sales provisions for the last three years (in thousands):

	<b>Returns and Allowances</b>	<b>Rebates</b>	<b>Chargebacks</b>	<b>Other Sales Deductions</b>	<b>Total</b>
Balance at January 1, 2009	\$ 38,982	\$ 104,667	\$ 35,982	\$ 5,142	\$ 184,773
Current year provision	20,220	396,599	495,721	49,368	961,908
Prior year provision	(1,287)	(5,749)	1,164		(5,872)
Payments or credits	(9,641)	(371,074)	(480,963)	(48,450)	(910,128)
<b>Balance at December 31, 2009</b>	<b>\$ 48,274</b>	<b>\$ 124,443</b>	<b>\$ 51,904</b>	<b>\$ 6,060</b>	<b>\$ 230,681</b>
Additions related to acquisitions	11,000	11,175	9,703	7,833	39,711
Current year provision	20,019	632,034	519,537	54,969	1,226,559
Prior year provision	(2,520)	(1,791)	21		(4,290)
Payments or credits	(11,752)	(562,636)	(493,345)	(53,542)	(1,121,275)
<b>Balance at December 31, 2010</b>	<b>\$ 65,021</b>	<b>\$ 203,225</b>	<b>\$ 87,820</b>	<b>\$ 15,320</b>	<b>\$ 371,386</b>
Additions related to acquisitions	3,594	194			3,788
Current year provision	52,027	842,674	801,543	85,147	1,781,391
Prior year provision	3,697	2,312			6,009
Payments or credits	(34,264)	(739,494)	(772,542)	(79,125)	(1,625,425)
<b>Balance at December 31, 2011</b>	<b>\$ 90,075</b>	<b>\$ 308,911</b>	<b>\$ 116,821</b>	<b>\$ 21,342</b>	<b>\$ 537,149</b>

*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 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

## Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

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

## **Table of Contents**

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 agreements, as described above. Indirect rebates are rebates paid to indirect customers which have purchased our products from a wholesaler under a contract with us.

## Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

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. We estimate an accrual for managed-care, Medicaid and Medicare Part D 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 and estimated future trends. 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

**Table of Contents**

(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. As a result, our Medicaid rebate provision includes an estimate of outstanding claims for end-customer sales that occurred but for which the related claim has not been billed, and an estimate for future claims that will be made when inventory in the distribution channel is sold through to plan participants. Our calculation also requires other estimates, such as estimates of sales mix, to determine which sales are subject to rebates and the amount of such rebates. 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 estimate 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. 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 our customers 2.0% 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 thirty to sixty 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;



## **Table of Contents**

the estimated decline in the market price of our product, which we determine based on historical experience and input from customers; 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, tradenames 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 of the product. In the event the carrying value of the asset exceeds the undiscounted future cash flows of the product 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 net income 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/or 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.

During 2011, the Company recorded a pre-tax non-cash impairment charge of \$22.7 million to completely impair its cost method investment in a privately-held company focused on the development of an innovative treatment for certain types of cancer. This impairment was recorded due to the negative clinical trial results related to this company's lead asset.

During 2010 and 2009, we did not recognize an impairment charge as a result of our review of long-lived assets.

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 2 to 20 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, net income and net income per share to decrease. The value of these licenses is subject to continuing scientific, medical and marketplace uncertainty.

Acquired customer relationships are recorded at fair value upon acquisition and are amortized using estimated useful lives ranging from 13 to 17 years, with a weighted average useful life of approximately 16 years. We determine amortization periods for customer relationships 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 customer relationships, contractual terms and our plans regarding our future relations with our customers. 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.

Acquired developed technology is recorded at fair value upon acquisition and amortized using estimated useful lives ranging from 3 to 20 years, with a weighted average useful life of approximately 16 years. We

**Table of Contents**

determine amortization periods for developed technology based on our assessment of various factors impacting estimated useful lives and 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. The value of these assets is subject to continuing scientific, medical and marketplace uncertainty.

Acquired tradenames are recorded at fair value upon acquisition and, if deemed to have definite lives, are amortized using estimated useful lives ranging from 15 to 30 years, with a weighted average useful life of approximately 22 years. We determine amortization periods for tradenames 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 tradename and our plans regarding the future use of the tradename. 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.

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

Endo tests goodwill and indefinite-lived intangible assets for impairment annually, or more frequently if events or changes in circumstances indicate that the asset might be impaired. Our annual assessment is performed as of January 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 value. A Step II analysis would be required if the fair value of the reporting unit is lower than its carrying value. If the fair value of the reporting unit exceeds its carrying value, 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. Although the Company has four operating segments, Branded Pharmaceuticals, Generics, Devices and Services, we have determined that the Company has seven reporting units; (1) Pain, (2) Generics, (3) Urology, Endocrinology and Oncology (UEO), (4) Anatomical Pathology Services, (5) Urology Services, (6) HealthTronics Information Technology Solutions (HITS) and (7) American Medical Systems (AMS).

***Goodwill***

As of January 1, 2012, our annual assessment date, we completed our annual recoverability review. Based upon recent market conditions, and, in some cases, a lack of comparable market transactions for similar assets, Endo determined that an income approach using a discounted cash flow model was an appropriate valuation methodology to determine each reporting unit's fair value. The income approach converts future amounts to a single present value amount (discounted cash flow model). Our discounted cash flow models are highly reliant on various assumptions, including estimates of future cash flow (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. We believe we have appropriately reflected our best estimates of the assumptions that market participants would use in determining the fair value of our reporting units at the measurement dates.

There were no goodwill impairments as a result of performing our annual assessment. The results of our analyses showed that the fair value of each of our reporting units significantly exceeded their respective carrying values, with the exception of the AMS and HITS reporting units. These reporting units were recently acquired in 2011, and, as expected, there was a close correlation between the respective reporting units' fair values and carrying values.

***Indefinite-lived intangible assets***

On November 11, 2011, the Company decided to terminate development of its octreotide implant for the treatment of acromegaly and, on December 27, 2011, terminated its pagoclone development program after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the

## **Table of Contents**

commercial potential for the products. Accordingly, we recorded pre-tax non-cash impairment charges of \$8.0 million and \$9.0 million, respectively, in 2011 to completely write-off the remaining pargolone intangible asset and the octreotide acromegaly intangible asset.

During the fourth quarter of 2011, the Company received a deficiency from the FDA on an ANDA submission for one of its lead assets in this portfolio. Subsequently, in early 2012, the Company terminated its development program for this asset as a result of the regulatory challenges and changes in the development timeline resulting from the FDA's request. In addition, as a result changes in market conditions since the acquisition date, there has been a significant deterioration in the commercial potential for this product. Accordingly, we recorded a pre-tax non-cash impairment charge of \$71.0 million in 2011 to write off the intangible asset in its entirety, which was assigned to our generics segment and recorded in the Asset impairment charges line of our Consolidated Statements of Operations.

In early 2012, the Company terminated Penwest's A0001 development program after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, we recorded a pre-tax non-cash impairment charges of \$1.6 million in 2011 to completely write-off the A0001 intangible asset.

As of January 1, 2012, the Company tested its indefinite-lived intangible assets for recoverability. Similar to the approach for testing goodwill recoverability, Endo determined that an income approach using a discounted cash flow model was an appropriate valuation methodology to determine each indefinite-lived asset's fair value. Our discounted cash flow models are highly reliant on various assumptions, including estimates of future cash flow (including long-term growth rates), probability of commercial feasibility of each related project, discount rate, and expectations about variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows. We believe we have appropriately reflected our best estimates of the assumptions that market participants would use in determining the fair value of our indefinite-lived intangible assets at the measurement date. There were no additional impairments recorded as a result of performing our annual assessment other than those previously discussed above.

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

Effective January 1, 2009, 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 IPR&D and contingent consideration 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.

**Table of Contents**

We account for contingent consideration in accordance with applicable guidance provided within the business combination rules. As part of our consideration for the Indevus and Qualitest acquisitions, we are contractually obligated to pay certain consideration resulting from the outcome of future events. Therefore, we are required to update our assumptions each reporting period, based on new developments, and record such amounts at fair value until such consideration is satisfied.

*Indevus*

The Indevus Contingent Consideration Agreements were measured and recognized at fair value upon the Indevus Acquisition Date and are required to be re-measured on a recurring basis, with changes to fair value recorded in Acquisition-related items, net in the accompanying Consolidated Statements of Operations. The fair values were determined using a probability-weighted discounted cash flow model, or income approach. This fair value measurement technique is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. The valuation of each Indevus Contingent Consideration Agreement is described in further detail below:

*Aveed™ Contingent Consideration* The range of the undiscounted amounts the Company could pay under the Aveed™ Contingent Cash Consideration Agreement is between zero and approximately \$175.0 million. Under this agreement, there are three scenarios that could potentially lead to amounts being paid to the former stockholders of Indevus. These scenarios are (1) obtaining an Aveed™ With Label approval, (2) obtaining an Aveed™ Without Label approval and (3) achieving the \$125.0 million sales milestone on or prior to the fifth anniversary of the date of the first commercial sale of Aveed™ should the Aveed™ Without Label approval be obtained. The fourth scenario is Aveed™ not receiving approval within three years of the closing of the Offer, which would result in no payment to the former stockholders of Indevus. Each scenario was assigned a probability based on the current regulatory status of Aveed™. The resultant probability-weighted cash flows were then discounted using a discount rate of U.S. Prime plus 300 basis points, which the Company believes is appropriate and is representative of a market participant assumption. Using this valuation technique, the fair value of the contractual obligation to pay the Aveed™ Contingent Consideration was determined to be zero at December 31, 2011, \$7.1 million at December 31, 2010, and \$133.1 million on the Indevus Acquisition Date.

*Octreotide Contingent Consideration* The range of the undiscounted amounts the Company could pay under the Octreotide Contingent Cash Consideration Agreement is between zero and approximately \$91.0 million. Under this agreement, the two scenarios that require consideration are (1) approval of octreotide on or before the fourth anniversary of the closing of the Offer or (2) no octreotide approval on or before the fourth anniversary of the closing of the Offer. Each scenario was assigned a probability based on the current development stage of octreotide. The resultant probability-weighted cash flows were then discounted using a discount rate of U.S. Prime plus 300 basis points, which the Company believes is appropriate and is representative of a market participant assumption. Using this valuation technique, the fair value of the contractual obligation to pay the Octreotide Contingent Consideration was determined to be zero at both December 31, 2011 and December 31, 2010 and \$39.8 million on the Indevus Acquisition Date.

*Valera Contingent Consideration* The range of the undiscounted amounts the Company could pay under the Valera Contingent Cash Consideration Agreement is between zero and approximately \$33.0 million. The fair value of the Valera Contingent Consideration is estimated using the same assumptions used for the Aveed™ Contingent Cash Consideration Agreement and Octreotide Contingent Cash Consideration Agreement, except that the probabilities associated with the Valera Contingent Consideration take into account the probability of obtaining the Octreotide Approval on or before the fourth anniversary of the closing of the Offer. This is due to the fact that the Valera Contingent Consideration will not be paid unless octreotide for the treatment of acromegaly is approved prior to April 18, 2012. Using this valuation technique, the fair value of the contractual

---

**Table of Contents**

obligation to pay the Valera Contingent Consideration was determined to be zero at both December 31, 2011 and December 31, 2010 and \$13.7 million on the Indevus Acquisition Date.

At December 31, 2011, the aggregate fair value of the three Indevus Contingent Consideration Agreements decreased from \$7.1 million at December 31, 2010 to zero at December 31, 2011. This decrease primarily reflects management's current assessment of the probability that it will not be obligated to make contingent consideration payments based on the anticipated timeline for the NDA filings and FDA approvals of Aveed™ and octreotide for the treatment of acromegaly. The decrease in the liability was recorded as a gain and was included in Acquisition-related items, net in the accompanying Consolidated Statements of Operations.

As of December 31, 2011, there were no changes to the range of the undiscounted amounts the Company may be required to pay under any of the Indevus Contingent Consideration Agreements.

*Qualitest*

On November 30, 2010 (the Qualitest Acquisition Date), Endo acquired Qualitest, who was party to an asset purchase agreement with Teva Pharmaceutical Industries Ltd (Teva) (the Teva Agreement). Pursuant to this agreement, Qualitest 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 range of the undiscounted amounts the Company could pay under the Teva Agreement is between zero and \$12.5 million. The Company is accounting for the Teva Contingent Consideration in the same manner as if it had entered into that arrangement with respect to its acquisition of Qualitest. Accordingly, the fair value was estimated based on a probability-weighted discounted cash flow model, or income approach. The resultant probability-weighted cash flows were then discounted using a discount rate of U.S. Prime plus 300 basis points. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. Using this valuation technique, the fair value of the contractual obligation to pay the Teva Contingent Consideration was determined to be \$8.7 million at December 31, 2011 and \$9.0 million at December 31, 2010 and the Qualitest Acquisition Date, respectively.

The decrease balance at December 31, 2011 compared to December 31, 2010 primarily reflects changes of our present value assumptions associated with our valuation model. The decrease in the liability was recorded as a gain and is included in Acquisition-related items, net in the accompanying Consolidated Statements of Operations.

As of December 31, 2011, there were no changes to the range of the undiscounted amounts the Company may be required to pay under the Teva Agreement.

*Income taxes*

Provisions for income taxes are calculated on reported pre-tax income based on current tax laws, statutory tax rates and available tax incentives and planning opportunities in various jurisdictions in which we operate. Such provisions differ from the amounts currently receivable or payable because certain items of income and expense are recognized in different time periods for financial reporting purposes than for income tax purposes. We recognize deferred taxes by the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred income taxes are recognized for differences between the financial statement and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. Significant judgment is required in determining income tax provisions and evaluating tax positions. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The factors used to assess the likelihood of realization are the Company's

## **Table of Contents**

forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. Failure to achieve forecasted taxable income in applicable tax jurisdictions could affect the ultimate realization of deferred tax assets and could result in an increase in the Company's effective tax rate on future earnings.

At December 31, 2011, we had \$444.8 million of gross deferred tax assets, which included federal and state net operating loss carryforwards (NOLs) of approximately \$178.5 million, research and development credit carryforwards of \$18.2 million, capital loss carryforwards of \$16.4 million, alternative minimum tax and foreign tax credits of \$2.6 million and temporary differences of approximately \$229.1 million. At December 31, 2011, our NOLs and research and development credit carryforwards were related to multiple tax jurisdictions, including federal and various state jurisdictions, which expire at intervals between 2012 and 2032. We evaluate the potential realization of our deferred tax benefits on a jurisdiction-by-jurisdiction basis. Our analysis of the realization considers the probability of generating taxable income or other sources of income as defined within the applicable income tax authoritative guidance, which could be utilized to support the assets over the permitted carryforward period in each jurisdiction. Where we have determined under the more likely than not standard that we do not have a better-than-50% probability of realization, we establish a valuation allowance against that portion of the deferred tax asset where our analysis and judgment indicates a less-than-50% probability of realization. Based on our forecasted taxable income within these jurisdictions, we believe we will generate sufficient future taxable income to realize a significant portion of our deferred tax assets associated with our NOLs and research and development credit carryforwards. However, the Company does not anticipate future capital gains that would be required to obtain the tax benefit of our net unrealized capital loss. Accordingly, this deferred tax asset is offset by a valuation allowance of \$16.4 million at December 31, 2011. In addition, due to our historical losses in certain state jurisdictions and the absence of sources of income, we have established a \$5.1 valuation allowance for our state NOL carryforwards.

On a periodic basis, we evaluate the realizability of our deferred tax assets and liabilities and will adjust such amounts in light of changing facts and circumstances, including but not limited to future projections of taxable income, tax legislation, rulings by relevant tax authorities, tax planning strategies and the progress of ongoing tax audits. Settlement of filing positions that may be challenged by tax authorities could impact the income tax position in the year of resolution.

### ***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. Contingent accruals are recorded 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.

### ***Stock-based compensation***

The Company accounts for its stock-based compensation plans in accordance with the guidance for share-based payments. Accordingly, all stock-based compensation 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. Determining the appropriate fair-value model and calculating the fair value of share-based awards at the date of grant requires judgment. We use the Black-Scholes option pricing model to estimate the fair value of employee stock options.

The Black-Scholes option pricing model utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield (which is expected 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 stock price and other factors. To the extent volatility of our stock price increases in the future, our estimates of the fair value of stock options granted

## **Table of Contents**

in the future could increase, thereby increasing stock-based compensation expense in future periods. 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, including an estimate of the number of share-based awards which will be forfeited due to employee turnover. Changes in the estimated forfeiture rate may have a significant effect on share-based compensation, as the effect of adjusting the rate for all expense amortization is recognized in the period the forfeiture estimate is changed. If the actual forfeiture rate is higher than the estimated forfeiture rate, then an adjustment is made to increase the estimated forfeiture rate, which will result in a decrease to the expense recognized in the financial statements. If the actual forfeiture rate is lower than the estimated forfeiture rate, then an adjustment is made to decrease the estimated forfeiture rate, which will result in an increase to the expense recognized in the financial statements. Changes in the inputs and assumptions can materially affect the measurement of the estimated fair value of our employee stock options. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense. Also, the accounting estimate of stock-based compensation expense is reasonably likely to change from period to period as further stock options are granted and adjustments are made for stock option forfeitures and cancellations.

The fair value of our restricted stock grants is based on the fair market value of our common stock on the date of grant discounted for expected future dividends.

## **RECENT ACCOUNTING PRONOUNCEMENTS**

In December 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2010-29 on interim and annual disclosure of pro forma financial information related to business combinations. The new guidance clarifies the acquisition date that should be used for reporting the pro forma financial information in which comparative financial statements are presented. It is effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010. The provisions of this ASU have been incorporated into this filing for our 2011 acquisitions.

In December 2010, the FASB issued ASU 2010-28 on accounting for goodwill. The guidance clarifies the impairment test for reporting units with zero or negative carrying amounts. The guidance is effective for fiscal years and interim periods within those years beginning after December 15, 2011. The adoption is not expected to have a material impact on the Company's Consolidated Financial Statements.

In December 2010, the FASB issued ASU 2010-27 on accounting for the annual fee imposed by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act. The new guidance specifies that the liability for the fee should be estimated and recorded in full upon the first qualifying sale with a corresponding deferred cost that is amortized to expense. It is effective on a prospective basis for calendar years beginning after December 31, 2010. The amount expensed in 2011 related to this fee was approximately \$18.0 million in 2011, which we charged as an operating expense ratably throughout 2011.

In May 2011, the FASB issued ASU 2011-04 on fair value disclosures. This guidance amends certain accounting and disclosure requirements related to fair value measurements. It is effective on a prospective basis for interim and annual periods beginning after December 15, 2011. Early application is not permitted. The Company is currently evaluating ASU 2011-04 but we do not expect the impact of adoption to be material.

In June 2011, the FASB issued ASU 2011-05 on the presentation of comprehensive income, which amends current comprehensive income guidance. This accounting update eliminates the option to present the components of other comprehensive income as part of the statement of shareholders' equity. Instead, the Company must report comprehensive income in either a single continuous statement of comprehensive income which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. ASU 2011-05 was initially to be effective for public companies during the interim and annual periods beginning after December 15, 2011 with early adoption permitted.

**Table of Contents**

However, the changes in ASU 2011-05 that relate to the presentation of reclassification adjustments to other comprehensive income were deferred in December 2011 upon the FASB's issuance of ASU 2011-12, which allows the FASB time to redeliberate whether to present the effects of reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income on the face of the financial statements for all periods presented. While the FASB is considering the operational concerns about the presentation requirements for reclassification adjustments and the needs of financial statement users for additional information about reclassification adjustments, the Company is required to continue reporting reclassifications out of accumulated other comprehensive income consistent with the presentation requirements in effect before ASU 2011-05. All other requirements in ASU 2011-05 are not affected by ASU 2011-12, including the requirement to report comprehensive income either in a single continuous financial statement or in two separate but consecutive financial statements. Public entities should apply these requirements for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of ASU 2011-05 and ASU 2011-12 will not have an impact on the Company's consolidated financial position, results of operations or cash flows as it only requires a change in the format of the current presentation.

In September 2011, the FASB issued ASU 2011-08 on testing goodwill for impairment, which permits an entity to make a qualitative assessment of whether it is more likely than not that a reporting unit's fair value is less than its carrying value before applying the two-step goodwill impairment model that is currently in place. If it is determined through the qualitative assessment that reporting unit's fair value is more likely than not greater than its carrying value, the remaining impairment steps would be unnecessary. The qualitative assessment is optional, allowing companies to go directly to the quantitative assessment. ASU 2011-08 will be effective for annual and interim goodwill impairment tests performed in fiscal years beginning after December 15, 2011, with early adoption permitted. The Company is currently evaluating ASU 2011-08.

**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 Term Loan Facility, money market funds, and long-term marketable debt securities portfolio. Additionally, if we were to utilize amounts under our Revolving Credit Facility, we could be exposed to interest rate risk. At December 31, 2011, our Term Loan Facility includes floating-rate debt of approximately \$1.9 billion. Based on this amount, a 1% rise in interest rates would result in approximately \$19 million in incremental annual interest expense. Our current and long-term marketable debt securities classified as available for sale consist of auction-rate securities. Our investments in marketable securities are governed by our investment policy, which has been approved by our Board of Directors. Our investment policy seeks to preserve the value of capital, consistent with maximizing return on the Company's investment, while maintaining adequate liquidity. To achieve this objective, we maintain our portfolio in a variety of high credit quality debt securities. Generally, our interest rate risk with respect to these investments is limited due to yields earned, which approximate current interest rates. We attempt to mitigate default risk by maintaining our portfolio investments in diversified, high-quality investment grade securities with limited time to maturity. We constantly monitor our investment portfolio and position our portfolio to respond appropriately to a reduction in credit rating of any investment issuer, guarantor or depository.

As of December 31, 2011 and December 31, 2010, we had no other assets or liabilities that have significant interest rate sensitivity.

*Investment Risk*

At December 31, 2011 and 2010, we had publicly traded equity securities totaling \$1.6 million and \$6.2 million included in long-term marketable securities, respectively. The fair value of our investments are subject to significant fluctuations due to the volatility of the stock market, changes in general economic conditions and



## **Table of Contents**

changes in the financial condition of the companies we invest in. Based on the fair value of the publicly traded equity securities we held at December 31, 2011, an assumed 25%, 40% and 50% adverse change in the market prices of these securities would result in a corresponding decline in total fair value of approximately \$0.4 million, \$0.7 million and \$0.8 million, respectively. Based on the fair value of the publicly traded equity securities we held at December 31, 2010, an assumed 25%, 40% and 50% adverse change in the market prices of these securities would result in a corresponding decline in total fair value of approximately \$1.5 million, \$2.5 million and \$3.1 million, respectively. 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 Risk*

Our operations outside of the U.S. are maintained primarily in their local currency. 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 stockholders' equity. Gains and losses on foreign currency transactions and short term inter-company receivables from foreign subsidiaries are included in Other income, net.

The reported results of our foreign operations will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. We have entered into various foreign exchange forward contracts to manage a portion of our exposure to foreign exchange rate fluctuations on our forecasted sales to and receivables from certain subsidiaries, denominated in euros, British pounds, Canadian dollars and Australian dollars.

In addition, we purchase Lidoderm<sup>®</sup>, 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. In addition, we have certain licensing arrangements which could require us to make payments upon certain regulatory and sales milestones, denominated in Euros.

A 10% change in foreign currency exchange rates would not have a material impact on our financial condition, results of operations or cash flows.

### *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(a) under the caption Consolidated Financial Statements as part of this Annual Report on Form 10-K.

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

Not applicable.

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

### **(a) Evaluation of Disclosure Controls and Procedures**

The Company's management, with the participation of the Company's Chief Executive Officer and Chief 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, 2011. Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of December 31, 2011.



**Table of Contents**

***(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(a) 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(a) of this Annual Report on Form 10-K under the caption "Report of Independent Registered Public Accounting Firm" and incorporated herein by reference.

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

The Company acquired Qualitest and AMS on November 30, 2010 and June 17, 2011, respectively. The Company began to integrate these acquired companies into its internal control over financial reporting structure subsequent to their respective acquisition dates. As such, there have been changes during the year ended December 31, 2011 associated with the establishment and continued integration of internal control over financial reporting with respect to these acquired companies.

There were no other changes in the Company's internal control over financial reporting during the fourth quarter of 2011 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Table of Contents**

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

None.

**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 2012 Annual Meeting of Stockholders (2012 Proxy Statement).

**Executive Officers**

For information concerning Endo's executive officers, see Item 1. Business Executive Officers of the Registrant and our 2012 Proxy Statement.

**Code of Ethics**

The information concerning our Code of Conduct is incorporated herein by reference from our 2012 Proxy Statement.

**Audit Committee**

The information concerning our Audit Committee is incorporated herein by reference from our 2012 Proxy Statement.

**Audit Committee Financial Experts**

The information concerning our Audit Committee Financial Experts is incorporated herein by reference from our 2012 Proxy Statement.

**Item 11. *Executive Compensation***

The information required under this Item is incorporated herein by reference from our 2012 Proxy Statement.

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

*Equity Compensation Plan Information.* The following information relates to plans in effect as of December 31, 2011 under which equity securities of Endo may be issued to employees and directors. The Endo Pharmaceuticals Holdings Inc. 2004, 2007 and 2010 Stock Incentive Plans and the American Medical Systems Holdings, Inc. 2005 Stock Incentive Plan provide that stock options may be granted thereunder to non-employee consultants.

Plan Category	Column A Number of securities to be issued upon exercise of outstanding options, warrants and rights	Column B Weighted-average exercise price of outstanding  options, warrants and rights(1)	Column C Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column A)
<b>Equity compensation plans approved by security holders</b>			
American Medical Systems Holdings, Inc. 2005 Stock Incentive Plan	1,523,770	24.46	3,277,664
Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan	2,017,688	23.70	
Endo Pharmaceuticals Holdings Inc. 2007 Stock Incentive Plan	3,220,774	21.17	
Endo Pharmaceuticals Holdings Inc. 2010 Stock Incentive Plan	3,510,730	33.26	7,791,841

(1) Excludes shares of restricted stock units outstanding

The other information required under this Item is incorporated herein by reference from our 2012 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 2012 Proxy Statement.

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

Information about the fees for 2011 and 2010 for professional services rendered by our independent registered public accounting firm is incorporated herein by reference from our 2012 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 2012 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 Consolidated Financial Statements.

2. Consolidated Financial Statement Schedule:

**Table of Contents****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, 2009	\$ 1,465	\$	\$ (442)	\$ 1,023
Year Ended December 31, 2010	\$ 1,023	\$ 855	\$ (748)	\$ 1,130
Year Ended December 31, 2011	\$ 1,130	\$ 4,170	\$ (1,092)	\$ 4,208

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.

**Table of Contents**

**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 PHARMACEUTICALS HOLDINGS INC.

(Registrant)

*/s/* DAVID P. HOLVECK  
**Name: David P. Holveck**  
**Title: President and Chief Executive Officer**

**(Principal Executive Officer)**

*/s/* ALAN G. LEVIN  
**Name: Alan G. Levin**  
**Title: Executive Vice President, Chief Financial Officer**

**(Principal Financial Officer)**

*/s/* DANIEL A. RUDIO  
**Name: Daniel A. Rudio**  
**Title: Vice President, Controller and Principal Accounting Officer (Principal Accounting Officer)**

Date: February 29, 2012

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

Signature	Title	Date
<i>/s/</i> DAVID P. HOLVECK  <b>David P. Holveck</b>	Director, President and Chief Executive Officer	February 29, 2012
<i>/s/</i> ALAN G. LEVIN  <b>Alan G. Levin</b>	Executive Vice President, Chief Financial Officer	February 29, 2012
*	Chairman and Director	February 29, 2012
<b>Roger H. Kimmel</b>		
*	Director	February 29, 2012
<b>John J. Delucca</b>		
*	Director	February 29, 2012
<b>Nancy J. Hutson, Ph.D.</b>		



Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

*	Director	February 29, 2012
<b>Michael Hyatt</b>		
*	Director	February 29, 2012
<b>William P. Montague</b>		
*	Director	February 29, 2012
<b>David B. Nash, M.D., M.B.A.</b>		
*	Director	February 29, 2012
<b>Joseph C. Scodari</b>		
*	Director	February 29, 2012
<b>William F. Spengler</b>		
*By: /s/ CAROLINE B. MANOGUE	Attorney-in-fact, pursuant to a Power of Attorney filed with this Report as Exhibit 24	February 29, 2012
<b>Caroline B. Manogue</b>		

**Table of Contents**

**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Management's Report on Internal Control Over Financial Reporting</u>	F-2
<u>Reports of Independent Registered Public Accounting Firm</u>	F-3, F-4
<u>Consolidated Balance Sheets as of December 31, 2011 and 2010</u>	F-5
<u>Consolidated Statements of Operations for the Years Ended December 31, 2011, 2010 and 2009</u>	F-6
<u>Consolidated Statements of Stockholders' Equity and Comprehensive Income for the Years Ended December 31, 2011, 2010 and 2009</u>	F-7
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2011, 2010 and 2009</u>	F-9
<u>Notes to Consolidated Financial Statements for the Years Ended December 31, 2011, 2010 and 2009</u>	F-10

**Table of Contents**

**MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

The management of Endo Pharmaceuticals Holdings Inc. 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 Pharmaceuticals Holdings Inc.'s internal control system was designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation and fair presentation of its published financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Endo Pharmaceuticals Holdings Inc.'s management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2011. 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. Based on our assessment we believe that, as of December 31, 2011, the Company's internal control over financial reporting is effective based on those criteria.

Endo Pharmaceuticals Holdings Inc.'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, 2011. This report appears on page F-4.

/s/ DAVID P. HOLVECK  
David P. Holveck

President and Chief Executive Officer

/s/ ALAN G. LEVIN  
Alan G. Levin  
Executive Vice President, Chief Financial Officer  
February 29, 2012

**Table of Contents**

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Endo Pharmaceuticals Holdings Inc.

Chadds Ford, Pennsylvania

We have audited the accompanying consolidated balance sheets of Endo Pharmaceuticals Holdings Inc. and subsidiaries (the Company) as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity and comprehensive income, and cash flows for each of the three years in the period ended December 31, 2011. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedule based on our 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 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 audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Endo Pharmaceuticals Holdings Inc. and subsidiaries as of December 31, 2011 and 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such 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.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2011, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 29, 2012 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Philadelphia, Pennsylvania

February 29, 2012

**Table of Contents**

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Endo Pharmaceuticals Holdings Inc.

Chadds Ford, Pennsylvania

We have audited the internal control over financial reporting of Endo Pharmaceuticals Holdings Inc. and subsidiaries (the Company) as of December 31, 2011, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible 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 an opinion on the Company's internal control over financial reporting 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel 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 (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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 the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended December 31, 2011 of the Company and our report dated February 29, 2012 expressed an unqualified opinion on those financial statements and financial statement schedule.

/s/ DELOITTE & TOUCHE LLP

Philadelphia, Pennsylvania

February 29, 2012

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****CONSOLIDATED BALANCE SHEETS****DECEMBER 31, 2011 AND 2010****(In thousands, except share and per share data)**

	<b>2011</b>	<b>2010</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 547,620	\$ 466,214
Accounts receivable, net of allowance of \$4,208 and \$1,130 at December 31, 2011 and 2010	733,222	547,807
Inventories, net	262,419	178,805
Prepaid expenses and other current assets	29,732	22,841
Income taxes receivable		3,143
Deferred income taxes	215,103	140,724
<b>Total current assets</b>	<b>1,788,096</b>	<b>1,359,534</b>
MARKETABLE SECURITIES	19,105	23,509
PROPERTY, PLANT AND EQUIPMENT, NET	297,731	215,295
GOODWILL	2,558,041	715,005
OTHER INTANGIBLES, NET	2,504,124	1,531,760
OTHER ASSETS	125,486	67,286
<b>TOTAL ASSETS</b>	<b>\$ 7,292,583</b>	<b>\$ 3,912,389</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 260,385	\$ 241,114
Accrued expenses	732,831	469,721
Current portion of long-term debt	88,265	24,993
Acquisition-related contingent consideration	4,925	
Income taxes payable	35,372	
<b>Total current liabilities</b>	<b>1,121,778</b>	<b>735,828</b>
DEFERRED INCOME TAXES	617,677	217,334
ACQUISITION-RELATED CONTINGENT CONSIDERATION	3,762	16,050
LONG-TERM DEBT, LESS CURRENT PORTION, NET	3,424,329	1,045,801
OTHER LIABILITIES	85,446	94,047
COMMITMENTS AND CONTINGENCIES (NOTE 14)		
<b>STOCKHOLDERS EQUITY:</b>		
Preferred Stock, \$0.01 par value; 40,000,000 shares authorized; none issued		
Common Stock, \$0.01 par value; 350,000,000 shares authorized; 138,337,002 and 136,309,917 shares issued; 117,158,880 and 116,057,895 outstanding at December 31, 2011 and 2010, respectively	1,383	1,363
Additional paid-in capital	952,325	860,882
Retained earnings	1,551,910	1,364,297
Accumulated other comprehensive loss	(9,436)	(1,161)
Treasury stock, 21,178,122 and 20,252,022 shares at December 31, 2011 and 2010, respectively	(518,492)	(483,790)
<b>Total Endo Pharmaceuticals Holdings Inc. stockholders equity</b>	<b>1,977,690</b>	<b>1,741,591</b>

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

Noncontrolling interests	61,901	61,738
Total stockholders' equity	2,039,591	1,803,329
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 7,292,583</b>	<b>\$ 3,912,389</b>

See notes to consolidated financial statements.

F-5

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009**

(In thousands, except per share data)

	2011	2010	2009
<b>REVENUES:</b>			
Net pharmaceutical product sales	\$ 2,209,089	\$ 1,601,192	\$ 1,451,577
Devices revenues	300,299		
Services and other revenues	220,733	115,037	9,264
<b>TOTAL REVENUES</b>	<b>2,730,121</b>	<b>1,716,229</b>	<b>1,460,841</b>
<b>COSTS AND EXPENSES:</b>			
Cost of revenues	1,065,208	504,757	375,058
Selling, general and administrative	824,534	547,605	534,523
Research and development	182,286	144,525	185,317
Asset impairment charges	116,089	35,000	69,000
Acquisition-related items, net	33,638	18,976	(93,081)
<b>OPERATING INCOME</b>	<b>508,366</b>	<b>465,366</b>	<b>390,024</b>
<b>INTEREST EXPENSE, NET</b>	<b>148,024</b>	<b>46,601</b>	<b>37,718</b>
<b>LOSS (GAIN) ON EXTINGUISHMENT OF DEBT, NET</b>	<b>11,919</b>		<b>(4,025)</b>
<b>OTHER INCOME, NET</b>	<b>(3,268)</b>	<b>(1,933)</b>	<b>(3,329)</b>
<b>INCOME BEFORE INCOME TAX</b>	<b>351,691</b>	<b>420,698</b>	<b>359,660</b>
<b>INCOME TAX</b>	<b>109,626</b>	<b>133,678</b>	<b>93,324</b>
<b>CONSOLIDATED NET INCOME</b>	<b>\$ 242,065</b>	<b>\$ 287,020</b>	<b>\$ 266,336</b>
Less: Net income attributable to noncontrolling interests	54,452	28,014	
<b>NET INCOME ATTRIBUTABLE TO ENDO PHARMACEUTICALS HOLDINGS INC.</b>	<b>\$ 187,613</b>	<b>\$ 259,006</b>	<b>\$ 266,336</b>
<b>NET INCOME PER SHARE ATTRIBUTABLE TO ENDO PHARMACEUTICALS HOLDINGS INC.:</b>			
Basic	\$ 1.61	\$ 2.23	\$ 2.27
Diluted	\$ 1.55	\$ 2.20	\$ 2.27
<b>WEIGHTED AVERAGE SHARES:</b>			
Basic	116,706	116,164	117,112
Diluted	121,178	117,951	117,515

See notes to consolidated financial statements.



