UNITED STATES
RITIES AND EXCHANGE COMMISSION

Washington, DC 20549

# FORM 10-K

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ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURIT EXCHANGE ACT OF 1934.

For the fiscal year ended December 31, 2010

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the transition period from

Commission file number: 001-15989

# ENDO PHARMACEUTICALS HOLDINGS INC.

(Exact name of registrant as specified in its charter)

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:

Title of Each Class

Name of Each Exchange on Which Registered

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), an (2) has been subject to such filing requirements for the past 90 days. Yes $\square$ No $\square$
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 no 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 $\square$ No $\boxtimes$
The aggregate market value of the voting common equity held by non-affiliates as of June 30, 2010 was \$2,251,905,366 based on a
closing sale price of \$21.82 per share as reported on the NASDAQ Global Select Market on June 30, 2010. 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

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Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of February 18, 2011: 117,286,788

Documents Incorporated by Reference

Portions of the registrant's proxy statement to be filed with the SEC pursuant to Regulation 14A in connection with the registrant's 2011 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, 2010.

# ENDO PHARMACEUTICALS HOLDINGS INC.

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#### FORWARD-LOOKING STATEMENTS

Statements contained or incorporated by reference in this document contain information that includes or is based on "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements, including estimates of future revenues, future expenses, future net income and future earnings 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. Also, statements including words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "will," "may" or similar expressions are forward-looking statements. We have based these forward-looking statements on our current expectations and projections about the growth of our business, our financial performance and the development of our industry. Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described in 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. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements contained or incorporated by reference in this document include those factors described in this document under Item 1A titled "Risk Factors," including, but not limited to:

- our ability to successfully develop, commercialize and market new products;
- timing and results of pre-clinical or clinical trials on new products;
- our ability to obtain regulatory approval of any of our pipeline products;
- the effect of healthcare reform on our business;
- competition for the business of our branded and generic products, and in connection with our acquisition of rights to intellectual property assets;
- our ability to sustain our sales and profitability on generic pharmaceutical products over time;
- our ability to keep our Qualitest manufacturing facilities in compliance with regulatory requirements;
- market acceptance of our future products;
- government regulation of the pharmaceutical industry;
- our dependence on a small number of products;
- our dependence on outside manufacturers for the manufacture of most of our products;
- our dependence on third parties to supply raw materials and to provide services for certain core aspects of our business;
- new regulatory action or lawsuits relating to our use of narcotics in most of our core products;
- our exposure to product liability claims and product recalls and the possibility that we may not be able to adequately insure ourselves;
- our ability to protect our proprietary technology;
- the successful efforts of manufacturers of branded pharmaceuticals to use litigation and legislative and regulatory efforts to limit the use of generics and certain other products;
- our ability to successfully implement our acquisition and in-licensing strategy;
- regulatory or other limits on the availability of controlled substances that constitute the active ingredients of some of our products and products in development;
- the availability of third-party reimbursement for our products;

- the outcome of any pending or future litigation or claims by third parties or the government, and the performance of indemnitors with respect to claims for which we have the right to be indemnified;
- our dependence on sales to a limited number of large pharmacy chains and wholesale drug distributors for a large portion of our total revenues;
- significant litigation expenses to defend or assert patent infringement claims;
- any interruption or failure by our suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us;
- 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;
- existing suppliers become unavailable or lose their regulatory status as an approved source, causing an
  inability to obtain required components, raw materials or products on a timely basis or at commercially
  reasonable prices;
- the loss of branded product exclusivity periods and related intellectual property;
- our ability to successfully execute our strategy;
- disruption of our operations if our information systems fail or if we are unsuccessful in implementing necessary upgrades or new software;
- our ability to maintain or expand our business if we are unable to retain or attract key personnel and continue to attract additional professional staff;
- our ability to successfully integrate HealthTronics, Inc. (HealthTronics), Penwest Pharmaceuticals Co. (Penwest), and Generics International (US Parent), Inc. (Qualitest or Qualitest Pharmaceuticals), and realize all anticipated benefits of our acquisitions;
- · HealthTronics' ability to establish or maintain relationships with physicians and hospitals; and
- HealthTronics' ability to comply with special risks and requirements related to its medical products manufacturing business.

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, however, to consult any further disclosures we make on related subjects in our reports filed with the Securities and Exchange Commission (SEC). Also note that we provide the preceding 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 the preceding to be a complete discussion of all potential risks or uncertainties.

#### PART I

#### Item 1. Business

# Overview

Endo Pharmaceuticals Holdings Inc., which we refer to as "Endo", "we", "us", or the "Company", is a United States-based, specialty healthcare solutions company focused on branded products and generics, and devices and services. We are redefining 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. Most recently, we have moved in this direction through our acquisition of Qualitest, which expands and diversifies our generic drug product offerings and enhances our pain management portfolio, and through our acquisition of HealthTronics, which has expanded and diversified our reach as a provider of healthcare services and medical devices and our presence in urology.

We have a portfolio of branded pharmaceuticals that includes established brand names such as Lidoderm®, Opana® ER and Opana®, Percocet®, Frova®, Voltaren® Gel, Vantas®, Valstar®, and Supprelin® LA. Branded products comprised approximately 86% of our total revenues in 2010. Our non-branded generic portfolio, which accounted for 9% of total revenues in 2010, currently consists of products primarily focused in pain management. We 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. Revenue from our devices and services portfolio accounted for the remainder of our revenues for the year ended December 31, 2010. We generated total revenues of \$1.72 billion for the year ended December 31, 2010.

In November, 2010, we acquired Qualitest, a leading United States based privately-held generics company. As a combined company, we expect to deliver more comprehensive healthcare solutions across our diversified businesses in Branded Pharmaceuticals, Generics, and Devices and Services in key therapeutic areas including pain and urology. Qualitest, the sixth largest U.S. generics company, as measured by prescriptions filled in the year ended December 31, 2010, is focused on cost-competitive, high-quality manufactured products with cost advantages or with high barriers to entry. We believe Qualitest brings critical mass to our current generics business, further diversifies our business lines and product offerings and enhances our portfolio of pain management products.

In September 2010, we acquired our partner on Opana® ER, 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, a provider of healthcare services and manufacturer of medical devices, primarily for the urology community.

Financial information presented herein reflects the operating results of HealthTronics from July 2, 2010, Penwest from September 20, 2010, and Qualitest from November 30, 2010.

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. Financial information presented herein reflects the operating results of Indevus from February 23, 2009.

We have established research and development expertise in analgesics and have expanded our research and development capabilities in other therapeutic areas such as endocrinology, oncology, and urology. As such, we believe we are well positioned to pursue research and development opportunities across these therapeutic areas.

Certain of our functions are outsourced, including some of our manufacturing and distribution. Currently, our primary suppliers of contract manufacturing services are Novartis Consumer Health, Inc. and Teikoku Seiyaku Co., Ltd.

We have dedicated sales forces in the United States, consisting of 493 Endo pharmaceutical sales representatives and 228 contracted sales representatives focusing primarily on pain products, 81 Endo sales representatives focusing primarily on bladder and prostate cancer products, 34 Endo medical center representatives focusing on the treatment of central precocious puberty and 51 Endo account executives focusing on managed markets customers. We market our branded pharmaceuticals to primary care physicians and

specialty physicians, including those specializing in pain management, orthopedics, neurology, rheumatology, surgery, anesthesiology, urology and pediatric endocrinology. Our sales force also targets retail pharmacies and other healthcare professionals throughout the United States.

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 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 company better able to respond to the changing economics that drive the U.S. healthcare environment and to improve outcomes for patients, providers and payers. 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 two 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, as well as 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 providers, payers and patients 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 devices and 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, including a tamper resistant formulation of Opana® ER, which is currently under Food and Drug Administration (FDA) review; and
- 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 46 abbreviated new drug applications (ANDAs) under active FDA review in multiple therapeutic areas, including pain management, urology, central nervous system (CNS) disorders, immunosuppression, oncology and hypertension. We anticipate that 24 ANDAs will be filed in 2011 and 2012.

We believe that recent healthcare reform in the United States places a premium on providing cost-effective healthcare solutions like those we offer, including those that we expect the combination of the Qualitest and

Endo generics businesses will provide. Applying the Qualitest and Endo technology platforms 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.

#### **Our Competitive Strengths**

We believe that, to execute our strategy successfully, 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 thoughtfully and deliberately executed a number of corporate acquisitions in 2010 in order 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 pathways of care. 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<sup>®</sup>. Lidoderm<sup>®</sup> contributed approximately 46% of our business' revenue in 2010, compared to 52% and 61% of our business' revenue in 2009 and 2008, respectively. Our acquisitions of Qualitest and HealthTronics have also contributed to our diversification. Through HealthTronics, we provide healthcare services and manufacture medical devices for the urology community. See "Providing healthcare services and the manufacture of medical devices" in this section.

Established portfolio of branded products. On the branded pharmaceuticals side of our business, 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 and Opana®, Percocet®, Percodan®, Frova®, Voltaren® Gel, Supprelin® LA, Vantas®, Valstar®, and Fortesta<sup>TM</sup> 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 two NDAs filed with the FDA, two products in Phase III trials and two products in Phase II trials. We have also initiated development efforts for medical devices and have multiple programs at concept and developments stages across urology, uro-oncology, endocrinology and urogynocology. For a more detailed description of our development pipeline, see "Products in Development."

Research and development expertise. Our research and development effort is 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. Additionally, subsequent to our acquisition of Qualitest, 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, 2010, our research and development and regulatory affairs staff consisted of 243 employees, based primarily in Westbury, New York, Huntsville, Alabama, and at our corporate headquarters in Chadds Ford, Pennsylvania. Our research and development expenses, including upfront and milestone payments were \$144.5 million in 2010, \$185.3 million in 2009, and \$110.2 million in 2008.

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 pre-clinical 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, consisting of 493 Endo pharmaceutical sales representatives and 228 sales contracted representatives focusing primarily on pain products, 81 Endo sales representatives focusing primarily on bladder and prostate cancer products, 34 Endo medical center representatives focusing on the treatment of central precocious puberty and 51 Endo account executives focusing on managed markets customers. 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 United States. 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. Our managed markets staff as of December 31, 2010 consisted of 51 employees.

Expanding focus on generic products. Following the Qualitest acquisition, the combined generics business has 46 ANDAs under active FDA review in multiple therapeutic areas, including pain management, urology, CNS disorders, immunosuppression, oncology and hypertension. We anticipate that 24 ANDAs will be filed in 2011 and 2012 combined. 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. Likewise, Qualitest, a leading generics company in the United States, has a business model focused on being the lowest-cost producer of products, in categories with high barriers to entry and a lower level of competition. Qualitest's business is focused in categories where there are fewer challenges from low-cost operators in markets such as China and India, with approximately 32% of Qualitest's product portfolio being comprised of controlled substances, which cannot be manufactured off-shore and imported into the United States. In addition, approximately 21% of Qualitest's product portfolio is made up of liquids, which are uneconomical to ship into the United States. We expect that the Qualitest acquisition will provide us with an opportunity to improve our overall profitability by optimizing our combined portfolio for high volume and growth and strengthening our U.S. generics competitive position, product pipeline, portfolio and capabilities.

Providing healthcare services and the manufacture of medical devices. Through our HealthTronics subsidiary, we provide healthcare services and manufacture 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, medical products manufacturing, sales, and maintenance, and image guided radiation therapy (IGRT) technical services for cancer treatment centers such as providing technical (non-physician) personnel to operate equipment, leasing equipment, or helping physicians establish or manage IGRT treatment centers.

Strong balance sheet and significant cash flow. Historically, we have generated significant cash flow from operating activities due to a unique combination of strong brand equity, attractive margins and low capital expenditures. For the year ended December 31, 2010, we generated \$454 million of cash from operations. We expect that sales of our currently marketed products and HealthTronics' devices and services, together with our stronger U.S. generics competitive position, product pipeline portfolio and capabilities that we obtained from our

acquisition of Qualitest, will allow us to continue to generate significant cash flow from operations in the future. We maintain a strong balance sheet with modest leverage levels and ample liquidity, which gives us flexibility to make strategic investments in our business. As of December 31, 2010, we had \$490 million of cash and marketable securities and up to \$500 million of availability under the Revolving Credit Facility, not including an expansion option of up to \$200 million thereunder.

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, and their expertise has contributed to our success in identifying, consummating and integrating such acquisitions. Members of our management team have consummated four acquisitions since 2009 (Indevus, HealthTronics, Penwest, and Qualitest), have received FDA approval on more than nineteen new products and product line extensions since 1997, and, as a result of several successful product launches, have grown our total revenues from \$108 million in 1998 to over \$1.7 billion in 2010.

# **Our Industry**

# Pain Management Market

According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled \$22.2 billion in 2010. This represents an approximate 7% compounded annual growth rate since 2006. Our primary area of focus within this market is analgesics and, specifically, opioid analgesics. In 2010, analgesics were the third most prescribed medication in the United States with nearly 311 million prescriptions written for this classification.

Opioid analgesics is a segment that comprised approximately 80% of the analgesic prescriptions for 2010 and represented almost 58% of the overall U.S. pain management market. Total U.S. sales for the opioid analgesic segment were \$8.5 billion in 2010, representing a compounded annual growth rate of 10% since 2006. With the launch of Voltaren® Gel in 2008, Endo gained presence in the osteoarthritis market competing in the analgesic non-narcotic and anti-arthritic classes which together had over 179 million prescriptions written in 2010, representing 42% of the U.S. pain management market. The U.S. sales for the analgesic non-narcotic and anti-arthritic markets were \$13.7 billion with a compound annual growth rate of 5% since 2006.

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 was projected to reach 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 in 2009, Endo entered the urology, endocrinology and oncology markets, specifically the prostate cancer therapeutic area with Vantas®, the bladder oncology space with Valstar® and Urocidin<sup>TM</sup>, and the central precocious puberty therapeutic area with Supprelin® LA. With our early 2011 launch of Fortesta<sup>TM</sup> 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<sup>TM</sup>. As a

result of our acquisition of HealthTronics, we now offer a full suite of urology products and services with the addition of lithotripsy, benign prostate hyperplasia and prostate cancer therapies, as well as anatomical pathology services for the detection and diagnosis of cancer and other conditions.

# 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 United States 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 United States, 7,000 patients are estimated to have CPP with approximately 2,000 diagnosed annually. CPP is treated by pediatric endocrinologists in the United States where there are approximately 600 practicing pediatric endocrinologists. In 2010, the market for drugs to treat CPP, reported by IMS Health NSP, was approximately \$125 million in the United States.

#### 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 200,000 men in the United States are diagnosed with prostate cancer and 30,000 die from this disease.

#### Bladder cancer overview

There are more than 500,000 people in the United States alive with a history of bladder cancer, which is the fourth most common cancer among men and the eleventh most common among women in the United States. The American Cancer Society estimated approximately 70,530 new cases of bladder cancer and 14,680 deaths from this disease in the United States in 2010. The 2011 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 seven of every 100 patients diagnosed with bladder cancer. Standard treatment of CIS of the urinary bladder is transurethral resection of the 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 United States 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 United States, TRT sales have dramatically increased, from approximately \$484 million in 2005 to over \$1.3 billion in 2010, representing a compounded annual growth rate of 18% since 2005.

# **Products and Services Overview**

The following table summarizes select products in our branded and generic portfolios as well as select products in development:

Branded Pharmaceuticals	Active Ingredient(s)	Status
Lidoderm®	lidocaine 5%	Marketed
	oxymorphone hydrochloride	Marketed
Opana® ER Opana®	oxymorphone hydrochloride	Marketed
Percocet®	oxycodone hydrochloride and acetaminophen	Marketed
Voltaren® Gel(1)	diclofenac sodium topical gel 1%	Marketed
Frova®(2)	frovatriptan succinate	Marketed
Supprelin® LA	histrelin acetate	Marketed
Vantas®	histrelin acetate	Marketed
Sanctura XR®(3)	trospium chloride	Marketed
Sanctura®(4)	trospium chloride	Marketed
Valstar®	valrubicin	Marketed
Percodan®	oxycodone hydrochloride and aspirin	Marketed
Fortesta <sup>TM</sup> Gel(5)	2% testosterone	Marketed
		er er fall er fill de sooi. Ook een sooi f
Generics	Active Ingredient(s)	Status
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	carisoprodól	Marketed
Hydrocortisone Promethazine	hydrocortisone	Marketed
Promethazine	promethazine	Marketed
Multi Vitamins	multi vitamins	Marketed
Acetaminophen and codeine	acetaminophen and codeine	Marketed
Spironolactone	spironolactone	Marketed
Butalbital, acetaminophen, and caffeine	butalbital, acetaminophen, and caffeine	Marketed
Methocarbamol	methocarbamol	Marketed
Methocarbamol Allopurinol	allopurinol	Marketed
	lactulose	Marketed
Hydrochlorothiazide	hydrochlorothiazide	Marketed
Prednisone	prednisone	Marketed
Prednisone Nystatin	nystatin	Marketed
	Andrew Terror Standard	Status
1 Todado III 20 Volopillo II	Active Ingredient(s)	<del></del>
Oxymorphone(6)	oxymorphone hydrochloride	NDA Filed
Aveed <sup>TM</sup> (7)	testosterone undecanoate	NDA Filed
Octreotide implant – acromegaly*	octreotide acetate	Phase III
Urocidin™(8)	mycobacterial cell wall-DNA complex	Phase III
Axomadol(6)	axomadol phosphate	Phase II
Axomadol(6) Pagoclone(9)	pagoclone	Phase II

<sup>\*</sup> Granted orphan drug designation.

- (1) Licensed marketing rights from Novartis Consumer Health, Inc.
- (2) Licensed marketing rights from Vernalis Development Limited.
- (3) Licensed marketing and development rights from Supernus Pharmaceuticals Inc.
- (4) Licensed marketing and development rights from Madaus GmbH.

- (5) Licensed marketing and development rights from Strakan International Limited.
- (6) Licensed marketing and development rights from Grünenthal GMBH.
- (7) Licensed marketing and development rights from BayerSchering Pharma AG.
- (8) Licensed marketing and development rights from Bioniche Life Sciences.
- (9) Licensed marketing and development rights from Aventis Pharma S.A.

# **Branded Pharmaceuticals**

Lidoderm<sup>®</sup>. Lidoderm<sup>®</sup> was launched in September 1999. A topical patch product containing lidocaine, Lidoderm<sup>®</sup> 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<sup>®</sup> 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 2010, 2009, and 2008, Lidoderm<sup>®</sup> net sales were \$782.6 million, \$763.7 million, and \$765.1 million, respectively. Lidoderm<sup>®</sup> accounted for approximately 46% of our 2010 total revenues.

Opana® and Opana® ER. 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, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg and 40 mg tablets. Opana® (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 5 mg and 10 mg tablets. Opana® ER and Opana® net sales were \$299.1 million, \$230.6 million, and \$180.4 million in 2010, 2009, and 2008, respectively. Opana® ER and Opana® accounted for approximately 17% of our 2010 total revenues.

**Percocet**<sup>®</sup>. Launched in 1976, Percocet<sup>®</sup> is approved for the treatment of moderate-to-moderately severe pain. The Percocet<sup>®</sup> family of products had net sales of \$121.3 million, \$127.1 million, and \$130.0 million in the years 2010, 2009, and 2008, respectively. The Percocet<sup>®</sup> franchise accounted for approximately 7% of our 2010 total revenues.

Voltaren® Gel. We launched Voltaren® Gel in March 2008 upon closing of the license and supply agreement with Novartis AG and Novartis Consumer Health, Inc. Voltaren® Gel (diclofenac sodium topical gel) 1% 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 United States for osteoarthritis since 2001. Voltaren® Gel was granted marketing exclusivity in the United States 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 2010, 2009, and 2008, net sales of Voltaren® Gel were \$104.9 million, \$78.9 million, and \$23.8 million, respectively.

Frova®. We began shipping Frova® upon closing of the license agreement with Vernalis in mid-August 2004, and we initiated our promotional efforts in September 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 2010, 2009, and 2008, Frova® net sales were \$59.3 million, \$57.9 million, and \$58.0 million, respectively.

Supprelin® LA. Supprelin® LA was launched in the United States in June 2007. Supprelin® LA is a soft, flexible 12-month hydrogel implant based on our patented Hydron 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 United States through a specialty sales force primarily to pediatric endocrinologists. Net sales of Supprelin® LA were \$46.9 million in 2010 and \$27.8 million in 2009.