**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE INCOME****YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009****(In thousands, except share data)**

	Common Stock		Endo Pharmaceuticals Holdings Inc. Shareholders			Treasury Stock		Total Endo Pharmaceuticals Holdings Inc.		Total Stockholders Equity
	Number of Shares	Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Number of Shares	Amount	Stockholders Equity	Noncontrolling Interests	
BALANCE, JANUARY 1, 2009	134,302,004	\$ 1,343	\$ 793,285	\$ 838,955	\$ (1,656)	(17,716,303)	\$ (424,816)	\$ 1,207,111	\$	\$ 1,207,111
Compensation related to stock-based awards			19,593					19,593		19,593
Forfeiture of restricted stock awards	(1,131)									
Exercise of options	554,827	6	8,031					8,037		8,037
Tax benefits of stock awards			(3,693)					(3,693)		(3,693)
Common stock issued	130,912	1	251					252		252
Treasury stock acquired										
Comprehensive income:										
Unrealized loss on securities, net of tax					(225)			(225)		(225)
Net income				266,336				266,336		266,336
Total comprehensive income								\$ 266,111	\$	\$ 266,111
BALANCE, DECEMBER 31, 2009	134,986,612	\$ 1,350	\$ 817,467	\$ 1,105,291	\$ (1,881)	(17,716,303)	\$ (424,816)	\$ 1,497,411	\$	\$ 1,497,411
Compensation related to stock-based awards			22,909					22,909		22,909
Exercise of options	965,013	9	20,874					20,883		20,883
Tax benefits of stock awards			(805)					(805)		(805)
Common stock issued	358,292	4	437					441		441
Treasury stock acquired						(2,535,719)	(58,974)	(58,974)		(58,974)
Noncontrolling interests acquired in business combinations									63,227	63,227
								(28,870)	(28,870)	(28,870)

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

Distributions to noncontrolling interests				
Buy-out of noncontrolling interests, net			(633)	(633)
Comprehensive income:				
Unrealized gain on securities, net of tax		720	720	720
Net income	259,006		259,006	287,020

Total comprehensive income \$ 259,726 \$ 28,014 \$ 287,740

BALANCE, DECEMBER 31, 2010	136,309,917	\$ 1,363	\$ 860,882	\$ 1,364,297	\$ (1,161)	(20,252,022)	\$ (483,790)	\$ 1,741,591	\$ 61,738	\$ 1,803,329
----------------------------	-------------	----------	------------	--------------	------------	--------------	--------------	--------------	-----------	--------------

F-7

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE INCOME****YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009 (Continued)****(In thousands, except share data)**

	Common Stock		Endo Pharmaceuticals Holdings Inc. Shareholders			Treasury Stock		Total Endo Pharmaceuticals Holdings Inc. Stockholders		Noncontrolling Interests	Total Stockholders Equity
	Number of Shares	Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Number of Shares	Amount	Equity			
Compensation related to stock-based awards			46,013					46,013			46,013
Forfeiture of restricted stock awards	(8,009)										
Exercise of options	1,274,280	12	28,946					28,958			28,958
Tax benefits of stock awards			3,780					3,780			3,780
Common stock issued	760,814	8	479					487			487
Treasury stock acquired						(926,100)	(34,702)	(34,702)			(34,702)
Distributions to noncontrolling interests									(53,997)		(53,997)
Buy-out of noncontrolling interests, net									(292)		(292)
Replacement equity issued in connection with the AMS acquisition			12,220					12,220			12,220
Other			5					5			5
Comprehensive income:											
Net unrealized loss on securities, net of tax					(419)			(419)			(419)
Foreign currency translation loss, net of tax					(8,071)			(8,071)			(8,071)
Fair value adjustment on derivatives designated as cash flow hedges, net of tax					215			215			215
Net income				187,613				187,613	54,452		242,065
Total comprehensive income								\$ 179,338	\$ 54,452		\$ 233,790
	138,337,002	\$ 1,383	\$ 952,325	\$ 1,551,910	\$ (9,436)	(21,178,122)	\$ (518,492)	\$ 1,977,690	\$ 61,901		\$ 2,039,591

BALANCE,  
DECEMBER 31,  
2011

See notes to consolidated financial statements.

F-8

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009**

(In thousands)

	2011	2010	2009
<b>OPERATING ACTIVITIES:</b>			
Net income	\$ 242,065	\$ 287,020	\$ 266,336
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	237,414	108,404	80,381
Stock-based compensation	46,013	22,909	19,593
Amortization of debt issuance costs and premium/discount	32,788	22,013	19,503
Provision for bad debts		855	
Selling, general and administrative expenses paid in shares of common stock	234	220	251
Deferred income taxes	(75,877)	(15,420)	(36,395)
Loss (gain) on disposal of property, plant and equipment	76	154	(16)
Change in the fair value of acquisition-related contingent consideration	(7,363)	(51,420)	(128,090)
Loss on auction-rate securities rights		15,659	11,662
Gain on trading securities		(15,420)	(15,222)
Loss (gain) on extinguishment of debt, net	11,919		(4,025)
Asset impairment charges	116,089	35,000	69,000
Gain on sale of business	(824)		
Changes in assets and liabilities which provided (used) cash:			
Accounts receivable	(107,609)	(84,659)	(62,584)
Inventories	(8,703)	13,894	12,920
Prepaid and other assets	(2,156)	(4,003)	13,554
Accounts payable	(30,269)	30,145	12,068
Accrued expenses	205,020	93,346	34,112
Other liabilities	(3,029)	(5,612)	9,653
Income taxes receivable/payable	46,327	561	(7,295)
<b>Net cash provided by operating activities</b>	<b>702,115</b>	<b>453,646</b>	<b>295,406</b>
<b>INVESTING ACTIVITIES:</b>			
Purchases of property, plant and equipment	(59,383)	(19,891)	(12,415)
Proceeds from sale of property, plant and equipment	1,626	356	
Purchases of investments	(14,025)		
Proceeds from investments	85,025		
Proceeds from sales of trading securities		231,125	23,750
License fees	(2,300)	(400)	(4,485)
Acquisitions, net of cash acquired	(2,393,397)	(1,105,040)	(250,359)
Proceeds from sale of business	12,990		
Other investments	(4,628)	(2,473)	(2,000)
<b>Net cash used in investing activities</b>	<b>(2,374,092)</b>	<b>(896,323)</b>	<b>(245,509)</b>
<b>FINANCING ACTIVITIES:</b>			
Capital lease obligations repayments	(1,444)	(313)	(250)
Purchase of common stock	(34,702)	(58,974)	
Tax benefits of stock awards	5,909	1,944	717
Exercise of Endo Pharmaceuticals Holdings Inc. Stock Options	28,954	20,883	8,037
Proceeds from issuance of 2019 and 2022 Notes	900,000		
Proceeds from issuance of 2020 Notes		386,576	
Proceeds from issuance of Term Loans	2,200,000	400,000	
Proceeds from other indebtedness	500	1,696	
Principal payments on HealthTronics senior credit facility		(40,000)	

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

Principal payments on Qualitest debt		(406,758)	
Principal payments on Term Loans	(689,876)		
Payment on AMS Convertible Notes	(519,040)		
Principal payments on other indebtedness		(61,559)	(120,470)
Deferred financing fees	(82,504)	(13,563)	(5,162)
Payment for contingent consideration	(827)		
Distributions to noncontrolling interests	(53,997)	(28,870)	
Buy-out of noncontrolling interests, net of contributions	(292)	(633)	
<b>Net cash provided by (used in) financing activities</b>	<b>1,752,681</b>	<b>200,429</b>	<b>(117,128)</b>
Effect of foreign exchange rate	702		
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>81,406</b>	<b>(242,248)</b>	<b>(67,231)</b>
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	466,214	708,462	775,693
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 547,620</b>	<b>\$ 466,214</b>	<b>\$ 708,462</b>
<b>SUPPLEMENTAL INFORMATION:</b>			
Interest paid	\$ 81,458	\$ 22,187	\$ 19,265
Income taxes paid	\$ 150,299	\$ 143,529	\$ 126,431
<b>SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>			
Purchase of property, plant and equipment financed by capital leases	\$ 4,279	\$ 689	\$ 235
Accrual for purchases of property, plant and equipment	\$ 11,704	\$ 6,793	\$ 2,635

See notes to consolidated financial statements.

---

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009**

**NOTE 1. DESCRIPTION OF BUSINESS**

Endo Pharmaceuticals Holdings Inc., together with its subsidiaries, which we refer to as Endo, we, us or the Company, is a U.S. based, specialty healthcare solutions company focused on branded and generic pharmaceuticals, devices and services. We aim to partner with healthcare professionals and payment providers to deliver a suite of complementary branded and generic drugs, devices and clinical data to meet the needs of patients in areas such as pain management, urology, oncology and endocrinology. The Company was incorporated on November 18, 1997 under the laws of the State of Delaware.

In the first quarter of 2009, we acquired Indevus Pharmaceuticals (Indevus), a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. On July 2, 2010, we acquired HealthTronics, Inc. a provider of healthcare services and manufacturer of certain related medical devices, primarily for the urology community. On September 20, 2010, we acquired Penwest Pharmaceuticals Co., a drug development company. On November 30, 2010, we acquired Qualitest, a privately-held generics company in the U.S. On June 17, 2011, we acquired AMS, a worldwide developer and provider of technology solutions to physicians treating men's and women's pelvic health conditions.

In the fourth quarter of 2011, as a result of our strategic planning process, the Company's executive leadership team reorganized the manner in which it views our various business activities. Management's intention was to better understand the entity's performance, better assess its prospects and future cash flow potential and ultimately make more informed operating decisions about resource allocation and the enterprise as a whole. Based on this change, we reassessed our reporting structure under the applicable accounting guidance and determined that the Company now has four reportable segments. We have retrospectively revised the segment presentation for all periods presented reflecting the change from three to four reportable segments. This change in our segments has no impact on the Company's consolidated financial statements for all years presented.

For a complete description of our segment results, see Note 6. Segment Results.

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

*Principles of Consolidation* The Consolidated Financial Statements include the accounts of Endo Pharmaceuticals Holdings Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated.

As a result of the HealthTronics acquisition, we now own interests in various partnerships and limited liability corporations, or LLCs. We consolidate our investments in these partnerships or LLCs, where we, as the general partner or managing member, exercise effective control, even though our ownership is less than 50%. The related governing agreements provide us with broad powers, and the other parties do not participate in the management of the entity and do not have the substantial ability to remove us. We have reviewed each of the underlying agreements and determined we have effective control; however, if it was determined this control did not exist, these investments would be reflected on the equity method of accounting. Although this would change individual line items within our consolidated financial statements, it would have no effect on our net income and/or total stockholders' equity attributable to Endo Pharmaceuticals Holdings Inc.

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

**Table of Contents**

*Use of Estimates* In preparing the consolidated financial statements, we use certain estimates and assumptions that affect reported amounts and disclosures, including amounts recorded in connection with acquisitions. These estimates and underlying assumptions can impact all elements of our consolidated financial statements. We regularly evaluate our estimates and assumptions using historical experience and other factors, including the economic environment. Our estimates often are based on complex judgments, probabilities and assumptions that we believe to be reasonable but that are inherently uncertain and unpredictable.

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. These and other risks and uncertainties are discussed in Part 1 Item 1A of this report, Risk Factors .

*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:

	2011	2010	2009
Cardinal Health, Inc.	25%	33%	35%
McKesson Corporation	24%	28%	29%
AmerisourceBergen Corporation.	13%	15%	16%

Revenues from these customers are included within our Branded Pharmaceuticals and Generics segments.

The Company derives a majority of its total revenues from a limited number of products. Products that accounted for 10% or more of our total revenues during the years ended December 31 were as follows:

	2011	2010	2009
Lidoderm®	30%	46%	52%
Opana® ER	14%	14%	12%

We have agreements with Novartis Consumer Health, Inc., Novartis AG, Teikoku Seiyaku Co., Ltd., Almac Pharma Services, Sharp Corporation and Noramco Inc. for the manufacture and supply of a substantial portion of our existing pharmaceutical products. Additionally, we utilize UPS Supply Chain Solutions, Inc. for customer service support, warehouse and distribution services, see Note 14. Commitments and Contingencies.

*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. 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 chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and allowances are reasonably



## **Table of Contents**

determinable, and when collectability is reasonably assured. 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 during the period following launch.

### *Devices*

As a result of our acquisition of AMS, we sell products in this segment through a direct sales force. A portion of our revenue is generated from consigned inventory or from inventory with field representatives. For these products, revenue is recognized at the time the product has been used or implanted. For all other transactions, we recognize revenue when title to the goods and risk of loss transfer to our customers providing there are no remaining performance obligations required from us or any matters requiring customer acceptance. In cases where we utilize distributors or ship product directly to the end user, we recognize revenue upon shipment provided all revenue recognition criteria have been met.

### *Services*

Our fees for the urology and pathology services performed by our HealthTronics business are recorded when the procedure is performed and are based on contracted rates. Management fees from our HealthTronics limited partnerships are recorded monthly when earned.

*Sales Deductions* When we recognize net sales from the sale of our products, we simultaneously record an adjustment to revenue for estimated chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and allowances. 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. 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, absent any alternative future uses. 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 of accumulated amortization.

## **Table of Contents**

*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, 2011, 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.

*Marketable Securities* 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. In rare or unique circumstances, management may determine that a one-time transfer of securities from available-for-sale to a trading classification is appropriate.

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. Fair value is determined based on observable market quotes or valuation models using assessments of counterparty credit worthiness, credit default risk or underlying security and overall capital market liquidity. 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.

Generally, the Company classifies marketable securities as current when maturity is less than or equal to twelve months or, if time to maturity is greater than twelve months, when they represent investments of cash that are intended to be used in current operations.

The cost of securities sold is based on the specific identification method. Auction-rate securities that become illiquid as a result of a failed auction are generally classified as non-current assets as the Company cannot predict when future auctions related to these securities will be successful.

*Cost of Revenues* Cost of revenues includes all costs directly related to bringing both purchased and manufactured products to their final selling destination, as well as providing our services to our customers. 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 on certain licensed products, inspection costs, depreciation, amortization of intangible assets, warehousing costs, freight charges, costs to operate our equipment, and other shipping and handling activity.

*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 and auction-rate debt securities 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 62% and 79% of our trade accounts receivable balance represent amounts due from three customers at December 31, 2011 and 2010, respectively.

## **Table of Contents**

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.

*Property, plant and equipment* Property, plant and equipment are stated at cost less accumulated depreciation. Depreciation is computed over the estimated useful life of the related assets, ranging from 1 to 35 years, 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.

*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 2 to 20 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.

*Customer Relationships* Acquired customer relationships are recorded at fair value upon acquisition and are amortized using estimated useful lives ranging from 13 to 17 years, with a weighted average useful life of approximately 16 years. We determine amortization periods for customer relationships 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 customer relationships, contractual terms and our plans regarding our future relations with our customers. 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.

*Developed Technology* Acquired developed technology is recorded at fair value upon acquisition and amortized using estimated useful lives ranging from 3 to 20 years, with a weighted average useful life of approximately 16 years. We determine amortization periods for developed technology based on our assessment of various factors impacting estimated useful lives and 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. The value of these assets is subject to continuing scientific, medical and marketplace uncertainty.

*Tradenames* Acquired tradenames are recorded at fair value upon acquisition and, if deemed to have definite lives, are amortized using estimated useful lives ranging from 15 to 30 years, with a weighted average useful life of approximately 22 years. We determine amortization periods for tradenames 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 tradename and our plans regarding the future use of the tradename. 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.

*Asset Impairment Charges* Long-lived assets, which includes property, plant and equipment, and other intangible assets, are assessed for impairment whenever events or changes in circumstances indicate the carrying

## **Table of Contents**

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 value of the asset exceeds the undiscounted future cash flows generated by that asset and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be 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 acquired after January 1, 2009 is initially capitalized and considered indefinite-lived assets subject to annual impairment reviews or more often upon the occurrence of certain events. The review 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 value, an impairment loss is recognized for the difference. For those compounds that reach commercialization, the assets are amortized over the expected useful lives. Prior to January 1, 2009, amounts allocated to acquired IPR&D were expensed at the date of acquisition.

*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 January 1st of each year or more frequently if events or changes in circumstances indicate that the asset might be impaired. The impairment model prescribes a two-step method for determining a goodwill impairment. In the first step, we determine the fair value of our seven reporting units using a discounted cash flow analysis. If the net book values of our reporting units exceed the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting units' fair value to all of its assets and liabilities using the acquisition method prescribed under authoritative guidance for business combinations with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit's goodwill is less than its carrying amount.

*Advertising Costs* Advertising costs are expensed as incurred and included in Selling, general and administrative expenses and amounted to \$55.1 million, \$44.3 million and \$56.9 million for the years ended December 31, 2011, 2010 and 2009, respectively.

*Income Taxes* Provisions for income taxes are calculated on reported pre-tax income based on current tax laws, statutory tax rates and available tax incentives and planning opportunities in various jurisdictions in which we operate. Such provisions differ from the amounts currently receivable or payable because certain items of income and expense are recognized in different time periods for financial reporting purposes than for income tax purposes. We recognize deferred taxes by the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred income taxes are recognized for differences between the financial statement and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. Significant judgment is required in determining income tax provisions and evaluating tax positions. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The factors used to assess the likelihood of realization are the Company's forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. Failure to achieve forecasted taxable income in applicable tax jurisdictions could affect the ultimate realization of deferred tax assets and could result in an increase in the Company's effective tax rate on future earnings.

## **Table of Contents**

We must recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate resolution.

*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. Contingent accruals are recorded 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.

*Contingent Consideration* We account for contingent consideration in a purchase business combination in accordance with applicable guidance provided within the business combination rules. As discussed in Note 3. Fair Value Measurements and Note 5. Acquisitions, as part of our consideration for certain of our acquisitions, we could be contractually obligated to pay additional purchase price consideration upon the achievement of certain regulatory, commercial or other milestones. Therefore, we are required to update our assumptions each reporting period, based on new developments, and record such amounts at fair value until such consideration is satisfied.

*Stock-Based Compensation* Effective January 1, 2006, the Company adopted the fair value recognition provisions for share based compensation using the modified-prospective-transition method. Under that transition method, compensation cost recognized during the years ended December 31, 2011, 2010 and 2009 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value.

*Segment Information* In the fourth quarter of 2011, as a result of our strategic planning process, the Company's executive leadership team reorganized the manner in which it views our various business activities. Management's intention was to better understand the entity's performance, better assess its prospects and future cash flow potential and ultimately make more informed operating decisions about resource allocation and the enterprise as a whole. Based on this change, we reassessed our reporting structure under the applicable accounting guidance and determined that the Company now has four reportable segments: (1) Branded Pharmaceuticals, (2) Generics, (3) Devices and (4) Services. We have retrospectively revised the segment presentation for all periods presented reflecting the change from three to four reportable segments. This change in our segments has no impact on the Company's consolidated financial statements for all years presented. A summary of our total revenues to external customers and adjusted income (loss) before income tax for each of our segments is found in Note 6. Segment Results.

*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 stockholders. 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 stockholders' equity.

*Treasury Stock* Treasury stock consists of shares of Endo Pharmaceuticals Holdings Inc. that have been issued but subsequently reacquired. We account for treasury stock purchases under the cost method. In accordance with the cost method, we account for the entire cost of acquiring shares of our stock as treasury stock, which is a contra equity account. If these shares are reissued, we would use an average cost method for determining cost. Proceeds in excess of cost would then be credited to additional paid-in capital. No treasury shares have been reissued as of December 31, 2011.

*Foreign Currency Translation* The financial statements for operations outside the U.S. are maintained primarily in their local currency. All assets and liabilities of our international subsidiaries, which maintain their

## **Table of Contents**

financial statements in local currency, are translated to U.S. dollars at year-end exchange rates, while elements of the statement of operations are translated at average exchange rates in effect during the year. Translation adjustments arising from the use of differing exchange rates are included in accumulated other comprehensive income in stockholders' equity with the exception of inter-company balances not considered permanently invested which are included in Other income, net. The balance of cumulative translation adjustments included in accumulated other comprehensive income was \$8.1 million at December 31, 2011. Gains and losses on foreign currency transactions are also included in Other income, net.

*Derivatives and Hedging Activities* All derivatives are recorded in the Consolidated Balance Sheets at fair value. Changes in the fair value of derivatives are recorded each period in earnings or other comprehensive income depending on the type of hedging instrument and the effectiveness of those hedges. See Note 19. Derivative Instruments and Hedging Activities for a description of our derivative instruments and hedging activities.

*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 entity's own common stock and (2) classified in stockholders' equity in its statement of financial position are not considered to be derivative financial instruments if the appropriate provisions are met. Accordingly, we have recorded the Convertible Notes as long-term debt in the accompanying Consolidated Balance Sheets.

Concurrent with the issuance of the Convertible Notes we entered into privately negotiated common stock 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 13. Stockholders' 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 accompanying Consolidated Balance Sheets.

### *Recent Accounting Pronouncements*

In December 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2010-29 on interim and annual disclosure of pro forma financial information related to business combinations. The new guidance clarifies the acquisition date that should be used for reporting the pro forma financial information in which comparative financial statements are presented. It is effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010. The provisions of this ASU have been incorporated into this filing for our 2011 acquisitions.

In December 2010, the FASB issued ASU 2010-28 on accounting for goodwill. The guidance clarifies the impairment test for reporting units with zero or negative carrying amounts. The guidance is effective for fiscal years and interim periods within those years beginning after December 15, 2011. The adoption is not expected to have a material impact on the Company's Consolidated Financial Statements.

---

**Table of Contents**

In December 2010, the FASB issued ASU 2010-27 on accounting for the annual fee imposed by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act. The new guidance specifies that the liability for the fee should be estimated and recorded in full upon the first qualifying sale with a corresponding deferred cost that is amortized to expense. It is effective on a prospective basis for calendar years beginning after December 31, 2010. The amount expensed in 2011 related to this fee was approximately \$18.0 million in 2011, which we charged as an operating expense ratably throughout 2011.

In May 2011, the FASB issued ASU 2011-04 on fair value disclosures. This guidance amends certain accounting and disclosure requirements related to fair value measurements. It is effective on a prospective basis for interim and annual periods beginning after December 15, 2011. Early application is not permitted. The Company is currently evaluating ASU 2011-04 but we do not expect the impact of adoption to be material.

In June 2011, the FASB issued ASU 2011-05 on the presentation of comprehensive income, which amends current comprehensive income guidance. This accounting update eliminates the option to present the components of other comprehensive income as part of the statement of stockholders' equity. Instead, the Company must report comprehensive income in either a single continuous statement of comprehensive income which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. ASU 2011-05 was initially to be effective for public companies during the interim and annual periods beginning after December 15, 2011 with early adoption permitted.

However, the changes in ASU 2011-05 that relate to the presentation of reclassification adjustments to other comprehensive income were deferred in December 2011 upon the FASB's issuance of ASU 2011-12, which allows the FASB time to redeliberate whether to present the effects of reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income on the face of the financial statements for all periods presented. While the FASB is considering the operational concerns about the presentation requirements for reclassification adjustments and the needs of financial statement users for additional information about reclassification adjustments, the Company is required to continue reporting reclassifications out of accumulated other comprehensive income consistent with the presentation requirements in effect before ASU 2011-05. All other requirements in ASU 2011-05 are not affected by ASU 2011-12, including the requirement to report comprehensive income either in a single continuous financial statement or in two separate but consecutive financial statements. Public entities should apply these requirements for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of ASU 2011-05 and ASU 2011-12 will not have an impact on the Company's consolidated financial position, results of operations or cash flows as it only requires a change in the format of the current presentation.

In September 2011, the FASB issued ASU 2011-08 on testing goodwill for impairment, which permits an entity to make a qualitative assessment of whether it is more likely than not that a reporting unit's fair value is less than its carrying value before applying the two-step goodwill impairment model that is currently in place. If it is determined through the qualitative assessment that reporting unit's fair value is more likely than not greater than its carrying value, the remaining impairment steps would be unnecessary. The qualitative assessment is optional, allowing companies to go directly to the quantitative assessment. ASU 2011-08 will be effective for annual and interim goodwill impairment tests performed in fiscal years beginning after December 15, 2011, with early adoption permitted. The Company is currently evaluating ASU 2011-08.

**NOTE 3. FAIR VALUE MEASUREMENTS**

The financial instruments recorded in our Consolidated Balance Sheets include cash and cash equivalents, accounts receivable, marketable securities, auction-rate securities rights, equity and cost method investments, accounts payable, acquisition-related contingent consideration, our debt obligations, and derivative instruments. Included in 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 per unit, which assists in

**Table of Contents**

ensuring 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 cash and cash equivalents, accounts receivable and accounts payable approximate their fair values.

The following table presents the carrying amounts and estimated fair values of our other financial instruments for the years ended December 31 (in thousands):

	2011		2010	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
<b>Current assets:</b>				
Derivative instruments	\$ 1,471	\$ 1,471		
<b>Long-term assets:</b>				
Auction-rate securities	17,463	17,463	17,332	17,332
Equity securities	1,642	1,642	6,177	6,177
Equity and cost method investments	20,661	N/A	34,677	N/A
	\$ 41,237		\$ 58,186	
<b>Current liabilities:</b>				
Acquisition-related contingent consideration short-term	\$ 4,925	\$ 4,925		
Current portion of Term Loan Facility Due 2015			22,500	22,500
Current portion of Term Loan A Facility Due 2016	84,375	84,375		
3.25% AMS Convertible Notes due 2036	841	841		
4.00% AMS Convertible Notes due 2041	131	131		
Current portion of other long-term debt	2,918	2,918	2,493	2,493
Derivative instruments	119	119		
<b>Long-term liabilities:</b>				
Acquisition-related contingent consideration long-term	\$ 3,762	\$ 3,762	\$ 16,050	\$ 16,050
1.75% Convertible Senior Subordinated Notes Due 2015, net	299,222	330,950	278,922	324,257
Term Loan Facility Due 2015, less current portion			377,500	380,038
Term Loan A Facility Due 2016, less current portion	1,387,500	1,372,119		
Term Loan B Facility Due 2018	438,250	439,017		
7.00% Senior Notes Due 2019	500,000	532,500		
7.00% Senior Notes Due 2020, net	396,618	424,750	386,716	403,308
7.25% Senior Notes Due 2022	400,000	422,500		
Other long-term debt, less current portion	2,739	2,739	2,663	2,663
Minimum Voltaren® Gel royalties due to Novartis	20,100	20,100	38,922	38,922
	\$ 3,541,500	\$ 3,641,746	\$ 1,125,766	\$ 1,190,231

Equity securities consist of publicly traded common stock, the value of which is based on a quoted market price. These securities are not held to support current operations and are therefore classified as non-current assets.

The acquisition-related contingent consideration, which is required to be measured at fair value on a recurring basis, consists primarily of contingent cash consideration related to the November 2010 acquisition of Qualitest. The fair value of our acquisition-related contingent consideration is determined using an income approach (present value technique), which is discussed in more detail below.



## **Table of Contents**

The fair value of our 1.75% Convertible Senior Subordinated Notes is based on an income approach known as the binomial lattice model which incorporated certain inputs and assumptions, including scheduled coupon and principal payments, the conversion feature inherent in the Convertible Notes, the put feature inherent in the Convertible Notes, and stock price volatility assumptions of 33% in 2011 and 2010 that were based on historic volatility of the Company's common stock and other factors. The fair values of Term Loan Facilities and 2019, 2020, and 2022 Notes were estimated using a discounted cash flow model based on the contractual repayment terms of the respective instruments and discount rates that reflect current market conditions.

The total fair value of various foreign exchange forward contracts as of December 31, 2011 includes assets of \$1.5 million reported in Accounts receivable, net and liabilities of \$0.1 million, reported in Accrued expenses. We measure our derivative instruments at fair value on a recurring basis using significant observable inputs. Refer to Note 19. Derivative Instruments and Hedging Activities for more information regarding our derivative instruments.

The minimum Voltaren® Gel royalty due to Novartis AG was recorded at fair value at inception during 2008 using an income approach (present value technique) and is being accreted up to the maximum potential future payment of \$60.0 million. We believe the carrying amount of this minimum royalty guarantee at December 31, 2011 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, 2011.

The fair value of equity method and cost method investments is not readily available nor have we estimated the fair value of these investments and disclosure is not required. The Company is not aware of any identified events or changes in circumstances that would have a significant adverse effect on the carrying value of any of our equity or cost method investments included in our Consolidated Balance Sheet at December 31, 2011.

As of December 31, 2011, the Company held certain assets and liabilities that are required to be measured at fair value on a recurring basis. 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.

**Table of Contents**

The Company's financial assets and liabilities measured at fair value on a recurring basis at December 31, 2011 and December 31, 2010, were as follows (in thousands):

	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, 2011</b>				
<b>Assets:</b>				
Money market funds	\$ 110,816	\$	\$	\$ 110,816
Equity securities	1,642			1,642
Derivative instruments		1,471		1,471
Auction-rate securities			17,463	17,463
<b>Total</b>	<b>\$ 112,458</b>	<b>\$ 1,471</b>	<b>\$ 17,463</b>	<b>\$ 131,392</b>
<b>Liabilities:</b>				
Derivative instruments	\$	\$ 119	\$	\$ 119
Acquisition-related contingent consideration short-term			4,925	4,925
Acquisition-related contingent consideration long-term			3,762	3,762
<b>Total</b>	<b>\$</b>	<b>\$ 119</b>	<b>\$ 8,687</b>	<b>\$ 8,806</b>

	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, 2010</b>				
<b>Assets:</b>				
Money market funds	\$ 149,318	\$	\$	\$ 149,318
Equity securities	6,177			6,177
Auction-rate securities			17,332	17,332
<b>Total</b>	<b>\$ 155,495</b>	<b>\$</b>	<b>\$ 17,332</b>	<b>\$ 172,827</b>
<b>Liabilities:</b>				
Acquisition-related contingent consideration long-term			16,050	16,050
<b>Total</b>	<b>\$</b>	<b>\$</b>	<b>\$ 16,050</b>	<b>\$ 16,050</b>

*Overview of Auction-Rate Securities*

Auction-rate securities are long-term variable rate bonds tied to short-term interest rates. After the initial issuance of the securities, the interest rate on the securities is reset periodically, at intervals established at the time of issuance (e.g., every seven, twenty-eight, or thirty-five days; every six months; etc.). In an active market, auction-rate securities are bought and sold at each reset date through a competitive bidding process, often referred to as a "Dutch auction". Auctions are successful when the supply and demand of securities are in balance. Financial institutions brokering the auctions would also participate in the auctions to balance the supply and demand. Beginning in the second half of 2007, auctions

## Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

began to fail for specific securities and in mid-February 2008 auction failures became common, prompting market participants, including financial institutions, to cease or limit their exposure to the auction-rate market. Given the current negative liquidity conditions in the global credit markets, the auction-rate securities market remains inactive. Consequently, our auction-rate securities are currently illiquid through the normal auction process. As a result of the inactivity in the market, quoted market prices and other observable data are not available or their utility is limited.

F-21

## **Table of Contents**

Our auction-rate securities consist of municipal bonds with an auction reset feature, the underlying assets of which are student loans that are backed substantially by the federal government and have underlying credit ratings of AAA as of December 31, 2011. The issuers have been making interest payments promptly.

### *Overview of Auction-Rate Securities Rights*

In October 2008, UBS AG (UBS) made an offer (the UBS Offer) to the Company and other clients of UBS Securities LLC and UBS Financial Services Inc. (collectively, the UBS Entities), pursuant to which the Company received auction-rate securities rights (the Rights) to sell to UBS all auction-rate securities held by the Company as of February 13, 2008 in a UBS account (the Eligible Auction-Rate Securities). The Rights permitted the Company to require UBS to purchase the Eligible Auction-Rate Securities for a price equal to par value plus any accrued but unpaid dividends or interest beginning on June 30, 2010 and ending on July 2, 2012.

On November 10, 2008, the Company accepted the UBS Offer, awarding the UBS Entities the sole discretion and right to sell or otherwise dispose of, and/or enter orders in the auction process with respect to the Eligible Auction-Rate Securities on the Company's behalf until the Expiration Date, without prior notification, so long as the Company receives a payment of par value plus any accrued but unpaid dividends or interest upon any sale or disposition.

### *Subsequent Accounting for Auction-Rate Securities and Auction-Rate Securities Rights*

Concurrent with the acceptance of the UBS offer, the Company made a one-time election to re-classify the Eligible Auction-Rate Securities from an available-for-sale security to a trading security. Subsequent changes to the fair value of these trading securities resulted in \$15.4 million and \$15.2 million of income during the years ended December 31, 2010 and 2009, respectively, recorded in Other income, net in the Consolidated Statements of Operations.

As a result of our fair value election for the Rights, the fair value of the Rights was re-measured each reporting period with the corresponding changes in fair value reported in earnings. In June 2010, the Rights were exercised and all Eligible Auction-Rate Securities were sold at par. Accordingly, the Rights were written off in their entirety.

At December 31, 2011 and 2010, the fair value of the Rights was zero. Accordingly, the decrease in fair value during 2010 of \$15.7 million was recognized as a charge to earnings and included in Other income, net in the Consolidated Statements of Operations.

### *Valuation of the Auction-Rate Securities*

The Company determined that an income approach (present value technique) that maximizes the use of observable market inputs is the preferred approach to measuring the fair value of our securities. Specifically, the Company used the discount rate adjustment technique to determine an indication of fair value.

To calculate a price for our auction-rate securities, the Company calculates duration to maturity, coupon rates, market required rates of return (discount rate) and a discount for lack of liquidity in the following manner:

The Company identifies the duration to maturity of the auction-rate securities as the time at which principal is available to the investor. This can occur because the auction-rate security is paying a

**Table of Contents**

coupon that is above the required rate of return, and the Company treats the security as being called. It can also occur because the market has returned to normal and the Company treats the auctions as having recommenced. Lastly, and most frequently, the Company treats the principal as being returned as prepayment occurs and at the maturity of the security. The initial life used for each remaining security, representing time to maturity, was eight years as of December 31, 2011.

The Company calculates coupon rates based on estimated relationships between the maximum coupon rate (the coupon rate in event of a failure) and market interest rates. The representative coupon rate was 3.61% on December 31, 2011 and 5.10% on December 31, 2010. The Company calculates appropriate discount rates for securities that include base interest rates, index spreads over the base rate, and security-specific spreads. These spreads include the possibility of changes in credit risk over time. The spread over the base rate applied to our securities was 204 basis points at December 31, 2011 and 218 basis points at December 31, 2010.

The Company believes that a market participant would require an adjustment to the required rate of return to adjust for the lack of liquidity. We do not believe it is unreasonable to assume a 150 basis points adjustment to the required rate of return and a term of either three, four or five years to adjust for this lack of liquidity. The increase in the required rate of return decreases the prices of the securities. However, the assumption of a three, four or five-year term shortens the times to maturity and increases the prices of the securities. The Company has evaluated the impact of applying each term and the reasonableness of the range indicated by the results. The Company chose to use a four-year term to adjust for the lack of liquidity as we believe it is the point within the range that is most representative of fair value. The Company's conclusion is based in part on the fact that the fair values indicated by the results are reasonable in relation to each other given the nature of the securities and current market conditions.

At December 31, 2011, the fair value of our auction-rate securities, as determined by applying the above described discount rate adjustment technique, was approximately \$17.5 million, representing a 7%, or \$1.3 million discount from their original purchase price or par value. This compares to approximately \$17.3 million, representing an 8%, or \$1.5 million discount from their original purchase price or par value. We believe we have appropriately reflected our best estimate of the assumptions that market participants would use in pricing the assets in a current transaction to sell the asset at the measurement date. Accordingly, the carrying value of our auction-rate securities at December 31, 2011 and 2010 were reduced by approximately \$1.3 million and \$1.5 million, respectively. These adjustments appropriately reflect the changes in fair value, which the Company attributes to liquidity issues rather than credit issues.

The portion of the 2010 decline in fair value related to the Eligible Auction-Rate Securities was recorded in earnings as an other-than-temporary impairment charge or as changes in the fair value of trading securities. The Company has assessed the portion of the decline in fair value not associated with the Eligible Auction-Rate Securities to be temporary due to the financial condition and near-term prospects of the underlying issuers, our intent and ability to retain our investment in the issuers for a period of time sufficient to allow for any anticipated recovery in market value and based on the extent to which fair value is less than par. Accordingly, we recorded a \$0.1 million gain and a \$0.4 million loss in shareholders' equity in accumulated other comprehensive loss as of December 31, 2011 and 2010, respectively. Securities not subject to the UBS Offer are analyzed each reporting period for other-than-temporary impairment factors. Any future fluctuation in fair value related to these instruments that the Company judges to be temporary, including any recoveries of previous write-downs, would be recorded to other comprehensive income. If the Company determines that any future valuation adjustment was other-than-temporary, it would record a charge to earnings as appropriate. However, there can be no assurance that our current belief that the securities not subject to the UBS Offer will recover their value will not change.

*Valuation of the Auction-Rate Securities Rights*

Until the Rights were exercised and all UBS securities were sold on June 30, 2010, the Company valued the Rights using an income approach (present value technique) that maximized the use of observable market. Specifically, the Company used the discount rate adjustment technique to determine an indication of fair value.

---

## **Table of Contents**

### *Overview of Acquisition-Related Contingent Consideration*

At December 31, 2011 and December 31, 2010, the fair value of the contingent consideration is \$8.7 million and \$16.1 million, respectively. The material components of this obligation are discussed below.

*Indevus* On February 23, 2009 (the Indevus Acquisition Date), the Company completed its initial tender offer for all outstanding shares of common stock of Indevus and completed its acquisition of Indevus on March 23, 2009, at which time Indevus became a wholly-owned subsidiary of the Company. The Indevus Shares were purchased at a price of \$4.50 per Indevus Share, net to the seller in cash, plus contractual rights to receive up to an additional \$3.00 per Indevus Share in contingent cash consideration payments related to potential future regulatory and commercial milestones related to Aveed™ (the Aveed™ Contingent Cash Consideration Agreement) and the octreotide NDA for the treatment of acromegaly (the Octreotide Contingent Cash Consideration Agreement). Additionally, upon the acquisition of Indevus, the Company assumed a pre-existing contingent consideration obligation relating to Indevus' acquisition of Valera Pharmaceuticals, Inc. (the Valera Contingent Consideration Agreement), which could entitle former Valera shareholders to receive consideration from the Company upon U.S. Food and Drug Administration (FDA) approval of the octreotide implant for the treatment for acromegaly.

*Qualitest* On November 30, 2010 (the Qualitest Acquisition Date), Endo acquired Qualitest, which was party to an asset purchase agreement with Teva Pharmaceutical Industries Ltd (Teva) (the Teva Agreement). Pursuant to this agreement, Qualitest 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).

### *Valuation of the Acquisition-Related Contingent Consideration*

*Indevus* The Indevus Contingent Consideration Agreements were measured and recognized at fair value upon the Indevus Acquisition Date and are required to be re-measured on a recurring basis, with changes to fair value recorded in Acquisition-related items, net in the accompanying Consolidated Statements of Operations. The fair values were determined using a probability-weighted discounted cash flow model, or income approach. This fair value measurement technique is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. The valuation of each Indevus Contingent Consideration Agreement is described in further detail below:

*Aveed™ Contingent Consideration* The range of the undiscounted amounts the Company could pay under the Aveed™ Contingent Cash Consideration Agreement is between zero and approximately \$175.0 million. Under this agreement, there are three scenarios that could potentially lead to amounts being paid to the former stockholders of Indevus. These scenarios are (1) obtaining an Aveed™ With Label approval, (2) obtaining an Aveed™ Without Label approval and (3) achieving the \$125.0 million sales milestone on or prior to the fifth anniversary of the date of the first commercial sale of Aveed™ should the Aveed™ Without Label approval be obtained. The fourth scenario is Aveed™ not receiving approval within three years of the closing of the Offer, which would result in no payment to the former stockholders of Indevus. Each scenario was assigned a probability based on the current regulatory status of Aveed™. The resultant probability-weighted cash flows were then discounted using a discount rate of U.S. Prime plus 300 basis points, which the Company believes is appropriate and is representative of a market participant assumption. Using this valuation technique, the fair value of the contractual obligation to pay the Aveed™ Contingent Consideration was determined to be zero at December 31, 2011, \$7.1 million at December 31, 2010 and \$133.1 million on the Indevus Acquisition Date.

*Octreotide Contingent Consideration* The range of the undiscounted amounts the Company could pay under the Octreotide Contingent Cash Consideration Agreement is between zero and approximately \$91.0 million. Under this agreement, the two scenarios that require consideration are (1) approval of octreotide on or before the fourth anniversary of the closing of the Offer or (2) no octreotide approval

## Table of Contents

on or before the fourth anniversary of the closing of the Offer. Each scenario was assigned a probability based on the current development stage of octreotide. The resultant probability-weighted cash flows were then discounted using a discount rate of U.S. Prime plus 300 basis points, which the Company believes is appropriate and is representative of a market participant assumption. Using this valuation technique, the fair value of the contractual obligation to pay the Octreotide Contingent Consideration was determined to be zero at both December 31, 2011 and December 31, 2010 and \$39.8 million on the Indevus Acquisition Date.

*Valera Contingent Consideration* The range of the undiscounted amounts the Company could pay under the Valera Contingent Cash Consideration Agreement is between zero and approximately \$33.0 million. The fair value of the Valera Contingent Consideration is estimated using the same assumptions used for the Aveed™ Contingent Cash Consideration Agreement and Octreotide Contingent Cash Consideration Agreement, except that the probabilities associated with the Valera Contingent Consideration take into account the probability of obtaining the Octreotide Approval on or before the fourth anniversary of the closing of the Offer. This is due to the fact that the Valera Contingent Consideration will not be paid unless octreotide for the treatment of acromegaly is approved prior to April 18, 2012. Using this valuation technique, the fair value of the contractual obligation to pay the Valera Contingent Consideration was determined to be zero at both December 31, 2011 and December 31, 2010 and \$13.7 million on the Indevus Acquisition Date.

At December 31, 2011, the aggregate fair value of the three Indevus Contingent Consideration Agreements decreased to zero at December 31, 2011 from \$7.1 million at December 31, 2010. This decrease primarily reflects management's current assessment of the probability that it will not be obligated to make contingent consideration payments based on the anticipated timeline for the NDA filings and FDA approvals of Aveed™. The decrease in the liability was recorded as a gain and was included in Acquisition-related items, net in the accompanying Consolidated Statements of Operations.

*Qualitest* On November 30, 2010 (the Qualitest Acquisition Date), Endo acquired Qualitest, who was party to an asset purchase agreement with Teva Pharmaceutical Industries Ltd (Teva) (the Teva Agreement). Pursuant to this agreement, Qualitest 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 range of the undiscounted amounts the Company could pay under the Teva Agreement is between zero and \$12.5 million. The Company is accounting for the Teva Contingent Consideration in the same manner as if it had entered into that arrangement with respect to its acquisition of Qualitest. Accordingly, the fair value was estimated based on a probability-weighted discounted cash flow model, or income approach. The resultant probability-weighted cash flows were then discounted using a discount rate of U.S. Prime plus 300 basis points. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. Using this valuation technique, the fair value of the contractual obligation to pay the Teva Contingent Consideration was determined to be \$8.7 million at December 31, 2011 and \$9.0 million at December 31, 2010 and the Qualitest Acquisition Date, respectively.

The decrease balance at December 31, 2011 compared to December 31, 2010 primarily reflects changes of our present value assumptions associated with our valuation model. The decrease in the liability was recorded as a gain and is included in Acquisition-related items, net in the accompanying Consolidated Statements of Operations.

**Table of Contents***Fair Value Measurements Using Significant Unobservable Inputs*

The following table presents changes to the Company's financial assets and liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the year ended December 31, 2011 (in thousands):

	<b>Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Auction-rate Securities</b>	
<b>Assets:</b>		
Balance at January 1, 2011	\$	17,332
Securities sold or redeemed		
Securities purchased or acquired		
Transfers in and/or (out) of Level 3		
Changes in fair value recorded in earnings		
Unrealized gains included in other comprehensive loss		131
Balance at December 31, 2011	\$	17,463
	<b>Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Acquisition-related Contingent Consideration</b>	
<b>Liabilities:</b>		
Balance at January 1, 2011	\$	(16,050)
Amounts (acquired) sold / (issued) settled, net		
Transfers in and/or (out) of Level 3		
Changes in fair value recorded in earnings		7,363
Balance at December 31, 2011	\$	(8,687)

The following table presents changes to the Company's financial assets and liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the year ended December 31, 2010 (in thousands):

	<b>Fair Value Measurements Using Significant Unobservable Inputs (Level 3)</b>		
	<b>Auction-rate Securities</b>	<b>Auction-rate Securities Rights</b>	<b>Total</b>
<b>Assets:</b>			
Balance at January 1, 2010	\$ 207,334	\$ 15,659	\$ 222,993
Securities sold or redeemed	(205,050)		(205,050)
Securities purchased or acquired			
Transfers in and/or (out) of Level 3			
Changes in fair value recorded in earnings	15,420	(15,659)	(239)
Unrealized gain included in other comprehensive loss	(372)		(372)
Balance at December 31, 2010	\$ 17,332	\$	\$ 17,332





**Table of Contents**

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Acquisition-related Contingent Consideration
<b>Liabilities:</b>	
Balance at January 1, 2010	\$ (58,470)
Amounts (acquired) sold / (issued) settled, net	(9,000)
Transfers in and/or (out) of Level 3	
Changes in fair value recorded in earnings	51,420
Balance at December 31, 2010	\$ (16,050)

At December 31, 2011 and 2010, the fair values of the Company's trading securities were zero. The following is a summary of available-for-sale securities held by the Company as of December 31, 2011 (in thousands):

	Amortized Cost	Available-for-sale Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Value
<b>December 31, 2011:</b>				
Money market funds	\$ 110,816	\$	\$	\$ 110,816
<i>Total included in cash and cash equivalents</i>	\$ 110,816	\$	\$	\$ 110,816
Auction-rate securities	18,800		(1,337)	17,463
Equity securities	1,766		(124)	1,642
<i>Long-term available-for-sale securities</i>	\$ 20,566	\$	\$ (1,461)	\$ 19,105
<i>Total available-for-sale securities</i>	\$ 131,382	\$	\$ (1,461)	\$ 129,921

At December 31, 2011, our investments in auction-rate securities consisted of two securities which, as of December 31, 2011, had been in an unrealized loss position for more than twelve months. As previously discussed, the Company has determined that the gross unrealized losses associated with the auction-rate securities are not other-than-temporary.

At December 31, 2011, our equity securities consisted of investments in the stock of three publically traded companies. As of December 31, 2011, two of these investments had been in an unrealized loss position for less than twelve months and one had been in an unrealized loss position for more than twelve months. Due to changes in circumstances surrounding one of our equity securities in the second half of 2011, we recorded a non-cash, other-than-temporary impairment charge of \$3.8 million to reduce the cost basis of this investment to its current fair value. This impairment was recorded in the Asset impairment charges line in our 2011 Consolidated Statement of Operations. The Company does not believe the remaining unrealized losses are other-than-temporary at December 31, 2011 primarily because the Company has both the ability and intent to hold these investments for a period of time we believe will be sufficient to recover such losses.

**Table of Contents**

The following is a summary of available-for-sale securities held by the Company as of December 31, 2010 (in thousands):

	Amortized Cost	Available-for-sale Gross Unrealized Gains	Available-for-sale Gross Unrealized (Losses)	Fair Value
<b>December 31, 2010:</b>				
Money market funds	\$ 149,318	\$	\$	\$ 149,318
<i>Total included in cash and cash equivalents</i>	\$ 149,318	\$	\$	\$ 149,318
Auction-rate securities	18,800		(1,468)	17,332
Equity securities	5,564	613		6,177
<i>Long-term available-for-sale securities</i>	\$ 24,364	\$ 613	\$ (1,468)	\$ 23,509
<i>Total available-for-sale securities</i>	\$ 173,682	\$ 613	\$ (1,468)	\$ 172,827

At December 31, 2010, our investments in auction-rate securities consisted of two securities which, as of December 31, 2010, had been in an unrealized loss position for more than twelve months. As previously discussed, the Company determined that the gross unrealized losses associated with the auction-rate securities were not other-than-temporary.

At December 31, 2010, our equity securities consisted of investments in the stock of three publically traded companies. As of December 31, 2010, one of these investments had been in an unrealized loss position for less than twelve months and two were in an unrealized gain position. The Company did not believe the unrealized losses associated with our equity securities were other-than-temporary at December 31, 2010 primarily because the Company had both the ability and intent to hold these investments for a period of time we believed would be sufficient to recover such losses.

We did not sell any of our remaining auction-rate securities during 2011. During 2010, we sold \$230.3 million of auction-rate securities at par value. During the year ended December 31, 2009, we sold \$23.8 million of auction-rate securities at par value. There were no realized holding gains and losses resulting from the sales of our auction-rate securities and variable rate demand obligations during the periods ended December 31, 2011 and 2010. The cost of securities sold is based on the specific identification method.

The underlying assets of our auction-rate securities are student loans. Student loans are insured by the Federal Family Education Loan Program, or FFELP.

As of December 31, 2011, the yields on our long-term auction-rate securities were 0.24%. These yields represent the predetermined maximum reset rates that occur upon auction failures according to the specific terms within each security's prospectus. Total interest recognized on our auction-rate securities during 2011, 2010 and 2009 was less than \$0.1 million, \$0.7 million and \$2.4 million, respectively. The issuers have been making interest payments promptly.

**Table of Contents**

The amortized cost and estimated fair value of available-for-sale debt and equity securities by contractual maturities are shown below (in thousands). Actual maturities may differ from contractual maturities because borrowers may have the right to call or prepay obligations with or without call or prepayment penalties.

	December 31, 2011		December 31, 2010	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Available-for-sale debt securities:				
Due in less than 1 year	\$	\$	\$	\$
Due in 1 to 5 years				
Due in 5 to 10 years				
Due after 10 years	18,800	17,463	18,800	17,332
Equity securities	1,766	1,642	5,564	6,177
Total	\$ 20,566	\$ 19,105	\$ 24,364	\$ 23,509

**NOTE 4. INVENTORIES**

Inventories are comprised of the following for the years ended December 31 (in thousands):

	2011	2010
Raw materials	\$ 103,064	\$ 45,957
Work-in-process	51,063	34,208
Finished goods	108,292	98,640
Total	\$ 262,419	\$ 178,805

Inventory amounts in the table above are shown net of obsolescence. Our reserve for obsolescence is not material to the Consolidated Balance Sheets for any of the periods presented and therefore has not been separately disclosed.

**NOTE 5. ACQUISITIONS****AMS**

On June 17, 2011 (the AMS Acquisition Date), the Company completed its acquisition of all outstanding shares of common stock of AMS for approximately \$2.4 billion in aggregate consideration, including \$70.8 million related to existing AMS stock-based compensation awards and certain other amounts, at which time AMS became a wholly-owned subsidiary of the Company. AMS's shares were purchased at a price of \$30.00 per share.

AMS is a worldwide developer and provider of technology solutions to physicians treating men's and women's pelvic health conditions. The AMS business and applicable services include:

*Men's Health.*

AMS supplies surgical solutions for the treatment of male urinary incontinence, the involuntary release of urine from the body. The fully implantable AMS 800® system includes an inflatable urethral cuff to restrict flow through the urethra and a control pump that allows the patient to discreetly open the cuff when he wishes to urinate. Since 2000, AMS has also been selling the InVance® sling system, a less-invasive procedure for men with moderate incontinence, and in 2007, AMS released the AdVance® sling system for the treatment of mild to moderate stress urinary incontinence. AMS also offers the UroLume® endoprosthesis stent as a less invasive procedure for patients who may not be good surgical candidates, as well as for men suffering from bulbar urethral strictures.



## **Table of Contents**

AMS also supplies penile implants to treat erectile dysfunction, the inability to achieve or maintain an erection sufficient for sexual intercourse, with a series of semi-rigid malleable prostheses and a complete range of more naturally functioning inflatable prostheses, including the AMS 700<sup>®</sup> MS. AMS has refined its implants over the years with improvements to the AMS 700<sup>®</sup> series of inflatable prostheses, including the AMS 700 LGX<sup>®</sup> and the MS Pump<sup>®</sup>. Another key factor that distinguishes AMS's products is the use of the InhibiZon<sup>®</sup> antibiotic coating, which received FDA approval in July 2009 for AMS's product claim that InhibiZon<sup>®</sup> reduces the rate of revision surgery due to surgical infections.

### *Women's Health.*

AMS offers a broad range of systems, led by Monarc<sup>®</sup> and MiniArc<sup>®</sup>, 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. Monarc<sup>®</sup> incorporates unique helical needles to place a self-fixating, sub-fascial hammock through the obturator foramen. AMS's MiniArc<sup>®</sup> Single-Incision Sling for stress incontinence was released in 2007 and requires just one incision to surgically place a small sling under the urethra, which minimizes tissue disruption and potential for blood loss, thereby allowing the procedure to be done with less anesthesia on an outpatient basis. In 2010, AMS launched the MiniArc Precise<sup>™</sup>, which is designed to enhance the ease and accuracy of placement of the MiniArc<sup>®</sup> device.

AMS also offers solutions for pelvic floor prolapse and other pelvic floor disorders, which may be caused by pregnancy, labor, and childbirth. In 2008, AMS introduced the Elevate<sup>®</sup> transvaginal pelvic floor repair system, with no external incisions. Using an anatomically designed needle and self-fixating tips, Elevate<sup>®</sup> allows for safe, simple and precise mesh placement through a single vaginal incision. The posterior system was launched in 2008 and the anterior system was launched in 2009.

### *BPH Therapy.*

AMS's products can be used to relieve restrictions on the normal flow of urine from the bladder caused by bladder obstructions, generally the result of BPH or bulbar urethral strictures. AMS offers men experiencing a physical obstruction of the prostatic urethra an alternative to a TURP, with the GreenLight<sup>™</sup> photovaporization of the prostate. This laser therapy is designed to reduce the comorbidities associated with TURP. AMS's GreenLight<sup>™</sup> XPS and MoXy<sup>™</sup> Liquid Cooled Fiber provide shorter treatment times with similar long-term results compared to other laser systems. The GreenLight<sup>™</sup> laser system offers an optimal laser beam that balances vaporization of tissue with coagulation to prevent blood loss and providing enhanced surgical control compared to other laser systems. AMS also offers the StoneLight<sup>®</sup> laser and SureFlex<sup>™</sup> fiber optics for the treatment of urinary stones. StoneLight<sup>®</sup> is a lightweight and portable 15-watt holmium laser that offers the right amount of power to effectively fragment most urinary stones. The SureFlex<sup>™</sup> fiber optic line is engineered to deliver more energy safely and effectively, even under maximum scope deflection, for high performance holmium laser lithotripsy.

AMS's TherMatr<sup>®</sup> product is designed for those men not yet to the point of urethral obstruction, but for whom symptomatic relief is desired. It is a less-invasive tissue ablation technique that can be performed in a physician's office using microwave energy delivered to the prostate.

The acquisition of AMS furthers Endo's evolution from a pharmaceutical product-driven company to a healthcare solutions provider, strengthens our leading core urology franchise and expands our presence in the medical devices market. We believe the combination of AMS with Endo's existing platform will provide additional cost-effective solutions across the entire urology spectrum.

The operating results of AMS from and including June 18, 2011 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheet as of December 31, 2011 reflects the acquisition of AMS.

**Table of Contents**

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

	June 17, 2011 (As initially reported)	Measurement period adjustments	June 17, 2011 (As adjusted)
Cash and cash equivalents	\$ 47,289	\$	\$ 47,289
Commercial paper	71,000		71,000
Accounts receivable	73,868		73,868
Other receivables	791	(161)	630
Inventories	75,525	(156)	75,369
Prepaid expenses and other current assets	7,133		7,133
Income taxes receivable	11,179	(1,712)	9,467
Deferred income taxes	15,360	(820)	14,540
Property, plant and equipment	57,372	(959)	56,413
Other intangible assets	1,390,000	(130,000)	1,260,000
Other assets	4,581		4,581
<b>Total identifiable assets</b>	<b>\$ 1,754,098</b>	<b>\$ (133,808)</b>	<b>\$ 1,620,290</b>
Accounts payable	\$ 9,437	\$ 890	\$ 10,327
Accrued expenses	45,648	187	45,835
Deferred income taxes	507,019	(90,384)	416,635
Long-term debt	520,012	363	520,375
Other liabilities	23,578		23,578
<b>Total liabilities assumed</b>	<b>\$ 1,105,694</b>	<b>\$ (88,944)</b>	<b>\$ 1,016,750</b>
Net identifiable assets acquired	\$ 648,404	\$ (44,864)	\$ 603,540
Goodwill	\$ 1,752,427	\$ 44,009	\$ 1,796,436
<b>Net assets acquired</b>	<b>\$ 2,400,831</b>	<b>\$ (855)</b>	<b>\$ 2,399,976</b>

The above estimated fair values of assets acquired and liabilities assumed are provisional and are based on the information that was available as of the AMS Acquisition Date to estimate the fair value of assets acquired and liabilities assumed. The Company believes that information provides a reasonable basis for estimating the fair values but the Company is waiting for additional information necessary to finalize those amounts, particularly with respect to the estimated fair value of intangible assets, property, plant and equipment, contingent assets and liabilities, and deferred income taxes. Thus, the provisional measurements of fair value reflected are subject to change. Such changes could be significant. The Company expects to finalize the valuation and complete the purchase price allocation as soon as practicable but no later than one year from the AMS Acquisition Date. Measurement period adjustments related primarily to revisions in estimated cash flows for certain products after obtaining additional information regarding facts and circumstances existing as of the AMS Acquisition Date.

**Table of Contents**

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

	Valuation (in millions)	Amortization Period (in years)
<b>Customer Relationships:</b>		
Men's Health	\$ 97.0	17
Women's Health	37.0	15
BPH	26.0	13
Total	\$ 160.0	16
<b>Developed Technology:</b>		
Men's Health	\$ 690.0	18
Women's Health	150.0	9
BPH	161.0	18
Total	\$ 1,001.0	16
<b>Tradename:</b>		
AMS	\$ 45.0	30
GreenLight	12.0	15
Total	\$ 57.0	27
<b>In Process Research &amp; Development:</b>		
Oracle	\$ 12.0	n/a
Genesis	14.0	n/a
TOPAS	8.0	n/a
Other	8.0	n/a
Total	\$ 42.0	n/a
Total other intangible assets	\$ 1,260.0	n/a

The fair value of the developed technology, IPR&D and customer relationship 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 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 fair value of the AMS and GreenLight tradenames were estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to license the AMS or GreenLight tradename. Thus, we derived the hypothetical royalty income from the projected revenues of AMS and GreenLight products, respectively. Cash flows were assumed to extend through the remaining economic useful life of each class of intangible asset.

The \$1,796.4 million of goodwill has been assigned to our Devices segment. The goodwill recognized is attributable primarily to strategic and synergistic opportunities across the entire urology spectrum, expected corporate synergies, the assembled workforce of AMS and other factors. Approximately \$14.5 million of goodwill is expected to be deductible for income tax purposes.

Deferred tax assets of \$14.5 million are related primarily to federal net operating loss and credit carryforwards of AMS and its subsidiaries. Deferred tax liabilities of \$416.6 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.





**Table of Contents**

The Company recognized \$28.8 million of AMS acquisition-related costs that were expensed during 2011. These costs are included in Acquisition-related items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	<b>Acquisition-related Costs</b>	
	<b>Year Ended</b>	
	<b>December 31, 2011</b>	
Bank fees	\$	16,070
Legal, separation, integration, and other costs		12,684
<b>Total</b>	<b>\$</b>	<b>28,754</b>

The amounts of revenue and net loss of AMS included in the Company's Consolidated Statements of Operations from and including June 18, 2011 to December 31, 2011 are as follows (in thousands, except per share data):

	<b>Revenue and Income</b>	
	<b>included in the</b>	
	<b>Consolidated</b>	
	<b>Statements of</b>	
	<b>Operations from</b>	
	<b>and including June 18,</b>	
	<b>2011 to December 31, 2011</b>	
Revenue	\$	300,299
Net loss attributable to Endo Pharmaceuticals Holdings Inc.	\$	(329)
Basic and diluted net loss per share	\$	

The following supplemental pro forma information presents the financial results as if the acquisition of AMS had occurred on January 1, 2010 for the years ended December 31, 2011 and 2010. 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, 2010, nor are they indicative of any future results.

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>Pro forma consolidated results (in thousands, except per share data):</b>		
Revenue	\$ 2,968,497	\$ 2,259,104
Net income attributable to Endo Pharmaceuticals Holdings Inc.	\$ 214,487	\$ 199,776
Basic net income per share	\$ 1.84	\$ 1.72
Diluted net income per share	\$ 1.77	\$ 1.69

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of AMS to reflect factually supportable adjustments that give effect to events that are directly attributable to the AMS Acquisition, including the borrowing under the 2011 Credit Facility, 2019 Notes, and 2022 Notes as well as the additional depreciation and amortization that would have been charged assuming the fair value adjustments primarily to property, plant and equipment, inventory, and intangible assets, had been applied on January 1, 2010, together with the consequential tax effects.

**Qualitest**

On November 30, 2010 (the Qualitest Acquisition Date), Endo completed its acquisition of all of the issued and outstanding capital stock of Generics International (US Parent), Inc. (Qualitest) from an affiliate of Apax Partners, L.P. for approximately \$770.0 million. In addition, Endo paid \$406.8 million to retire Qualitest's outstanding debt and related interest rate swap on November 30, 2010. In connection with the Qualitest acquisition,



**Table of Contents**

\$108 million of the purchase price was placed into two separate escrow accounts. One of the escrow accounts was \$8 million, some of which was used to fund working capital adjustments, as defined in the Qualitest Stock Purchase Agreement. This escrow was settled during the third quarter of 2011. There is also a \$100 million escrow account that will be used to fund all claims arising out of or related to the Qualitest acquisition.

In connection with the \$100 million escrow account, to the extent that we are able to realize tax benefits for costs that are funded by the escrow account, we will be required to share these tax benefits with Apax.

Qualitest is a manufacturer and distributor of generic drugs and over-the-counter pharmaceuticals throughout the U.S. Qualitest's product portfolio is comprised of 175 product families in various forms including tablets, capsules, creams, ointments, suppositories, and liquids. This acquisition has enabled us to gain critical mass in our generics business while strengthening our pain portfolio through a larger breadth of product offerings.

The operating results of Qualitest from November 30, 2010 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheet as of December 31, 2010 reflects the acquisition of Qualitest, effective November 30, 2010, the date the Company obtained control of Qualitest.

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

	November 30, 2010 (As initially reported)	Measurement period adjustments	November 30, 2010 (As adjusted)
Cash and cash equivalents	\$ 21,828	\$	\$ 21,828
Accounts receivable	93,228		93,228
Other receivables	1,483		1,483
Inventories	95,000		95,000
Prepaid expenses and other current assets	2,023	(122)	1,901
Deferred income taxes	63,509	7,531	71,040
Property, Plant and equipment	135,807		135,807
Other intangible assets	843,000	(7,000)	836,000
<b>Total identifiable assets</b>	<b>\$ 1,255,878</b>	<b>\$ 409</b>	<b>\$ 1,256,287</b>
Accounts payable	\$ 27,422	\$ (1)	\$ 27,421
Accrued expenses	55,210	4,141	59,351
Deferred income taxes	207,733	(412)	207,321
Long-term debt	406,758		406,758
Other liabilities	9,370	117	9,487
<b>Total liabilities assumed</b>	<b>\$ 706,493</b>	<b>\$ 3,845</b>	<b>\$ 710,338</b>
Net identifiable assets acquired	\$ 549,385	\$ (3,436)	\$ 545,949
Goodwill	\$ 219,986	\$ 4,112	\$ 224,098
<b>Net assets acquired</b>	<b>\$ 769,371</b>	<b>\$ 676</b>	<b>\$ 770,047</b>

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the Qualitest Acquisition Date. As of December 31, 2011, our measurement period adjustments are complete.

**Table of Contents**

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>		
Hydrocodone and acetaminophen	\$ 119.0	17
Oxycodone and acetaminophen	30.0	17
Promethazine	46.0	16
Isosorbide Mononitrate ER	42.0	16
Multi Vitamins	38.0	16
Trazodone	17.0	16
Butalbital, acetaminophen, and caffeine	25.0	16
Tripnevifem	16.0	13
Spironolactone	13.0	17
Hydrocortisone	34.0	16
Hydrochlorothiazide	16.0	16
Controlled Substances	52.0	16
Oral Contraceptives	8.0	13
Others	162.0	17
Total	\$ 618.0	16
<b>In Process Research &amp; Development:</b>		
Generics portfolio with anticipated 2011 launch	\$ 63.0	n/a
Generics portfolio with anticipated 2012 launch	30.0	n/a
Generics portfolio with anticipated 2013 launch	17.0	n/a
Generics portfolio with anticipated 2014 launch(1)	88.0	n/a
Total	\$ 198.0	n/a
<b>Tradename:</b>		
Qualitest tradename	\$ 20.0	15
Total	\$ 20.0	15
Total other intangible assets	\$ 836.0	n/a

- (1) During the fourth quarter of 2011, the Company received a deficiency from the FDA on an ANDA submission for one of its lead assets in this portfolio. Subsequently, in early 2012, the Company terminated its development program for this asset as a result of the regulatory challenges and changes in the development timeline resulting from the FDA's request. In addition, as a result changes in market conditions since the acquisition date, there has been a significant deterioration in the commercial potential for this product. Accordingly, we recorded a pre-tax non-cash impairment charge of \$71.0 million in 2011 to write off the intangible asset in its entirety, which was assigned to our generics segment and recorded in the Asset impairment charges line of our Consolidated Statements of Operations.

The fair value of the developed technology assets and IPR&D assets were estimated using an 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 probability-weighted cash flows discounted at rates 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. Cash flows were generally assumed to extend through economic useful life of the developed technology, IPR&D asset, or tradename. The fair value of the Qualitest tradename was estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to license the Qualitest tradename. Thus, we derived the hypothetical royalty income from the projected revenues

of Qualitest.

F-35

**Table of Contents**

The \$224.1 million of goodwill was assigned to our Generics segment. The goodwill recognized is attributable primarily to expected purchasing, manufacturing and distribution synergies as well as its assembled workforce. Approximately \$170.4 million of goodwill is expected to be deductible for income tax purposes.

Deferred tax assets of \$71.0 million are related primarily to federal and state net operating loss and credit carryforwards of Qualitest and its subsidiaries. Deferred tax liabilities of \$207.3 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

The Company recognized \$8.0 million and \$38.8 million of Qualitest acquisition-related items, net that were expensed during 2011 and 2010, respectively. These amounts are included in Acquisition-related items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	<b>Acquisition-related Costs Year Ended December 31,</b>	
	<b>2011</b>	<b>2010</b>
Bank fees	\$	\$ 14,215
Legal, separation, integration, and other costs	8,284	24,572
Changes in fair value of acquisition-related contingent consideration	(313)	
Total	\$ 7,971	\$ 38,787

The amounts of revenue and net loss of Qualitest included in the Company's Consolidated Statements of Operations for the year ended December 31, 2010 are as follows (dollars in thousands, except per share data):

	<b>Revenue and Net Loss included in the Consolidated Statements of Operations from November 30, 2010 to December 31, 2010</b>	
	<b>\$</b>	<b></b>
Revenue	\$	30,323
Net loss	\$	(3,056)
Basic and diluted loss per share	\$	(0.03)

The following supplemental pro forma information presents the financial results as if the acquisition of Qualitest had occurred on January 1, 2010 for the year ended December 31, 2010. 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, 2010, nor are they indicative of any future results.

	<b>Year Ended December 31, 2010</b>	
	<b>\$</b>	<b></b>
<b>Pro forma consolidated results (in thousands, except per share data):</b>		
Revenue	\$	2,038,761
Net income attributable to Endo Pharmaceuticals Holdings Inc.	\$	243,710
Basic net income per share	\$	2.10
Diluted net income per share	\$	2.07

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of Qualitest to reflect the additional depreciation and amortization that would have been charged assuming the fair value adjustments primarily to property, plant and equipment and intangible assets, had been applied on January 1, 2010, together with the consequential tax effects.





**Table of Contents***Penwest Pharmaceuticals Co.*

On September 20, 2010 (the Penwest Acquisition Date), the Company completed its tender offer for the outstanding shares of common stock of Penwest and on November 4, 2010, we closed this acquisition for approximately \$171.8 million in aggregate cash consideration, at which time Penwest became our wholly-owned subsidiary. On August 22, 2011, Penwest was merged into Endo Pharmaceuticals Inc., at which time Penwest ceased its existence as a separate legal entity.

This transaction contributes to Endo's core pain management franchise and permits us to maximize the value of our oxycodone franchise.

The operating results of Penwest from September 20, 2010 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheets as of December 31, 2010 reflects the acquisition of Penwest, effective September 20, 2010, the date the Company obtained control of Penwest.

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

	<b>September 20, 2010</b>
Cash and cash equivalents	\$ 22,343
Marketable securities	800
Accounts receivable	10,866
Other receivables	131
Inventories	407
Prepaid expenses and other current assets	493
Deferred income taxes	29,765
Property, plant and equipment	915
Other intangible assets	111,200
Other assets	2,104
<b>Total identifiable assets</b>	<b>\$ 179,024</b>
Accounts payable	\$ 229
Income taxes payable	160
Penwest shareholder liability	
Accrued expenses	1,542
Deferred income taxes	40,168
Other liabilities	4,520
<b>Total liabilities assumed</b>	<b>\$ 46,619</b>
<b>Net identifiable assets acquired</b>	<b>\$ 132,405</b>
Goodwill	\$ 39,361
<b>Net assets acquired</b>	<b>\$ 171,766</b>

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the Penwest Acquisition Date. As of December 31, 2011, our measurement period adjustments are complete.

**Table of Contents**

The valuation of the intangible assets acquired and related amortization periods are as follows (in millions):

	Valuation	Amortization Period (in years)
<b>In Process Research &amp; Development:</b>		
Otsuka	\$ 5.5	n/a
A0001(1)	1.6	n/a
Total	\$ 7.1	n/a
<b>Developed Technology:</b>		
Opana® ER	\$ 104.1	10
Total	\$ 104.1	10
Total other intangible assets	\$ 111.2	n/a

- (1) The Company terminated Penwest's A0001 development program after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, we recorded a pre-tax, non-cash impairment charge of \$1.6 million to write off this intangible asset in its entirety, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our 2011 Consolidated Statement of Operations.

The fair values of the IPR&D assets and developed technology asset were estimated using an income approach. To calculate fair value, the Company used probability-weighted cash flows discounted at rates considered appropriate given the inherent risks associated with the asset. The Company believes that the level and timing of cash flows appropriately reflect market participant assumptions. Cash flows were generally assumed to extend through economic useful life of our developed technology or IPR&D asset.

The \$39.4 million of goodwill was assigned to our Branded Pharmaceuticals segment. The goodwill recognized is attributable primarily to the control premium associated with our oxymorphone franchise and other factors. None of the goodwill is expected to be deductible for income tax purposes.

Deferred tax assets of \$29.8 million are related primarily to federal net operating loss and credit carryforwards of Penwest. Deferred tax liabilities of \$40.2 million are related primarily to the difference between the book basis and tax basis of the identifiable intangible assets.

The Company recognized \$0.3 million and \$10.7 million of Penwest acquisition-related costs that were expensed during 2011 and 2010, respectively. These costs are included in Acquisition-related items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	Acquisition-related Costs Year Ended December 31,	
	2011	2010
Bank fees	\$	\$ 3,865
Legal, separation, integration, and other costs	259	6,815
Total	\$ 259	\$ 10,680

Due to the pro forma impacts of eliminating the pre-existing intercompany royalties between Penwest and Endo, which were determined to be at fair value, we have not provided supplemental pro forma information as amounts are not material to the Consolidated Statements of Operations.

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

We have also considered the impacts of Penwest, since the date we obtained a majority interest, on our Consolidated Statement of Operations and concluded amounts were not material.

F-38

## **Table of Contents**

### *HealthTronics, Inc.*

On July 2, 2010 (the HealthTronics Acquisition Date), the Company completed its initial tender offer for all outstanding shares of common stock of HealthTronics and obtained effective control of HealthTronics. On July 12, 2010, Endo completed its acquisition of HealthTronics for approximately \$214.8 million in aggregate cash consideration for 100% of the outstanding shares, at which time HealthTronics became a wholly-owned subsidiary of the Company. HealthTronics shares were purchased at a price of \$4.85 per HealthTronics Share. In addition, Endo paid \$40 million to retire HealthTronics debt that had been outstanding under its Senior Credit Facility. As a result of the acquisition, the HealthTronics Senior Credit Facility was terminated.

HealthTronics is a provider of healthcare services and manufacturer of certain related medical devices, primarily for the urology community. The HealthTronics business and applicable services include:

### *Lithotripsy services.*

HealthTronics provides lithotripsy services, which is a medical procedure where a device called a lithotripter transmits high energy shockwaves through the body to break up kidney stones. Lithotripsy services are provided principally through limited partnerships and other entities that HealthTronics manages, which use lithotripters. In 2011, physician partners used our lithotripters to perform approximately 50,000 procedures in the U.S. While the physicians render medical services, HealthTronics does not. As the general partner of limited partnerships or the manager of other types of entities, HealthTronics also provide services relating to operating its lithotripters, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting with payors, hospitals, and surgery centers.

### *Prostate treatment services.*

HealthTronics provides treatments for benign and cancerous conditions of the prostate. In treating benign prostate disease, HealthTronics deploys three technologies in a number of its partnerships above: (1) PVP, (2) TUNA, and (3) TUMT. All three technologies apply an energy source which reduces the size of the prostate gland. For treating prostate and other cancers, HealthTronics uses a procedure called cryosurgery, a process which uses lethal ice to destroy tissue such as tumors for therapeutic purposes. In April 2008, HealthTronics acquired Advanced Medical Partners, Inc., which significantly expanded its cryosurgery partnership base. In July 2009, HealthTronics acquired Endocare, Inc., which manufactures both the medical devices and related consumables utilized by its cryosurgery operations and also provides cryosurgery treatments. The prostate treatment services are provided principally by using equipment that HealthTronics leases from limited partnerships and other entities that HealthTronics manages. Benign prostate disease and cryosurgery cancer treatment services are billed in the same manner as its lithotripsy services under either retail or wholesale contracts. HealthTronics also provides services relating to operating the equipment, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting.