Vantas®. Vantas® was launched in the United States in November 2004. Vantas® is a soft, flexible 12-month hydrogel implant based on our patented Hydron® 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 them the rights to market Vantas® throughout Europe as well as certain other countries. Vantas® is also approved in Thailand, Singapore, Malaysia, and Argentina. Net sales of Vantas® were \$17.0 million in 2010 and \$20.0 million in 2009, primarily in the United States.

Valstar®. Valstar® is a sterile solution for intravesical instillation of valrubicin, a chemotherapeutic anthracycline derivative, and is the only product currently approved by the FDA for therapy of bacillus Calmette-Guerin (BCG)-refractory carcinoma in situ (CIS) of the urinary bladder. 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 submitted a supplemental new drug application (sNDA) to the FDA seeking approval to reintroduce Valstar® and in February 2009, the FDA approved this sNDA. In September 2009, we launched Valstar® for the treatment of patients with BCG-refractory CIS of the bladder. We continue to work closely with the manufacturer to build quantities of the product to support the increasing demand for Valstar®. Net sales of Valstar® were \$14.1 million in 2010 and \$3.4 million in 2009.

*Hydron*® *Implant*. The Hydron® 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® and Supprelin® LA.

The Hydron® 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 Hydron® Implant delivers drugs at zero-order kinetics and the duration of delivery can be predetermined over a range of times. While we will continue using this technology, we have decided to stop using the "Hydron®" name and plan to use "MedLaunch<sup>TM</sup>" to describe this technology.

Sanctura<sup>®</sup>. Sanctura<sup>®</sup>, a muscarinic receptor antagonist for the treatment of OAB, was launched in August 2004. Sanctura<sup>®</sup> is indicated for the treatment of OAB with symptoms of urinary incontinence, urgency and urinary frequency. Sanctura<sup>®</sup> belongs to the anticholinergic class of compounds and binds specifically to muscarinic receptors. These compounds relax smooth muscles, such as the detrusor muscle in the bladder, thus decreasing bladder contractions. Overactive or unstable detrusor muscle function is believed to be one of the principal causes of OAB symptoms. Current treatments in the United States for OAB include compounds in the same therapeutic class as Sanctura<sup>®</sup>. In November 1999, we licensed the exclusive rights to develop and market Sanctura<sup>®</sup> in the United States from Madaus GmbH (Madaus). In September 2007, we sublicensed these rights to Allergan, Inc (Allergan). We receive royalties from Allergan on net sales of Sanctura<sup>®</sup> in the United States. We had co-promoted Sanctura<sup>®</sup> in the United States with our marketing partner, Allergan, however, our right to co-promote expired in September 2009.

Sanctura XR<sup>®</sup>. Sanctura XR<sup>®</sup> is a once-daily formulation of Sanctura<sup>®</sup>, our currently marketed product for the treatment of OAB. Sanctura XR<sup>®</sup> belongs to a class of anticholinergic compounds known as muscarinic

receptor antagonists. Current treatments in the United States for OAB include compounds in the same therapeutic class as Sanctura XR®. Sanctura XR® is a quaternary ammonium compound, which we believe provides significant differentiation to the tertiary ammonium compounds currently being marketed for the treatment of OAB. Quaternary ammonium compounds are highly charged and hydrophilic with a limited ability to cross lipid membranes. The formulation of Sanctura XR® was developed under a development and license agreement with Supernus Pharmaceuticals, Inc. (Supernus), formerly Shire Laboratories, Inc. and we received exclusive, worldwide rights. In November 2006, we licensed to Madaus the exclusive rights to sell Sanctura XR® in all countries outside of the United States, except for Canada, Japan, Korea and China. We receive royalties from Madaus on the net sales of Sanctura XR® in these countries. In September 2007, we sublicensed to Allergan the United States rights to Sanctura XR®. We receive royalties from Allergan on the net sales of Sanctura XR® in the United States. In May 2008, we sublicensed to Allergan the rights to the Sanctura® franchise in Canada and Allergan could be required to pay future commercialization milestone payments to us. We had co-promoted Sanctura XR® in the United States with our marketing partner, Allergan, however, our right to co-promote expired in September 2009.

Fortesta<sup>TM</sup> Gel. Fortesta<sup>TM</sup> Gel is a patented two percent (2%) testosterone transdermal gel for testosterone replacement therapy in male hypogonadism. A metered dose delivery system permits accurate dose adjustments to increase the ability to individualize patient treatment. 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>TM</sup> Gel in the United States. 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>TM</sup> Gel. Fortesta<sup>TM</sup> Gel was approved by the FDA in December of 2010 as a treatment for men suffering from low testosterone (Low T), also known as hypogonadism, and was launched in the first quarter of 2011.

*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 net sales in the 2010 fiscal year.

# Generics

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.

One of our generic products is an oxycodone hydrochloride and acetaminophen product, Endocet<sup>®</sup>, which accounted for approximately 5% of our total revenues in 2010. Another of our generic products is morphine sulfate extended-release tablets, which accounted for 1% of our total revenues in 2010. Prior to our acquisition of Qualitest in November 2010, the balance of our generic portfolio consisted of a few other products, none of which accounted for more than 1% of our total revenues in 2010. The Qualitest acquisition resulted in an additional \$30.3 million in total revenues for our generics business during 2010, which was included in our consolidated results from November 30, 2010.

With the acquisition of Qualitest, we are expanding and diversifying our generic product pipeline. We principally pursue the development and marketing of generic pharmaceuticals that either have one or more barriers to entry or can leverage our low-cost manufacturing network in the United States and abroad. The characteristics of the products that we may target for generic development or sourcing may include:

- complex formulation or development characteristics;
- regulatory or legal challenges;
- difficulty in raw material sourcing; or

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• products sourced primarily in the United States where our lower cost United States manufacturing gives us an advantage.

We believe products with these characteristics will face a lesser degree of competition, therefore providing longer product life cycles and/or higher profitability than other commodity generic products. As of December 31, 2010, the combined generics business has 46 abbreviated new drug applications (ANDAs) under active FDA review in multiple therapeutic areas, including pain management, urology, central nervous system (CNS) disorders, immunosuppression, oncology and hypertension. We anticipate that 24 ANDAs will be filed in 2011 and 2012 combined.

### Products in Development

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, including those obtained through our acquisition of Indevus are as follows:

Aveed<sup>TM</sup>. Aveed<sup>TM</sup> is a novel, long-acting injectable testosterone preparation for the treatment of male hypogonadism. If approved, Aveed<sup>TM</sup> would be the first long-acting injectable testosterone preparation available in the United States in the growing market for testosterone replacement therapies. The U.S. rights to Aveed<sup>TM</sup> were acquired from Schering AG, Germany, in July 2005. Although not yet approved in the United States, Aveed<sup>TM</sup> is approved in and currently marketed in Europe and a number of other countries. In May 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.

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. In the United States alone, it is currently estimated that 14 million men have low testosterone levels; however, only about 9% are currently being treated.

In June 2008, an approvable letter was received from the FDA indicating that the Aveed<sup>™</sup> NDA may be approved if the Company is able to adequately respond to certain clinical deficiencies related to the product. In September 2008, an 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>.

On December 2, 2009, we received a complete response letter from the FDA regarding Aveed<sup>TM</sup>. In the complete response letter, the FDA has requested information from Endo to address the agency's concerns regarding rare but serious adverse events, including post-injection anaphylactic reaction and pulmonary oily microembolism. The letter also specified that the proposed risk evaluation mitigation strategy (REMS) is not sufficient. In 2010, 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. 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.

Oxymorphone. Oxymorphone is an opioid analgesic product that serves as the basis for two of our currently marketed products: Opana® ER and Opana®. In December 2007, we entered into a license, development and supply agreement with Grünenthal GMBH for the exclusive clinical development and commercialization rights in Canada and the United States for a new oral formulation of long-acting oxymorphone, which is designed to be crush resistant. Under the terms of this agreement Grünenthal is responsible for development efforts to conduct pharmaceutical formulation development and will manufacture any such product or products which obtain FDA

approval. Endo is responsible for conducting clinical development activities and for all development costs incurred to obtain regulatory approval. Under the terms of the agreement, Endo has paid and could become obligated to pay additional amounts upon the achievement of 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.

In July 2010, we filed an NDA with the FDA for a new extended-release formulation of oxymorphone, which is a semi-synthetic opioid analgesic intended for the treatment of moderate to severe chronic pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time. The NDA submission is based on a non-clinical and clinical development program designed to demonstrate the crush-resistant properties of this formulation of oxymorphone. In September 2010, we received notification from the FDA that this NDA has been granted priority review status. In January 2011, we received a complete response letter from the FDA. The letter did not require that additional clinical studies be conducted for approval of the NDA. We have begun to address the issue described in the complete response letter and will work closely with the FDA to finalize our response. We are confident that we can address the issue set forth, currently anticipate responding to the FDA by mid 2011 and would expect a six month review cycle once our response is filed.

Octreotide implant. The octreotide implant utilizes our patented Hydron® 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.

Acromegaly is a chronic hormonal disorder that occurs when a tumor of the pituitary gland causes the excess production of GH. It usually affects middle-aged adults and, if untreated, causes enlargement of certain bones, cartilage, muscles, organs and other tissue, leading to serious illness and potential premature death. There are approximately 1,000 new acromegalic patients diagnosed per year and 18,000 total patients in the United States.

In November 2007, positive results from the Phase II trial in patients with acromegaly showed that the octreotide implant effectively suppressed levels of GH and IGF-1 (insulin-like growth factor-1, the mediator of growth hormone's effects) at rates similar to those seen with current FDA approved injectable formulations of octreotide. In addition, the drug was well tolerated. In September 2008, a Phase III clinical trial was initiated. The trial is designed to test the efficacy, safety and tolerability of the octreotide implant in patients with acromegaly.

The octreotide implant is also currently in Phase II clinical trials for the treatment of carcinoid syndrome. Carcinoid syndrome is a group of symptoms associated with carcinoid tumors, which are tumors of the small intestine, colon, appendix, and bronchial tubes in the lungs that originate from cells of the neuroendocrine system. Carcinoid syndrome occurs in approximately 10% of the patients with carcinoid tumors, usually after the tumor has spread to the liver or lung.

In February 2011, the FDA requested that additional pre-clinical studies, including a carcinogenicity study, be completed prior to the submission of the NDA for the octreotide implant for the treatment of acromegaly. Although this development causes a delay of up to four years in the timing associated with regulatory approval, the Company intends to continue the development of this product and is encouraged by recent preliminary results from its Phase III study.

In addition, the Company recently assessed all of its in-process research and development 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.

*Urocidin*<sup>™</sup>. Urocidin<sup>™</sup> 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<sup>TM</sup> in the United States with an option for global rights. We exercised our option for global rights in the first quarter of 2010.

Axomadol. Axomadol is a patented new chemical entity discovered by Grünenthal GMBH and currently in Phase II development for the treatment of moderate to moderately severe chronic pain. In February 2009, we entered into a Development, License and Supply Agreement with Grünenthal, granting us the exclusive right in North America to develop and market axomadol.

**Pagoclone.** Pagoclone is a novel, non-benzodiazepine, GSBA-A receptor modulator and is under development as a treatment for stuttering. Stuttering is a disease of uncertain etiology that affects approximately three million adults and children in the United States. The treatment for stuttering consists mainly of behavioral modification and speech therapy as there are currently no drugs approved in the U.S. for the treatment of stuttering.

Anti-androgen program. 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, focused primarily on castration-resistant prostate cancer.

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.

#### **Devices and Services**

Through our HealthTronics subsidiary, we provide healthcare services and manufacture medical devices, primarily for the urology community, including:

Lithotripsy services. Through HealthTronics, 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 2010, physician partners used our lithotripters to perform approximately 50,000 procedures in the United States. We do not render any medical services; rather, the physicians do.

Our HealthTronics subsidiary provides our lithotripsy services through two types of contracts, retail and wholesale. Retail contracts are contracts where we contract with the hospital and private insurance payers. Wholesale contracts are contracts where we contract only with the hospital. The two approaches functionally differ in that, under a retail contract, we generally bill for the entire non-physician fee for all patients other than governmental pay patients, for which the hospital bills the non-physician fee. Under a wholesale contract, the hospital generally bills for the entire non-physician fee for all patients. In both cases, the billing party contractually bears the costs associated with the billing service, including pre-certification, as well as non-collection. The non-billing party is generally entitled to its fees regardless of whether the billing party actually collects the non-physician fee. Accordingly, under the wholesale contracts where we are the non-billing party, the hospital generally receives a greater proportion of the total non-physician fee to compensate for its billing costs and collection risk. Conversely, under the retail contracts where we generally provide the billing services and bear the collection risk, we receive a greater portion of the total non-physician fee. 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 payers, hospitals and surgery centers.

Prostate treatment services. Through HealthTronics, we also 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, (2) trans-urethral needle ablation, and (3) trans-urethral microwave therapy 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. In April 2008, HealthTronics acquired Advanced Medical Partners, Inc., which significantly expanded our cryosurgery partnership base. In July 2009, HealthTronics acquired Endocare Inc., which manufactures both the medical devices and the related consumables used by our cryosurgery operations and also provides 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. Benign prostate disease and cryosurgery cancer treatment services are billed in the same manner as our lithotripsy services, under either retail or wholesale contracts. We also provide services relating to operating the equipment, including scheduling, staffing, training, quality assurance, regulatory compliance and contracting.

Radiation therapy services. Through HealthTronics, we also provide IGRT technical services for cancer treatment centers. Our IGRT technical services may relate to providing the technical (non-physician) personnel to operate a physician practice group's IGRT equipment, leasing IGRT equipment to a physician practice group, providing services related to helping a physician practice group establish an IGRT treatment center or managing an IGRT treatment center. Since July 2, 2010 (the HealthTronics Acquisition Date), this business has contributed approximately \$2.6 million to our total revenues for the year ended December 31, 2010.

Anatomical pathology services. Through HealthTronics, we also provide anatomical pathology services primarily to the urology community. We have one pathology lab located in Georgia, HealthTronics Laboratory Solutions, Laboratories, that provides laboratory detection and diagnosis services to urologists throughout the United States. 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, we continue to 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. HealthTronics, through its Endocare acquisition, 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. We develop and manufacture these devices for the treatment of prostate and renal cancers, and we believe that our proprietary technologies may 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.

# 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 United States. Our competitors vary depending upon therapeutic and product categories. Competitors include many of the major brand name and generic manufacturers of pharmaceuticals, especially those doing business in the United States. In the market for branded pharmaceuticals, our competitors, including Abbott Laboratories, Johnson & Johnson, Cephalon, Inc., 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<sup>®</sup>. 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 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®, Opana® ER, and Sanctura XR®. For a full description of these competitive activities, including the litigation related to Paragraph IV filings, see Note 14 of 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. With the acquisition of Qualitest, 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 and 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 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.

In our device manufacturing operations, we compete with other manufacturers of minimally invasive medical devices in our markets. The primary competitors include Dornier MedTech GmbH, Siemens AG, Storz Medical, Richard Wolf GmbH, Direx and Galil Medical, Ltd.

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 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 revenues during the years ended December 31 are as follows:

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Cardinal Health, Inc.	<u>.</u>	33%	35% 36%
McKesson Corporation		28%	29% 31%
AmerisourceBergen Corporation		15%	16% 15%

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 five such agreements.

### Patents, Trademarks, Licenses and Proprietary Property

As of February 18, 2011, we held approximately: 155 U.S. issued patents, 70 U.S. patent applications pending, 483 foreign issued patents, and 223 foreign patent applications pending. In addition, as of February 18, 2011, we have licenses for approximately 69 U.S. issued patents, 12 U.S. patent applications pending, 165 foreign issued patents and 124 foreign patent applications pending. The following table sets forth information as of February 18, 2011 regarding each of our currently held material patents:

Patent No.	Patent Expiration*	Relevant Product	Ownership	Jurisdiction Where Granted
5,464,864	November 7, 2015	Frova®	Exclusive License	USA
5,616,603	April 1, 2014	Frova®	Exclusive License	USA
5,637,611	June 10, 2014	Frova®	Exclusive License	USA
5,827,871	October 27, 2015	Frova <sup>®</sup>	Exclusive License	USA
5,962,501	December 16, 2013	Frova®	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®	Exclusive License	USA
5,741,510	March 30, 2014	Lidoderm <sup>®</sup>	Exclusive License	USA
7,410,978	February 1, 2025	Sanctura XR®	Exclusive License	USA
7,759,359	November 4, 2024	Sanctura XR®	Exclusive License	USA
7,763,635	November 4, 2024	Sanctura XR®	Exclusive License	USA
7,781,448	November 4, 2024	Sanctura XR®	Exclusive License	USA
7,781,449	November 4, 2024	Sanctura XR®	Exclusive License	USA
5,292,515	March 8, 2011	Supprelin® LA and Vantas®	Owned	USA
5,662,933	September 9, 2013	Opana® ER	Owned	USA
5,958,456	September 9, 2013	Opana® ER	Owned	USA
7,276,250	February 4, 2023	Opana® ER	Owned	USA
2131647	September 8, 2014	Opana® ER	Owned	Canada
2208230	November 4, 2016	Opana® ER	Owned	Canada
2251816	April 18, 2017	Opana® ER	Owned	Canada

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.

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 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, included in the Consolidated Financial Statements 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. 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 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 United States;

- 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 facility or
  facilities to assess compliance with the FDA's current Good Manufacturing Practice (eGMP)
  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 25, 2010, 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 clinical trials gov website. The rule becomes 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 as 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 risk evaluation and mitigation strategies, or 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 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. Two products sold by Endo were included in the list of affected opioid drugs: Opana® ER and morphine sulfate 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. 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 NDA's 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 are implemented by the FDA, could impact 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 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 other periods of exclusivity may be available if the listed drug is indicated for use in a rare disease or is studied for pediatric indications.

#### Medical Device Regulation

Under the FFDCA, medical devices, such as those manufactured and marketed by HealthTronics, are classified into one of three classes—Class I, Class II or Class 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 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 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, and pre-market approval prior to marketing.

HealthTronics currently markets Class I and Class II medical devices. Most Class II devices require pre-market clearance by the FDA through the 510(k) pre-market notification process. When a 510(k) is required, the manufacturer must submit to the FDA a pre-market 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. All of our marketed devices have been cleared for marketing pursuant to the 510(k) process.

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 penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA's refusal to grant future pre-market 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 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 though 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 consideration 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. The extent to which the FDA will implement some or all of its planned action items 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 with 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.

We believe that we and our suppliers and outside manufacturers are currently in compliance with cGMP requirements.

Following a routine FDA inspection in September 2007 primarily in the area of drug safety, an FDA Form 483 Notice of Inspectional Observations was issued to us detailing two observations that were made by the inspector. The observations focused on procedures for handling product complaints and recordkeeping regarding adverse drug experiences for the required period of time. We provided to the FDA a comprehensive remediation plan which addressed the issues outlined in the observations, along with the timeline for completing the corrective actions. Implementation of the remediation plans was completed in January 2009. The FDA performed a follow up audit in June 2009 to verify the corrective actions outlined in the remediation plan. The inspection was concluded with no additional issues found.

#### 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 FFDCA, and failure to abide by these regulations can result in 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, sufentanil, 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 must annually apply to the DEA for procurement and production quotas in order to obtain and produce these substances. As a result, our quotas may not be sufficient to meet commercial demand or complete clinical trials. Moreover, the DEA may adjust these quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. 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 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 U.S. 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 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 makes major changes to the U.S. healthcare system.

While some provisions of the U.S. Health Reform Law go into effect this year, most of the provisions will not begin to be implemented until 2014 and beyond. Since implementation will be incremental to the enactment date of the law, there are still many challenges and uncertainties ahead. Such a comprehensive reform measure may require expanded implementation efforts on the part of federal and state agencies embark on rule-making to develop the specific components of their new authority. The Company is monitoring closely the implementation of the new law. In addition, the Company will continue to monitor attempts by Republicans to repeal, replace, or defund the U.S. Health 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 passage of the U.S. Health Reform Law is expected to result in a transformation of the delivery and payment for health care services in the United States. The combination of these measures will expand health insurance coverage to include an estimated 32 million Americans who have not been insured. 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 our products.