### *Anatomical pathology services.*

HealthTronics provides anatomical pathology services primarily to the urology community. HealthTronics has one pathology lab located in Georgia, which provides laboratory detection and diagnosis services to urologists throughout the U.S. In addition, in July 2008, HealthTronics acquired Uropath LLC, now referred to as HealthTronics Laboratory Solutions, which managed pathology laboratories located at Uropath sites for physician practice groups located in Texas, Florida and Pennsylvania. Through HealthTronics Laboratory Solutions, HealthTronics continues to provide administrative services to in-office pathology labs for practice groups and pathology services to physicians and practice groups with its lab equipment and personnel at the HealthTronics Laboratory Solutions laboratory sites.

**Table of Contents**

*Medical products manufacturing, sales and maintenance.*

HealthTronics manufactures and sells medical devices focused on minimally invasive technologies for tissue and tumor ablation through cryoablation, which is the use of lethal ice to destroy tissue, such as tumors, for therapeutic purposes. HealthTronics develops and manufactures these devices for the treatment of prostate and renal cancers and our proprietary technologies also have applications across a number of additional markets, including the ablation of tumors in the lung, liver metastases and palliative intervention (treatment of pain associated with metastases). HealthTronics manufactures the related spare parts and consumables for these devices. HealthTronics also sells and maintains lithotripters and related spare parts and consumables.

The acquisition of HealthTronics reflects Endo's desire to continue expanding our business beyond pain management into complementary medical areas where HealthTronics can be innovative and competitive. We believe this expansion will enable us to be a provider of multiple healthcare solutions and services that fill critical gaps in patient care.

The operating results of HealthTronics from July 2, 2010 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheets as of December 31, 2010 reflects the acquisition of HealthTronics, effective July 2, 2010, the date the Company obtained control of HealthTronics.

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

	<b>July 2, 2010</b>
Cash and cash equivalents	\$ 6,769
Accounts receivable	33,388
Other receivables	1,006
Inventories	12,399
Prepaid expenses and other current assets	5,204
Deferred income taxes	46,489
Property, plant and equipment	30,687
Other intangible assets	73,124
Other assets	5,210
<b>Total identifiable assets</b>	<b>\$ 214,276</b>
Accounts payable	\$ 3,084
Accrued expenses	20,510
Deferred income taxes	22,376
Long-term debt	43,460
Other liabilities	1,785
<b>Total liabilities assumed</b>	<b>\$ 91,215</b>
<b>Net identifiable assets acquired</b>	<b>\$ 123,061</b>
Noncontrolling interests	\$ (63,227)
Goodwill	\$ 155,009
<b>Net assets acquired</b>	<b>\$ 214,843</b>

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the HealthTronics Acquisition Date. As of December 31, 2011, our measurement period adjustments are complete.

**Table of Contents**

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

	Valuation (in millions)	Amortization Period (in years)
Endocare Developed Technology	\$ 46.3	10
HealthTronics Tradename	14.6	15
Service Contract(1)	12.2	n/a
Total	\$ 73.1	n/a

(1) This intangible asset relates to our IGRT business, which was sold in September 2011 for approximately \$13.0 million. Accordingly, the carrying amount of this asset was reduced to zero at the time of sale.

The fair value of the developed technology asset was 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 probability-weighted cash flows discounted at rates 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. Cash flows were assumed to extend through the economic useful life of the purchased technology. The fair value of the HealthTronics Tradename was estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to license the HealthTronics Tradename. Thus, we derived the hypothetical royalty income from the projected revenues of HealthTronics' services.

HealthTronics has investments in partnerships and limited liability companies (LLCs) where we, as the general partner or managing member, exercise effective control. Accordingly, we consolidate various entities where we do not own 100% of the entity in accordance with the accounting consolidation principles. As a result, we are required to fair value the noncontrolling interests as part of our purchase price allocation. To calculate fair value, the Company used historical transactions which represented Level 2 data points within the fair value hierarchy to calculate applicable multiples of each respective noncontrolling interest in the partnerships and LLCs.

The \$155.0 million of goodwill has been assigned to our Services segment. The goodwill recognized is attributable primarily to strategic and synergistic opportunities across the HealthTronics network of urology partnerships, expected corporate synergies, the assembled workforce of HealthTronics and other factors. Approximately \$33.6 million of goodwill is expected to be deductible for income tax purposes.

Deferred tax assets of \$46.5 million are related primarily to federal net operating loss and credit carryforwards of HealthTronics and its subsidiaries. Deferred tax liabilities of \$22.4 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

The Company recognized \$3.7 million and \$20.9 million of HealthTronics acquisition-related costs that were expensed during 2011 and 2010, respectively. These costs are included in Acquisition-related items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	Acquisition-related Costs Year Ended December 31,	
	2011	2010
Bank fees	\$	\$ 2,017
Acceleration of outstanding HealthTronics stock-based compensation		7,924
Legal, separation, integration, and other costs	3,704	10,988
Total	\$ 3,704	\$ 20,929



**Table of Contents**

The amounts of revenue and net loss of HealthTronics included in the Company's Consolidated Statements of Operations for the year ended December 31, 2010 are as follows (dollars in thousands, except per share data):

	<b>Revenue and Net Loss included in the Consolidated Statements of Operations from July 2, 2010 to December 31, 2010</b>
Revenue	\$ 102,144
Net loss	\$ (8,098)
Basic and diluted loss per share	\$ (0.07)

The following supplemental pro forma information presents the financial results as if the acquisition of HealthTronics had occurred on January 1, 2010 for the year ended December 31, 2010. 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, 2010, nor are they indicative of any future results.

	<b>Year Ended December 31, 2010</b>
<b>Pro forma consolidated results (in thousands, except per share data):</b>	
Revenue	\$ 1,814,918
Net income attributable to Endo Pharmaceuticals Holdings Inc.	\$ 264,165
Basic net income per share	\$ 2.27
Diluted net income per share	\$ 2.24

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of HealthTronics to reflect the additional depreciation and amortization that would have been charged assuming the fair value adjustments primarily to property, plant and equipment, and intangible assets, had been applied on January 1, 2010, together with the consequential tax effects.

*Indevus*

On February 23, 2009 (the Indevus Acquisition Date), the Company completed its initial tender offer for all outstanding shares of common stock of Indevus. Through purchases in subsequent offering periods, the exercise of a top-up option and a subsequent merger (the Indevus Merger), the Company completed its acquisition of Indevus on March 23, 2009, at which time Indevus became a wholly-owned subsidiary of the Company.

The Indevus shares were purchased at a price of \$4.50 per share, net to the seller in cash, plus contractual rights to receive up to an additional \$3.00 per share in contingent cash consideration payments, pursuant to the terms of the Indevus Agreement and Plan of Merger, dated as of January 5, 2009 (the Indevus Merger Agreement). Accordingly, the Company paid approximately \$368.0 million in aggregate initial cash consideration for the Indevus shares and entered into the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement (each as defined in the Indevus Merger Agreement), providing for the payment of up to an additional \$3.00 per share in contingent cash consideration payments, in accordance with the terms of the initial tender offer.

The total cost to acquire all outstanding Indevus shares pursuant to the initial tender offer and the Indevus Merger Agreement could be up to an additional approximately \$267.0 million, if Endo is obligated to pay the maximum amounts under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement. The fair value of those potential obligations is zero at December 31, 2011.

Indevus was a specialty pharmaceutical company engaged in the acquisition, development, and commercialization of products to treat conditions in urology, endocrinology and oncology. Following the completion of the Indevus Merger, Indevus was renamed Endo Pharmaceuticals Solutions Inc.



**Table of Contents**

Approved products assumed in the acquisition included Sanctura<sup>®</sup> (trospium chloride) and Sanctura XR<sup>®</sup> (trospium chloride extended release capsules) for the treatment of overactive bladder (OAB); Supprelin<sup>®</sup> LA (histrelin acetate) for treating central precocious puberty (CPP); Vantas<sup>®</sup> (histrelin) for the palliative treatment of advanced prostate cancer; Delatestryl<sup>®</sup> (testosterone enanthate) for the treatment of male hypogonadism; Hydron<sup>®</sup> Implant, which is used as a drug delivery device and provides for a sustained release of a broad spectrum of drugs continuously; and Valstar<sup>®</sup> (valrubicin) for therapy of bacillus Calmette-Guerin (BCG)-refractory carcinoma *in situ* (as CIS) of the bladder.

As of December 31, 2011, Aveed<sup>™</sup> (testosterone undecanoate) represents the primary development product from the Indevus acquisition. Aveed<sup>™</sup> is expected to be the first long-acting injectable testosterone preparation available in the U.S. for the treatment of male hypogonadism in the growing market for testosterone replacement therapies. Aveed<sup>™</sup> had historically been referred to as Nebido<sup>®</sup>. On May 6, 2009, we received notice from the FDA that Nebido<sup>®</sup> was unacceptable as a proprietary name for testosterone undecanoate. In August 2009, we received approval from FDA to use the name Aveed<sup>™</sup>. On May 18, 2010, a new patent covering Aveed<sup>™</sup> was issued by the U.S. Patent and Trademark Office. The patent's expiration date is March 14, 2027. The Company acquired U.S. rights to Aveed<sup>™</sup> from Schering AG, Germany, in July 2005. In June 2008, we received an approvable letter from the FDA indicating that the NDA may be approved if the Company is able to adequately respond to certain clinical deficiencies related to the product. In September 2008, agreement was reached with the FDA with regard to the additional data and risk management strategy. In March 2009, the FDA accepted for review the complete response submission to the new drug application for Aveed<sup>™</sup> intramuscular injection. On December 2, 2009, we received a complete response letter from the FDA regarding Aveed<sup>™</sup> in response to our March 2009 complete response submission. In the complete response letter, the FDA has requested information from Endo to address the agency's concerns regarding very rare but serious adverse events, including post-injection anaphylactic reaction and pulmonary oily microembolism. The letter also specified that the proposed Risk Evaluation and Mitigation Strategy (REMS) is not sufficient. In 2010 and 2011, we met with the FDA to discuss the existing clinical data provided to the FDA as well as the potential path-forward. The Company is evaluating how best to address the concerns of the FDA and intends to have future dialogue with the agency regarding a possible regulatory pathway and is preparing a complete response. The outcome of future communications with the FDA could have a material impact on (1) management's assessment of the overall probability of approval, (2) the timing of such approval, (3) the targeted indication or patient population and (4) the likelihood of additional clinical trials.

Management believes the Company's acquisition of Indevus is particularly significant because it reflects our commitment to expand our business beyond pain management into complementary medical areas where we believe we can be innovative and competitive. The combined company markets products through its differentially deployed field sales forces and has the capability to develop innovative new therapies using a novel drug delivery technology.

The operating results of Indevus from February 23, 2009 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheet as of December 31, 2009 reflects the acquisition of Indevus, effective February 23, 2009, the date the Company obtained control of Indevus. The acquisition date fair value of the total consideration transferred was \$540.9 million, which consisted of the following (in thousands):

	<b>Fair Value of Consideration Transferred</b>
Cash	\$ 368,034
Contingent consideration	172,860
<b>Total</b>	<b>\$ 540,894</b>

**Table of Contents**

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

	<b>February 23, 2009</b>
Cash and cash equivalents	\$ 117,675
Accounts receivable	14,591
Inventories	17,157
Prepaid and other current assets	8,322
Property, plant and equipment	8,856
Other intangible assets	532,900
Deferred tax assets	167,749
Other non-current assets	1,331
<b>Total identifiable assets</b>	<b>\$ 868,581</b>
Accounts payable	\$ 5,116
Accrued expenses	26,725
Convertible notes	72,512
Non-recourse notes	115,235
Deferred tax liabilities	210,647
Other non-current liabilities	18,907
<b>Total liabilities assumed</b>	<b>449,142</b>
<b>Net identifiable assets acquired</b>	<b>\$ 419,439</b>
Goodwill	\$ 121,455
<b>Net assets acquired</b>	<b>\$ 540,894</b>

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the Indevus Acquisition Date.

Of the \$532.9 million of acquired intangible assets, \$255.9 million was assigned to IPR&D. The remaining \$277.0 million has been assigned to license rights and is subject to a weighted average useful life of approximately 11 years.

**Table of Contents**

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

	Valuation (in millions)	Amortization Period (in years)
<b>In Process Research &amp; Development:</b>		
Valstar <sup>®</sup> (1)	\$ 88.0	n/a
Aveed <sup>™</sup> (2)	100.0	n/a
Octreotide(3)	31.0	n/a
Pagoclone(4)	21.0	n/a
Pro2000(5)	4.0	n/a
Other	11.9	n/a
<b>Total</b>	<b>\$ 255.9</b>	<b>n/a</b>
<b>License Rights:</b>		
Hydrogel Polymer	\$ 22.0	10
Vantas <sup>®</sup>	36.0	10
Sanctura <sup>®</sup> Franchise	94.0	12
Supprelin <sup>®</sup> LA	124.0	10
Other	1.0	4
<b>Total</b>	<b>\$ 277.0</b>	<b>11</b>
<b>Total other intangible assets</b>	<b>\$ 532.9</b>	

- (1) The FDA approved the sNDA for Valstar<sup>®</sup> subsequent to the Indevus Acquisition Date. Therefore, Valstar<sup>®</sup> was initially classified as IPR&D and subsequently transferred to License Rights upon obtaining FDA approval and is being amortized over a 15 year useful life.
- (2) As a result of the FDA's complete response letter related to our filed NDA, we performed an impairment analysis during the fourth quarter ended December 31, 2009. We concluded there was a decline in the fair value of the indefinite-lived intangible. Accordingly, we recorded a \$65.0 million impairment charge, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our Consolidated Statements of Operations.
- (3) As part of our 2010 annual review of all IPR&D assets, we conducted an in-depth review of both octreotide indications. This review covered a number of factors including the market potential of each product given its stage of development, taking into account, among other things, issues of safety and efficacy, product profile, competitiveness of the marketplace, the proprietary position of the product and its potential profitability. Our 2010 review resulted in no impact to the carrying value of our octreotide acromegaly intangible asset. However, the analysis identified certain commercial challenges with respect to the octreotide carcinoid syndrome intangible asset including the expected rate of physician acceptance and the expected rate of existing patients willing to switch therapies. Upon analyzing the Company's research and development priorities, available resources for current and future projects, and the commercial potential for octreotide carcinoid syndrome, the Company decided to discontinue development of octreotide for the treatment of carcinoid syndrome. As a result of the above developments, the Company recorded a pre-tax non-cash impairment charge of \$22.0 million in 2010 to write-off, in its entirety, the octreotide carcinoid syndrome intangible asset, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our Consolidated Statements of Operations. On November 11, 2011, the Company separately decided to terminate development of the octreotide implant for the treatment of acromegaly after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, we recorded a pre-tax non-cash impairment charge of \$9.0 million in 2011 to completely write-off the octreotide acromegaly intangible asset, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our Consolidated Statements of Operations.

---

**Table of Contents**

- (4) In May 2010, Teva terminated the development and licensing arrangement with us upon the completion of the Phase IIb study. We concluded there was a decline in the fair value of the indefinite-lived intangible asset. Accordingly, we recorded a \$13.0 million impairment charge, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our Consolidated Statements of Operations. On December 27, 2011, the Company terminated its pagoclone development program after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, we recorded a pre-tax non-cash impairment charges of \$8.0 million in 2011 to completely write-off the pagoclone intangible asset, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our Consolidated Statements of Operations.
- (5) In December 2009, our Phase III clinical trials for Pro2000 provided conclusive results that the drug was not effective. We concluded there was no further value or alternative future uses associated with this indefinite-lived asset. Accordingly, we recorded a \$4.0 million impairment charge to write-off the Pro2000 intangible asset in its entirety, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our Consolidated Statements of Operations.

The fair value of the IPR&D assets and License Rights assets, with the exception of the hydrogel polymer technology, were estimated using an 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 probability-weighted cash flows discounted at rates 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. Cash flows were generally assumed to extend either through or beyond the patent life of each product, depending on the circumstances particular to each product. The fair value of the hydrogel polymer technology was estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to license the technology. The hydrogel polymer technology is currently used in the following products: Vantas<sup>®</sup> and Supprelin<sup>®</sup> LA. Thus, we derived the hypothetical royalty income from the projected revenues of those drugs. The fair value of the hydrogel polymer technology also includes an existing royalty payable by the Company to the certain third party partners based on the net sales derived from drugs that use the hydrogel polymer technology. Discount rates applied to the estimated cash flows for all intangible assets acquired ranged from 13% to 20%, depending on the current stage of development, the overall risk associated with the particular project or product and other market factors. We believe the discount rates used are consistent with those that a market participant would use.

The \$121.5 million of goodwill was assigned to our Branded Pharmaceuticals segment. The goodwill recognized is attributable primarily to the potential additional applications for the hydrogel polymer technology, expected corporate synergies, the assembled workforce of Indevus and other factors. None of the goodwill is expected to be deductible for income tax purposes.

The deferred tax assets of \$167.7 million are related primarily to federal net operating loss and credit carryforwards of Indevus and its subsidiaries. The deferred tax liabilities of \$210.6 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

**Table of Contents**

During the years ended December 31, 2011, 2010 and 2009, we recorded \$7.1 million in income, \$51.4 million in income and \$93.1 million in income for Indevus acquisition-related items, net. These amounts are included Acquisition-related items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	Acquisition-related Costs Year Ended December 31,		
	2011	2010	2009
Investment bank fees, includes Endo and Indevus	\$	\$	\$ 13,030
Legal, separation, integration, and other items			21,979
Changes in fair value of acquisition-related contingent consideration	(7,050)	(51,420)	(128,090)
Total	\$ (7,050)	\$ (51,420)	\$ (93,081)

The amounts of revenue and net loss of Indevus included in the Company's Consolidated Statements of Operations for the year ended December 31, 2009 are as follows (dollars in thousands, except per share data):

	February 23, 2009 to December 31, 2009
Revenue	\$ 66,719
Net loss	\$ (107,779)
Basic and diluted loss per share	\$ (0.92)

*Other*

In the second half of 2011, as part of our effort to increase and broaden the relationships within the urology community, we acquired two electronic medical records software companies, Intuitive Medical Software, LLC and meridianEMR, Inc., which individually and combined represent immaterial acquisitions. These acquisitions provide electronic medical records for urologists. Together, these acquisitions provide access to approximately 1,850 urologists using data platforms that will enhance service offerings in urology practice management.

**NOTE 6. SEGMENT RESULTS**

In the fourth quarter of 2011, as a result of our strategic planning process, the Company's executive leadership team reorganized the manner in which it views our various business activities. Management's intention was to better understand the entity's performance, better assess its prospects and future cash flow potential and ultimately make more informed operating decisions about resource allocation and the enterprise as a whole. Based on this change, we reassessed our reporting structure under the applicable accounting guidance and determined that the Company now has four reportable segments. We have retrospectively revised the segment presentation for all periods presented reflecting the change from three to four reportable segments. This change in our segments has no impact on the Company's consolidated financial statements for all years presented.

The four reportable business segments in which the Company now operates include: (1) Branded Pharmaceuticals, (2) Generics, (3) Devices and (4) Services. Each segment derives revenue from the sales or licensing of their respective products or services and is discussed below.

***Branded Pharmaceuticals***

This group of products includes a variety of branded prescription products related to treating and managing pain as well as our urology, endocrinology and oncology products. The marketed products that are included in this reporting segment include Lidoderm®, Opana® ER and Opana®, Percocet®, Voltaren® Gel, Frova®, Supprelin® LA, Vantas®, Valstar® and Fortesta® Gel.

## **Table of Contents**

### ***Generics***

This segment is comprised of our legacy Endo non-branded generic portfolio and the portfolio from our recently acquired Qualitest business. Our generics business has historically focused on selective generics related to pain that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. With the addition of Qualitest, the segment's product offerings now include products in the pain management, urology, central nervous system (CNS) disorders, immunosuppression, oncology, women's health and hypertension markets, among others.

### ***Devices***

The Devices segment currently focuses on providing technology solutions to physicians treating men's and women's pelvic health conditions and operates in the following business lines: men's health, women's health, and BPH therapy. These business lines are discussed in greater detail within Note 5. Acquisitions. We distribute devices through our direct sales force and independent sales representatives in the U.S., Canada, Australia, Brazil and Western Europe. Additionally, we distribute devices through foreign independent distributors, primarily in Europe, Asia, and South America, who then sell the products to medical institutions. None of our devices or services customers or distributors accounted for ten percent or more of our total revenues during 2011, 2010 or 2009. Foreign subsidiary sales are predominantly to customers in Western Europe, Canada, Australia and Brazil.

### ***Services***

The Services segment provides urological services, products and support systems to urologists, hospitals, surgery centers and clinics across the U.S. These services are sold through the following business lines: lithotripsy services, prostate treatment services, anatomical pathology services, medical products manufacturing, sales and maintenance and electronic medical records services. These business lines are discussed in greater detail within Note 5. Acquisitions.

We evaluate segment performance based on each segment's adjusted income (loss) before income tax. We define adjusted income (loss) before income tax as income (loss) before income tax before certain upfront and milestone payments to partners, acquisition-related items, net, cost reduction initiatives, impairments of long-lived assets, amortization of intangible assets related to marketed products and customer relationships, inventory step-up recorded as part of our acquisitions, non-cash interest expense, and certain other items that the Company believes do not reflect its core operating performance.

Certain corporate general and administrative expenses are not allocated and are therefore included within Corporate unallocated. We calculate consolidated adjusted income (loss) before income tax by adding the adjusted income (loss) before income tax of each of our reportable segments to corporate unallocated adjusted income (loss) before income tax.

**Table of Contents**

The following table displays our revenue by reportable segment (in thousands):

	Twelve Months Ended December 31,		
	2011	2010	2009
Total revenues to external customers			
Branded Pharmaceuticals	\$ 1,657,767	\$ 1,467,572	\$ 1,336,110
Generics	566,854	146,513	124,731
Devices(1)	300,299		
Services	205,201	102,144	
Total consolidated revenues to external customers	\$ 2,730,121	\$ 1,716,229	\$ 1,460,841

- (1) The following table displays our devices revenue by geography (in thousands). International revenues were not material to any of our other segments for any of the years presented.

	2011	2010	2009
<b>Devices:</b>			
United States	\$ 202,462	\$	\$
International	97,837		
Total devices revenues	\$ 300,299	\$	\$

The following table displays our adjusted income (loss) before income tax by reportable segment (in thousands):

	Twelve Months Ended December 31,		
	2011	2010	2009
Adjusted income (loss) before income tax			
Branded Pharmaceuticals	\$ 890,951	\$ 757,453	\$ 642,997
Generics	107,204	24,722	28,557
Devices	82,418		
Services	68,769	35,538	
Corporate unallocated	(318,100)	(194,459)	(174,994)
Total consolidated adjusted income (loss) before income tax	\$ 831,242	\$ 623,254	\$ 496,560

**Table of Contents**

The table below provides reconciliations of our consolidated adjusted income (loss) before income tax to our consolidated income before income tax, which is determined in accordance with U.S. GAAP (in thousands):

	<b>Twelve Months Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
Total consolidated adjusted income before income tax	\$ 831,242	\$ 623,254	\$ 496,560
Upfront and milestone payments to partners	(28,098)	(23,850)	(77,099)
Acquisition-related items, net	(33,638)	(18,976)	93,081
Cost reduction initiatives	(21,821)	(17,245)	(2,549)
Asset impairment charges	(116,089)	(35,000)	(69,000)
Amortization of intangible assets related to marketed products and customer relationships	(190,969)	(83,974)	(62,931)
Inventory step-up	(49,438)	(6,289)	(11,268)
Non-cash interest expense	(18,952)	(16,983)	(14,719)
(Loss) gain on extinguishment of debt, net	(11,919)		4,025
Accrual for unfavorable court decision for litigation	(11,263)		
Other income (expense), net	2,636	(239)	3,560
 Total consolidated income before income tax	 \$ 351,691	 \$ 420,698	 \$ 359,660

The following represents additional selected financial information for our reportable segments (in thousands):

	<b>Twelve Months Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
<b>Depreciation expense:</b>			
Branded Pharmaceuticals	\$ 13,264	\$ 13,259	\$ 13,400
Generics	11,468	1,676	822
Devices	4,984		
Services	12,330	6,000	
Corporate unallocated	3,799	2,894	2,628
 Total depreciation expense	 \$ 45,845	 \$ 23,829	 \$ 16,850
 <b>Amortization expense:</b>			
Branded Pharmaceuticals	\$ 104,439	\$ 78,647	\$ 63,531
Generics	39,078	3,068	
Devices	42,099		
Services	5,953	2,860	
 Total amortization expense	 \$ 191,569	 \$ 84,575	 \$ 63,531

Interest income and expense are considered corporate items and are not allocated to our segments. Asset information is not accounted for at the segment level and consequently is not reviewed or included within our internal management reporting. Therefore, the Company has not disclosed asset information for each reportable segment.

**NOTE 7. LICENSE AND COLLABORATION AGREEMENTS***Commercial Products*

*Novartis AG and Novartis Consumer Health, Inc.*



## Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

On March 4, 2008, we entered into a License and Supply Agreement (the Voltaren® Gel Agreement) with and among Novartis AG and Novartis Consumer Health, Inc (Novartis) to obtain the exclusive U.S. marketing rights for the prescription medicine Voltaren® Gel (Voltaren® Gel or Licensed Product). Voltaren® Gel received

F-50

## Table of Contents

regulatory approval in October 2007 from the FDA, becoming the first topical prescription treatment for use in treating pain associated with osteoarthritis and the first new product approved in the U.S. for osteoarthritis since 2001. Voltaren® Gel was granted marketing exclusivity in the U.S. as a prescription medicine until October 2010.

Under the terms of the five-year Voltaren® Gel Agreement, Endo made an upfront cash payment of \$85 million. Endo has agreed to pay royalties to Novartis on annual Net Sales of the Licensed Product, subject to certain thresholds as defined in the Voltaren® Gel Agreement. In addition, Endo has agreed to make certain guaranteed minimum annual royalty payments of \$30 million per year payable in the fourth and fifth year of the Voltaren® Gel Agreement, which may be reduced under certain circumstances, including Novartis's failure to supply the Licensed Product, subject to certain limitations including the launch of a generic to the Licensed Product in the U.S. These guaranteed minimum royalties will be creditable against royalty payments on an annual basis such that Endo's obligation with respect to each year is to pay the greater of (i) royalties payable based on annual net sales of the Licensed Product or (ii) the guaranteed minimum royalty for such Voltaren® Gel Agreement year. Royalties to Novartis of \$17.7 million were incurred during 2011. No royalties to Novartis were incurred in 2010. Novartis is also eligible to receive a one-time milestone payment of \$25 million if annual net sales of Voltaren® Gel exceed \$300 million in the U.S. The \$85 million upfront payment and the present value of the guaranteed minimum royalties have been capitalized as an intangible asset in the amount of \$129 million, representing the fair value of the exclusive license to market Voltaren® Gel. We are amortizing this intangible asset into cost of revenues over its estimated five-year useful life.

Endo is solely responsible to commercialize the Licensed Product during the term of the Voltaren® Gel Agreement. With respect to each year during the term of the Voltaren® Gel Agreement, subject to certain limitations, Endo is required to incur a minimum amount of annual advertising and promotional expenses on the commercialization of the Licensed Product, which may be reduced under certain circumstances including Novartis's failure to supply the Licensed Product. In addition, Endo is required to perform a minimum number of face-to-face one-on-one discussions with physicians and other healthcare practitioners (Details) for the purpose of promoting the Licensed Product within its approved indication during each year of the Voltaren® Gel Agreement which may be reduced under certain circumstances including Novartis's failure to supply the Licensed Product. Further, during the term of the Voltaren® Gel Agreement, Endo will share in the costs of certain clinical studies and development activities initiated at the request of the FDA or as considered appropriate by Novartis and Endo.

During the term of the Voltaren® Gel Agreement, Endo has agreed to purchase all of its requirements for the Licensed Product from Novartis. The price was fixed for the first year and subject to annual changes based upon changes in the producer price index and raw materials.

Novartis has the exclusive right, at its sole discretion, to effect a switch of the Licensed Product from a prescription product to an over-the-counter (OTC) product in the U.S. (an OTC Switch) by filing an amendment or supplement to the Licensed Product New Drug Application or taking any other action necessary or advisable in connection therewith to effect the OTC Switch, and thereafter to commercialize such OTC product. Notwithstanding the foregoing, Novartis shall not launch an OTC equivalent product prior to a time specified in the Voltaren® Gel Agreement, and Novartis shall not take any action that results in the loss of the prescription product status for the Licensed Product prior to such time. Novartis will notify Endo if it submits a filing to the FDA in respect of an OTC equivalent product. In the event that Novartis gains approval of an OTC equivalent product that results in the Licensed Product being declassified as a prescription product, then Novartis will make certain royalty payments to Endo on net sales of such OTC equivalent product in the U.S. by Novartis, its affiliates and their respective licensees or sublicensees as set forth in the Voltaren® Gel Agreement. As a condition to the payment of any and all such royalties, net sales of the Licensed Product in the U.S. must have exceeded a certain threshold prior to the launch of the OTC equivalent product by Novartis or its affiliates.

The initial term of the Voltaren® Gel Agreement will expire on June 30, 2013. Endo has the option to extend the Voltaren® Gel Agreement for two successive one year terms. The Voltaren® Gel Agreement will remain in

**Table of Contents**

place after the first two renewal terms unless either party provides written notice of non-renewal to the other party at least six months prior to the expiration of any renewal term after the first renewal term or the Voltaren® Gel Agreement is otherwise terminated in accordance with its terms. Among other standard and customary termination rights granted under the Voltaren® Gel Agreement, the Voltaren® Gel Agreement can be terminated by either party upon reasonable written notice, if either party has committed a material breach that has not been remedied within ninety (90) days from the giving of written notice. Endo may terminate the Voltaren® Gel Agreement by written notice upon the occurrence of several events, including the launch in the U.S. of a generic to the Licensed Product. Novartis may terminate the Voltaren® Gel Agreement upon reasonable written notice (1) if Endo fails to deliver a set percentage of the minimum Details in any given six-month period under the Voltaren® Gel Agreement; or (2) on or after the launch in the U.S. of an OTC equivalent product by Novartis, 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 Voltaren® Gel Agreement are less than a certain defined dollar amount.

*Hind Healthcare Inc.*

In November 1998, Endo entered into a license agreement (the Hind License Agreement) with Hind Healthcare Inc. (Hind), for the sole and exclusive right to develop, use, market, promote and sell Lidoderm® in the U.S. Under the terms of the Hind License Agreement, Endo paid Hind approximately \$10 million based upon the achievement of certain milestones and capitalized this amount as an intangible asset representing the fair value of these exclusive rights. In addition, we were required to pay Hind nonrefundable royalties based on net sales of Lidoderm® until this obligation expired on November 23, 2011 pursuant to the terms of the Hind License Agreement. Royalties were recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm®. The royalty rate was 10% of net sales including a minimum royalty of at least \$500,000 per year. During 2011, 2010 and 2009, we recorded \$77.9 million, \$86.8 million and \$84.9 million for these royalties to Hind, respectively, which we recorded as a reduction to net sales. At December 31, 2011 and 2010, \$13.4 million and \$23.0 million, respectively, is recorded as a royalty payable and included in accounts payable in the accompanying Consolidated Balance Sheets. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico.

*Vernalis Development Limited*

In July 2004, we entered into a License Agreement with Vernalis Development Limited (Vernalis) under which Vernalis agreed to license, exclusively to us, rights to market frovatriptan succinate (Frova®) in North America (the Vernalis License Agreement). Frova® was launched June 2002 in the U.S. and indicated for the acute treatment of migraine headaches in adults. Under the terms of the Vernalis License Agreement, we paid Vernalis an upfront fee of \$30 million and annual \$15 million payments each in 2005 and 2006. We capitalized the \$30 million up-front payment and the present value of the two \$15 million anniversary payments. We are amortizing this intangible asset into cost of revenues on a straight-line basis over its estimated life of twelve and one-half years.

In addition, Vernalis could receive one-time milestone payments for the achievement of defined annual net sales targets. These sales milestone payments increase based on increasing net sales targets ranging from a milestone of \$10 million on \$200 million in net sales to a milestone of \$75 million on \$1.2 billion in net sales. These sales milestones could total up to \$255 million if all of the defined net sales targets are achieved. Beginning on January 1, 2007, we began paying royalties to Vernalis based on the net sales of Frova®. The term of the license agreement is for the shorter of the time (i) that there are valid claims on the Vernalis patents covering Frova® or there is market exclusivity granted by a regulatory authority, whichever is longer, or (ii) until the date on which a generic version of Frova® is first offered, but in no event longer than 20 years. We can terminate the license agreement under certain circumstances, including upon one years' written notice. In July 2007, Vernalis and Endo entered into an Amendment (Amendment No. 3) to the License Agreement dated July 14, 2004. Under Amendment No. 3, Vernalis granted an exclusive license to Endo to make, have made, use, commercialize and have commercialized Frova® in Canada, under the Canadian Trademark.

---

**Table of Contents**

In February 2008, we entered into Amendment No. 4 to the Vernalis License Agreement (Amendment No. 4). In addition to amending certain specific terms and conditions of the License Agreement, Amendment No. 4 sets forth an annual minimum net sales threshold such that no royalties will be due on annual U.S. net sales of Frova<sup>®</sup> less than \$85 million. Prior to this amendment, royalties were payable by us to Vernalis on all net sales of Frova<sup>®</sup> in the U.S. Now, once the annual minimum net sales amount is reached, royalty payments will be due only on the portion of annual net sales that exceed the \$85 million threshold.

On August 15, 2011, the parties amended the Vernalis License Agreement (Amendment No. 5). Pursuant to Amendment No. 5, Vernalis assigned to the Company certain patents which were previously exclusively licensed by the Company. Amendment No. 5 did not alter the financial arrangement between the parties.

*The Population Council*

The Company markets certain of its products utilizing the hydrogel polymer technology pursuant to an agreement between Indevus (now, Endo Pharmaceuticals Solutions Inc.) and the Population Council. Unless earlier terminated by either party in the event of a material breach by the other party, the term of the agreement is the shorter of twenty-five years from October 1997 or until the date on which The Population Council receives approximately \$40 million in payments from the Company. The Company is required to pay to The Population Council 3% of its net sales of Vantas<sup>®</sup> and any polymer implant containing a luteinizing hormone-releasing hormone (LHRH) analog. We are also obligated to pay royalties to the Population Council ranging from 0.5% of net sales to 4% of net sales under certain conditions. We are also obligated to pay the Population Council 30% of certain profits and payments received in certain territories by the Company from the licensing of Vantas<sup>®</sup> or any other polymer implant containing an LHRH analog and 5% for other implants.

*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<sup>®</sup> Gel in the U.S. (the ProStrakan Agreement). Fortesta<sup>®</sup> Gel, a patented two percent (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. Under the terms of the ProStrakan Agreement, Endo paid ProStrakan an up-front cash payment of \$10 million, which was recorded as research and development expense.

The Company received FDA approval 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 \$7.5 million was triggered during the second quarter of 2011 pursuant to the terms of the ProStrakan Agreement, at which time it was recorded to cost of revenues. ProStrakan could potentially receive up to approximately \$167.5 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 Oxymorphone Agreement) with Grünenthal for the exclusive clinical development and commercialization rights in Canada and the U.S. for a new oral formulation of Opana<sup>®</sup> ER, which is designed to be crush-resistant. Under the terms of the Grünenthal Oxymorphone Agreement, we paid approximately \$4.9 million for the successful completion of a clinical milestone in 2010, which was recorded as research and development expense. In

---

**Table of Contents**

December 2011, the FDA approved a new formulation of Opana® ER designed to be crush-resistant, which will continue to be called Opana® ER. Endo will be expediting the production of the crush-resistant formulation of Opana® ER at a third party manufacturing facility managed by Grünenthal.

As of December 31, 2011, the Company has capitalized the one-time approval milestones to Grünenthal for \$5.1 million. This obligation was settled in January 2012. We are amortizing this intangible asset into cost of revenues over its estimated useful life. Additional payments of approximately 55.4 million euros (approximately \$71.8 million at December 31, 2011) 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 new formulation of Opana® ER approved by the FDA in December 2011. These payments are recorded in Cost of revenues in our Consolidated Financial Statements and must be paid in U.S. dollars within 45 days after each calendar quarter.

*Products in Development*

*Impax Laboratories, Inc.*

In June 2010, the Company entered into a Development and Co-Promotion Agreement (the Impax Agreement) with Impax Laboratories, Inc. (Impax), whereby the Company was granted a royalty-free license for the co-exclusive rights to co-promote a next generation Parkinson's disease product. Under the terms of the Impax Agreement, Endo paid Impax an upfront payment of \$10 million in 2010, which was recorded as research and development expense. The Company could be obligated to pay up to approximately \$30 million in additional payments linked to the achievement of future clinical, regulatory, and commercial milestones related to the development product. Prior to the completion of Phase III trials, Endo may only terminate the Impax Agreement upon a material breach.