The overall impact of the U.S. Health Reform Law is uncertain. Changes to the Medicaid fee for service and Medicaid Managed Care plans drove the bulk of the impact on our business in 2010. There are a number of other

provisions in the legislation that, collectively, are expected to have a small impact, including an additional rebate for new formulations of oral solid dosage forms of innovator drugs, the expansion of 340B pricing and the revision of the definition of AMP by removing "retail pharmacy class of trade." These various elements of healthcare reform adversely impacted our total revenues by approximately \$20 million for the year ending December 31, 2010. Other elements will begin to have an effect in 2011. In particular, reducing the size of the Medicare Part D coverage gap (donut hole), and the payment of an annual fee based on branded prescription drug sales to specified government programs will both have an incremental effect next year. As a result, the overall impact of Healthcare reform in 2011 is expected to increase compared to 2010.

#### 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 United States, 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 such 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 of 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 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 or 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 of 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), and misrepresentations with respect to the services rendered. 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 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 U.S. Health Report Law also imposes federal "sunshine" provisions, requiring reporting of various types of payments to physicians and teaching hospitals, beginning with payments made in 2012.

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, 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 patient or any payor, including, without limitation, Medicare, for any DHS furnished by HealthTronics to a Medicare beneficiary, when the physician ordering the test, 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 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 government payor 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.

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, warehousing, distribution, customer service, certain financial functions, certain research and development activities and medical affairs. Our most significant service agreement is with UPS Supply Chain Solutions, Inc. For a complete description of these agreements, see Note 14 of the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

# 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 and finished goods. Our most significant agreements are with Novartis Consumer Health, Inc., Novartis AG, Teikoku Seiyaku Co., Ltd., Mallinckrodt Inc., Noramco, Inc., and Sharp Corporation. In addition, through our agreement with Ventiv Commercial Services, LLC, we maintain a contracted field force consisting of approximately 228 sales representatives, 24 district managers, one project manager, and one national sales director. 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 extend the term of our services agreement with Ventiv, it may have a material adverse effect on our business, financial condition, results of operations and cash flows.

For a complete description of these agreements, see Note 14 of 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 counterparties 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. "Acquisitions, License and Collaboration Agreements," included in the Consolidated Financial Statements 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 18, 2011, we had 2,947 employees, of which 288 are engaged in research and development and regulatory work, 800 in sales and marketing, 276 in quality assurance and 1,583 in general and administrative capacities. Our employees are not represented by unions, and we believe that our relations with our employees are good.

# **Executive Officers of the Registrant**

The following table sets forth information as of February 19, 2011 regarding each of our current executive officers:

Name	Age	Position and Offices
David P. Holveck	65	President and Chief Executive Officer and Director
Julie H. McHugh	46	Chief Operating Officer
Alan G. Levin	48	Executive Vice President, Chief Financial Officer
		Executive Vice President, Research and Development
Caroline B. Manogue	42	Executive Vice President, Chief Legal Officer and Secretary

# **Biographies**

Our executive officers are briefly described below:

DAVID P. HOLVECK, 65, 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, the Board of Directors of the Eastern Technology Council as well as the Board of Directors of Light Sciences Oncology, Inc., an oncology research company.

JULIE H. MCHUGH, 46, was appointed Chief Operating Officer in March 2010. Prior to joining Endo, Ms. McHugh was the Chief Executive Officer of Nora Therapeutics, Inc., a venture capital backed biotech start-up focused on developing novel therapies for the treatment of infertility disorders. Prior to joining Nora Therapeutics, she was Company Group Chairman for Johnson & Johnson's Worldwide Virology Business Unit where she led a growing area of the corporation's pharmaceutical business, including the global launches of PREZISTA® and INTELENCE® and oversight of an 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, and was responsible for the product development and commercialization of REMICADE®, a breakthrough therapeutic for Crohn's disease, rheumatoid arthritis and several other autoimmune disorders. 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 Visitors for the Smeal College of Business of the Pennsylvania State University, the Board of Directors for the Nathaniel Adamczyk Foundation, and was 2009 Chairman of the Board of Directors for the Pennsylvania Biotechnology Association.

ALAN G. LEVIN, 48, began as our 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; an Editorial Advisor for the *Journal of Accountancy*; and a member of the Advisory Board of Celtic Therapeutics, a private equity firm.

IVAN P. GERGEL, M.D., 50, was appointed Executive Vice President, Research & Development 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., managing more than 900 physicians, scientists and staff at the Research Institute. 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 and a member of PhRMA's Research and Development Executive Committee.

CAROLINE B. MANOGUE, 42, has served as our Executive Vice President, Chief Legal Officer and Secretary since 2004. Prior to joining Endo in 2000 as our 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. She has more than 15 years' experience in securities and M&A law. Ms. Manogue received her J.D. from Fordham Law School and her B.A. cum laude from Middlebury College. She is a member of the PhRMA Law Section Executive Committee and the Board of Trustees of the Healthcare Institute of New Jersey.

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 (intended to be an inactive textual reference only).

#### **Risks Related to Our Business**

We face intense competition, in particular from companies that develop rival products to our branded 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. 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 United States. In the market for branded pharmaceuticals, our competitors, including Abbott Laboratories, Johnson & Johnson, King Pharmaceuticals Inc., Cephalon, Inc., Pfizer, Inc., Purdue Pharma, L.P., Allergan, Inc. and Watson Pharmaceuticals Inc., vary depending on product category, dosage strength and drug-delivery systems. 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. It is possible that developments by our competitors will make our products or technologies uncompetitive or obsolete. Because we are smaller than many 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 existing products or new products we develop.

Our branded products face competition from generic versions. Generic versions are generally significantly cheaper than the branded version, and, where available, may be required or encouraged in preference to 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, including Percocet<sup>®</sup>, has had and will continue to have a material adverse effect on the net sales and profitability of our branded products.

Additionally, we compete to acquire the intellectual property assets that we require to continue to develop and broaden our product range. 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. 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 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 only to 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 company 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, or the conclusion of litigation in the generic's favor or expiration of the patent(s). If the litigation is so 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 patents in suit.

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. (together, Teikoku) received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) from Watson Laboratories, Inc. (Watson) advising of the filing of an ANDA for a generic version of Lidoderm® (lidocaine topical patch 5%). The Paragraph IV Certification Notice refers to U.S. Patent No. 5,827,529 (the '529 patent), which covers the formulation of Lidoderm<sup>®</sup>, 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, which would expire in June 2012. On March 4, 2010, Watson filed an Answer and Counterclaims, claiming the '529 patent is invalid or not infringed. Litigation is inherently uncertain and we cannot predict the outcome of our case against Watson. If Watson wins this lawsuit and is able to obtain FDA approval of its product, it may be able launch its generic version of Lidoderm® prior to the '529 patent's expiration in 2015. Additionally, it is possible that another generic manufacturer would seek to launch a generic version of Lidoderm® and challenge the '529 patent. For a complete description of the related legal proceeding see Note 14 of the Consolidated Financial Statements included in Part IV, Item 15 of this Report.

In October 2010, Teikoku obtained a license to U.S. Patent No. 5,741,510 (the '510 patent) and subsequently listed this patent in the FDA's Orange Book. The '510 patent expires in March 2014. The '510 patent is currently the subject of litigation in the United States District Court for the Eastern District of Texas (LecTec Corporation v. Chattem, Inc., et al., Civil Action No. 5:08-CV-00130-DF), and although neither the Company nor Teikoku is a party to that litigation, if the litigation is decided in a manner adverse to the '510 patent (i.e., the patent is found invalid), the '510 patent may be of limited utility to us in the future in preventing the introduction of generic versions of Lidoderm<sup>®</sup>. Likewise, if Watson or any other generic manufacturer certifies against the '510 patent and subsequently succeeds in proving noninfringement, invalidity, or unenforceability of the '510 patent and is able to obtain FDA approval of its product, such manufacturer may be able launch its generic version of Lidoderm® prior to the '510 patent's expiration in 2014. In addition to the '529 and '510 patents, the Company also holds a license from Hind Health Care, Inc. to U.S. Patent Nos. 5,411,738 and 5,601,838 (the Hind patents), both of which are listed in the FDA's Orange Book for Lidoderm®. The Hind patents will expire in May 2012. Watson presumably submitted a Paragraph III certification with respect to the Hind patents, which indicated that it would not introduce its generic Lidoderm® product prior to the expiration of those patents. It is possible, however, that another generic manufacturer seeking approval of a generic version of Lidoderm® could challenge the Hind patents.

In January 2011, the Company and Teikoku received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) from Mylan Technologies Inc. (Mylan) advising of the filing of an ANDA for a generic version of Lidoderm<sup>®</sup> (lidocaine topical patch 5%). The Paragraph IV Certification Notice refers to the '510 patent and the '529 patent. The Company is currently reviewing the details of this notice from Mylan and will pursue all

available legal and regulatory pathways in defense of Lidoderm<sup>®</sup>. If we are unsuccessful, however, and Mylan is able to obtain FDA approval of its product, it may be able to launch its generic version of Lidoderm<sup>®</sup> prior to the applicable patents' expirations in 2014 and 2015. Additionally, it is possible that another generic manufacturer would seek to launch a generic version of Lidoderm<sup>®</sup> and challenge the applicable patents.

Notwithstanding the foregoing patent litigation, even if Watson or Mylan or any other generic manufacturer were to be successful with respect to 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 Lidoderm®. In December 2006, the Division-of Bioequivalence, Office of Generic Drugs, Center for Drug Evaluation and Research (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 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®, 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, in order to assure that the generic product has the same labeling, efficacy and safety profile as Lidoderm<sup>®</sup>. 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; those comments 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 they too intend, to vigorously defend Lidoderm®'s intellectual property rights 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. 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.

We currently anticipate that Lidoderm® will represent a decreasing percentage of our annual sales without taking into account any potential future business development transactions. However, if a generic version of Lidoderm® were introduced to the market before 2015, our revenues from Lidoderm® would decrease significantly and, depending on the timing of such introduction and its effect on Lidoderm® pricing, could have a material adverse effect on our business, results of operations, financial condition and cash flows as well as our stock price.