*Bioniche Life Sciences Inc.*

In July 2009, the Company entered into a License, Development and Supply Agreement (the Bioniche Agreement) with Bioniche Life Sciences Inc. and Bioniche Urology Inc. (collectively, Bioniche), whereby the Company licensed from Bioniche the exclusive rights to develop and market Bioniche's proprietary formulation of Mycobacterial Cell Wall-DNA Complex (MCC), known as Urocidin™, in the U.S. with an option for global rights. We exercised our option for global rights in the first quarter of 2010. Urocidin™ is a patented formulation of MCC developed by Bioniche for the treatment of non-muscle-invasive bladder cancer that is currently undergoing Phase III clinical testing. Under the terms of the Bioniche Agreement, Endo paid Bioniche an up-front cash payment of \$20.0 million in July 2009 and milestone payments of \$11.0 million in 2009 and \$4.0 million in 2010 resulting from the achievement of contractual milestones, which were recorded as research and development expense. In addition, Bioniche could potentially receive up to approximately \$67.0 million and \$26.0 million in additional payments linked to the achievement of future clinical, regulatory, and commercial milestones related to two separate indications for Urocidin™. Bioniche will manufacture Urocidin™ and receive a transfer price for supply based on a percentage of Endo's annual net sales of Urocidin™. Endo may terminate the Bioniche Agreement upon 180 days' prior written notice.

*BayerSchering*

In July 2005, Indevus (now, Endo Pharmaceuticals Solutions Inc.) licensed exclusive U.S. rights from Schering AG, Germany, now BayerSchering Pharma AG (BayerSchering) to market a long-acting injectable testosterone preparation for the treatment of male hypogonadism that we refer to as Aved™ (the BayerSchering Agreement). The Company is responsible for the development and commercialization of Aved™ in the U.S.

---

**Table of Contents**

BayerSchering is responsible for manufacturing and supplying the Company with finished product. As part of the BayerSchering Agreement, Indevus agreed to pay to BayerSchering up to \$30.0 million in up-front, regulatory milestone, and commercialization milestone payments, including a \$5.0 million payment due upon approval by the FDA to market Aveed™. Indevus also agreed to pay to BayerSchering 25% of net sales of Aveed™ to cover both the cost of finished product and royalties. The BayerSchering Agreement expires ten years from the first commercial sale of Aveed™. Either party may also terminate the BayerSchering Agreement in the event of a material breach by the other party.

In October 2006, Indevus entered into a supply agreement with BayerSchering pursuant to which BayerSchering agreed to manufacture and supply Indevus with all of its requirements for Aveed™ for a supply price based on net sales of Aveed™. The supply price is applied against the 25% of net sales owed to BayerSchering pursuant to the BayerSchering Agreement. The BayerSchering Agreement expires ten years after the first commercial sale of Aveed™.

*Hydron Technologies, Inc.*

In November 1989, GP Strategies Corporation (GP Strategies), then known as National Patent Development Corporation, entered into an agreement (the Hydron Agreement) with Dento-Med Industries, Inc., now known as Hydron Technologies, Inc. In June 2000, Valera Pharmaceuticals, Inc. (Valera, now a wholly-owned subsidiary of the Company known as Endo Pharmaceuticals Valera Inc.) entered into a contribution agreement with GP Strategies, pursuant to which Valera acquired the assets of GP Strategies' drug delivery business, including all intellectual property, and all of GP Strategies' rights under the Hydron Agreement, and certain other agreements with The Population Council and Shire US, Inc.

Pursuant to the Hydron Agreement, the Company has the exclusive right to manufacture, sell and distribute any prescription drug or medical device and certain other products made with the hydrogel polymer technology. Hydron Technologies retained an exclusive, worldwide license to manufacture, market or use products composed of, or produced with the use of, the hydrogel polymer technology in certain consumer and oral health fields. Neither party is prohibited from manufacturing, exploiting, using or transferring the rights to any new non-prescription drug product containing the hydrogel polymer technology, subject to certain exceptions, for limited exclusivity periods. Subject to certain conditions and exceptions, the Company is obligated to supply certain types of polymer to Hydron Technologies and Hydron Technologies is obligated to purchase such products from the Company. Under the Hydron Agreement, the Company also has the title to the Hydron® trademark and must maintain such trademark throughout the world. The Company has decided to stop using the Hydron® trademark and plans to transfer the title to such trademark to Hydron Technologies pursuant to the Hydron Agreement. This agreement continues indefinitely, unless terminated earlier by the parties. Each party may owe royalties up to 5% to the other party on certain products under certain conditions.

*BioDelivery Sciences International, Inc.*

In January 2012, the Company signed a worldwide license and development agreement (the BioDelivery Agreement) with BioDelivery Sciences International, Inc. (BioDelivery) for the exclusive rights to develop and commercialize BEMA® Buprenorphine. BEMA® Buprenorphine is a transmucosal form of buprenorphine, a partial mu-opiate receptor agonist, which incorporates a bioerodible mucoadhesive (BEMA®) technology. BEMA® Buprenorphine is currently in phase III trials for the treatment of moderate to severe chronic pain. At this time, the Company made an upfront payment to BioDelivery for \$30.0 million, which will be expensed in the first quarter of 2012. In the future, Endo could be obligated to pay royalties based on net sales of BEMA® Buprenorphine and commercial and regulatory milestone payments of up to approximately \$150.0 million. We currently expect that approximately \$15.0 million of this amount will become payable in the first quarter of 2012 based on the achievement of certain regulatory milestones. Endo may terminate the BioDelivery Agreement at any time upon six months written notice. Unless terminated earlier, the BioDelivery Agreement shall expire, on a

## **Table of Contents**

country by country basis, upon the later to occur of ten years from the date of first commercial sale in a particular country or the date on which the last valid claim of the applicable BioDelivery patents in a particular country has expired or been invalidated or found unenforceable.

### *Orion Corporation*

In January 2011, the Company entered into a Discovery, Development and Commercialization Agreement (the 2011 Orion Agreement) with Orion Corporation (Orion) to exclusively co-develop products for the treatment of certain cancers and solid tumors. Under the terms of the 2011 Orion Agreement, Endo and Orion each contributed four research programs to the collaboration to be conducted pursuant to the agreement. The development of each research program shall initially be the sole responsibility of the contributing party. However, upon the achievement of certain milestones, the non-contribution party shall have the opportunity to, at its option, obtain a license to jointly develop and commercialize any research program contributed by the other party for amounts defined in the 2011 Orion Agreement. Subject to certain limitations, upon the first commercial sale of any successfully launched jointly developed product, Endo shall be obligated to pay royalties to Orion based on net sales of the corresponding product in North America (the Endo territory) and Orion shall be obligated to pay royalties to Endo on net sales of the corresponding product in certain European countries (the Orion territory). The 2011 Orion Agreement shall expire in January 2016, unless terminated early or extended pursuant to the terms of the agreement. In January 2011, Endo exercised its option to obtain a license to jointly develop and commercialize Orion's Anti-Androgen program focused on castration-resistant prostate cancer, one of Orion's four contributed research programs, and made a corresponding payment to Orion for \$10 million, which was expensed as Research and development in the first quarter of 2011.

### *EpiCept Corp.*

In December 2003, we entered into a license granting us exclusive, worldwide rights to certain patents of EpiCept Corp. (EpiCept) as well as exclusive, worldwide commercialization rights to EpiCept's LidoPAIN<sup>®</sup> BP product (EpiCept Agreement). The EpiCept Agreement provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept's LidoPAIN<sup>®</sup> BP product. Under this Agreement, we made an upfront payment to EpiCept of \$7.5 million which we capitalized as an intangible asset representing the fair value of the exclusive right and the patents. We are amortizing this intangible asset over its useful life of thirteen (13) years. EpiCept has also retained an option to co-promote the LidoPAIN<sup>®</sup> BP product. Milestone payments made by Endo under this agreement, including regulatory milestones and sales thresholds, could total up to \$82.5 million. In addition, the EpiCept Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The EpiCept Agreement generally lasts until the underlying patents expire. In January 2009, EpiCept announced that it was discontinuing all drug discovery activities including the development of LidoPAIN<sup>®</sup> BP. However, the Company intends to maintain its patent rights conveyed by the EpiCept Agreement.

### *Other*

We have entered into certain other collaboration and discovery agreements with third parties for the development of pain management and other products. These agreements require us to share in the development costs of such products and grant marketing rights to us for such products.

We have also licensed from universities and other similar firms, rights to certain technologies or intellectual property, generally in the field of pain management. We are generally required to make upfront payments as well as other payments upon successful completion of regulatory or sales milestones. In addition, these agreements generally require us to pay royalties on sales of the products arising from these agreements. These agreements generally permit Endo to terminate the agreement with no significant continuing obligation.

**Table of Contents****NOTE 8. PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment is comprised of the following for the years ended December 31 (in thousands):

	2011	2010
Buildings and land	\$ 121,573	\$ 88,871
Machinery and equipment	113,992	90,503
Leasehold improvements	36,233	25,995
Computer equipment and software	73,302	51,208
Assets under capital leases	5,461	1,952
Furniture and fixtures	16,365	11,286
Assets under construction	42,516	13,818
Property, plant and equipment, gross	409,442	283,633
Less accumulated depreciation	(111,711)	(68,338)
Property, plant and equipment, net	\$ 297,731	\$ 215,295

Depreciation expense was \$45.8 million, \$23.8 million and \$16.9 million for the years ended December 31, 2011, 2010 and 2009, respectively.

On October 28, 2011, our subsidiary Endo Pharmaceuticals Inc. entered into a lease agreement with RT/TC Atwater LP, a Delaware limited partnership, for a new Company headquarters to consist of approximately 300,000 square feet of office space located at 1400 Atwater Boulevard, Malvern, Pennsylvania. The term of this triple net lease is twelve years and includes three renewal options, each for an additional sixty (60)-month period. The lease is expected to commence in early 2013 with a monthly lease rate for the initial year of \$0.5 million, increasing by 2.25% each year thereafter. Under the terms of this lease, we will have a continuous and recurring right throughout the initial four (4) years of the lease term to lease up to approximately one hundred fifty thousand (150,000) additional square feet. We are responsible for all tenant improvement costs, less a tenant improvement allowance of \$45 per square foot.

This lease will be accounted for as a direct financing arrangement whereby the Company will record, over the construction period, the full cost of the asset in Property, plant and equipment, net. A corresponding liability will be recorded, net of leasehold improvements paid for by the Company.

**NOTE 9. GOODWILL AND OTHER INTANGIBLES**

For the year ended December 31, 2011, changes in the carrying amount of Goodwill consisted of the following (in thousands):

	Carrying Amount
Balance at December 31, 2010	\$ 715,005
Goodwill acquired during the period	1,802,189
Measurement period adjustments	45,407
Effect of currency translation	(4,560)
Balance at December 31, 2011	\$ 2,558,041

In June 2011, we acquired AMS. As a result of this acquisition, we recognized goodwill of approximately \$1.8 billion. This acquisition is discussed in greater detail in Note 5. Acquisitions. In September and November 2011, we acquired two electronic medical records software companies, Intuitive Medical Software, LLC and meridianEMR, Inc., respectively. The remaining goodwill acquired during the period relates to immaterial acquisitions in 2011. Of the \$2.6 billion of goodwill recorded on our Consolidated Balance Sheets at December 31, 2011, \$290.8 million is assigned to our Branded Pharmaceuticals segment, \$275.2 is assigned to our Generics segment, \$1.8 billion is assigned to our Devices segment and \$200.2 million is assigned to our Services segment.





**Table of Contents**

As of January 1, 2012, our annual assessment date, we tested each of our seven reporting units for impairment. The results of our analyses showed that no goodwill impairments exist.

Based upon recent market conditions, and, in some cases, a lack of comparable market transactions for similar assets, Endo determined that an income approach using a discounted cash flow model was an appropriate valuation methodology to determine each reporting units fair value. The income approach converts future amounts to a single present value amount (discounted cash flow model). Our discounted cash flow models are highly reliant on various assumptions, including estimates of future cash flow (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. We believe we have appropriately reflected our best estimate of the assumptions that market participants would use in determining the fair value of our reporting units at the measurement date.

Our other intangible assets consisted of the following at December 31, 2011 and 2010, respectively (in thousands):

	December 31, 2011	December 31, 2010
<b>Indefinite-lived intangibles:</b>		
In-process research and development	\$ 221,400	\$ 271,000
Tradenames		27,000
<i>Total indefinite-lived intangibles</i>	\$ 221,400	\$ 298,000
<b>Definite-lived intangibles:</b>		
Licenses (weighted average life of 10 years)	647,239	638,142
Less accumulated amortization	(256,903)	(185,706)
Licenses, net	\$ 390,336	\$ 452,436
Customer relationships (weighted average life of 16 years)	159,632	
Less accumulated amortization	(5,460)	
Customer relationships, net	\$ 154,172	\$
Tradenames (weighted average life of 22 years)	91,600	14,600
Less accumulated amortization	(4,142)	(486)
Tradenames, net	\$ 87,458	\$ 14,114
Developed technology (weighted average life of 16 years)	1,774,300	768,400
Less accumulated amortization	(125,695)	(14,614)
Developed technology, net	\$ 1,648,605	\$ 753,786
Service contract		13,424
Less accumulated amortization		
Service contract, net	\$	\$ 13,424
Other (weighted average life of 11 years)	2,200	
Less accumulated amortization	(47)	
Other, net	\$ 2,153	\$

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

<i>Total definite-lived intangibles, net (weighted average life of 15 years)</i>	\$ 2,282,724	\$ 1,233,760
<b>Other intangibles, net</b>	<b>\$ 2,504,124</b>	<b>\$ 1,531,760</b>

F-58

**Table of Contents**

Changes in the gross carrying amount of our other intangible assets for the year ended December 31, 2010, are as follows:

(in thousands)	Gross carrying amount
Balance at December 31, 2010:	\$ 1,732,566
Acquisitions	1,394,200
Measurement period adjustments	(133,658)
Patents	2,000
Opana® ER	5,097
Sale of IGRT	(12,166)
Impairment of octreotide acromegaly	(9,000)
Impairment of pagoclone	(8,000)
Impairment of undisclosed generic product	(71,000)
Impairment of A0001	(1,600)
Effect of currency translation	(2,368)
Other	300
 Balance at December 31, 2011:	 \$ 2,896,371

In September 2011, the IGRT business was sold for approximately \$13.0 million, at which time the related intangible asset, which had a gross carrying amount of \$12.2 million, was reduced to zero.

The octreotide implant utilized our hydrogel polymer technology to deliver six months of octreotide, a long-acting octapeptide that mimics the natural hormone somatostatin to block production of growth hormone (GH), for the treatment of acromegaly, a chronic hormonal disorder that occurs when a tumor of the pituitary gland causes the excess production of GH. On November 11, 2011, the Company decided to terminate development of the octreotide implant for the treatment of acromegaly after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, we recorded a pre-tax, non-cash impairment charge of \$9.0 million to write off this intangible asset in its entirety, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our 2011 Consolidated Statement of Operations.

Pagoclone is a novel, non-benzodiazepine, GABA-A receptor modulator and was under development as a treatment for persistent developmental stuttering. On December 27, 2011, the Company terminated its pagoclone development program after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, we recorded a pre-tax, non-cash impairment charge of \$8.0 million to write off this intangible asset in its entirety, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our 2011 Consolidated Statement of Operations.

During the fourth quarter of 2011, the Company received a deficiency from the FDA on an ANDA submission for one of its lead assets in this portfolio. Subsequently, in early 2012, the Company terminated its development program for this asset as a result of the regulatory challenges and changes in the development timeline resulting from the FDA's request. In addition, as a result changes in market conditions since the acquisition date, there has been a significant deterioration in the commercial potential for this product. Accordingly, we recorded a pre-tax non-cash impairment charge of \$71.0 million in 2011 to write off the intangible asset in its entirety, which was assigned to our generics segment and recorded in the Asset impairment charges line of our Consolidated Statements of Operations.

In addition, in 2012, the Company terminated Penwest's A0001 development program after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential

**Table of Contents**

for the product. Accordingly, we recorded a pre-tax, non-cash impairment charge of \$1.6 million to write off this intangible asset in its entirety, which was assigned to our Branded Pharmaceuticals segment and was recorded in the Asset impairment charges line in our 2011 Consolidated Statement of Operations.

Amortization expense was \$191.6 million, \$84.6 million and \$63.5 million for the years ended December 31, 2011, 2010 and 2009, respectively. As of December 31, 2011, estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2011 is as follows (in thousands):

2012	\$ 229,117
2013	\$ 187,341
2014	\$ 173,786
2015	\$ 172,876
2016	\$ 171,670

**NOTE 10. ACCRUED EXPENSES**

Accrued expenses are comprised of the following for each of the years ended December 31 (in thousands):

	2011	2010
Chargebacks	\$ 116,821	\$ 87,820
Returns and allowances	90,075	65,021
Rebates	308,911	203,225
Other sales deductions	21,342	15,320
Other	195,682	98,335
Total	\$ 732,831	\$ 469,721

**NOTE 11. OTHER INCOME, NET**

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

	2011	2010	2009
Gain on trading securities		(15,420)	(15,222)
Loss on auction-rate securities rights		15,659	11,662
Other (income) expense, net	(3,268)	(2,172)	231
Other income, net	\$ (3,268)	\$ (1,933)	\$ (3,329)

**NOTE 12. INCOME TAXES**

The components of our income before income tax by geography were as follows (in thousands):

	2011	2010	2009
United States	\$ 349,174	\$ 420,698	\$ 359,660
International	2,517		
Total income before income tax	\$ 351,691	\$ 420,698	\$ 359,660

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

Income tax consists of the following for each of the years ended December 31 (in thousands):

	2011	2010	2009
<b>Current:</b>			
Federal	\$ 153,421	\$ 128,793	\$ 116,372
Foreign	1,954		
State	27,140	22,451	17,036
<b>Total current income tax</b>	<b>182,515</b>	<b>151,244</b>	<b>133,408</b>
<b>Deferred:</b>			
Federal	(68,110)	(8,139)	(18,621)
Foreign	(815)		
State	(18,546)	(6,871)	(5,884)
<b>Total deferred income tax</b>	<b>(87,471)</b>	<b>(15,010)</b>	<b>(24,505)</b>
<b>Excess tax benefits (shortfall) of stock options exercised</b>	<b>4,015</b>	<b>(1,051)</b>	<b>(3,689)</b>
<b>Valuation allowance</b>	<b>10,567</b>	<b>(1,505)</b>	<b>(11,890)</b>
<b>Total income tax</b>	<b>\$ 109,626</b>	<b>\$ 133,678</b>	<b>\$ 93,324</b>

F-60

**Table of Contents**

A reconciliation of income tax at the federal statutory income tax rate to the total income tax provision for each of the years ended December 31 (in thousands):

	2011	2010	2009
Federal income tax at the statutory rate	\$ 123,092	\$ 147,245	\$ 125,888
Noncontrolling interests	(19,058)	(9,805)	
State income tax, net of federal benefit	7,590	8,447	6,729
Research and development credit	(3,883)	(3,667)	(2,915)
Orphan drug credit	(2,013)	(904)	
Uncertain tax positions	(6,741)	1,148	1,574
Change in valuation allowance	8,984		
Effect of permanent items:			
Branded prescription drug fee	6,307		
Changes in contingent consideration	(2,215)	(15,673)	(40,503)
Domestic production activities deduction	(10,626)	(4,357)	(1,453)
Transaction-related expenses	2,843	9,612	3,256
Other	5,346	1,632	748
 Total income tax	 \$ 109,626	 \$ 133,678	 \$ 93,324

In order to conform to current and prior year presentation, state taxes related to Research and Development credits, permanent items and Uncertain tax positions as of December 31, 2009 have been reclassified to State income tax, net of federal benefit. This reclassification has no impact on the effective tax rate for all years presented.

The tax effects of temporary differences that comprise the current and non-current deferred income tax amounts shown on the balance sheets for the years ended December 31 are as follows (in thousands):

	2011	2010
Deferred tax assets:		
Accrued expenses	\$ 167,565	\$ 100,068
Compensation related to stock options	26,125	18,328
Purchased in-process research and development	673	1,820
Net operating loss carryforward	178,524	209,618
Capital loss carryforward	16,047	16,914
Research and development credit carryforward	18,206	15,371
Uncertain tax positions	8,684	17,383
Other-than-temporary impairment of auction-rate securities		550
Prepaid royalties	5,524	9,115
Other	23,496	10,543
 Total gross deferred income tax assets	 444,844	 399,710
Deferred tax liabilities:		
Property, plant, equipment, and intangibles	(815,566)	(434,013)
Non-cash interest expense	(10,315)	(8,171)
Other		(7,859)
 Total gross deferred income tax liabilities	 (825,881)	 (450,043)
 Valuation allowance	 (21,537)	 (26,277)

## Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

Net deferred income tax (liability) asset	\$ (402,574)	\$ (76,610)
---	--------------	-------------

At December 31, 2011, our NOLs and research and development credit carryforwards were related to multiple tax jurisdictions, including federal and various state jurisdictions, which expire at intervals between 2012 and 2032.

In general, it is the practice and intention of the Company to reinvest the earnings of its non-U.S. subsidiaries in those operations. As of December 31, 2011, the Company has not made a provision for U.S. or

F-61



**Table of Contents**

additional foreign withholding taxes on approximately \$89.2 of the excess of the amount for financial reporting over the tax basis of investments in foreign subsidiaries that are essentially permanent in duration. Generally, such amounts become subject to U.S. taxation upon the remittance of dividends and under certain other circumstances. It is not practicable to estimate the amount of deferred tax liability related to investments in these foreign subsidiaries.

We evaluate our tax positions using the prescribed two-step process. Step 1 Recognition, requires the Company to determine whether a tax position, based solely on its technical merits, has a likelihood of more than 50 percent (more-likely-than-not) that the tax position taken will be sustained upon examination. Step 2 Measurement, which is only addressed if Step 1 has been satisfied, requires the Company to measure the tax benefit as the largest amount of benefit, determined on a cumulative probability basis that is more-likely-than-not to be realized upon ultimate settlement.

The Company records accrued interest and penalties related to unrecognized tax benefits in income tax expense. Interest and penalties resulted in an income tax benefit of \$3.4 million in 2011 and expense of \$1.0 million in 2010.

A reconciliation of the change in the uncertain tax benefits (UTB) balance from January 1, 2009 to December 31, 2011 is as follows (in thousands):

	<b>Unrecognized Tax Benefit Federal, State, and Foreign Tax</b>
UTB Balance at January 1, 2009	\$ 19,304
Gross additions for current year positions	7,609
Gross additions for prior period positions	217
Gross reductions for prior period positions	(27)
Decrease due to settlements	
Decrease due to lapse of statute of limitations	
UTB Balance at December 31, 2009	\$ 27,103
Gross additions for current year positions	6,293
Gross additions for prior period positions	
Gross reductions for prior period positions	(2,887)
Decrease due to settlements	(351)
Decrease due to lapse of statute of limitations	(679)
Additions related to acquisitions	9,702
UTB Balance at December 31, 2010	\$ 39,181
Gross additions for current year positions	2,082
Gross additions for prior period positions	133
Gross reductions for prior period positions	(1,078)
Decrease due to settlements	(13,790)
Decrease due to lapse of statute of limitations	(4,220)
Additions related to acquisitions	18,320
UTB Balance at December 31, 2011	\$ 40,628
Accrued interest and penalties	6,295
Total UTB balance including accrued interest and penalties	\$ 46,923
Current portion (included in accrued expenses)	\$
Non-current portion (included in other liabilities)	\$ 46,923

## Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

The Company and its subsidiaries are routinely examined by various taxing authorities, which have proposed adjustments to tax for issues such as certain tax credits and the deductibility of certain expenses. While it is possible that one or more of these examinations may be resolved within the next twelve months, it is not

F-62

## **Table of Contents**

anticipated that the total amount of unrecognized tax benefits will significantly increase or decrease within the next twelve months. In addition, the expiration of statutes of limitations for various jurisdictions is expected to reduce the unrecognized tax benefits balance by an insignificant amount.

The Company files income tax returns in the U.S. Federal jurisdictions, and various state and foreign jurisdictions. The Company is subject to U.S. Federal, state and local, and non-U.S. income tax examinations by tax authorities. The Company is awaiting final notification for closure of Federal tax years 2003 through 2005, which the Company considers to be effectively settled. In general, the Company is no longer subject to U.S. Federal, state and local, and foreign income tax examinations by tax authorities for years before 2004. The Company believes that it has provided adequately for uncertain tax positions relating to all open tax years by tax jurisdiction.

The total amount of gross unrecognized tax benefits as of December 31, 2011 is \$46.9 million, including interest and penalties, of which \$26.5 million, if recognized, would affect the Company's effective tax rate. The change in the total amount of unrecognized tax benefits did not have a material impact on the Company's results of operations for the year ended December 31, 2011 or our financial position as of December 31, 2011. Any future adjustments to our uncertain tax position liability will result in an impact to our income tax provision and effective tax rate.

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.

## **NOTE 13. STOCKHOLDERS' EQUITY**

### **Common Stock**

At our 2008 Annual Meeting held on June 26, 2008, our stockholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation which increased the total number of shares of common stock, \$0.01 par value, that the Company is authorized to issue from 175,000,000 to 350,000,000.

Subject to certain limitations, we are permitted to pay dividends under our indebtedness. See Note 18. Debt for further details.

### **Preferred Stock**

The Board of Directors may, without further action by the stockholders, issue a series of Preferred Stock and fix the rights and preferences of those shares, including the dividend rights, dividend rates, conversion rights, exchange rights, voting rights, terms of redemption, redemption price or prices, liquidation preferences, the number of shares constituting any series and the designation of such series. As of December 31, 2011, no shares of Preferred Stock have been issued.

### ***Stock-Based Compensation***

#### **Endo Pharmaceuticals Holdings Inc. 2000, 2004, 2007, and 2010 Stock Incentive Plans and the American Medical Systems Holdings, Inc. 2005 Stock Incentive Plan**

On August 11, 2000, we established the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan. The 2000 Stock Incentive Plan reserved an aggregate of 4,000,000 shares of common stock of the Company for issuance to employees, officers, directors and consultants. The 2000 Stock Incentive Plan provided for the issuance of stock options, restricted stock, stock bonus awards, stock appreciation rights or performance awards. The 2000 Stock incentive Plan expired in 2010. In May 2004, our stockholders approved the Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan. The maximum number of shares of Company stock reserved for issuance under the 2004 Stock Incentive Plan is 4,000,000 shares. The 2004 Plan provides for the

**Table of Contents**

grant of stock options, stock appreciation rights, shares of restricted stock, performance shares, performance units or other share-based awards that may be granted to executive officers and other employees of the Company, including officers and directors who are employees, to non-employee directors and to consultants to the Company. In May 2007, our stockholders approved the Endo Pharmaceuticals Holdings Inc. 2007 Stock Incentive Plan. The maximum number of shares of Company stock reserved for issuance under the 2007 Stock Incentive Plan is 7,000,000 shares (subject to adjustment for certain transactions), but in no event may the total number of shares of Company stock subject to awards awarded to any one participant during any tax year of the Company exceed 750,000 shares (subject to adjustment for certain transactions). During 2009, 43,500 restricted stock units and 66,503 non-qualified stock options were granted to an executive officer of the Company as an inducement to commence employment with the Company. The restricted stock units and non-qualified stock options were granted outside of the 2007 Stock Incentive Plan but are subject to the terms and conditions of the 2007 Stock Incentive Plan and the applicable award agreements. In May 2010, our stockholders approved the Endo Pharmaceuticals Holdings Inc. 2010 Stock Incentive Plan. The maximum number of shares of Company stock reserved for issuance under the Plan includes 8,000,000 shares plus the number of shares of Company stock reserved but unissued under the Company's 2004 and 2007 Stock Incentive Plans as of April 28, 2010 and may be increased to include the number of shares of Company stock that become available for reuse under these plans following April 28, 2010, subject to adjustment for certain transactions. Notwithstanding the foregoing, of the 8,000,000 shares originally reserved for issuance under this Plan, no more than 4,000,000 of such shares shall be issued as awards, other than options, that are settled in the Company's stock. In no event may the total number of shares of Company stock subject to awards awarded to any one participant during any tax year of the Company, exceed 1,000,000 shares (subject to adjustment for certain transactions). In June 2011, in connection with our acquisition of AMS, we assumed the AMS 2005 Stock Incentive Plan. As of the AMS Acquisition Date, the number of shares of Company stock reserved for issuance under the Plan was 5,269,152. Approximately 21.8 million shares were reserved for future issuance upon exercise of options granted or to be granted under the Endo 2000, 2004, 2007, and 2010 Stock Incentive Plans and the AMS 2005 Stock Incentive Plan. As of December 31, 2011, stock options, restricted stock awards, performance stock units and restricted stock units have been granted under the Stock Incentive Plans.

The Company accounts for its stock-based compensation plans in accordance with the applicable accounting guidance. Accordingly, all stock-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 stock-based compensation expense of \$46.0 million, \$22.9 million and \$19.6 million during 2011, 2010 and 2009, respectively. As of December 31, 2011, the total remaining unrecognized compensation cost related to all non-vested stock-based compensation awards amounted to \$101.5 million. This expected cost does not include the impact of any future stock-based compensation awards.

Presented below is the allocation of stock-based compensation as recorded in our Consolidated Statements of Operations for the years ended December 31 (in thousands).

	2011	2010	2009
Selling, general and administrative expenses	\$ 39,305	\$ 19,229	\$ 17,211
Research and development expenses	6,214	3,680	2,382
Cost of revenues	494		
Total stock-based compensation expense	\$ 46,013	\$ 22,909	\$ 19,593

**Stock Options**

For all of the Company's stock-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.

**Table of Contents**

Expected volatilities utilized in the model are based mainly on the historical volatility of the Company's stock 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 under the Endo 2000, 2004, 2007, and 2010 Stock Incentive Plans and the AMS 2005 Stock Incentive Plan (since June 18, 2011) for the three-year period ended December 31, 2011 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, January 1, 2009	4,659,382	\$ 23.95		
Granted	2,216,544	\$ 19.30		
Exercised	(554,827)	\$ 14.48		
Forfeited	(300,864)	\$ 24.11		
Expired	(861,694)	\$ 24.67		
Outstanding, December 31, 2009	5,158,541	\$ 22.84		
Granted	2,210,537	\$ 22.23		
Exercised	(965,013)	\$ 21.64		
Forfeited	(305,033)	\$ 21.72		
Expired	(207,632)	\$ 30.44		
Outstanding, December 31, 2010	5,891,400	\$ 22.60		
Granted	3,865,575	\$ 29.66		
Exercised	(1,274,280)	\$ 22.80		
Forfeited	(335,049)	\$ 26.54		
Expired	(32,179)	\$ 26.49		
Outstanding, December 31, 2011	8,115,467	\$ 25.79	7.08	\$ 73,458,624
Vested and expected to vest, December 31, 2011	7,491,190	\$ 25.57	6.99	\$ 69,292,646
Exercisable, December 31, 2011	2,553,890	\$ 23.84	5.51	\$ 27,616,803

The total intrinsic value of options exercised during the years ended December 31, 2011, 2010 and 2009 was \$29.0 million, \$9.0 million and \$3.6 million, respectively. The weighted-average grant date fair value of the stock options granted during the years ended December 31, 2011, 2010 and 2009 was \$11.97, \$7.66 and \$7.47 per option, respectively, determined using the following assumptions:

	2011	2010	2009
Average expected term (years)	5.00	5.25	5.22
Risk-free interest rate	2.0%	2.4%	2.0%
Dividend yield	0.00	0.00	0.00
Expected volatility	32%	34%	40%

The weighted average remaining requisite service period of the non-vested stock options is 2.3 years. As of December 31, 2011, the total remaining unrecognized compensation cost related to non-vested stock options amounted to \$45.4 million. This unrecognized compensation cost does not include the impact of any future stock-based compensation awards.

**Table of Contents**

The following table summarizes information about stock options outstanding under our 2000, 2004, 2007, and 2010 Stock Incentive Plans and the AMS 2005 Stock Incentive Plan at December 31, 2011:

**2000, 2004, 2007, and 2010 Stock Incentive Plans and the AMS 2005 Stock Incentive Plan Options Outstanding**

<b>Number</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Weighted Average Exercise Price</b>	<b>Number Exercisable</b>	<b>Exercisable Weighted Average Exercise Price</b>	<b>Range of Exercise Prices</b>
<b>Outstanding</b>					
8,115,467	7.08	\$ 25.79	2,553,890	\$ 23.84	\$ 9.29-41.83

**Restricted Stock Units**

During the years ended December 31, 2011, 2010 and 2009, the Company granted restricted stock units to employees and non-employee directors of the Company as part of their annual stock compensation award. We recognize expense for our restricted stock units using the straight-line method over the requisite service period. The total value of compensation expense for restricted stock units is equal to the closing price of Endo shares on the date of grant.

A summary of our restricted stock units activity during the years ended December 31, 2011, 2010 and 2009 is presented below:

	<b>Number of Shares</b>	<b>Aggregate Intrinsic Value</b>
Outstanding, January 1, 2009	548,353	
Granted	1,133,186	
Forfeited	(86,286)	
Vested	(118,012)	
Outstanding, December 31, 2009	1,477,241	
Granted	1,411,140	
Forfeited	(357,546)	
Vested	(319,532)	
Outstanding, December 31, 2010	2,211,303	
Granted	1,158,562	
Forfeited	(181,752)	
Vested	(558,331)	
Outstanding, December 31, 2011	2,629,782	\$ 91,082,527
Vested and expected to vest, December 31, 2011	2,333,839	\$ 80,014,361

The weighted average remaining requisite service period of the non-vested restricted stock units is 2.0 years. The weighted-average grant date fair value of the restricted stock units granted during the years ended December 31, 2011, 2010 and 2009 was \$33.51, \$21.39 and \$19.43 per unit, respectively. As of December 31, 2011, the total remaining unrecognized compensation cost related to non-vested restricted stock units amounted to \$48.4 million. This unrecognized compensation cost does not include the impact of any future stock-based compensation awards.

**Restricted Stock Awards**

We recognize expense for our restricted stock using the straight-line method over the requisite service period. The total value of compensation expense for restricted stock is equal to the closing price of Endo shares on the date of grant.

**Table of Contents**

A summary of our restricted stock activity during the years ended December 31, 2011, 2010 and 2009 is presented below:

	Number of Shares	Weighted Average Fair Value Per Share	Aggregate Intrinsic Value
Non-vested, January 1, 2009	5,655	\$ 29.84	
Granted		\$	
Forfeited	(1,131)	\$ 29.84	
Vested	(4,524)	\$ 29.84	\$ 92,832
Non-vested, December 31, 2009		\$	
Granted		\$	
Forfeited		\$	
Vested		\$	\$
Non-vested, December 31, 2010		\$	
Granted	199,413	\$ 30.40	
Forfeited	(8,009)	\$ 27.51	
Vested	(17,787)	\$ 32.96	\$ 276,551
Non-vested, December 31, 2011		\$ 30.27	

The weighted average remaining requisite service period of the non-vested restricted stock awards was approximately 2.5 years.

**Performance Shares**

Beginning in the first quarter ended March 31, 2010, the Company began to award performance stock units (PSU) to certain key employees. These PSUs are tied to both Endo's overall financial performance and Endo's financial performance relative to the financial performance of a selected industry group. Awards are granted annually, with each award covering a three-year performance cycle. Each PSU is convertible to one share of Endo common stock. Performance measures used to determine the actual number of performance shares issuable upon vesting include an equal weighting of Endo's total shareholder return (TSR) performance compared to the performance group over the three-year performance cycle and Endo's three-year cumulative revenue performance as compared to a three-year revenue target. TSR relative to peers is considered a market condition while cumulative revenue performance is considered a performance condition under applicable authoritative guidance. PSUs granted for the year ended December 31, 2011 and 2010 totaled 160,000 and 163,000, respectively. As of December 31, 2011, there was approximately \$7.7 million of total unrecognized compensation costs related to PSUs. That cost is expected to be recognized over a weighted-average period of 3.0 years.

**Share Repurchase Program**

In April 2008, our Board of Directors approved a share repurchase program, authorizing the Company to repurchase in the aggregate up to \$750 million of shares of its outstanding common stock. Purchases under this program may be made from time to time in open market purchases, privately-negotiated transactions, and accelerated stock repurchase transactions or otherwise, as determined by Endo.

This program does not obligate Endo to acquire any particular amount of common stock. Additional purchases, if any, will depend on factors such as levels of cash generation from operations, cash requirements for investment in the Company's business, repayment of future debt, if any, current stock price, market conditions and other factors. The share repurchase program may be suspended, modified or discontinued at any time. As a result of a two-year extension approved by the Board of Directors in February 2012, the share repurchase plan is set to expire in April 2014.

---

**Table of Contents**

We did not purchase any shares of our common stock during the year ended December 31, 2009. During the years ended December 31, 2011 and 2010, pursuant to the existing share repurchase program, we purchased approximately 0.9 million and 2.5 million shares of our common stock on the open market for a total purchase price of totaling approximately \$34.7 million and \$59.0 million, respectively.

***Employee Stock Purchase Plan***

At our Annual Meeting of Stockholders held in May of 2011, our shareholders approved the Endo Pharmaceuticals Holdings Inc. Employee Stock Purchase Plan (the ESPP). The 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 percent of their eligible compensation, subject to certain limitations, to purchase shares of common stock at 85 percent of the lower of the closing price of Endo common stock 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 share of our common stock on the first day of the offering period, subject to certain adjustments. Compensation expense will be calculated in accordance with the applicable accounting guidance and will be 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 one percent 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 of Stock 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.

The ESPP became effective on May 25, 2011 when approved by the Company's stockholders, with the plan commencing on January 1, 2012. Accordingly, there was no impact to our Consolidated Financial Statements in 2011.

**NOTE 14. COMMITMENTS AND CONTINGENCIES**

**Manufacturing, Supply and Other Service Agreements**

We contract with various third party manufacturers, suppliers and service providers to provide us with raw materials used in our products and semi-finished and finished goods, as well as certain packaging and labeling and sales and marketing services. Our most significant agreements are with Novartis Consumer Health, Inc. and Novartis AG (collectively, Novartis), Teikoku Seiyaku Co., Ltd., Mallinckrodt Inc., Noramco, Inc., Sharp Corporation, and Ventiv Commercial Services, 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 a material adverse effect on our business, financial condition, results of operations and cash flows.

***Novartis Manufacturing Agreement***

On May 3, 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc. whereby Novartis Consumer Health, Inc. has agreed to manufacture certain of our commercial products and products in development. We are required to purchase, on an annual basis, a minimum amount of product from Novartis Consumer Health, Inc. The purchase price per product is equal to a predetermined amount per unit, subject to periodic adjustments. This agreement had a five-year initial term, with automatic five-year renewals thereafter. In August 2005, we extended this agreement until 2011. On February 23, 2011, we gave notice to Novartis Consumer Health, Inc. that we would terminate this agreement effective February 2014. At December 31, 2011, based on the currently manufactured products at Novartis Consumer Health, Inc., we are required to purchase a minimum of approximately \$11.2 million of product from Novartis Consumer Health, Inc. per year, or pro rata portion thereof, until the effective date of the termination of this agreement. Amounts purchased pursuant to this agreement were \$66.3 million, \$54.9 million and \$51.5 million for the years ended December 31, 2011, 2010 and 2009, respectively.



## **Table of Contents**

In December 2011, Novartis Consumer Health, Inc.'s Lincoln, Nebraska manufacturing facility was temporarily shut down to facilitate its implementation of certain manufacturing process improvements. These improvements are intended to address the possibility of rare instances of errors in the packaging of the tablets, potentially resulting in product mix-ups. The temporary supply disruption is not related to the efficacy or safety of Endo's products. As a result, there will be a short-term supply constraint of Opana® ER and certain other Endo analgesic products manufactured at this facility, including Opana®, Voltaren® Gel, oxymorphone hydrochloride, Percocet®, Percodan®, Endocet®, Endodan®, morphine sulfate ER and Zydone®.

Endo will be expediting the production of the new formulation of Opana® ER, designed to be crush-resistant, at a third party manufacturing facility managed by Endo's development partner, Grünenthal. The Company estimates that it will be in full production at this facility by early second quarter. Endo will also begin production of Voltaren® Gel at an alternative Novartis Consumer Health, Inc. manufacturing source to begin during early second quarter of 2012 and, as a result, expects short-term disruption for patients on this therapy. We anticipate supply to return to normal levels during early in the second quarter of 2012. Endo had already initiated the manufacturing of Percocet® and Endocet® at its Huntsville, Alabama facility as a result of its acquisition of Qualitest in 2010 and, as a result, expects minimal disruption to patients on these products. Separately, Endo also has plans to put additional procedures in place to assist Novartis Consumer Health, Inc. in restarting production at the Lincoln, Nebraska manufacturing facility.

### *Novartis License and Supply Agreement*

Pursuant to the March 2008 Voltaren® Gel License and Supply Agreement (the Voltaren® Gel Agreement) with Novartis AG and Novartis Consumer Health, Inc. Endo has agreed to purchase from Novartis all of its requirements for Voltaren® Gel during the entire term of the Voltaren® Gel Agreement. The price of product purchased under the Voltaren® 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 Voltaren® Gel Agreement were \$30.4 million, \$27.1 million and \$13.1 million for the years ended December 31, 2011, 2010 and 2009, respectively.

As part of the Voltaren® Gel Agreement, we also agreed to undertake advertising and promotion of Voltaren® Gel (A&P Expenditures), subject to certain thresholds set forth in the Voltaren® Gel Agreement. We agreed to spend a minimum of \$15 million on A&P Expenditures during the first Voltaren® Gel Agreement Year which ended on June 30, 2009. During the second Voltaren® Gel Agreement Year beginning on July 1, 2009 and extended through June 30, 2010, we had agreed to spend a minimum of \$20 million on A&P Expenditures. During the third Voltaren® Gel Agreement Year beginning on July 1, 2010 and extending through June 30, 2011, we had agreed to spend 15% of prior year sales or approximately \$13 million on A&P Expenditures. During the fourth Voltaren® Gel Agreement Year beginning on July 1, 2011 and extending through June 30, 2012, we have agreed to spend 13% of prior year sales or approximately \$16 million on A&P Expenditures; however, this amount may be reduced pursuant to the Voltaren® Gel Agreement due to Novartis's failure to supply Voltaren® Gel. In subsequent Agreement Years, the minimum A&P Expenditures set forth in the Voltaren® Gel Agreement are determined based on a percentage of net sales of Voltaren® Gel, which may be reduced under certain circumstances, including Novartis's failure to supply Voltaren® Gel.

Amounts incurred by Endo for such A&P Expenditures were \$18.7 million, \$18.0 million and \$15.6 million for the years ended December 31, 2011, 2010 and 2009, respectively.

## **Table of Contents**

### *Teikoku Seiyaku Co., Ltd.*

Under the terms of our 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 us in the U.S. We also have an option to extend the supply area to other territories. On April 24, 2007, we amended the Teikoku agreement (the Amended Agreement). The material components of the Amended Agreement are as follows:

We agreed to purchase a minimum number of patches per year through 2012, representing the noncancelable portion of the Amended Agreement.

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. Since future price changes are unknown, we have used prices currently existing under the Amended Agreement, and estimated our minimum purchase requirement to be approximately \$34.0 million per year through 2012. The minimum purchase requirement shall remain in effect subsequent to 2012, except that Endo has the right to terminate the Amended Agreement after 2012, if we fail to meet the annual minimum requirement.

Following cessation of our 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 Endo, we will pay to Teikoku annual royalties based on our annual net sales of Lidoderm®.

The Amended Agreement will expire on December 31, 2021, unless terminated in accordance with its terms. Either party may terminate this Agreement, upon thirty (30) days written notice, in the event that Endo fails to purchase the annual minimum quantity for each year after 2012 (e.g., 2013 through 2021) upon thirty (30) days written notice. Notwithstanding the foregoing, after December 31, 2021, the Amended Agreement shall be automatically renewed on the first day of January each year unless (i) we and Teikoku agree to terminate the Amended Agreement upon mutual written agreement or (ii) either we or Teikoku terminates the Amended Agreement with 180-day written notice to the other party, which notice shall not in any event be effective prior to July 1, 2022.

On January 6, 2010, the parties amended the Teikoku Agreement, effective December 16, 2009. Pursuant to the amendment, Teikoku has agreed to supply Lidoderm® at a fixed price for a period of time after which the price will be adjusted at certain future dates based on a price index defined in the amendment.

Effective November 1, 2010, the parties amended the Teikoku Agreement. Pursuant to this amendment, Teikoku has agreed to supply additional Lidoderm® at no cost to Endo in each of 2011, 2012 and 2013 in the event Endo's firm orders of Product exceed certain thresholds in those years.

Amounts purchased pursuant to this agreement, as amended, were \$203.4 million, \$172.3 million and \$152.9 million for the years ended December 31, 2011, 2010 and 2009, respectively.

On November 23, 2011, our obligation to pay royalties to Hind under the Sole and Exclusive License Agreement dated as of November 23, 1998, as amended, between Hind and Endo ceased. Accordingly, on November 23, 2011, pursuant to the terms of the Teikoku Agreement, we began to incur royalties to Teikoku based on annual net sales of Lidoderm®. The royalty rate is 6% of net sales. During 2011, we recorded \$6.5 million for these royalties to Teikoku, which we recorded in our Consolidated Financial Statements as Cost of revenues. At December 31, 2011, \$6.5 million is recorded as a royalty payable and included in accounts payable in the accompanying Consolidated Balance Sheets.

### *Mallinckrodt Inc.*

Under the terms of our agreement (the Mallinckrodt Agreement) with Mallinckrodt Inc. (Mallinckrodt), Mallinckrodt manufactures and supplies to us certain narcotic active drug substances, in bulk form, and raw materials for inclusion in our controlled substance pharmaceutical products. There is no minimum annual



## **Table of Contents**

purchase commitment under the Mallinckrodt Agreement. However, we are required to purchase a fixed percentage of our annual requirements of each narcotic active drug substance covered by the Mallinckrodt Agreement from Mallinckrodt. The purchase price for these substances is equal to a fixed amount, adjusted on an annual basis. The initial term of this agreement was July 1, 1998 until September 30, 2013, with an automatic renewal provision for unlimited successive one-year periods. On September 30, 2011, we provided written notice to Mallinckrodt that the Company intends to let the Mallinckrodt Agreement expire effective September 30, 2013. The Company chose to allow the Mallinckrodt Agreement to expire in connection with its ongoing initiatives relating to the sourcing of active pharmaceutical ingredients. Prior to the expiration of the Mallinckrodt Agreement, the Company expects a new agreement with respect to narcotic active drug substances and raw materials to be put in place with a third party. The Company will continue to purchase certain narcotic active drug substances, in bulk form, under the terms of the Mallinckrodt Agreement through the expiration date.

Amounts purchased pursuant to this agreement were \$51.3 million, \$26.1 million and \$20.7 million for the years ended December 31, 2011, 2010 and 2009, respectively.

### *Noramco, Inc.*

Under the terms of our agreement (the Noramco Agreement) with Noramco Inc. (Noramco), Noramco manufactures and supplies to us certain narcotic active drug substances, in bulk form, and raw materials for inclusion in our controlled substance pharmaceutical products. There are no minimum annual purchase commitments under the Noramco Agreement. However, we are 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 is 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. On September 30, 2011, we provided written notice to Noramco that we intend to let the Noramco Agreement expire effective March 31, 2012. We will continue to purchase certain narcotic active drug substances, in bulk form, under the terms of the Noramco Agreement through the expiration date.

Amounts purchased from Noramco were \$55.5 million, \$13.9 million and \$3.2 million for the years ended December 31, 2011, 2010 and 2009, respectively.

### *Sharp Corporation*

Under the terms of our agreement (the Sharp Agreement) with Sharp Corporation (Sharp), a U.S. manufacturer, Sharp performs certain services for Endo including the packaging and labeling of Lidoderm® at its facility in Allentown, Pennsylvania, for commercial sale by us in the U.S. On December 6, 2010, the parties amended the Sharp Packaging and Labeling agreement, effective December 1, 2010, extending the agreement until March 15, 2015. The Sharp Agreement 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 ninety (90) days written notice.

Amounts purchased pursuant to the Sharp agreement were \$6.3 million, \$6.9 million and \$6.3 million for the years ended December 31, 2011, 2010 and 2009, respectively.

### *Ventiv Commercial Services, LLC*

On November 24, 2010, we entered into a services agreement (the Ventiv Agreement) with Ventiv Commercial Services, LLC (Ventiv).

## **Table of Contents**

Under the terms of the Ventiv Agreement, Ventiv provided to Endo certain sales and promotional services through a contracted field force of 228 sales representatives, 24 district managers, one project manager, and one national sales director, collectively referred to as the Ventiv Field Force. The Ventiv Field Force was required to perform a minimum number of face-to-face, one-on-one discussions with physicians and other health care practitioners for the purpose of promoting Voltaren<sup>®</sup> Gel, Lidoderm<sup>®</sup>, Frova<sup>®</sup>, Opana<sup>®</sup> ER, and other Endo products within their respective approved indications during each year of the Ventiv Agreement, subject to certain provisions.

Under the terms of the Ventiv Agreement, we incurred a one-time implementation fee that we recognized in Selling, general, and administrative expense in the second half of 2010. In addition, each month we were required to pay Ventiv a monthly fixed fee during the term of the Ventiv Agreement based on a pre-approved budget. Ventiv was also eligible to earn a performance-based bonus equal to the fixed management fee during each year of the Ventiv Agreement. This performance-based bonus was payable upon the satisfaction of certain conditions, including the sale of a minimum number of Voltaren<sup>®</sup> Gel tubes and a minimum number of Details achieved. The Ventiv Agreement expired on December 30, 2011.

On December 27, 2011, we entered into a new Sales and Promotional Services Agreement (the 2011 Ventiv Agreement) with Ventiv, effective as of December 30, 2011. Under the terms of the 2011 Ventiv Agreement, the Ventiv Field Force will promote Voltaren<sup>®</sup> Gel, Lidoderm<sup>®</sup>, Frova<sup>®</sup>, Opana<sup>®</sup> ER, Fortesta<sup>®</sup> Gel and any additional products added by Endo. The sales representatives will be required to perform face-to-face, one-on-one discussions with physicians and other health care practitioners promoting these products.

Endo will pay to Ventiv a monthly fixed fee during the term of the 2011 Ventiv Agreement based on a budget that has been approved by both Endo and Ventiv. During the term of the 2011 Ventiv Agreement, Ventiv will also be eligible to earn, in addition to the fixed management fee, an at-risk management fee. This at-risk management fee is payable upon the achievement of certain performance metrics that have been mutually agreed upon by the parties.

The 2011 Ventiv Agreement shall continue until December 30, 2013. Endo may extend the Current Term for an additional period by written notice delivered to Ventiv prior to the expiration of the then Current Term.

The expenses incurred with respect to Ventiv were \$38.4 million, \$10.9 million and \$21.6 million for the years ended December 31, 2011, 2010 and 2009 respectively.

### *UPS Supply Chain Solutions*

Under the terms of this agreement, we utilize UPS Supply Chain Solutions to provide customer service support, chargeback processing, accounts receivables management and warehouse, freight and distribution services for certain of our products in the U.S. The initial term of the agreement will extend to March 31, 2015. The agreement may be terminated by either party (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 become insolvent or bankrupt. In the event of termination of services provided under the Warehouse Distribution Services Schedule to the agreement (i) by Endo without cause or (ii) by UPS due to Endo's breach, failure by Endo to make payments when due, or Endo's insolvency, we would be required to pay UPS certain termination costs. Such termination costs would not exceed \$1.2 million. On February 21, 2012, we amended this agreement to provide for a reduced pricing structure, which includes new monthly fees, new variable fees and new termination fees.

### *General*

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 materially adverse effect on our business, financial condition, results of operations and cash flows.

## **Table of Contents**

### **Milestones and Royalties**

See Note 7. License and Collaboration Agreements for a complete description of future milestone and royalty commitments pursuant to our acquisitions, license and collaboration agreements.

### **Employment Agreements**

We have entered into employment agreements with certain members of management.

### **Research Contracts**

We routinely contract with universities, medical centers, contract research organizations and other institutions for the conduct of research and clinical studies on our behalf. These agreements are generally for the duration of the contracted study and contain provisions that allow us to terminate prior to completion.

### **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 relating to product liability, intellectual property, regulatory compliance and commercial matters. While we cannot predict the outcome of our ongoing legal proceedings and we intend to vigorously defend 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.

In view of the inherent difficulty of predicting the outcome of our various claims, legal proceedings and governmental investigations, particularly where there are many claimants and the claimants seek indeterminate damages and particularly given the various stages of our proceedings, we are unable to predict the outcome of these matters or the ultimate legal and financial liability, and at this time cannot reasonably estimate the possible loss or range of loss. Accordingly, there are claims, legal proceedings and governmental investigations in which we are involved where a loss is reasonably possible in future periods and for which we have not accrued a related liability. Likewise, it is reasonably possible that a future loss could exceed the related accrued liability.

#### *Department of Health and Human Services Subpoena*

As previously reported, in January 2007 and April 2011, the Company received subpoenas issued by the United States Department of Health and Human Services, Office of Inspector General (OIG) and the United States Department of Justice, respectively. The subpoenas request documents relating to Lidoderm® (lidocaine patch 5%), focused primarily on the sale, marketing and promotion of Lidoderm®. The Company is cooperating with the government in responding to the subpoenas. At this time, the Company cannot predict or determine the outcome of the government's 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.

#### *Pricing Litigation*

A number of cases were brought by state government entities that allege generally that our wholly-owned subsidiary, Endo Pharmaceuticals Inc. (EPI) and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid. These cases generally seek damages, treble damages, disgorgement of profits, restitution and attorneys' fees.

There is a previously reported case pending in the Circuit Court of Montgomery County, Alabama against EPI and numerous other pharmaceutical companies: *State of Alabama v. Abbott Laboratories, Inc., et al.* Without admitting any liability or wrongdoing, EPI and the plaintiff reached an agreement in principle to resolve this case on terms that are not material to the Company's business, results of operations, financial condition or cash flows.

## Table of Contents

In addition, there is a previously reported case pending in the Third Judicial District Court of Salt Lake County, Utah against EPI and numerous other pharmaceutical companies: *State of Utah v. Actavis US, Inc., et al.* As previously reported, there is a case pending in the 19th Judicial District, Parish of East Baton Rouge, Louisiana against EPI and numerous other pharmaceutical companies: *State of Louisiana v. Abbott Laboratories, Inc., et al.* These cases contain allegations similar to the allegations described above.

The Company intends to contest the above unresolved cases vigorously and to explore other options as appropriate in the best interests of the Company. 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 the Company or its subsidiaries.

### *Paragraph IV Certifications on Lidoderm®*

As previously reported, on January 15, 2010, the Company and the holders of the Lidoderm® NDA and relevant patent, Teikoku Seiyaku Co., Ltd., and Teikoku Pharma USA, Inc. (collectively, Teikoku) received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) (a Paragraph IV Notice) from Watson Laboratories, Inc. (Watson) advising of the filing of an Abbreviated New Drug Application (ANDA) for a generic version of Lidoderm® (lidocaine topical patch 5%). The Paragraph IV Notice refers to U.S. Patent No. 5,827,529, which covers the formulation of Lidoderm®, a topical patch to relieve the pain of post herpetic neuralgia launched in 1999. This patent is listed in the FDA's Orange Book and expires in October 2015. As a result of this Notice, on February 19, 2010, the Company and Teikoku filed a lawsuit against Watson in the United States District Court of the District of Delaware. 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. This lawsuit was recently heard by the United States District Court of the District of Delaware and concluded on February 14, 2012. We are currently waiting for the court's decision. In October 2010, Teikoku Pharma USA listed U.S. Patent No. 5,741,510 in the FDA Orange Book, and this patent expires in March 2014. On June 30, 2011, the Company and Teikoku filed a second lawsuit against Watson in the United States District Court of the District of Delaware alleging infringement of U.S. Patent Nos. 5,741,510, 6,096,333, and 6,096,334 which cover lidocaine patch formulations and manufacturing processes. The trial relating to this lawsuit has not yet been scheduled.

As previously reported, in January 2011, the Company and Teikoku received a Paragraph IV Notice from Mylan Technologies Inc. (Mylan) advising of the filing of an ANDA for a generic version of Lidoderm® (lidocaine topical patch 5%). The Paragraph IV Notice refers to U.S. Patent Nos. 5,827,529 and 5,741,510, which cover the formulation of Lidoderm®. These patents are listed in the FDA's Orange Book and expire in October 2015 and March 2014, respectively. On March 14, 2011, the Company filed a lawsuit against Mylan in the United States District Court for the District of Delaware, claiming that the Paragraph IV Notice served by Mylan failed to comply with the requirements of 21 U.S.C. sec. 355(b)(3)(C)(1) and 21 C.F.R. 214.95(a). In that suit, the Company seeks a declaration that Mylan's Paragraph IV Notice is null, void and without legal effect, and that as a result, Mylan has failed to properly trigger the ANDA litigation process. In the alternative, the Company alleges that Mylan's submission of its ANDA constitutes infringement of the '510 patent under 35 U.S.C. sec. 271(e)(2)(A). The trial relating to this lawsuit has not yet been scheduled.

Endo intends, and has been advised by Teikoku that they too intend, to vigorously defend Lidoderm®'s intellectual property rights and to pursue all available legal and regulatory avenues in defense of Lidoderm®, 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 and either Watson or Mylan is able to obtain FDA approval of its product, either Watson or Mylan may be able to launch its generic version of Lidoderm® prior to the applicable patents' expirations in 2014 and 2015. Additionally, we cannot predict or determine the timing or outcome of this litigation but will explore all options as appropriate in the best interests of the Company. In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of Lidoderm® and challenge the applicable patents.

**Table of Contents**

In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of Lidoderm® and challenge the applicable patents.

*Paragraph IV Certifications on Opana® ER*

As previously reported, starting in December 2007 through December 2011, the Company received notices from various generic drug manufacturers, including Impax Laboratories, Inc. (Impax), Actavis South Atlantic LLC (Actavis), Sandoz, Inc. (Sandoz), Barr Laboratories, Inc. (Teva), Watson Laboratories, Inc. (Watson), Roxane Laboratories, Inc. (Roxane) and most recently, Ranbaxy Inc. (Ranbaxy) advising of the filing by each such company of an ANDA for a generic version of Opana® ER (oxymorphone hydrochloride extended-release tablets CII). Each company's notice include a Paragraph IV Notice with respect to the patents that cover the non-tamper resistant formulation of Opana® ER. To date, except for the Ranbaxy litigation, the Company settled all of the Paragraph IV litigation relating to Opana® ER. Under the terms of the settlements, each generics manufacturer agreed not to challenge the validity or enforceability of patents relating to Opana® ER. As a result, Actavis launched generic non-tamper resistant Opana® ER 7.5 and 15 mg tablets on July 15, 2011. We expect Impax to launch production and sale of generic non-tamper resistant Opana® ER for 5, 10, 20, 30 and 40 mg tablets commencing on January 1, 2013. We expect Sandoz, Teva, Watson, Roxane and Actavis to launch production and sale of all strengths of generic non-tamper resistant Opana® ER commencing on July 1, 2013. We evaluated Ranbaxy's Paragraph IV notice and concluded that we will not sue Ranbaxy at this time. As a result, and because Ranbaxy filed a Paragraph III notice against two patents expiring September 9, 2013, we expect Ranbaxy to launch all strengths of Opana® ER commencing on September 9, 2013.

In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of Opana® ER and challenge the applicable patents. We intend to contest vigorously and pursue all available legal and regulatory avenues in defense of Opana® ER, including enforcement of our intellectual property rights and approved labeling. However, there can be no assurance that we will be successful. Additionally, we cannot predict or determine the timing or outcome of any of these litigations but will explore all options as appropriate in the best interests of the Company.

*Paragraph IV Certification on Frova®*

As previously reported, in July 2011, the Company and its licensor, Vernalis Development Limited received a notice from Mylan Technologies Inc. (Mylan) advising of the filing by Mylan of an ANDA for a generic version of Frova® (frovatriptan succinate) 2.5 mg tablets. Mylan's notice included a Paragraph IV Notice with respect to U.S. Patent Nos. 5,464,864, 5,561,603, 5,637,611, 5,827,871 and 5,962,501, which cover Frova®. These patents are listed in the FDA's Orange Book and expire between 2013 and 2015. As a result of this Paragraph IV Notice, on August 16, 2011, the Company filed a lawsuit against Mylan in the United States District Court for the District of Delaware alleging infringement of U.S. Patent Nos. 5,464,864, 5,637,611 and 5,827,871. 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. On September 22, 2011, Mylan filed an Answer and Counterclaims, claiming the asserted patents are invalid or not infringed.

Endo intends to vigorously defend Frova®'s intellectual property rights and to pursue all available legal and regulatory avenues in defense of Frova®, 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 and Mylan is able to obtain FDA approval of its product, Mylan may be able to launch its generic version of Frova® prior to the applicable patents' expirations in 2014 and 2015. Additionally, we cannot predict or determine the timing or outcome of this litigation but will explore all options as appropriate in the best interests of the Company. In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of Frova® and challenge the applicable patents.



---

**Table of Contents**

*MCP Cases*

Qualitest, and in certain cases the Company or certain of its subsidiaries, along with several other pharmaceutical manufacturers, have been named as defendants in numerous lawsuits in various federal and state courts alleging personal injury resulting from the use of the prescription medicine metoclopramide. Plaintiffs in these suits allege various personal injuries including tardive dyskinesia, other movement disorders, and death. The Company intends to contest these cases vigorously and to explore other options as appropriate in the best interests of the Company. 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 additional litigation will be brought against the Company or its subsidiaries. Subject to certain terms and conditions, we will be indemnified by the former owners of Qualitest with respect to metoclopramide litigation arising out of the sales of the product by Qualitest between January 1, 2006 and the date on which the acquisition was completed, subject to an overall liability cap of \$100 million for all claims arising out of or related to the acquisition, including the claims described above.

*Propoxyphene Cases*

Qualitest and, in certain cases, the Company or certain of its subsidiaries, along with several other pharmaceutical manufacturers, have been named as defendants in several lawsuits originally filed in various federal and state courts alleging personal injury resulting from the use of prescription pain medicines containing propoxyphene. Plaintiffs in these suits allege various personal injuries including cardiac impairment and damage. In August 2011, a multidistrict litigation (MDL) was formed, and cases pending in federal court are now coordinated in the Eastern District of Kentucky as part of MDL No. 2226. The Company intends to contest all of these cases vigorously and to explore other options as appropriate in the best interests of the Company. 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 additional litigation will be brought against the Company or its subsidiaries. Subject to certain terms and conditions, we will be indemnified by the former owners of Qualitest with respect to propoxyphene litigation arising out of the sales of the product by Qualitest between January 1, 2006 and the date on which the acquisition was completed, subject to an overall liability cap of \$100 million for all claims arising out of or related to the acquisition, including the claims described above.

*Vaginal Mesh Cases*

On October 20, 2008, the FDA issued a Public Health Notification regarding potential complications associated with transvaginal placement of surgical mesh to treat POP and 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, 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 this July 2011 update, the FDA maintained that adverse events are not rare, as previously reported, and 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. FDA also convened an advisory panel which met on September 8-9, 2011 to further address the safety and effectiveness of transvaginal surgical mesh used to treat POP and SUI. At the conclusion of the meetings, the advisory panel recommended reclassifying transvaginal mesh products used to treat POP to Class III devices (premarket approval) and recommended that manufacturers of these products be required to conduct additional post-market surveillance studies. The advisory panel recommended that transvaginal surgical mesh products used to treat SUI

## **Table of Contents**

remain as Class II devices. Regarding retropubic and transobturator (TOT) slings, the advisory panel recommended that no additional post-market surveillance studies are necessary. Regarding mini-slings, the advisory panel recommended premarket study for new devices and additional post-market surveillance studies. The advisory panel's recommendations are now under consideration by FDA.

On January 3, 2012, the FDA ordered manufacturers of transvaginal surgical mesh used for pelvic organ prolapse and of single incision mini-slings for urinary incontinence, such as AMS, to conduct post-market safety studies and to monitor adverse event rates relating to the use of these products. These class-wide post-market study orders apply to eighteen AMS pelvic floor repair and mini-sling products. AMS is in the process of complying with these orders. In these orders, the FDA also noted that it is still considering the recommendation of the September 9, 2011 advisory committee that urogynecological surgical mesh for transvaginal repair of pelvic organ prolapse be reclassified from Class II to Class III.

Since 2008, AMS, and more recently, in certain cases the Company or certain of its 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. Plaintiffs in these suits allege various personal injuries including chronic pain, incontinence and inability to control bowel function, and permanent deformities. On February 7, 2012, a multidistrict litigation (MDL) was formed, and cases pending in federal court are now consolidated in the Southern District of West Virginia as part of MDL No. 2325. AMS and the Company intend to contest all of these cases vigorously and to explore other options as appropriate in the best interests of AMS and the Company. 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 additional litigation will be brought against the Company or its subsidiaries.

### *Other Legal Proceedings*

In addition to the above proceedings, 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, we are not involved in any arbitration and/or other legal proceeding that we expect to have a material effect on our business, financial condition, results of operations and cash flows.

**Table of Contents****Leases**

We lease automobiles and office and laboratory facilities under certain noncancelable operating leases that expire from time to time through 2018. These leases are renewable at our option. A summary of minimum future rental payments required under operating and capital leases as of December 31, 2011 are as follows (in thousands):

	<b>Capital Leases</b>	<b>Operating Leases</b>
2012	\$ 1,730	\$ 13,682
2013	\$ 1,646	\$ 10,909
2014	\$ 250	\$ 9,266
2015	\$ 182	\$ 5,705
2016	\$ 30	\$ 3,260
Thereafter	\$	\$ 4,359
<b>Total minimum lease payments</b>	<b>\$ 3,838</b>	<b>\$ 47,181</b>
Less: Amount representing interest	122	
<b>Total present value of minimum payments</b>	<b>\$ 3,716</b>	
Less: Current portion of such obligations	1,639	
<b>Long-term capital lease obligations</b>	<b>\$ 2,077</b>	

Expense incurred under operating leases was \$22.5 million, \$17.2 million and \$12.2 million for the years ended December 31, 2011, 2010 and 2009, respectively.

**NOTE 15. SAVINGS AND INVESTMENT PLAN AND DEFERRED COMPENSATION PLANS***Savings and Investment Plan*

On September 1, 1997, we established a defined contribution Savings and Investment Plan (the Endo 401(k) Plan) covering all employees. Employee contributions are made on a pre-tax basis under section 401(k) of the Internal Revenue Code (the Code). We match up to six percent of the participants' contributions subject to limitations under section 401(k) of the Code. Participants are fully vested with respect to their own contributions. Participants are fully vested with respect to our contributions after one year of continuous service.

On July 2, 2010, the Company acquired HealthTronics, which sponsored the HealthTronics, Inc. and Subsidiaries 401(k) Plan (the HealthTronics Plan). The HealthTronics Plan was a defined contribution profit-sharing plan with a 401(k) option covering all employees of HealthTronics, Inc. In June, 2011, former HealthTronics employees began to participate in the Endo 401(k) Plan and the HealthTronics Plan assets were transferred into the Endo 401(k) Plan.

On November 30, 2010, the Company acquired Qualitest, which sponsored the Qualitest Pharmaceuticals 401(k) Plan (the Qualitest Plan). The Qualitest Plan is a defined contribution profit-sharing plan with a 401(k) option covering all employees of Qualitest, Inc. In January 2012, former Qualitest employees began to participate in the Endo 401(k) Plan and the Qualitest Plan assets were transferred into the Endo 401(k) Plan.

On June 17, 2011, the Company acquired AMS, which sponsors the AMS Savings and Investment Plan (the AMS Plan). The AMS Plan is a defined contribution profit-sharing plan with a 401(k) option covering all employees of AMS. The Company intends to merge the AMS Plan into the Endo 401(k) Plan in 2013.

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

Contributions by us to the various 401(k) plans amounted to \$15.0 million, \$9.8 million and \$8.3 million for the years ended December 31, 2011, 2010 and 2009, respectively.

F-78

**Table of Contents***Executive Deferred Compensation Plan*

In December 2007, the Board of Directors (the Board) of Endo Pharmaceuticals Holdings Inc. adopted the Endo Pharmaceuticals Holdings Inc. Executive Deferred Compensation Plan (the Deferred Compensation Plan) and the Endo Pharmaceuticals Holdings Inc. 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 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 as a lump sum. 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, and also provides for a company match on the first six percent of deferrals to the extent not provided for under the Savings and Investment Plan. Payment occurs as elected, either in lump sum or in installments.

*Directors Deferred Compensation Plan*

Also in December 2007, the Board adopted the Endo Pharmaceuticals Holdings Inc. Directors Deferred Compensation Plan, effective January 1, 2008. The purpose of the Plan is to promote the interests of the Company and the stockholders of the Company by providing non-employee Directors the opportunity to defer up to 100% of meeting fees, retainer fees, and restricted stock units, with payout to occur as elected either in lump sum or installments.

**NOTE 16. NET INCOME PER SHARE**

The following is a reconciliation of the numerator and denominator of basic and diluted net income per share for the years ended December 31 (in thousands, except per share data):

	2011	2010	2009
<b>Numerator:</b>			
Net income attributable to Endo Pharmaceuticals Holdings Inc. common stockholders	\$ 187,613	\$ 259,006	\$ 266,336
<b>Denominator:</b>			
For basic per share data weighted average shares	116,706	116,164	117,112
Dilutive effect of common stock equivalents	2,306	1,202	403
Dilutive effect of 1.75% Convertible Senior Subordinated Notes and warrants	2,166	585	
<b>For diluted per share data weighted average shares</b>	<b>121,178</b>	<b>117,951</b>	<b>117,515</b>
Basic net income per share attributable to Endo Pharmaceuticals Holdings Inc	\$ 1.61	\$ 2.23	\$ 2.27
<b>Diluted net income per share attributable to Endo Pharmaceuticals Holdings Inc</b>	<b>\$ 1.55</b>	<b>\$ 2.20</b>	<b>\$ 2.27</b>

Basic net income per share is computed based on the weighted average number of common shares outstanding during the period. Diluted income per common share is computed based on the weighted average number of common shares outstanding and, if there is net income during the period, the dilutive impact of common stock equivalents outstanding during the period. Common stock equivalents are measured under the treasury stock method.

The 1.75% Convertible Senior Subordinated Notes due April 15, 2015 are only included in the diluted net income per share calculation using the treasury stock method during periods in which the average market price of

**Table of Contents**

our common stock was above the applicable conversion price of the Convertible Notes, or \$29.20 per share. 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 stock during the period, and included that number in the total diluted shares outstanding for the period.

We have entered into convertible note hedge and warrant agreements that, in combination, have the economic effect of reducing the dilutive impact of the Convertible Notes. However, we separately analyze 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 are excluded because their impact would be anti-dilutive. The treasury stock method is applied when the warrants are in-the-money with the proceeds from the exercise of the warrant used to repurchase shares based on the average stock price in the calculation of diluted weighted average shares. Until the warrants are in-the-money, they have no impact to the diluted weighted average share calculation. The total number of shares that could potentially be included if the warrants were exercised is approximately 13 million.

The following reconciliation shows the maximum potential dilution of shares currently excluded from the calculation of diluted net income per share for the years ended December 31 (in thousands):

	2011	2010	2009
Weighted average shares excluded:			
1.75% Convertible senior subordinated notes due 2015 and warrants(1)	23,827	25,408	25,993
Employee stock-based awards	2,043	2,721	4,681
	25,870	28,129	30,674

(1) Amounts represent the incremental potential total dilution that could occur if our Convertible Notes and warrants were converted to shares of our common stock.

**NOTE 17. COST OF REVENUES**

The components of cost of revenues for the years ended December 31 (in thousands) were as follows:

	2011	2010	2009
Cost of net pharmaceutical product sales	\$ 823,455	\$ 451,096	\$ 375,058
Cost of devices revenues	124,217		
Cost of services and other revenues	117,536	53,661	
Total cost of revenues	\$ 1,065,208	\$ 504,757	\$ 375,058

**Table of Contents****NOTE 18. DEBT**

The components of our total indebtedness for the years ended December 31 (in thousands), were as follows:

	December 31, 2011	December 31, 2010
1.75% Convertible Senior Subordinated Notes due 2015	\$ 379,500	\$ 379,500
Unamortized discount on 1.75% Convertible Senior Subordinated Notes due 2015	(80,278)	(100,578)
<i>1.75% Convertible Senior Subordinated Notes due 2015, net</i>	<i>\$ 299,222</i>	<i>\$ 278,922</i>
7.00% Senior Notes due 2019	\$ 500,000	\$
7.00% Senior Notes due 2020	\$ 400,000	\$ 400,000
Unamortized initial purchaser's discount	(3,382)	(13,284)
<i>7.00% Senior Notes due 2020, net</i>	<i>\$ 396,618</i>	<i>\$ 386,716</i>
7.25% Senior Notes due 2022	\$ 400,000	\$
3.25% AMS Convertible Notes due 2036	\$ 841	\$
4.00% AMS Convertible Notes due 2041	\$ 131	\$
Term Loan Facility Due 2015	\$	\$ 400,000
Term Loan A Facility Due 2016	\$ 1,471,875	\$
Term Loan B Facility Due 2018	\$ 438,250	\$
Other long-term debt	\$ 5,657	\$ 5,156
<i>Total long-term debt, net</i>	<i>\$ 3,512,594</i>	<i>\$ 1,070,794</i>
Less current portion	\$ 88,265	\$ 24,993
<b>Total long-term debt, less current portion, net</b>	<b>\$ 3,424,329</b>	<b>\$ 1,045,801</b>

**Credit Facility**

In October 2009, we established a \$300 million, three-year senior secured revolving credit facility (the 2009 Credit Facility) with JP Morgan Chase Bank, Barclays Capital and certain other lenders. The 2009 Credit Facility was available for letters of credit, working capital and general corporate purposes. The 2009 Credit Facility also permitted up to \$100 million of additional revolving or term loan commitments from one or more of the existing lenders or other lenders.