The Company is also aware of various ANDA filings containing Paragraph IV certifications under 21 U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release tablets. For a complete description of these and other legal proceedings, see Note 14 of the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

## 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 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.

#### Most of our total revenues come from a small number of products.

The following table displays our revenues by product category and as a percentage of total revenues for the years ended December 31 (dollars in thousands):

	2010		2009		2008		
	\$	%	\$	%	\$	%	
Lidoderm®	782,609	46	\$ 763,698	52	\$ 765,097	61	
Opana® ER and Opana®	299,080	17	230,631	16	180,429	· 14	
Percocet®	121,347	7	127,090	9	129,966	10	
Voltaren® Gel	104,941	6	78,868	5	23,791	. 2	
Frova®	59,299	3	57,924	4	58,017	5	
Supprelin® LA	46,910	3	27,822	-2			
Other brands	53,386	3	50,077	3	10,904	<u>1</u>	
Total brands*	1,467,572	86	1,336,110	91	1,168,204	93	
Total generics	146,513	9	124,731	9	92,332	7	
Total devices and service revenue	102,144	6		_	·		
Total revenues*	1,716,229	100	\$1,460,841	100	\$1,260,536	100	

<sup>\* -</sup> 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 from 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 our proprietary technology, which is vital to our business, is uncertain.

Our success, competitive position and amount of 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 that we may develop in the future. Our policy is to seek patent protection and 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 advance is made that 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 (PTO) 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 United States than abroad. Foreign patents may be more difficult to protect and/or the remedies available may be less extensive than in the United States. 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 those patents internationally. 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 that we were the first creator of the inventions covered by 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 with patents or patent applications we have obtained or licensed for our use, 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 upon 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 or that competitors will not know of, 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. Moreover, we cannot assure you that our technology does not infringe upon any valid claims of patents that other parties own.

In the future, if we were found to be infringing on a patent, we might have to seek a license 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. Despite the use of confidentiality agreements and non-compete agreements, which themselves may be of limited effectiveness, 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.

Companies may not promote drugs for "off-label" uses – that is, uses that are not described in the product's labeling and that differ from those approved by the FDA. Under what is known as the "practice of medicine," physicians and other healthcare practitioners may prescribe drug products 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 or treatments, the Federal Food, Drug and Cosmetic Act (FFDCA) and FDA regulations significantly restrict permissible communications on the subject of off-label uses of drug products by pharmaceutical companies. The FDA, the Office of Inspector General of the Department of Health and Human Services (OIG), and the Department of Justice (DOJ) 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. 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 caselaw allow companies to engage in some forms of truthful, non-misleading, and non-promotional speech concerning 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 or the DOJ 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, management's attention could be diverted from our business operations and our reputation could be damaged.

In January 2007, we received a subpoena issued by the OIG. The subpoena requests documents relating to Lidoderm® (lidocaine patch 5%) focused primarily on the sale, marketing and promotion of Lidoderm®. We are cooperating with the government. 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. 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, 2010, goodwill and other intangibles comprised approximately 57% of our total assets. Goodwill and other intangible assets are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually.

Events giving rise to impairment are an inherent risk in the pharmaceutical industry 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 goodwill or other intangible assets occur.

## We may incur liability if our continuing medical or health education programs and/or product promotions are determined, or are perceived, to be inconsistent with regulatory guidelines.

The FDA regulations and the Anti-Kickback Statutes provide guidelines with respect to the type and scope of appropriate product promotion and continuing medical and health education activities. Although we endeavor to follow these regulations, should it be determined that we have not appropriately followed the guidelines, 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.

#### 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. 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. 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 U.S. 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. We seek to comply with anti-kickback statutes and to fit 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 U.S. federal healthcare programs (including Medicaid and Medicare). Any such violations 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 products to ensure that such claims are true, not misleading, supported by scientific evidence and consistent with the product's approved 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, civil and criminal sanctions.

Also, the federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from, the federal 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. Federal and state authorities and private whistleblower plaintiffs recently have brought actions against drug and device manufacturers alleging that the manufacturers' activities constituted aiding and abetting healthcare providers in the submission of false claims, alleging that the manufacturers themselves made false or misleading statements to the federal government, or alleging that the manufacturers improperly promoted their products for "off-label" uses not approved by the FDA, or pursuant to inducements prohibited by the federal Anti-Kickback Statute. Such investigations or litigation 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 provisions, 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®, 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®, faces or did face numerous lawsuits, including class action lawsuits, related to OxyContin® misuse or abuse. We may be subject to litigation similar to the OxyContin® suits related to any narcotic-containing product that we market.

The FDA or the U.S. Drug Enforcement Administration (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 (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. 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.

In December 2007, we entered into a license, development and supply agreement with Grünenthal AG for the exclusive clinical development and commercialization rights in Canada and the United States for a new oral formulation of long-acting oxymorphone (an opioid), which is designed to be crush resistant. In July 2010, we filed an NDA with the FDA for a new extended-release formulation of oxymorphone, which is a semi-synthetic opioid analysesic intended for the treatment of moderate to severe chronic pain in patients requiring continuous. around-the-clock opioid treatment for an extended period of time. The NDA submission is based on a non-clinical and clinical development program designed to demonstrate the crush-resistant properties of this formulation of oxymorphone. In September 2010, we received notification from the FDA that this NDA has been granted priority review status. In November 2010, we were informed by the FDA that it no longer saw a need to convene a public advisory committee meeting to review our NDA, which the FDA had previously contemplated as a joint meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. In January 2011, we received a complete response letter from the FDA. The letter did not require that additional clinical studies be conducted for approval of the NDA. We have begun to address the issue described in the complete response letter and will work closely with the FDA to finalize our response. We are confident that we can address the issue set forth, currently anticipate responding to the FDA by mid 2011 and would expect a six month review cycle once our response is filed.

### 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 United States, 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 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, 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 (PMA) from the FDA, unless an exemption applies. In the 510(k) 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 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.

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, 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. Meeting regulatory requirements and evolving government standards may delay marketing of our new products for a considerable period of time, to impose costly procedures upon our activities and result in a competitive advantage to larger companies that compete against us.

We cannot assure you that the FDA or other regulatory agencies will approve 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 are sometimes more stringent than those that were applied in the past. For example, the FDA is currently evaluating the 510(k) process for clearing medical devices and may make substantial changes to industry requirements, including which devices are eligible for 510(k) clearance, the ability to rescind previously granted 510(k) clearances and additional requirements that may significantly impact the process. 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 (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 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 using 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 United States. 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," or 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 (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 (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. To date, the FDA has not responded, and the matter remains open.

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. See also "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 could have an adverse effect on the sales of these products. 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 ensure that the benefits of the drugs continue to outweigh the risks. The FDA has authority to require a REMS under the FDAAA when necessary to address whether the benefits of these products continue to outweigh the risks. In addition, on September 27, 2007, Congress re-authorized requirements for testing drug products in children, which may increase the time and cost necessary for new drug development. 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 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 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 NDA's 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.

# 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 products, other than generic products, 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. Even promising results from preclinical and early clinical studies do not always accurately predict results in later, large scale trials. A failure to demonstrate safety and efficacy would result in our failure to obtain regulatory approvals.

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. 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. 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 other regulatory agencies will approve 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. Any limitation on use imposed by the FDA or delay in or failure to obtain FDA approvals of products developed by us would adversely affect the marketing of these products and our ability to generate product revenue, as well as adversely affect the value of our securities.

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.

Acquisitions, such as the recent Indevus, HealthTronics, Penwest and Qualitest 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 in accordance with FDA regulations. Much of our 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.

# We face 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). 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 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 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 competition from other pharmaceutical companies.

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. 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.

#### We face intense competition from other manufacturers of generic versions of our generic products.

Our generic products compete with branded products and with generic versions made by or for other manufacturers, such as Mallinckrodt Inc. and Watson Pharmaceuticals, Inc. When additional versions of one of our generic products enter the market, we generally lose market share and our selling prices and margins on the 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.

# 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 FFDCA, 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 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 recall 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 resulting in costs connected to the recall and loss of revenue.

We have acquired Qualitest, and Qualitest is named as a defendant in a number of cases that have been filed in various state and federal courts that allege plaintiffs experienced injuries as a result of ingesting the prescription medicine metoclopramide, which is and has been manufactured and marketed by Qualitest. Many of these cases are in the discovery phase of the litigation, and certain cases have been scheduled for trial in the Fall of 2011. We may be subject to liabilities arising out of these cases, and will be 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 in the future. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against Qualitest. Subject to certain terms and conditions, we will be indemnified by the former owners of Qualitest with respect to, among other things, metoclopramide 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.

We cannot assure you that a product liability claim or series of claims brought against us would not have an 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.

# 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 and may in the future be the subject of similar cases. Depending on developments in the 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 assure you that 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, 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 (Medicare Modernization Act) of 2003 created a new prescription drug coverage program for people with Medicare through a new system of private market insurance providers beginning in January 2006. This 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, Medicare is not obligated to pay for drugs omitted from a formulary, 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. Further, since 2006, Medicare prescription drug program beneficiaries are not permitted to purchase private insurance policies, known as "Medigap" policies, to cover the cost of off-formulary medications. If our products are or become excluded from these formularies, 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 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 United States;
- 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 (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 (together, 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 Risk Factor – "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."

Our reporting and payment obligations under the Medicaid rebate program and other governmental 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 and the Federal Criminal False Claims Act, the former of 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 may result in payment of fines or exclusion from the Medicare, Medicaid, and/or other government healthcare programs.

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 under Medicaid. We intend to defend these lawsuits vigorously. 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. See "Legal proceedings" in Note 14 of the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K. 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 reporting and payment obligations are complex and we are continually evaluating the methods we use to calculate and report the amounts owed with respect to Medicaid and other government pricing programs. Our calculations are subject to review and 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 our processes for these calculations and our judgments supporting these calculations involve, and will continue to involve, subjective decisions, 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 fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from 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—and even in the absence of such ambiguity—a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. Any such penalties or sanctions 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.

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:

	<u> 2010</u>	2009	2008
Cardinal Health, Inc.	33%	35%	36%
McKesson Corporation	28%	29%	31%
AmerisourceBergen Corporation	15%	16%	15%

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.

We are currently dependent on outside manufacturers for the manufacture of a significant amount of our products; therefore, we will 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 one or more of our products. 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. In addition to FDA and DEA regulation, violation of standards enforced by the Environmental Protection Agency (the 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. pursuant to which Novartis Consumer Health Inc. has agreed to manufacture certain of our commercial products in addition to products in development. On February 23, 2011, we gave notice to Novartis that we would terminate this agreement effective February 2014. As of December 31, 2010, we are required to purchase a minimum of approximately \$14 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.

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 United States. 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 \$32 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.