Financing costs of \$5.2 million paid to establish the 2009 Credit Facility were deferred and were being amortized to interest expense over the life of the 2009 Credit Facility.

On November 30, 2010, we terminated the 2009 Credit Facility. Concurrent with the termination of the 2009 Credit Facility, we established a \$400 million, five-year senior secured term loan facility (the Term Loan Facility), and a \$500 million, five-year senior secured revolving credit facility (the 2010 Revolving Credit Facility and, together with the Term Loan Facility, the 2010 Credit Facility) with JP Morgan Chase Bank, Royal Bank of Canada, and certain other lenders. The 2010 Credit Facility was established primarily to finance our acquisition of Qualitest and was available for working capital, general corporate purposes and letters of credit. The agreement governing the 2010 Credit Facility (the 2010 Credit Agreement) also permitted up to \$200 million of additional revolving or term loan commitments from one or more of the existing lenders or other lenders with the consent of the JP Morgan Chase Bank (the administrative agent) without the need for consent from any of the existing lenders under the 2010 Credit Facility.

The obligations of the Company under the 2010 Credit Facility were guaranteed by certain of the Company's domestic subsidiaries and were secured by substantially all of the assets of the Company and the subsidiary guarantors. The 2010 Credit Facility contained certain usual and customary covenants, including, but

F-81



## Table of Contents

not limited to covenants to maintain maximum leverage and minimum interest coverage ratios. Borrowings under the 2010 Credit Facility bore interest at an amount equal to a rate calculated based on the type of borrowing and the Company's Leverage Ratio. For term loans and revolving loans (other than Swing Line Loans), the Company had been permitted to elect to pay interest based on an adjusted LIBOR rate plus between 2.00% and 2.75% or an Alternate Base Rate (as defined in the 2010 Credit Agreement) plus between 1.00% and 1.75%. The Company had also paid a commitment fee of between 35 to 50 basis points, payable quarterly, on the average daily unused amount of the Revolving Credit Facility.

Financing costs of \$16.5 million paid to establish the 2010 Credit Facility were deferred and were amortized to interest expense over the life of the 2010 Credit Facility. Financing costs associated with the 2009 Credit Facility not yet amortized as of November 30, 2010 totaled approximately \$3.2 million on November 30, 2010. In accordance with the applicable accounting guidance for debt modifications, upon the termination of the 2009 Credit Facility, approximately \$0.3 million of this amount was written off in proportion to decreased lending capacity provided by certain individual loan syndicates with a corresponding charge to earnings. The remaining \$2.9 million was deferred and will be amortized over the life of the 2010 Credit Facility.

On June 17, 2011, we terminated the 2010 Credit Facility. Concurrent with the termination of the 2010 Credit Facility, we established a \$1,500 million, five-year senior secured term loan facility (the Term Loan A Facility), a \$700 million, seven-year senior secured term loan facility (the Term Loan B Facility, and, together with the Term Loan A Facility, the Term Loan Facilities), and a \$500 million, five-year senior secured revolving credit facility (the 2011 Revolving Credit Facility and, together with the Term Loan Facilities, the 2011 Credit Facility) with Morgan Stanley Senior Funding, Inc., as administrative agent, Bank of America, N.A., as Syndication Agent, and certain other lenders. The 2011 Credit Facility was established primarily to finance our acquisition of AMS and is available for working capital, general corporate purposes and lines of credit. The agreement governing the 2011 Credit Facility (the 2011 Credit Agreement) also permits up to \$500 million of additional revolving or term loan commitments from one or more of the existing lenders or other lenders with the consent of Morgan Stanley Senior Funding, Inc. (the administrative agent) without the need for consent from any of the existing lenders under the 2011 Credit Facility.

The obligations of the Company under the 2011 Credit Facility are guaranteed by certain of the Company's domestic subsidiaries and are secured by substantially all of the assets of the Company and the subsidiary guarantors. The 2011 Credit Facility contains certain usual and customary covenants, including, but not limited to covenants to maintain maximum leverage and minimum interest coverage ratios. Borrowings under the 2011 Credit Facility bear interest at an amount equal to a rate calculated based on the type of borrowing and the Company's Leverage Ratio. For term A loans and revolving loans (other than Swing Line Loans), the Company is permitted to elect to pay interest based on an adjusted LIBOR rate plus between 1.75% and 2.50% or an Alternate Base Rate (as defined in the 2011 Credit Agreement) plus between 0.75% and 1.50%. For term B loans, the Company may elect to pay interest based on an adjusted LIBOR rate plus 3.00% or an Alternate Base Rate plus 2.00%. The Company will pay a commitment fee of between 37.5 to 50 basis points, payable quarterly, on the average daily unused amount of the Revolving Credit Facility.

Financing costs of \$56.2 million paid to establish the 2011 Credit Facility, including \$43.4 million paid to investment bankers that also helped structure the AMS acquisition, were deferred and are being amortized to interest expense over the life of the 2011 Credit Facility. Unamortized financing costs associated with the prior credit facilities as of November 30, 2010 totaled approximately \$14.7 million on June 17, 2011. In accordance with the applicable accounting guidance for debt modifications and extinguishments, approximately \$8.5 million of this amount was written off and is included in the Consolidated Statements of Operations as a Loss on extinguishment of debt, net. The remaining \$6.2 million was deferred to be amortized over the life of the 2011 Credit Facility.

In September 2011 and December 2011, we made prepayments of \$135.0 million and \$125.0 million, respectively, on our Term Loan B Facility. In accordance with the applicable accounting guidance for debt modifications and extinguishments, approximately \$3.4 million of the remaining unamortized financing costs

**Table of Contents**

were written off in connection with our 2011 prepayments and included in the Consolidated Statements of Operations as a Loss on extinguishment of debt, net. Pursuant to our rights under the 2011 Credit Agreement, we elected to apply a portion of the September 2011 prepayment against all remaining contractual payments such that we had no remaining principal payment obligations until the maturity of the Term Loan B Facility on June 17, 2018.

We recognized \$51.3 million and \$5.4 million of interest expense related to our Credit Facilities in 2011 and 2010, respectively.

**7.00% Senior Notes Due 2019**

On June 8, 2011, we issued \$500 million in aggregate principal amount of 7.00% Notes due 2019 (the 2019 Notes) at an issue price of par. The 2019 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. The 2019 Notes are senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain of the Company's domestic subsidiaries. Interest on the 2019 Notes is payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2012. The 2019 Notes will mature on July 15, 2019, subject to earlier repurchase or redemption in accordance with the terms of the Indenture incorporated by reference herein. We received proceeds of approximately \$485.9 million from the issuance, net of certain costs of the offering, including \$9.9 million of costs paid to investment bankers that also helped structure the AMS acquisition.

On or after July 15, 2015, the Company may on any one or more occasions redeem all or a part of the 2019 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 July 15 of the years indicated below:

<b>Payment Dates (between indicated dates)</b>	<b>Redemption Percentage</b>
From July 15, 2015 to and including July 14, 2016	103.500%
From July 15, 2016 to and including July 14, 2017	101.750%
From July 15, 2017 and thereafter	100.000%

In addition, at any time prior to July 15, 2015, Endo may on any one or more occasions redeem all or a part of the 2019 notes at a specified redemption price set forth in the Indenture, plus accrued and unpaid interest and additional interest, if any.

At any time prior to July 15, 2014, the Company may redeem up to 35% of the aggregate principal amount of the 2019 Notes at a specified redemption price set forth in the Indenture, plus accrued and unpaid interest and additional interest, if any, with the net cash proceeds of an equity offering subject to certain provisions. If the Company experiences certain change of control events, it must offer to repurchase the 2019 Notes at 101% of their principal amount, plus accrued and unpaid interest and additional interest, if any.

The Indenture contains covenants that, 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 the Company, create certain liens, merge, consolidate, or sell substantially all of the Company'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 2019 Notes receiving investment grade credit ratings.

We recognized \$20.4 million of interest expense related to our 2019 Notes in 2011.

**Table of Contents****7.00% Senior Notes Due 2020**

In November 2010, we issued \$400 million in aggregate principal amount of 7.00% Senior Notes due 2020 (the 2020 Notes) at an issue price of 99.105%. The 2020 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. The 2020 Notes are senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain of the Company's domestic subsidiaries. Interest on the 2020 Notes is payable semiannually in arrears on June 15 and December 15 of each year, beginning on June 15, 2011. The 2020 Notes will mature on December 15, 2020, subject to earlier repurchase or redemption in accordance with the terms of the Indenture incorporated by reference herein. We received proceeds of approximately \$386.6 million from the issuance, net of the initial purchaser's discount and certain other costs of the offering.

On or after December 15, 2015, the Company may on any one or more occasions redeem all or a part of the 2020 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 December 15 of the years indicated below:

<b>Payment Dates (between indicated dates)</b>	<b>Redemption Percentage</b>
From December 15, 2015 to and including December 14, 2016	103.500%
From December 15, 2016 to and including December 14, 2017	102.333%
From December 15, 2017 to and including December 14, 2018	101.167%
From December 15, 2018 and thereafter	100.000%

In addition, at any time prior to December 15, 2013, the Company may redeem up to 35% of the aggregate principal amount of the 2020 Notes at a specified redemption price set forth in the Indenture, plus accrued and unpaid interest and additional interest, if any, with the net cash proceeds of an equity offering subject to certain provisions. If the Company experiences certain change of control events, it must offer to repurchase the 2020 Notes at 101% of their principal amount, plus accrued and unpaid interest and additional interest, if any.

The Indenture contains covenants that, 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 the Company, create certain liens, merge, consolidate, or sell substantially all of the Company'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 2020 Notes receiving investment grade credit ratings.

We recognized \$29.3 million and \$3.1 million of interest expense related to our 2020 Notes in 2011 and 2010, respectively.

**7.25% Senior Notes Due 2022**

On June 8, 2011, we issued \$400 million in aggregate principal amount of 7.25% Senior Notes due 2022 (the 2022 Notes) at an issue price of par. The 2022 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. The 2022 Notes are senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain of the Company's domestic subsidiaries. Interest on the 2022 Notes is payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2012. The 2022 Notes will mature on January 15, 2022, subject to earlier repurchase or redemption in accordance with the terms of the Indenture incorporated by reference herein. We received proceeds of approximately \$388.7 million from the issuance, net of certain costs of the offering, including \$7.9 million of costs paid to investment bankers that also helped structure the AMS acquisition.

**Table of Contents**

On or after July 15, 2016, the Company may on any one or more occasions redeem all or a part of the 2022 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 July 15 of the years indicated below:

<b>Payment Dates (between indicated dates)</b>	<b>Redemption Percentage</b>
From July 15, 2016 to and including July 14, 2017	103.625%
From July 15, 2017 to and including July 14, 2018	102.417%
From July 15, 2018 to and including July 14, 2019	101.208%
From July 15, 2019 and thereafter	100.000%

In addition, at any time prior to July 15, 2016, Endo may on any one or more occasions redeem all or a part of the 2022 notes at a specified redemption price set forth in the Indenture, plus accrued and unpaid interest and additional interest, if any.

At any time prior to July 15, 2014, the Company may redeem up to 35% of the aggregate principal amount of the 2022 Notes at a specified redemption price set forth in the Indenture, plus accrued and unpaid interest and additional interest, if any, with the net cash proceeds of an equity offering subject to certain provisions. If the Company experiences certain change of control events, it must offer to repurchase the 2022 Notes at 101% of their principal amount, plus accrued and unpaid interest and additional interest, if any.

The Indenture contains covenants that, 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 the Company, create certain liens, merge, consolidate, or sell substantially all of the Company'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 2022 Notes receiving investment grade credit ratings.

We recognized \$16.8 million of interest expense related to our 2022 Notes in 2011.

**2011 Exchange Offer**

On October 14, 2011, the Company filed a Form S-4 Registration Statement with the Securities and Exchange Commission. On October 31, 2011, it filed a prospectus pursuant to Rule 424(b)(3). Pursuant to both filings, the Company offered to exchange the 2019 Notes, 2020 Notes and 2022 Notes for a like principal amount of new notes having identical terms that have been registered under the Securities Act of 1933, as amended. On November 30, 2011, 100% of the 2019 Notes, 2020 Notes and 2022 Notes had been properly tendered in the exchange offer and not withdrawn.

**1.75% Convertible Senior Subordinated Notes Due 2015**

In April 2008, we issued \$379.5 million in aggregate principal amount of 1.75% Convertible Senior Subordinated Notes due April 15, 2015 (the Convertible Notes) in a private offering for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended.

We received proceeds of approximately \$370.7 million from the issuance, net of the initial purchaser's discount and certain other costs of the offering. Interest is payable semiannually in arrears on each April 15 and October 15 with the first interest payment being made on October 15, 2008. The Convertible Notes will mature on April 15, 2015, unless earlier converted or repurchased by us.

**Table of Contents**

Holders of the Convertible Notes may convert their notes based on a conversion rate of 34.2466 shares of our common stock per \$1,000 principal amount of notes (the equivalent of \$29.20 per share), subject to adjustment upon certain events, only under the following circumstances as described in the indenture for the Convertible Notes: (1) during specified periods, if the price of our common stock reaches specified thresholds; (2) if the trading price of the Convertible Notes is below a specified threshold; (3) at any time after October 15, 2014; or (4) upon the occurrence of certain corporate transactions. We will be permitted to deliver cash, shares of Endo common stock or a combination of cash and shares, at our election, to satisfy any future conversions of the Convertible Notes. It is our current intention to settle the principal amount of any conversion consideration in cash.

Concurrently with the issuance of the Convertible Notes, we entered into a privately negotiated convertible note hedge transaction with affiliates of the initial purchasers. Pursuant to the hedge transaction we purchased common stock call options intended to reduce the potential dilution to our common stock upon conversion of the Convertible Notes by effectively increasing the initial conversion price of the Convertible Notes to \$40.00 per share, representing a 61.1% conversion premium over the closing price of our common stock on April 9, 2008 of \$24.85 per share. The call options allow us to purchase up to approximately 13.0 million shares of our common stock at an initial strike price of \$29.20 per share. The call options expire on April 15, 2015 and must be net-share settled. The cost of the call option was approximately \$107.6 million. In addition, we sold warrants to affiliates of certain of the initial purchasers whereby they have the option to purchase up to approximately 13.0 million shares of our common stock at an initial strike price of \$40.00 per share. The warrants expire on various dates from July 14, 2015 through October 6, 2015 and must be net-share settled. We received approximately \$50.4 million in cash proceeds from the sale of these warrants. The warrant transaction could have a dilutive effect on our net income per share to the extent that the price of our common stock exceeds the strike price of the warrants at exercise.

As discussed in Note 16. Net Income Per Share, in periods in which our common stock price exceeds the conversion price of the Convertible Notes or the strike price of the warrants, we include the effects of the additional shares that may be issued in our diluted net income per share calculation using the treasury stock method.

The carrying values of the debt and equity components of our Convertible Notes are as follows (in thousands):

	<b>December 31, 2011</b>	<b>December 31, 2010</b>
Principal amount of Convertible Notes	\$ 379,500	\$ 379,500
Unamortized discount related to the debt component(1)	(80,278)	(100,578)
<b>Net carrying amount of the debt component</b>	<b>\$ 299,222</b>	<b>\$ 278,922</b>
Carrying amount of the equity component	\$ 142,199	\$ 142,199

(1) Represents the unamortized portion of the original purchaser's discount and certain other costs of the offering as well as the unamortized portion of the discount created from the separation of the debt portion of our Convertible Notes from the equity portion. This discount will be amortized to interest expense over the term of the Convertible Notes.

We recognized \$26.9 million of interest expense related to our Convertible Notes for the year ended December 31, 2011, \$6.6 million of which related to the contractual interest payments and \$20.3 million of which related to the amortization of the debt discount and certain other costs of the offering. We recognized \$28.0 million of interest expense related to our Convertible Notes for the year ended December 31, 2010, \$9.3 million of which related to the contractual interest payments and \$18.6 million of which related to the amortization of the debt discount and certain other costs of the offering. We recognized \$23.8 million of interest

---

**Table of Contents**

expense related to our Convertible Notes for the year ended December 31, 2009, \$6.6 million of which related to the contractual interest payments and \$17.2 million of which related to the amortization of the debt discount and certain other costs of the offering.

***3.25% Convertible AMS Notes Due 2036 and 4.00% Convertible AMS Notes Due 2041***

As a result of our acquisition of AMS, the Company assumed AMS's 3.25% Convertible Notes due 2036 (the 2036 Notes) and 4.00% Convertible Notes due 2041 (the 2041 Notes and, together with the 2036 Notes, the AMS Notes). In accordance with the indentures governing the AMS Notes, the AMS Notes were immediately convertible upon the closing of Endo's acquisition of AMS. From the AMS Acquisition Date until the make whole premium on the 2036 Notes expired on August 9, 2011, we paid \$95.7 million to redeem \$61.4 million of the 2036 Notes at a stated premium of 1.5571. From the AMS Acquisition Date until the make whole premium on the 2041 Notes expired on August 1, 2011, we paid \$423.4 million to redeem \$249.9 million of the 2041 Notes at a stated premium of 1.6940. Our obligation remaining related to the AMS Notes is less than \$1.0 million at December 31, 2011, excluding accrued interest.

We recognized \$0.1 million of interest expense related to the AMS Notes in 2011.

***16% Non-recourse Notes due 2024***

On August 26, 2008, Indevus closed a private placement to institutional investors of \$105.0 million in aggregate principal amount of 16% non-convertible, non-recourse, secured promissory notes due 2024 (Non-recourse notes). The Non-recourse notes were issued by Ledgemont Royalty Sub LLC (Royalty Sub), which was a wholly-owned subsidiary of Indevus at the time of the Non-recourse note issuance and subsequently became a wholly-owned subsidiary of the Company upon our acquisition of Indevus. As of the Indevus Acquisition Date, the Company recorded these notes at their fair value of approximately \$115.2 million and began amortizing these notes to their face value of \$105.0 million at maturity in 2024.

In August 2009, the Company commenced a cash tender offer for any and all outstanding Non-recourse notes. The purpose of the tender offer was to acquire any and all Notes to reduce our consolidated interest expense. The tender offer included an early tender deadline, whereby holders of the Non-recourse notes could early tender and receive the total early consideration of \$1,000 per \$1,000 principal amount of the Non-recourse notes. Holders who tendered their Non-recourse notes after such time and at or prior to the expiration of the tender offer period were eligible to receive the tender offer consideration of \$950 per \$1,000 principal amount of Non-recourse notes, which was the total early consideration less the early tender payment. The tender offer expired on September 24, 2009, at 5:00 p.m., New York City time (the Expiration Time). As of the Expiration Time, \$48 million in Non-recourse notes had been validly tendered and not withdrawn. The Company accepted for payment and purchased Non-recourse notes at a purchase price of \$1,000 per \$1,000 principal amount, for a total amount of approximately \$48 million (excluding accrued and unpaid interest up to, but not including, the payment date for the Non-recourse notes, fees and other expenses in connection with the tender offer). The aggregate principal amount of Non-recourse notes purchased represents approximately 46% of the \$105 million aggregate principal amount of Non-recourse notes that were outstanding prior to the Expiration Time. Accordingly, the Company recorded a \$4.0 million gain on the extinguishment of debt, net of transaction costs. The gain was calculated as the difference between the aggregate amount paid to purchase the Non-recourse notes and their carrying amount.

During the third quarter of 2010, Endo notified the holders of its intent to exercise its option to redeem the remaining \$57 million of principal at 108% of the principal amount for approximately \$62 million (amount excludes accrued and unpaid interest) on November 5, 2010. The notes were redeemed in November 2010.

**Table of Contents*****Maturities***

Maturities on long-term debt for each of the next five years as of December 31, 2011 are as follows (in thousands):

	<b>December 31, 2011</b>
2012	\$ 87,292
2013	132,217
2014	150,666
2015	567,557
2016	918,979

**NOTE 19. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES**

We are exposed to certain risks relating to our ongoing business operations. With our June 2011 acquisition of AMS, we began using derivative instruments to mitigate a portion of our exposure to volatility in foreign currency exchange rates. Foreign currency exchange forward contracts are used to manage the currency risk associated with forecasted sales to and receivables from certain subsidiaries, denominated in their local currencies. We hedge only exposures in the ordinary course of business. We account for our derivative instruments at fair value, which is determined based on quoted prices for similar contracts.

We account for certain of our derivative instruments under hedge accounting provided we meet designation, documentary and analytic requirements. Hedge accounting creates the potential for a Consolidated Statement of Operations match between the changes in fair value of derivatives and the changes in the cost of the associated underlying transactions, in this case translation gain or loss. The effective portion of the change in the fair value of these foreign currency exchange contracts is reported in accumulated other comprehensive income, a component of stockholders' equity, and is recognized as an adjustment to other (expense) income, in the same period the related expenses are recognized in earnings. Ineffectiveness would occur when changes in the market value of the hedged transactions are not completely offset by changes in the market value of the derivatives. The ineffective portion of contracts designated for hedge accounting, the gain or loss from changes in the fair value of contracts not designated for hedge accounting, and contracts where hedge accounting is discontinued when it is determined the underlying transaction is not going to occur, are recognized currently in the Consolidated Statements of Operations. Amounts due from counterparties (unrealized hedge gains) or due to counterparties (unrealized hedge losses) are included in accounts receivable, net or other accrued expenses, respectively. Cash receipts or payments related to our derivatives are classified in the Consolidated Statements of Cash Flows as cash flows from operating activities, consistent with the related items being hedged, unless the derivative is not designated or does not qualify for hedge accounting, in which case the receipts or payments are classified in cash flows from investing activities.

At December 31, 2011, we have foreign currency exchange forward contracts outstanding which are designated as cash flow accounting hedges of currency fluctuations for a portion of our forecasted sales to certain subsidiaries, denominated in Euros, British pounds, Canadian dollars, Australian dollars, and Swedish Krona. These derivative instruments have remaining terms between one and twelve months. The notional amount of these foreign currency exchange forward contracts was \$46.8 million at December 31, 2011. We have also entered into foreign currency exchange forward contracts to manage a portion of our exposure to foreign exchange rate fluctuations on certain inter-company receivables denominated in Euros, British pounds, Canadian dollars, and Australian dollars. These contracts are not designated as accounting hedges and the associated underlying transactions are expected to occur within the next month. The notional amount of these contracts was \$10.8 million at December 31, 2011.

At December 31, 2011 the fair value of derivatives designated for hedge accounting of \$1.5 million was included in accounts receivable, net and the fair value of derivatives not designated for hedge accounting of \$0.1 million was included in other accrued expenses in the Consolidated Balance Sheet. The gain of \$0.8 million from

**Table of Contents**

contracts designated for hedge accounting was included in other comprehensive income and is expected to be reclassified into earnings within the next twelve months. The amount of gain from contracts not designated for hedge accounting recognized in other (income) in the Consolidated Statement of Operations during the year was \$2.0 million.

**NOTE 20. SUPPLEMENTAL GUARANTOR INFORMATION**

In connection with the 2019 Notes, 2020 Notes and 2022 Notes, we have included this supplemental guarantor disclosure in accordance with Rule 3-10(g) of Regulation S-X. The 2019 Notes, 2020 Notes, and 2022 Notes are fully and unconditionally guaranteed, jointly and severally, on a senior unsecured basis by the following nineteen subsidiaries (together, the Guarantor Subsidiaries):

Endo Pharmaceuticals Inc.	Endo Pharmaceuticals Solutions Inc.
Endo Pharmaceuticals Valera Inc.	Ledgemont Royalty Sub LLC
American Medical Systems Holdings, Inc.	American Medical Systems, Inc.
AMS Research Corporation	Laserscope
AMS Sales Corporation	Generics International (US Parent), Inc.
Generics International (US Midco), Inc.	Generics International (US Holdco), Inc.
Generics International (US), Inc.	Generics Bidco I, LLC
Generics Bidco II, LLC	Moore's Mill Properties LLC
Wood Park Properties LLC	Vintage Pharmaceuticals, LLC
Quartz Specialty Pharmaceuticals, LLC	

Each of the Guarantor Subsidiaries is 100 percent owned by us.

The following supplemental consolidating financial information presents the Consolidated Balance Sheets as of December 31, 2011 and 2010, the Consolidated Statements of Operations for the years ended December 31, 2011, 2010 and 2009 and the Consolidated Statements of Cash Flows for the years ended December 31, 2011, 2010 and 2009, for the Guarantor Subsidiaries as a group, and separately for our non-Guarantor Subsidiaries as a group.

The Consolidating Financial Statements are presented using the equity method of accounting for its investments in 100% owned subsidiaries. Under the equity method, the investments in subsidiaries are recorded at cost and adjusted for our share of the subsidiaries cumulative results of operations, capital contributions, distributions and other equity changes. The elimination entries principally eliminate investments in subsidiaries and intercompany balances and transactions. The financial information in this footnote should be read in conjunction with the consolidated financial statements presented and other notes related thereto contained in this Annual Report on Form 10-K for the year ended December 31, 2011.



**Table of Contents****CONSOLIDATING BALANCE SHEET**

(In thousands)

	As of December 31, 2011				
	Endo Pharmaceuticals Holdings Inc.	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated Total
<b>ASSETS</b>					
CURRENT ASSETS:					
Cash and cash equivalents	\$ 48,318	\$ 455,756	\$ 43,546	\$	\$ 547,620
Accounts receivable, net		656,265	74,584	2,373	733,222
Inventories, net		248,128	19,918	(5,627)	262,419
Prepaid expenses and other current assets		19,274	7,004	3,454	29,732
Deferred income taxes		205,606	9,497		215,103
Total current assets	48,318	1,585,029	154,549	200	1,788,096
INTERCOMPANY RECEIVABLES	1,777,233	7,322,603	193,223	(9,293,059)	
MARKETABLE SECURITIES		19,105			19,105
PROPERTY, PLANT AND EQUIPMENT, NET		268,572	29,469	(310)	297,731
GOODWILL		2,303,940	254,101		2,558,041
OTHER INTANGIBLES, NET		2,415,531	88,593		2,504,124
INVESTMENT IN SUBSIDIARIES	5,860,570	317,544		(6,178,114)	
OTHER ASSETS	87,099	27,338	31,049	(20,000)	125,486
TOTAL ASSETS	\$ 7,773,220	\$ 14,259,662	\$ 750,984	\$ (15,491,283)	\$ 7,292,583
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>					
CURRENT LIABILITIES:					
Accounts payable	\$	\$ 251,715	\$ 8,667	\$ 3	\$ 260,385
Accrued expenses	38,623	651,653	42,558	(3)	732,831
Current portion of long-term debt	84,376	972	2,917		88,265
Acquisition-related contingent consideration		4,925			4,925
Income taxes payable	(23,204)	71,900	(13,214)	(110)	35,372
Total current liabilities	99,795	981,165	40,928	(110)	1,121,778
INTERCOMPANY PAYABLES	2,267,572	6,978,697	46,790	(9,293,059)	
DEFERRED INCOME TAXES	6,573	611,625	(521)		617,677
ACQUISITION-RELATED CONTINGENT CONSIDERATION		3,762			3,762
LONG-TERM DEBT, LESS CURRENT PORTION, NET	3,421,590		2,739		3,424,329
OTHER LIABILITIES		94,915	10,531	(20,000)	85,446
STOCKHOLDERS EQUITY:					
Preferred Stock					
Common Stock	1,383		30,430	(30,430)	1,383
Additional paid-in capital	952,325	4,198,625	574,218	(4,772,843)	952,325
Retained earnings (deficit)	1,551,910	1,398,613	(15,364)	(1,383,249)	1,551,910
Accumulated other comprehensive (loss)	(9,436)	(7,740)	(668)	8,408	(9,436)
Treasury stock	(518,492)				(518,492)
Total Endo Pharmaceuticals Holdings Inc. stockholders equity	1,977,690	5,589,498	588,616	(6,178,114)	1,977,690
Noncontrolling interests			61,901		61,901
Total stockholders equity	1,977,690	5,589,498	650,517	(6,178,114)	2,039,591
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	\$ 7,773,220	\$ 14,259,662	\$ 750,984	\$ (15,491,283)	\$ 7,292,583

F-90

**Table of Contents****CONSOLIDATING BALANCE SHEET**

(In thousands)

	As of December 31, 2010				
	Endo Pharmaceuticals Holdings Inc.	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated Total
<b>ASSETS</b>					
<b>CURRENT ASSETS:</b>					
Cash and cash equivalents	\$ 45,400	\$ 404,169	\$ 16,645	\$	\$ 466,214
Accounts receivable, net		514,566	33,246	(5)	547,807
Inventories, net		168,003	10,802		178,805
Prepaid expenses and other current assets		18,091	4,750		22,841
Income taxes receivable	5,858	(8,814)	6,099		3,143
Deferred income taxes		130,933	9,791		140,724
Total current assets	51,258	1,226,948	81,333	(5)	1,359,534
INTERCOMPANY RECEIVABLES	(69,344)	3,013,958	6,866	(2,951,480)	
MARKETABLE SECURITIES		23,509			23,509
PROPERTY, PLANT AND EQUIPMENT, NET		186,109	29,186		215,295
GOODWILL		561,725	153,280		715,005
OTHER INTANGIBLES, NET		1,460,295	71,465		1,531,760
INVESTMENT IN SUBSIDIARIES	3,302,001	(32)		(3,301,969)	
OTHER ASSETS		62,964	4,322		67,286
<b>TOTAL ASSETS</b>	<b>\$ 3,283,915</b>	<b>\$ 6,535,476</b>	<b>\$ 346,452</b>	<b>\$ (6,253,454)</b>	<b>\$ 3,912,389</b>
<b>LIABILITIES AND STOCKHOLDERS</b>					
<b>EQUITY</b>					
<b>CURRENT LIABILITIES:</b>					
Accounts payable	\$	\$ 238,374	\$ 2,740	\$	\$ 241,114
Accrued expenses	1,388	456,063	12,275	(5)	469,721
Current portion of long-term debt	22,500		2,493		24,993
Total current liabilities	23,888	694,437	17,508	(5)	735,828
INTERCOMPANY PAYABLES	460,776	2,431,113	59,591	(2,951,480)	
DEFERRED INCOME TAXES	7,472	222,118	(12,256)		217,334
ACQUISITION-RELATED CONTINGENT CONSIDERATION	7,050	9,000			16,050
LONG-TERM DEBT, LESS CURRENT PORTION, NET	1,043,138		2,663		1,045,801
OTHER LIABILITIES		83,553	10,494		94,047
<b>STOCKHOLDERS EQUITY:</b>					
Preferred Stock					
Common Stock	1,363				1,363
Additional paid-in capital	860,882	1,833,515	214,844	(2,048,359)	860,882
Retained earnings (deficit)	1,364,297	1,262,901	(8,130)	(1,254,771)	1,364,297
Accumulated other comprehensive loss	(1,161)	(1,161)		1,161	(1,161)
Treasury stock	(483,790)				(483,790)
Total Endo Pharmaceuticals Holdings Inc. stockholders equity	1,741,591	3,095,255	206,714	(3,301,969)	1,741,591

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

Noncontrolling interests			61,738		61,738
Total stockholders' equity	1,741,591	3,095,255	268,452	(3,301,969)	1,803,329
<b>TOTAL LIABILITIES AND STOCKHOLDERS EQUITY</b>	<b>\$ 3,283,915</b>	<b>\$ 6,535,476</b>	<b>\$ 346,452</b>	<b>\$ (6,253,454)</b>	<b>\$ 3,912,389</b>

F-91

**Table of Contents****CONSOLIDATING STATEMENT OF OPERATIONS**

(In thousands)

For the Year Ended December 31, 2011

	Endo Pharmaceuticals Holdings Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
TOTAL REVENUES	\$	\$ 2,580,530	\$ 280,431	\$ (130,840)	\$ 2,730,121
COSTS AND EXPENSES:					
Cost of revenues		1,033,334	164,775	(132,901)	1,065,208
Selling, general and administrative	58	753,855	70,635	(14)	824,534
Research and development		182,333	(47)		182,286
Asset impairment charges		116,089			116,089
Acquisition-related items, net	(7,050)	39,734	954		33,638
OPERATING INCOME	6,992	455,185	44,114	2,075	508,366
INTEREST EXPENSE (INCOME), NET	38,908	109,060	56		148,024
LOSS ON EXTINGUISHMENT OF DEBT, NET	11,919				11,919
DIVIDEND INCOME FROM SUBSIDIARIES	(85,100)			85,100	
OTHER INCOME, NET		(2,812)	(580)	124	(3,268)
INCOME BEFORE INCOME TAX	41,265	348,937	44,638	(83,149)	351,691
INCOME TAX	(18,245)	129,673	(2,580)	778	109,626
EQUITY FROM EARNINGS (LOSS) IN SUBSIDIARIES	128,103	1,548		(129,651)	
CONSOLIDATED NET INCOME (LOSS)	\$ 187,613	\$ 220,812	\$ 47,218	\$ (213,578)	\$ 242,065
Less: Net income attributable to noncontrolling interests			54,452		54,452
NET INCOME (LOSS) ATTRIBUTABLE TO ENDO PHARMACEUTICALS HOLDINGS INC.	\$ 187,613	\$ 220,812	\$ (7,234)	\$ (213,578)	\$ 187,613

**Table of Contents****CONSOLIDATING STATEMENT OF OPERATIONS**

(In thousands)

For the Year Ended December 31, 2010

	Endo Pharmaceuticals Holdings Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
TOTAL REVENUES	\$	\$ 1,633,328	\$ 102,144	\$ (19,243)	\$ 1,716,229
COSTS AND EXPENSES:					
Cost of revenues		470,339	53,661	(19,243)	504,757
Selling, general and administrative	61	530,143	17,401		547,605
Research and development		144,525			144,525
Asset impairment charges		35,000			35,000
Acquisition-related items, net	(42,970)	46,635	15,311		18,976
OPERATING INCOME	42,909	406,686	15,771		465,366
INTEREST EXPENSE (INCOME), NET	23,953	22,681	(33)		46,601
OTHER INCOME, NET		(1,427)	(506)		(1,933)
INCOME BEFORE INCOME TAX	18,956	385,432	16,310		420,698
INCOME TAX	(7,985)	145,272	(3,609)		133,678
EQUITY FROM EARNINGS (LOSS) IN SUBSIDIARIES	232,065			(232,065)	
CONSOLIDATED NET INCOME (LOSS)	\$ 259,006	\$ 240,160	\$ 19,919	\$ (232,065)	\$ 287,020
Less: Net income attributable to noncontrolling interests			28,014		28,014
NET INCOME (LOSS) ATTRIBUTABLE TO ENDO PHARMACEUTICALS HOLDINGS INC.	\$ 259,006	\$ 240,160	\$ (8,095)	\$ (232,065)	\$ 259,006

F-93

**Table of Contents****CONSOLIDATING STATEMENT OF OPERATIONS**

(In thousands)

	For the Year Ended December 31, 2009				
	Endo Pharmaceuticals Holdings Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
TOTAL REVENUES	\$	\$ 1,460,841	\$	\$	\$ 1,460,841
COSTS AND EXPENSES:					
Cost of revenues		375,058			375,058
Selling, general and administrative	14,415	520,088	20		534,523
Research and development		185,317			185,317
Asset impairment charges		69,000			69,000
Acquisition-related items, net	(122,840)	29,759			(93,081)
OPERATING INCOME (LOSS)	108,425	281,619	(20)		390,024
INTEREST EXPENSE, NET	23,172	14,546			37,718
GAIN ON EXTINGUISHMENT OF DEBT, NET		(4,025)			(4,025)
OTHER INCOME, NET		(3,329)			(3,329)
INCOME (LOSS) BEFORE INCOME TAX	85,253	274,427	(20)		359,660
INCOME TAX	9,600	83,724			93,324
EQUITY FROM EARNINGS (LOSS) IN SUBSIDIARIES	190,683	(20)		(190,663)	
CONSOLIDATED NET INCOME (LOSS)	\$ 266,336	\$ 190,683	\$ (20)	\$ (190,663)	\$ 266,336
Less: Net income attributable to noncontrolling interests					
NET INCOME (LOSS) ATTRIBUTABLE TO ENDO PHARMACEUTICALS HOLDINGS INC.	\$ 266,336	\$ 190,683	\$ (20)	\$ (190,663)	\$ 266,336