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 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 these suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

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

If the manufacturing facilities we own as a result of our acquisition of Qualitest are unable to manufacture the Qualitest products or the manufacturing process is interrupted due to failure to comply with regulations or for other reasons, the manufacture of those products could be interrupted.

In November 2010, we acquired Qualitest's pharmaceutical manufacturing facilities located in Huntsville, Alabama and Charlotte, North Carolina (the Qualitest facilities). The Qualitest facilities currently manufacture many of the Qualitest products that we acquired. Because the manufacture of pharmaceutical products 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 for the manufacture of new products or for other products that are currently manufactured for us by third parties.

Failure by the Qualitest facilities to comply with regulatory requirements could adversely affect their ability to supply products to us. All facilities and manufacturing techniques used for the manufacture of pharmaceutical products must be operated in conformity with current Good Manufacturing Practices, or cGMPs. Compliance with the FDA's cGMP 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 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 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 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.

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, sufentanil 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 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, 2010, \$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.

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 2010, 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. However, based on our ability to access our cash and cash equivalents and our other liquid investments, and our expected operating cash flows, we do not expect to be required to sell these securities at a loss. However, there can be no assurance that we will not have to sell these securities at a loss.

## 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 five 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 United States, and product liability lawsuits related to pharmaceuticals, 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 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.

#### We are a holding company with no operations.

We are a holding company with no direct operations. Our principal assets are the equity interests we hold in our operating subsidiaries. As a result, we are dependent on loans, dividends and other payments from our subsidiaries to generate the funds necessary to meet our financial obligations. Our subsidiaries are legally distinct from us and have no obligation to make funds available to us.

# 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, for the twelve months ended December 31, 2010, our stock traded between \$19.19 and \$38.20 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<sup>®</sup>;
- developments concerning our or others' proprietary rights, including patents;
- · competitors' publicity regarding actual or potential products under development;
- regulatory developments in the United States and foreign countries, or announcements relating to these matters;
- period-to-period fluctuations in our financial results;
- new legislation in the United States 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 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 that the results of studies and clinical trials be provided by the investigator to the National Institutes of Health (NIH) for inclusion in a publicly-available database registry of clinical trials. There is an exception for clinical research performed on behalf of a sponsor who has not yet submitted an NDA in connection with the drug being studied; however, it is unclear what impact the potential publication of clinical research data for our products will have.

#### Actions that may be taken by significant stockholders may divert the time and attention of our board of directors and management from our business operations.

Campaigns by significant investors to effect changes at publicly traded companies have increased in recent years. In August 2007, affiliates of D.E. Shaw & Co., L.P., which, as of October 1, 2010, collectively beneficially own approximately 5 million shares of our outstanding common stock, sent letters to our Board of Directors suggesting, among other things, that the Company begin a process of evaluating strategic alternatives and explore a recapitalization. In April 2008, we reached an agreement with the D. E. Shaw group, pursuant to which Endo's Board of Directors nominated William F. Spengler at the 2008 Annual Meeting of Stockholders to serve as a member of the Company's Board of Directors. Mr. Spengler is an independent unaffiliated person who was recommended by D.E. Shaw to our Board of Directors. The D. E. Shaw group agreed to vote all of its shares in favor of the election of each of the Board's nominees at our 2008 Annual Meeting of Stockholders. At the 2008 Annual Meeting of Stockholders, the Company stockholders elected Mr. Spengler as a director of the Company. The D.E. Shaw group is no longer subject to any restrictions with respect to its shares in the Company.

If a proxy contest were to be pursued by any of our stockholders, it could result in substantial expense to the Company and consume significant attention of our management and Board of Directors. In addition, there can be no assurance that any stockholder will not pursue actions to effect changes in the management and strategic direction of the Company, including through the solicitation of proxies from the Company's stockholders.

# The regulatory approval process outside the United States 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 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 United States. To market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals 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 in this Annual Report on Form 10-K 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. Other than the approval of Vantas® for marketing in the European Union and certain other foreign jurisdictions, we may not be able to file for regulatory approvals or may not receive necessary approvals to commercialize our products in any foreign market. 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.

#### 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 Laboratories 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 brand pharmaceutical companies and generic pharmaceutical companies are facing increased government scrutiny in both the United States 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 their 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 Federal Trade Commission (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 are trying to pass legislation that would limit the types of settlement agreements generic manufacturers can enter into with brand companies. The impact of such pending litigation 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 United States. 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 manufacturers' price (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 2018);
- a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions (effective January 1, 2013);
- new requirements to report certain financial arrangements with physicians and others, including reporting any "transfer of value" made or distributed to prescribers and other healthcare providers 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);
- 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, beginning in 2014, 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
- 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).

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 and Qualitest.

The success of our recent acquisitions of HealthTronics, Penwest, and Qualitest 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 and Qualitest. If we are not able to successfully integrate certain aspects of these companies, 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 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.

# Third party payors could refuse to reimburse healthcare providers for use of HealthTronics' current or future service offerings and 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. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Lithotripsy treatments 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 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 to modify the way in which it operates the business.

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

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations 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 (HITECH), included in the American Recovery and Reinvestment Act of 2009, 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 health data security breaches, 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 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 legislation and several regulatory initiatives at the state and federal levels address patient privacy concerns. New federal legislation extensively regulates the use and disclosure of individually identifiable health-related information and the security and standardization of electronically maintained or transmitted health-related information. We do not yet know the total financial or other impact of these regulations on us. Continuing compliance with these regulations will likely require us to spend substantial sums, including, but not limited to, purchasing new computer systems, which could negatively impact financial results. Additionally, if we fail to comply with the privacy laws and regulations, 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.

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 law. 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 or other changes in the administration of or interpretation of existing legislation 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. However, 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 could be adversely affected by special risks and requirements related to its medical products manufacturing business.

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

- the need to comply with applicable federal Food and Drug Administration and foreign regulations
  relating to good manufacturing practices and medical device approval 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;
- · 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.

## We are 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 (CLIA) and associated regulations and anti-markup regulations, reassignment regulations, and Medicare usual charge regulations. Among the applicable state laws and regulations are 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 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 also 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. 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.

#### Penwest is dependent on a limited number of suppliers for the gums used in its TIMERx materials.

Penwest's TIMERx drug delivery systems are based on a hydrophilic matrix combining a heterodispersed mixture primarily composed of two polysaccharides, xanthan gum and locust bean gum, in the presence of dextrose. These gums are also used in Penwest's Geminex, gastroretentive and SyncroDose drug delivery systems. Penwest purchases these gums from a primary supplier. Penwest has qualified, or is in the process of qualifying, alternate suppliers with respect to such materials, but it can provide no assurance that interruptions in supplies will not occur in the future. TIMERx is the extended-release technology used in Opana® ER. Any interruption in TIMERx supply could have a material adverse effect on our sales of Opana® ER.

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

We currently have a moderate amount of indebtedness. As of December 31, 2010, we have total debt of approximately \$1,184.7 million, consisting of \$400.0 million of borrowings under the five-year senior secured term loan facility (the Term Loan Facility), \$400.0 million of 7.00% Senior Notes due 2020 (the Senior Notes), and \$384.7 million of other debt, representing the aggregate principal amounts. Additionally, we have unused availability under the five-year senior secured revolving credit facility (the Revolving Credit Facility and, together with the Term Loan Facility, the 2010 Credit Facility) of up to \$500.0 million, not including an up to \$200.0 million expansion option available under the Revolving Credit Facility, for total unused availability of up to \$700.0 million under the 2010 Credit Facility if the expansion option is exercised. Our 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.

We may also incur additional indebtedness in the future. For a description of our indebtedness, see Note 18 of the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

#### 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 indebtedness pursuant to the expansion option under our Revolving Credit Facility. The terms of the indenture will limit, but not prohibit, us or our subsidiaries from incurring additional indebtedness. 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 agreements governing our 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;
- 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.

# Our failure to comply with the agreements relating to our outstanding indebtedness, including as a result of events beyond our control, could result in a 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 crossacceleration of other debt agreements. 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 are 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 our 2010 Credit Facility. If the lenders under our 2010 Credit Facility accelerate the repayment of borrowings, we may not have sufficient assets to repay the obligations outstanding under our 2010 Credit Facility and our other indebtedness, including the Senior Notes. Furthermore, our borrowings under our 2010 Credit Facility are, and are expected to continue 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 of the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

# 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 other 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 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 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 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 our business, financial condition and other results of operations.

#### Item 1B. Unresolved Staff Comments

Not applicable.

#### Item 2. Properties

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

Property	Location	Purpose	Square Footage	Ownership
Painter's Crossing One Associates, L.P.(1)	Chadds Ford,	Corporate	approximately	Leased
	Pennsylvania	Headquarters	47,756 square feet	•
Painter's Crossing Two Associates, L.P.(2)	Chadds Ford,	Corporate	approximately	Leased
	Pennsylvania	Headquarters	64,424 square feet	
Painter's Crossing Three Associates, L.P.(3)	Chadds Ford,	Corporate	approximately	Leased
	Pennsylvania	Headquarters	48,600 square feet	
Brandywine Seven(4)	Chadds Ford,	Corporate	approximately	Leased
	Pennsylvania	Headquarters	23,949 square feet	•
177 Cantiaque Rock Road LLC(5)	Westbury, New	Research and	approximately	Leased
	York	Development	24,190 square feet	
Cedar Brook LP(6)	Cranbury, New	Distribution /	approximately	Leased
	Jersey	Manufacturing	51,000 square feet	
HEP Davis Spring, L.P.(7)	Austin, Texas	HealthTronics	approximately	Leased
	7	Headquarters and	67,405 square feet	
		Manufacturing /		
		Service		
•		Center		
Qualitest Building	Huntsville,	Qualitest	approximately	Owned
	Alabama	Headquarters /	280,000 square feet	
•		Distribution	P( )	•
Vintage Pharmaceuticals, LLC liquids	Huntsville,	Distribution /	approximately	Owned
formulation facility	Alabama	Manufacturing /	180,000 square feet	
		Laboratories	4 - 4	: '
Vintage Pharmaceuticals, LLC tablets	Huntsville,	Distribution /	approximately	Owned
manufacturing facility	Alabama	Manufacturing /	309,000 square feet	
		Laboratories		
Charlotte Building	Charlotte, North	Distribution /	approximately	Owned
	Carolina	Manufacturing /	60,000 square feet	i
And the second s	4	Laboratories		***
Charlotte Warehouse(8)	Charlotte, North	Distribution	approximately	Leased
	Carolina		58,000 square feet	