**Table of Contents****CONSOLIDATING STATEMENT OF CASH FLOWS**

(In thousands)

For the Year Ended December 31, 2011

	Endo Pharmaceuticals Holdings Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
<b>OPERATING ACTIVITIES:</b>					
Net cash provided by operating activities	\$ 64,311	\$ 577,150	\$ 60,654	\$	\$ 702,115
<b>INVESTING ACTIVITIES:</b>					
Purchases of property, plant and equipment		(49,895)	(9,488)		(59,383)
Proceeds from sale of property, plant and equipment		345	1,281		1,626
Purchases of investments		(14,025)			(14,025)
Proceeds from investments		85,025			85,025
License fees		(2,300)			(2,300)
Acquisitions, net of cash acquired		(2,341,143)	(52,254)		(2,393,397)
Proceeds from sale of business			12,990		12,990
Other investments		(4,628)			(4,628)
Intercompany activity		(30,430)		30,430	
Net cash used in investing activities		(2,357,051)	(47,471)	30,430	(2,374,092)
<b>FINANCING ACTIVITIES:</b>					
Capital lease obligations repayments		(1,212)	(232)		(1,444)
Purchase of common stock	(34,702)				(34,702)
Tax benefits of stock awards		6,145	(236)		5,909
Exercise of Endo Pharmaceuticals Holdings Inc. Stock Options	28,954				28,954
Proceeds from issuance of 2019 and 2022 Notes	900,000				900,000
Proceeds from issuance of Term Loans	2,200,000				2,200,000
Proceeds from other indebtedness			500		500
Principal payments on Term Loans	(689,876)				(689,876)
Payment on AMS Convertible Notes		(519,040)			(519,040)
Deferred financing fees	(82,504)				(82,504)
Payment for contingent consideration			(827)		(827)
Distributions to noncontrolling interests			(53,997)		(53,997)
Buy-out of noncontrolling interests, net of contributions			(292)		(292)
Intercompany activity	(2,383,265)	2,345,595	68,100	(30,430)	
Net cash (used in) provided by financing activities	(61,393)	1,831,488	13,016	(30,430)	1,752,681
Effect of foreign exchange rate			702		702
NET INCREASE IN CASH AND CASH EQUIVALENTS	2,918	51,587	26,901		81,406
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	45,400	404,169	16,645		466,214



Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 48,318	\$ 455,756	\$ 43,546	\$ 547,620
--	-----------	------------	-----------	------------

F-95

**Table of Contents****CONSOLIDATING STATEMENT OF CASH FLOWS**

(In thousands)

	For the Year Ended December 31, 2010				
	Endo Pharmaceuticals Holdings Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
<b>OPERATING ACTIVITIES:</b>					
Net cash (used in) provided by operating activities	\$ 15,435	\$ 179,754	\$ 258,457	\$	\$ 453,646
<b>INVESTING ACTIVITIES:</b>					
Purchases of property, plant and equipment		(15,500)	(4,391)		(19,891)
Proceeds from sale of property, plant and equipment		356			356
Proceeds from sales of trading securities		231,125			231,125
License fees		(400)			(400)
Acquisitions, net of cash acquired		(896,966)	(208,074)		(1,105,040)
Other investments		(2,473)			(2,473)
Net cash used in investing activities		(683,858)	(212,465)		(896,323)
<b>FINANCING ACTIVITIES:</b>					
Capital lease obligations repayments		(313)			(313)
Purchase of common stock	(58,974)				(58,974)
Tax benefits of stock awards		1,944			1,944
Exercise of Endo Pharmaceuticals Holdings Inc. Stock Options	20,883				20,883
Proceeds from issuance of 2020 Notes	386,576				386,576
Proceeds from issuance of Term Loans	400,000				400,000
Proceeds from other indebtedness		1,696			1,696
Principal payments on HealthTronics senior credit facility		(40,000)			(40,000)
Principal payments on Qualitest debt		(406,758)			(406,758)
Principal payments on other indebtedness		(61,559)			(61,559)
Deferred financing fees	(13,563)				(13,563)
Distributions to noncontrolling interests			(28,870)		(28,870)
Buy-out of noncontrolling interests, net of contributions			(633)		(633)
Intercompany activity	(747,543)	747,543			
Net cash provided by (used in) financing activities	(12,621)	242,553	(29,503)		200,429
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>2,814</b>	<b>(261,551)</b>	<b>16,489</b>		<b>(242,248)</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>42,586</b>	<b>665,720</b>	<b>156</b>		<b>708,462</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 45,400</b>	<b>\$ 404,169</b>	<b>\$ 16,645</b>	<b>\$</b>	<b>\$ 466,214</b>

**Table of Contents****CONSOLIDATING STATEMENT OF CASH FLOWS**

(In thousands)

For the Year Ended December 31, 2009

	Endo Pharmaceuticals Holdings Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
<b>OPERATING ACTIVITIES:</b>					
Net cash provided by operating activities	\$ (2)	\$ 295,408	\$	\$	\$ 295,406
<b>INVESTING ACTIVITIES:</b>					
Purchases of property, plant and equipment		(12,415)			(12,415)
Proceeds from sales of trading securities		23,750			23,750
License fees		(4,485)			(4,485)
Acquisitions, net of cash acquired		(250,359)			(250,359)
Other investments		(2,000)			(2,000)
Net cash (used in) investing activities		(245,509)			(245,509)
<b>FINANCING ACTIVITIES:</b>					
Capital lease obligations repayments		(250)			(250)
Tax benefits of stock awards		717			717
Exercise of Endo Pharmaceuticals Holdings Inc. Stock Options	8,037				8,037
Principal payments on other indebtedness		(120,470)			(120,470)
Deferred financing fees		(5,162)			(5,162)
Net cash provided by (used in) financing activities	8,037	(125,165)			(117,128)
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>8,035</b>	<b>(75,266)</b>			<b>(67,231)</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>34,551</b>	<b>740,986</b>	<b>156</b>		<b>775,693</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 42,586</b>	<b>\$ 665,720</b>	<b>\$ 156</b>	<b>\$</b>	<b>\$ 708,462</b>

**NOTE 21. SUBSEQUENT EVENTS*****Long-Term Incentive Compensation***

In early 2012, long-term incentive compensation in the form of stock options, restricted stock units and performance shares were granted to employees. Stock options will generally vest over 4 years and expire 10 years from the date of the grant. Restricted stock units will vest over 4 years and the performance shares will vest at the end of the cumulative 3-year performance period. The exercise price of the options granted was equal to the closing price on the dates of grant. The grant date fair value of the stock options, restricted stock units, and performance shares granted was approximately \$51.8 million.

**Table of Contents****NOTE 22. QUARTERLY FINANCIAL DATA (UNAUDITED)**

	March 31,	Quarter Ended		December 31,
		June 30,	September 30,	
(in thousands, except per share data)				
<b>2011(1)</b>				
Total revenues	\$ 560,026	\$ 607,611	\$ 759,078	\$ 803,406
Gross profit	\$ 328,468	\$ 370,914	\$ 456,906	\$ 508,625
Operating income	\$ 120,879	\$ 134,315	\$ 140,154	\$ 113,018
Net income attributable to Endo Pharmaceuticals Holdings Inc.	\$ 55,787	\$ 54,583	\$ 40,649	\$ 36,594
Net income per share attributable to Endo Pharmaceuticals Holdings Inc. (basic)	\$ 0.48	\$ 0.47	\$ 0.35	\$ 0.31
Net income per share attributable to Endo Pharmaceuticals Holdings Inc. (diluted)	\$ 0.46	\$ 0.44	\$ 0.34	\$ 0.30
Weighted average shares (basic)	116,354	116,663	116,816	116,992
Weighted average shares (diluted)	120,761	122,686	120,847	120,418
<b>2010(2)</b>				
Total revenues	\$ 364,412	\$ 396,524	\$ 444,103	\$ 511,190
Gross profit	\$ 270,339	\$ 289,308	\$ 310,183	\$ 341,642
Operating income	\$ 106,307	\$ 93,605	\$ 115,932	\$ 149,522
Net income attributable to Endo Pharmaceuticals Holdings Inc.	\$ 60,355	\$ 51,460	\$ 54,206	\$ 92,985
Net income per share attributable to Endo Pharmaceuticals Holdings Inc. (basic)	\$ 0.51	\$ 0.44	\$ 0.47	\$ 0.80
Net income per share attributable to Endo Pharmaceuticals Holdings Inc. (diluted)	\$ 0.51	\$ 0.44	\$ 0.46	\$ 0.77
Weighted average shares (basic)	117,347	116,060	115,469	115,781
Weighted average shares (diluted)	118,031	116,660	116,597	120,516

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.

- (1) Operating income for the year ended December 31, 2011 was impacted by milestone payments to collaborative partners of \$11.0 million, \$14.0 million, \$2.4 million and \$0.7 million in the first, second, third and fourth quarters, respectively. Operating income for the year ended December 31, 2011 was also impacted by (1) the acquisition-related items, net of \$6.1 million, \$17.6 million, \$5.8 million and \$4.1 million during the first, second, third and fourth quarters, respectively (2) impairment charges of \$22.7 million relating to a privately-held cost method investment during the third quarter and \$93.4 million relating to various long-lived assets during the fourth quarter (3) inventory step-up of \$13.8 million, \$3.0 million, \$23.9 million and \$8.7 million in the first, second, third and fourth quarters, respectively (4) amortization expense relating to intangible assets of \$37.4 million, \$40.6 million, \$59.0 million and \$54.6 million during the first, second, third and fourth quarters, respectively.
- (2) Operating income for the year ended December 31, 2010 was impacted by milestone payments to collaborative partners of \$3.0 million, \$15.9 million, \$0.3 million and \$4.7 million in the first, second, third and fourth quarters, respectively. Operating income for the year ended December 31, 2010 was also impacted by (1) the acquisition-related items, net of \$1.5 million, \$4.8 million, \$25.0 million and \$(12.3) million during the first, second, third and fourth quarters, respectively (2) impairment charges of \$13.0 million relating to pegoclone during the second quarter and impairment charges of \$22.0 million relating to octreotide during the fourth quarter (3) inventory step-up of \$1.3 million and \$5.0 million during the third and fourth quarters, respectively (4) amortization expense relating to intangible assets of \$17.3 million, \$17.3 million, \$19.6 million and \$30.4 million during the first, second, third and fourth quarters, respectively.

**Table of Contents**

**Exhibit Index**

<b>Exhibit No.</b>	<b>Title</b>
3.1	Amended and Restated Certificate of Incorporation of Endo Pharmaceuticals Holdings Inc. (Endo) (incorporated herein by reference to Exhibit 10.32 of the Form 10-Q for the Quarter ended June 30, 2008 filed with the Commission on August 1, 2008)
3.2	Amended and Restated By-laws of Endo (incorporated herein by reference to Exhibit 3.1 of the Current Report on Form 8-K filed with the Commission on December 15, 2011)
10.4	Agreement dated April 29, 2008 between Endo and D. E. Shaw Valence Portfolios, L.L.C. (on behalf of itself and its affiliates that are members of the 13D Group with respect to the Endo common stock) (incorporated herein by reference to Exhibit 99.1 of the Current Report on Form 8-K/A dated May 1, 2008)
10.6	Indenture by and between Endo Pharmaceuticals Holdings Inc. and The Bank of New York dated April 15, 2008 (incorporated herein by reference to Exhibit 4.1 of the Current Report on Form 8-K filed with the Commission on April 15, 2008)
10.7	Convertible Bond Hedge Transaction Confirmation entered into by and between Endo and Deutsche Bank AG, London Branch, dated April 9, 2008 (incorporated herein by reference to Exhibit 10.7 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.8	Issuer Warrant Transaction Confirmation entered into by and between Endo and Deutsche Bank AG, London Branch, dated April 9, 2008 (incorporated herein by reference to Exhibit 10.8 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.9	Issuer Share Repurchase Transaction Confirmation entered into by and between Endo and Deutsche Bank AG, London Branch, dated April 9, 2008 (incorporated herein by reference to Exhibit 10.9 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.10*	Sole and Exclusive License Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals Inc. (Endo Pharmaceuticals) and Hind HealthCare, Inc. (incorporated herein by reference to Exhibit 10.10 of the Registration Statement filed with the Commission on June 9, 2000)
10.11	Endo Pharmaceuticals Holdings Inc. Executive Deferred Compensation Plan (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated December 19, 2007)
10.12	Endo Pharmaceuticals Holdings Inc. 401(k) Restoration Plan (incorporated herein by reference to Exhibit 10.2 of the Current Report on Form 8-K dated December 19, 2007)
10.13	Endo Pharmaceuticals Holdings Inc. Directors Deferred Compensation Plan (incorporated herein by reference to Exhibit 10.13 of the Form 10-K for the year ended December 31, 2010 filed with the Commission on February 28, 2011)
10.14*	Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd (incorporated herein by reference to Exhibit 10.14 of the Registration Statement filed with the Commission on June 9, 2000)
10.14.1	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 herein by reference to Exhibit 10.14.1 of the Current Report on Form 8-K dated April 30, 2007)
10.14.2*	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 Inc. and Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc. (incorporated herein by reference to Exhibit 10.14.2 of the Current Report on Form 8-K dated January 11, 2010)

**Table of Contents**

<b>Exhibit No.</b>	<b>Title</b>
10.14.3*	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 Inc. and Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc. (incorporated herein by reference to Exhibit 10.14.3 of the Form 10-Q for the Quarter ended September 30, 2010 filed with the Commission on November 2, 2010)
10.16	Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16 of the Registration Statement filed with the Commission on June 9, 2000)
10.16.1	First Amendment, effective July 1, 2000, to the Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16.1 of the Current Report on Form 8-K dated April 14, 2006)
10.16.2	Second Amendment, dated April 10, 2006, to the Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16.2 of the Current Report on Form 8-K dated April 14, 2006)
10.16.3	Third Amendment, effective July 1, 2011, to the Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.118 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2011 filed with the Commission on October 31, 2011)
10.16.4	Fourth Amendment, effective July 31, 2011, to the Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.119 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2011 filed with the Commission on October 31, 2011)
10.16.5	Fifth Amendment, effective August 31, 2011, to the Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.120 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2011 filed with the Commission on October 31, 2011)
10.17*	Supply Agreement, dated as of January 1, 2001, by and between Vintage Pharmaceuticals, Inc. and Noramco, a division of McNeilab, Inc. (n/k/a Noramco, Inc.) (incorporated herein by reference to Exhibit 10.17 of the Form 10-K for the year ended December 31, 2010 filed with the Commission on February 28, 2011)
10.17.1*	First Amendment, effective January 16, 2007, to the Supply Agreement by and between Vintage Pharmaceuticals, LLC and Noramco, Inc. (incorporated herein by reference to Exhibit 10.17.1 of the Form 10-K for the year ended December 31, 2010 filed with the Commission on February 28, 2011)
10.17.2*	Second Amendment, effective May 7, 2008, to the Supply Agreement by and between Vintage Pharmaceuticals, Inc. and Noramco, Inc. (incorporated herein by reference to Exhibit 10.17.2 of the Form 10-K for the year ended December 31, 2010 filed with the Commission on February 28, 2011)
10.17.3*	Third Amendment, effective December 22, 2008, to the Supply Agreement by and between Vintage Pharmaceuticals, LLC and Noramco, Inc. (incorporated herein by reference to Exhibit 10.17.3 of the Form 10-K for the year ended December 31, 2010 filed with the Commission on February 28, 2011)
10.19*	Master Services Agreement, dated as of May 18, 2010, by and between Endo Pharmaceuticals Inc. and UPS Supply Chain Solutions, Inc. (incorporated herein by reference to Exhibit 10.19 of the Current Report on Form 8-K dated May 20, 2010)

**Table of Contents**

<b>Exhibit No.</b>	<b>Title</b>
10.19.1*	Amendment No. 1 to the Master Services Agreement between UPS Supply Chain Solutions, Inc. and Endo Pharmaceuticals Inc., dated February 21, 2012
10.21	Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.21 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.22	Endo Pharmaceuticals Holdings Inc. 2010 Stock Incentive Plan (incorporated herein by reference to Exhibit A of the 2010 Definitive Proxy Statement filed with the Commission on April 29, 2010)
10.28	Amended and Restated Employment Agreement, dated as of December 19, 2007, by and between Endo and Nancy J. Wysenski (incorporated herein by reference to Exhibit 10.29 of the Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)
10.28.1	Separation Agreement, dated as of August 25, 2009, by and between Endo and Nancy J. Wysenski (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated August 31, 2009)
10.31*	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 herein by reference to
	Exhibit 10.31 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.31.1*	Amendment No. 1 to the License and Supply Agreement by and by and among Novartis, AG, Novartis Consumer Health, Inc. and Endo Pharmaceuticals Inc. dated as of March 28, 2008 (incorporated herein by reference to Exhibit 10.31.1 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.32*	Sales and Promotional Services Agreement, effective December 30, 2011, by and between Ventiv Commercial Services, LLC and Endo Pharmaceuticals, Inc.
10.34	Lease Agreement, dated as of May 5, 2000, by and between Endo Pharmaceuticals and Painters Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34 of the Registration Statement filed with the Commission on June 9, 2000)
10.34.1	Amendment to Lease Agreement, dated as of November 6, 2006, by and between Endo Pharmaceuticals and Painters Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34.1 of the Form 10-Q for the quarter ended September 30, 2006 filed with the Commission on November 9, 2006)
10.35	Amended and Restated Employment Agreement, dated as of December 19, 2007, by and between Endo and Caroline B. Manogue (incorporated herein by reference to Exhibit 10.29 of the
	Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)
10.36	Employment Agreement between Endo Pharmaceuticals Holdings Inc. and Julie McHugh (incorporated herein by reference to Exhibit 10.2 of the Current Report on Form 8-K, dated March 12, 2010)
10.37	Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.37 of the Form 10-Q for the Quarter ended June 30, 2004 filed with the Commission on August 9, 2004)
10.38	Endo Pharmaceuticals Holdings Inc. Amended and Restated 2007 Stock Incentive Plan (incorporated herein by reference to Exhibit B of the Definitive Proxy Statement on Schedule 14A filed with the Commission on April 29, 2009)
10.39*	Master Development and Toll Manufacturing Agreement, dated as of May 3, 2001, by and between Novartis Consumer Health, Inc. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.39 of the Form 10-Q for the Quarter Ended June 30, 2001 filed with the Commission on August 14, 2001)

**Table of Contents**

<b>Exhibit No.</b>	<b>Title</b>
10.39.1	First Amendment, effective February 1, 2003, to the Master Development and Toll Manufacturing Agreement between Endo Pharmaceuticals and Novartis Consumer Health, Inc. (incorporated herein by reference to Exhibit 10.39.1 of the Form 10-Q for the Quarter Ended June 30, 2005 filed with the Commission on August 8, 2005)
10.39.2	Second Amendment, effective as of December 1, 2004, to the Master Development and Toll Manufacturing Agreement between Endo Pharmaceuticals and Novartis Consumer Health, Inc. (incorporated herein by reference to Exhibit 10.39.2 of the Form 10-Q for the Quarter Ended  June 30, 2005 filed with the Commission on August 8, 2005)
10.39.3	Letter of termination of Master Development and Toll Manufacturing Agreement dated February 23, 2011 between Endo Pharmaceuticals Inc. and Novartis Consumer Health, Inc. (incorporated herein by reference to Exhibit 10.39.3 of the Form 10-K for the year ended December 31, 2010 filed with the Commission on February 28, 2011)
10.40	Lease Agreement between Painters Crossing Three Associates, L.P. and Endo Pharmaceuticals dated January 19, 2007 (incorporated herein by reference to Exhibit 10.40 of the Annual Report on Form 10-K for the Year Ended December 31, 2006 filed with the Commission on March 1, 2007)
10.40.1	First Amendment to Lease Agreement, dated as of March 3, 2008 by and between Partners Crossing Three Associates, L.P. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.40.1 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.41	Policy of Endo Pharmaceuticals Holdings Inc. Relating to Insider Trading in Company Securities and Confidentiality of Information (incorporated herein by reference to Exhibit 10.41 of the  Form 10-Q for the Quarter ended March 31, 2005 filed with the Commission on May 10, 2005)
10.42	Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K, dated May 8, 2009)
10.43	Employment Agreement between Endo and Alan G. Levin (incorporated herein by reference to Exhibit 10.2 of the Current Report on Form 8-K, dated May 8, 2009)
10.45	Lease Agreement, dated as of November 13, 2003, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.45 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
10.45.1	Amendment to Lease Agreement, dated as of February 16, 2005, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.45.1 of the Current Report on Form 8-K dated February 18, 2005)
10.45.2	Amendment to Lease Agreement, dated as of November 6, 2006, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.34.1 of the Form 10-Q for the quarter ended September 30, 2006 filed with the Commission on November 9, 2006)
10.48*	License and Co-Promotion Rights Agreement, dated as of July 14, 2004, by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.48 of the Current Report on Form 8-K dated July 19, 2004)
10.48.2*	Second Amendment, dated as of December 12, 2005, to the License Agreement by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.2 of the Current Report on Form 8-K dated December 29, 2005)
10.48.4	Third Amendment, dated as of July 23, 2007, to the License Agreement by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.4 of the Current Report on Form 8-K dated July 27, 2007)



**Table of Contents**

<b>Exhibit No.</b>	<b>Title</b>
10.48.5*	Fourth Amendment, dated as of February 19, 2008, to the License Agreement by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.48.5 of the Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)
10.48.6	Fifth Amendment, dated as of August 15, 2011, to the License Agreement by and between Endo Pharmaceuticals and Vernalis Development Limited, dated July 14, 2004 (incorporated herein by reference to Exhibit 10.123 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2011 filed with the Commission on October 31, 2011)
10.50	Form of Stock Option Grant Agreement under the 2007 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.50 of the Form 10-K for the year ended December 31, 2008 filed with the Commission on March 2, 2009)
10.51	Form of Restricted Stock Unit Grant Agreement under the 2007 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.51 of the Form 10-K for the year ended  December 31, 2008 filed with the Commission on March 2, 2009)
10.52	Agreement and Plan of Merger dated January 5, 2009, by and between Endo, BTB Purchaser, and Indevus Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated January 5, 2009)
10.52.1	Amendment, dated January 7, 2009 to the Agreement and Plan of Merger, by and between Endo, BTB Purchaser, and Indevus Pharmaceuticals, Inc. (incorporated herein by reference to  Exhibit 10.1 of the Current Report on Form 8-K dated January 7, 2009)
10.52.2	Amendment No. 2, dated February 4, 2009, to the Agreement and Plan of Merger, by and among Endo, BTB Purchaser Inc. and Indevus Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1 of the Current Report on Form 8-K dated February 6, 2009)
10.54	Nebido® (n/k/a Aveed™) Contingent Cash Consideration Agreement, dated February 23, 2009, by and between Endo and American Stock Transfer and Trust Company (incorporated herein by reference to Exhibit 10.54 of the Form 10-K for the year ended December 31, 2008 filed with the Commission on March 2, 2009)
10.55	Octreotide Contingent Cash Consideration Agreement, dated February 23, 2009, by and between Endo and American Stock Transfer and Trust Company (incorporated herein by reference to Exhibit 10.55 of the Form 10-K for the year ended December 31, 2008 filed with the Commission on March 2, 2009)
10.57	Amended and Restated License, Commercialization and Supply Agreement executed September 18, 2007 between Indevus and Esprit Pharma, Inc. (n/k/a Allergan USA, Inc.) (incorporated herein by reference to Exhibit 10.1 to the Indevus Current Report on Form 8-K dated September 21, 2007)
10.58	First Amendment to Amended and Restated License, Commercialization and Supply Agreement between Indevus Pharmaceuticals, Inc. and Allergan USA, Inc. dated as of January 9, 2009 (incorporated herein by reference to Exhibit 10.1 to the Indevus Current Report on Form 8-K, dated January 15, 2009)
10.59	Form of Restricted Stock Unit Grant Agreement under the 2010 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.59 of the Form 10-K for the year ended  December 31, 2010 filed with the Commission on February 28, 2011)
10.60	Form of Stock Option Grant Agreement under the 2010 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.60 of the Form 10-K for the year ended December 31, 2010 filed with the Commission on February 28, 2011)

**Table of Contents**

<b>Exhibit No.</b>	<b>Title</b>
10.61	Agreement and Plan of merger, dated as of December 11, 2006, by and among Indevus, Hayden Merger Sub, Inc. and Valera Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1 to the Indevus Current Report on Form 8-K, dated December 12, 2006)
10.76	Stent Contingent Stock Rights Agreement, dated as of April 17, 2007, between Indevus and American Stock Transfer & Trust Company (incorporated herein by reference to Exhibit 10.2 to the Indevus Current Report on Form 8-K dated April 17, 2007)
10.76.1	Supplemental Stent CSR Agreement, dated as of March 23, 2009, by and between Endo American Stock Transfer & Trust (incorporated herein by reference to Exhibit 10.2 of the Current Report on Form 8-K dated March 23, 2009)
10.77	Octreotide Contingent Stock Rights Agreement, dated as of April 17, 2007, between Indevus and American Stock Transfer & Trust Company (incorporated herein by reference to Exhibit 10.3 to the Indevus Current Report on Form 8-K dated April 17, 2007)
10.77.1	Supplemental Octreotide CSR Agreement, dated as of March 23, 2009, by and between Endo American Stock Transfer & Trust (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated March 23, 2009)
10.80	Purchase and Sale Agreement by and between Ledgemont Royalty Sub LLC and Indevus dated August 26, 2008 (incorporated herein by reference to Exhibit 10.215 to the Indevus Form 10-K for the fiscal year ending September 30, 2008, filed with the Commission on December 11, 2008)
10.81	Note Purchase Agreement by and among Ledgemont Royalty Sub LLC, Indevus and the purchasers named therein dated August 26, 2008 (incorporated herein by reference to Exhibit 10.216 to the Indevus Form 10-K for the fiscal year ending September 30, 2008, filed with the Commission on December 11, 2008)
10.82	Indenture by and between Ledgemont Royalty Sub LLC and U.S. Bank National Association dated August 26, 2008 (incorporated herein by reference to Exhibit 10.217 to the Indevus Form 10-K for the fiscal year ending September 30, 2008, filed with the Commission on December 11, 2008)
10.83	Pledge and Security Agreement made by Indevus to U.S. Bank National Association, as Trustee, dated August 26, 2008 (incorporated herein by reference to Exhibit 10.218 to the Indevus Form 10-K for the fiscal year ending September 30, 2008, filed with the Commission on December 11, 2008)
10.88	Termination of Agreement dated September 12, 1990 between National Patent Development Corporation and The Population Council, Inc. dated October 1, 1997 (incorporated herein by reference to Exhibit 10.6 to the Valera Registration Statement on Form S-1 (File No. 333-123288) filed with the Commission on December 9, 2005)
10.88.1	Amendment to the Termination of the Joint Development Agreement between GP Strategies Corporation and The Population Council, Inc. dated November 29, 2001 (incorporated herein by reference to Exhibit 10.7 to the Valera Registration Statement on Form S-1 (File No. 333-123288) filed with the Commission on December 9, 2005)
10.88.2	Amendment No. 2 to Termination Agreement between Valera Pharmaceuticals, Inc. and The Population Council, Inc. dated August 31, 2004 (incorporated herein by reference to Exhibit 10.8 to the Valera Registration Statement on Form S-1 (File No. 333-123288) filed with the Commission on December 9, 2005)
10.90	Pledge and Security Agreement dated as of October 16, 2009 by and among Endo Pharmaceuticals Holdings Inc., the lenders named therein and JPMorgan Chase Bank, N.A., as administrative agent (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated October 22, 2009)

**Table of Contents**

<b>Exhibit No.</b>	<b>Title</b>
10.91	Agreement and Plan of Merger dated May 5, 2010, by and between Endo, HT Acquisition Corp., and HealthTronics, Inc. (incorporated herein by reference to Exhibit 2.1 of the Current Report on Form 8-K dated May 7, 2010)
10.94	Agreement and Plan of Merger, dated August 9, 2010, by and among Endo Pharmaceuticals Holdings Inc, West Acquisition Corp., and Penwest Pharmaceuticals Co. (incorporated herein by reference to Exhibit 2.1 of the Current Report on Form 8-K dated August 12, 2010)
10.96	Stock Purchase Agreement, dated September 28, 2010, by and among Endo Pharmaceuticals Inc., Endo Pharmaceuticals Holdings Inc., Generics International (US Parent), Inc., and Apax Quartz (Cayman) L.P. (incorporated herein by reference to Exhibit 2.1 of the Current Report on Form 8-K dated September 30, 2010)
10.97	Lease Agreement dated May 19, 2008, by and between HealthTronics, Inc. and HEP-Davis Spring, L.P. (incorporated by reference to Exhibit 10.2 to HealthTronics Current Report on  Form 8-K filed with the Securities and Exchange Commission on June 20, 2008)
10.98	Second Amendment to Lease Agreement, dated as of August 20, 2009, between HEP-Davis Spring, L.P. as landlord and HealthTronics, Inc. as tenant (incorporated by reference to Exhibit 10.2 of HealthTronics 10-Q filed with the Securities and Exchange Commission on November 6, 2009)
10.101	Indenture among the Company, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated November 23, 2010 (incorporated herein by reference to Exhibit 4.1 of the Current Report on Form 8-K filed with the Commission on November 24, 2010)
10.102	Form of 7.00% Senior Notes due 2020 dated November 23, 2010 (incorporated herein by reference to Exhibit 4.1 of the Current Report on Form 8-K filed with the Commission on November 24, 2010)
10.104	Agreement and Plan of Merger, among Endo Pharmaceuticals Holdings Inc., NIKA Merger Sub, Inc. and American Medical Systems Holdings, Inc., dated as of April 10, 2011 (incorporated herein by reference to Exhibit 2.1 of the Current Report on Form 8-K date April 15, 2011)
10.105	Commitment Letter to Endo Pharmaceutical Holdings, Inc., from Morgan Stanley Senior Funding, Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated and Bank of America, N.A., dated  April 10, 2011 (incorporated herein by reference to Exhibit 10.1 of the Current Report on  Form 8-K dated April 15, 2011)
10.106	Form of Amended and Restated Performance Award Agreement under the 2007 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.106 of the Quarterly Report on Form 10-Q for the Quarter Ended March 31, 2011 filed with the Commission on April 29, 2011)
10.107	Form of Performance Award Agreement under the 2010 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.107 of the Quarterly Report on Form 10-Q for the Quarter Ended  March 31, 2011 filed with the Commission on April 29, 2011)
10.108	Credit Facility, among Endo Pharmaceuticals Holdings Inc., the lenders named therein, Morgan Stanley Senior Funding, Inc. and Bank of America, N.A., dated as of June 17, 2011 (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the Commission on June 20, 2011)
10.109	Indenture among the Company, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011 (incorporated herein by reference to Exhibit 4.1 of the Current Report on Form 8-K filed with the Commission on June 9, 2011)
10.110	Form of 7% Senior Notes due 2019 (included in Exhibit 10.110) (incorporated herein by reference to Exhibit 4.2 of the Current Report on Form 8-K filed with the Commission on June 9, 2011)

**Table of Contents**

<b>Exhibit No.</b>	<b>Title</b>
10.111	Indenture among the Company, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011 (incorporated herein by reference to Exhibit 4.3 of the Current Report on Form 8-K filed with the Commission on June 9, 2011)
10.112	Form of 7 1/4% Senior Notes due 2022 (included in Exhibit 10.112) (incorporated herein by reference to Exhibit 4.4 of the Current Report on Form 8-K filed with the Commission on June 9, 2011)
10.115	American Medical Systems Holdings, Inc. 2005 Stock Incentive Plan (As Amended and Restated) (incorporated herein by reference to Exhibit 10.1 of the American Medical Systems Holdings, Inc. Form 10-Q for the Fiscal Quarter Ended April 4, 2009 filed with the Commission on May 13, 2009)
10.116	Form of Stock Option Agreement under the 2005 American Medical Systems Holdings, Inc. Stock Incentive Plan (incorporated herein by reference to Exhibit 10.116 of the Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2011 filed with the Commission on August 9, 2011)
10.117	Form of Stock Award Agreement under the 2005 American Medical Systems Holdings, Inc. Stock Incentive Plan (incorporated herein by reference to Exhibit 10.117 of the Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2011 filed with the Commission on August 9, 2011)
10.121	Executive Employment Agreement between Endo and David P. Holveck, dated as of October 27, 2011 (incorporated herein by reference to Exhibit 10.121 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2011 filed with the Commission on October 31, 2011)
10.122	Executive Employment Agreement between Endo and Ivan P. Gergel, dated as of October 27, 2011 (incorporated herein by reference to Exhibit 10.122 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2011 filed with the Commission on October 31, 2011)
10.124	Build to Suit Lease Agreement between Endo Pharmaceuticals Inc. and RT/TC Atwater LP (incorporated herein by reference to Exhibit 10.124 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2011 filed with the Commission on October 31, 2011)
10.125	First Supplemental Indenture, among Penwest Pharmaceuticals Co. and Generics International (US), Inc., as guaranteeing subsidiaries, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated December 13, 2010, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated November 23, 2010 (incorporated herein by reference as Exhibit 4.2 to the Form S-4 filed with the Commission on October 14, 2011)
10.126	Second Supplemental Indenture, among Generics Bidco I, LLC, as guaranteeing subsidiary, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated December 21, 2010, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated November 23, 2010 (incorporated herein by reference as Exhibit 4.3 to the Form S-4 filed with the Commission on October 14, 2011)
10.127	Third Supplemental Indenture, among Ledgemont Royalty Sub LLC, as guaranteeing subsidiary, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated February 17, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated November 23, 2010 (incorporated herein by reference as Exhibit 4.4 to the Form S-4 filed with the Commission on October 14, 2011)
10.128	Fourth Supplemental Indenture, among Vintage Pharmaceuticals, LLC, as guaranteeing subsidiary, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated April 5, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated November 23, 2010 (incorporated herein by reference as Exhibit 4.5 to the Form S-4 filed with the Commission on October 14, 2011)

**Table of Contents**

<b>Exhibit No.</b>	<b>Title</b>
10.129	Fifth Supplemental Indenture, among American Medical Systems Holdings, Inc., American Medical Systems, Inc., AMS Research Corporation, AMS Sales Corporation and Laserscope, as guaranteeing subsidiaries, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 22, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated November 23, 2010 (incorporated herein by reference as Exhibit 4.6 to the Form S-4 filed with the Commission on October 14, 2011)
10.130	Sixth Supplemental Indenture, among American Medical Systems, Inc. and Laserscope, as successor guarantors, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated August 16, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated November 23, 2010 (incorporated herein by reference as Exhibit 4.7 to the Form S-4 filed with the Commission on October 14, 2011)
10.131	Seventh 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 November 23, 2010 (incorporated herein by reference as Exhibit 4.8 to the Form S-4 filed with the Commission on October 14, 2011)
10.132	First Supplemental Indenture, among American Medical Systems Holdings, Inc., American Medical Systems, Inc., AMS Research Corporation, AMS Sales Corporation and Laserscope, as guaranteeing subsidiaries, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 17, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011 (incorporated herein by reference as Exhibit 4.11 to the Form S-4 filed with the Commission on October 14, 2011)
10.133	Second Supplemental Indenture, among American Medical Systems, Inc. and Laserscope, as successor guarantors, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated August 16, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011 (incorporated herein by reference as Exhibit 4.12 to the Form S-4 filed with the Commission on October 14, 2011)
10.134	Third 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 herein by reference as Exhibit 4.13 to the Form S-4 filed with the Commission on October 14, 2011)
10.135	First Supplemental Indenture, among American Medical Systems Holdings, Inc., American Medical Systems, Inc., AMS Research Corporation, AMS Sales Corporation and Laserscope, as guaranteeing subsidiaries, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 17, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011 (incorporated herein by reference as Exhibit 4.16 to the Form S-4 filed with the Commission on October 14, 2011)

**Table of Contents**

<b>Exhibit No.</b>	<b>Title</b>
10.136	Second Supplemental Indenture, among American Medical Systems, Inc. and Laserscope, as successor guarantors, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated August 16, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011 (incorporated herein by reference as Exhibit 4.17 to the Form S-4 filed with the Commission on October 14, 2011)
10.137	Third 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 herein by reference as Exhibit 4.18 to the Form S-4 filed with the Commission on October 14, 2011)
10.138	Endo Pharmaceuticals Holdings Inc. Employee Stock Purchase Plan (incorporated herein by reference to Exhibit A of the 2011 Definitive Proxy Statement filed with the Commission on April 29, 2011)
21	Subsidiaries of the Registrant
23	Consent of Independent Registered Public Accounting Firm
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 Pharmaceuticals Holdings Inc. s Annual Report on Form 10-K for the year ended December 31, 2011, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Stockholders Equity, (iv) the Consolidated Statements of Cash Flows and (v) 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.