<sup>(1) -</sup> Lease term ends August, 2012

<sup>(2) -</sup> Lease term ends January, 2015

<sup>(3) -</sup> Lease term ends March, 2018

<sup>(4) -</sup> Lease term ends January, 2015

<sup>(5) -</sup> Lease term ends May, 2013

<sup>(6) -</sup> Lease term ends March, 2015

<sup>(7) -</sup> Lease term ends September, 2015

<sup>(8) -</sup> Lease term ends May, 2021

#### Item 3. Legal Proceedings

The disclosures under Note 14, Commitments and Contingencies-Legal Proceedings, included in the Consolidated Financial Statements 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. (Removed and Reserved)

#### **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.

		Common ock
	High	Low
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
Year Ending December 31, 2009		
1st Quarter	\$26.14	\$16.29
2nd Quarter	\$18.55	\$15.75
3rd Quarter	\$23.37	\$16.81
4th Quarter	\$24.10	\$19.11

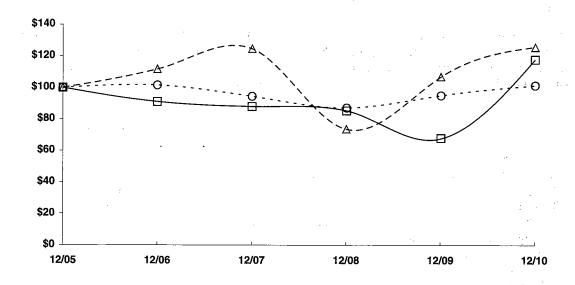
Holders . As of February 18, 2011, we estimate that there were approximately 57 record holders of our common stock.

Dividends. We have never declared or paid any cash dividends on our capital stock. In November 2010, 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 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. We also 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 million aggregate principal amount of 7.00% Senior Notes due 2020 (the Senior Notes). Subject to certain limitations, we are permitted to pay dividends under the 2010 Credit Facility and the indenture governing the Senior Notes.

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, 2005 and ending December 31, 2010. The graph assumes \$100 invested on December 31, 2005 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.

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

Among Endo Pharmaceuticals Holdings Inc., The NASDAQ Composite Index
And The NASDAQ Pharmaceutical Index



— Endo Pharmaceuticals Holdings Inc. — △ – NASDAQ Composite - · · · · · · · NASDAQ Pharmaceutical

\*\$100 invested on 12/31/05 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

	December 31,					
	2005	2006	2007	2008	2009	2010
Endo Pharmaceuticals Holdings Inc	\$100.00	\$ 91.14	\$ 88.14	\$85.53	\$ 67.81	\$118.01
NASDAQ Composite Index	\$100.00	\$111.74	\$124.67	\$73.77	\$107.12	\$125.93
NASDAQ Pharmaceutical Index	\$100.00	\$101.61	\$ 94.58	\$87.40	\$ 95.29	\$101.44

Recent sales of unregistered securities; Use of proceeds from registered securities. During the fourth quarter of 2010, the Company did not sell any unregistered securities.

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, 2010:

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, 2010 to October 31,-2010	_	\$ —		\$266,209,864
November 1, 2010 to November 30,				the first of
2010		_	.:	266,209,864
December 1, 2010 to December 31,				
2010		_	_	266,209,864
Total	<u> </u>	\$		\$266,209,864

#### 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.

As A control of the c	Year Ended December 31,							. *	
		2010		2009	-	2008		2007	2006
	-	· ·	(de	ollars in thou	ısar	ds, except pe	r sh	are data)	
Consolidated Statement of Operations Data:									• • .
Total revenues	\$1	,716,229	\$	1,460,841	\$	1,260,536	\$1	1,085,608	\$909,659
Operating income		465,366 420,698		390,024 359,660		387,474 391,828		317,226 353,250	210,529 233,734
Consolidated net income  Less: Net income attributable to	. <b>\$</b>	287,020	\$	266,336	\$	255,336	\$	227,440	\$137,839
noncontrolling interests  Net income attributable to Endo	-	28,014			_	4	_		
Pharmaceuticals Holdings Inc.	\$	259,006	\$	266,336	\$	255,336	\$	227,440	\$137,839
Basic and Diluted Net Income Per Share Attributable to Endo Pharmaceuticals Holdings Inc.:					-			٠	
Basic	\$	2.23	\$	2.27	\$	2.07	\$	1.70	\$ 1.03
Diluted	\$	2.20	\$	2.27	\$	2.06	\$	1.69	\$ 1.03
share attributable to Endo Pharmaceuticals						1			
Holdings Inc.  Shares used to compute diluted net income per share attributable to Endo Pharmaceuticals		116,164		117,112		123,248		133,903	133,178
Holdings Inc	<b>\$</b> :	117,951	\$	117,515	\$	123,720	\$	134,525	133,911 \$ —

	As of and for the Year Ended December 31,							
	2010	2009	2008	2007	2006			
		(do	ollars in thousan	ds)				
Consolidated Balance Sheet Data:								
Cash and cash equivalents	\$ 466,214	\$ 708,462	\$ 775,693	\$ 350,325	\$ 628,085			
Total assets	3,912,389	2,488,803	1,908,733	1,702,638	1,396,689			
Long-term debt, less current portion, net	1,045,801	322,534	243,150	_				
Other long-term obligations, including					-			
capitalized leases	327,431	196,678	71,999	13,390	17,602			
Total Endo Pharmaceuticals Holdings Inc.								
stockholders' equity	\$1,741,591	\$1,497,411	\$1,207,111	\$1,292,290	\$1,040,988			
Noncontrolling interests	61,738		_					
Total stockholders' equity	\$1,803,329	\$1,497,411	\$1,207,111	\$1,292,290	\$1,040,988			
Other Financial Data:	-							
Net cash provided by operating activities	\$ 453,646	\$ 295,406	\$ 355,627	\$ 365,742	\$ 345,334			
Net cash (used in) provided by investing								
activities	(896,323)	(245,509)	179,807	(614,528)	(66,449)			
Net cash provided by (used in) financing			2.4		*			
activities	\$ 200,429	\$ (117,128)	\$ (110,066)	\$ (28,974)	\$ (151,756)			

#### 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, this Report, including the following discussion, 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

Endo Pharmaceuticals Holdings Inc., which we refer to as "Endo", "we", "us", or the "Company", is a United States-based, specialty healthcare solutions company focused on branded products and generics, and devices and services. Endo is redefining its 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. Most recently, we have moved in this direction through our acquisition of Qualitest, which expands and diversifies our generic drug product offerings and enhances our pain management portfolio, and through our acquisition of HealthTronics, which has expanded and diversified our reach as a provider of healthcare services and medical devices and our presence in urology.

We have a portfolio of branded pharmaceuticals that includes established brand names such as Lidoderm®, Opana® ER and Opana®, Percocet®, Frova®, Voltaren® Gel, Vantas®, Valstar®, and Supprelin® LA. Branded products comprised approximately 86% of our revenues in the year ended December 31, 2010, with 46% of our revenues coming from Lidoderm®. Our non-branded generic portfolio, which accounted for 9% of revenues in the year ended December 31, 2010, currently consists of products primarily focused in pain management. We 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. Revenue from our devices and services portfolio accounted for the remainder of our revenues for the year ended December 31, 2010. We generated total revenues of \$1.72 billion for the year ended December 31, 2010.

In November 2010, we acquired Qualitest, a leading United States based privately-held generics company. As a combined company, we expect to deliver more comprehensive healthcare solutions across our diversified businesses in Branded Pharmaceuticals, Generics, and Devices and Services in key therapeutic areas including pain and urology. Qualitest, the sixth largest U.S. generics company, as measured by prescriptions filled in the year ended December 31, 2010, is focused on cost-competitive, high-quality manufactured products with cost advantages or with high barriers to entry. We believe Qualitest brings critical mass to our current generics business, further diversifies our business lines and product offerings and enhances our portfolio of pain management products.

In July 2010, we completed our acquisition of HealthTronics, a provider of healthcare services and manufacturer of medical devices, primarily for the urology community. In September 2010, we acquired Penwest, a drug development company.

Financial information presented herein reflects the operating results of HealthTronics from July 2, 2010, Penwest from September 20, 2010, and Qualitest from November 30, 2010.

In February 2009, we completed our acquisition of Indevus, a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology, endocrinology and oncology. Indevus' approved products include Sanctura® and Sanctura XR® for OAB, which are promoted in the United States by Allergan, Inc., Vantas® for advanced prostate cancer, Supprelin® LA for CPP, Delatestryl® for the treatment of hypogonadism and Valstar® for bladder cancer. We also acquired from Indevus a core urology and endocrinology portfolio containing multiple compounds in development including Aveed TM for hypogonadism and the octreotide implant for acromegaly and carcinoid syndrome. Financial information presented herein reflects the operating results of Indevus from February 23, 2009.

We have dedicated sales forces in the United States, consisting of 493 Endo pharmaceutical sales representatives and 228 sales contracted representatives focusing primarily on pain products, 81 Endo sales representatives focusing primarily on bladder and prostate cancer products, 34 Endo medical center representatives focusing on the treatment of central precocious puberty and 51 Endo account executives focusing on managed markets customers. We market our branded pharmaceuticals to primary care physicians and specialty physicians, including those specializing in pain management, orthopedics, neurology, rheumatology, surgery, anesthesiology, urology and pediatric endocrinology. Our sales force also targets retail pharmacies and other healthcare professionals throughout the United States.

## 2010—A Year in Review

During 2010, we achieved record revenues and further diversified our Branded Pharmaceuticals, Generics, and Devices and Services businesses in key therapeutic areas, including pain management and urology. We executed on our growth strategy by acquiring Qualitest, a leading generics pharmaceutical company and HealthTronics, a provider of healthcare services and manufacturer of medical devices primarily for the urology community. Our acquisition of Penwest contributed to our core pain management franchise and will permit us to maximize the value of our Opana® ER franchise. Additionally, in December 2010, the FDA approved Fortesta<sup>TM</sup> Gel as a treatment for men suffering from low testosterone (Low T), also known as hypogonadism. The approval of Fortesta<sup>TM</sup> Gel reinforces our commitment to men's health by providing an important new treatment option for millions of men with Low T. In 2010, we were committed to our strategy of delivering more comprehensive healthcare solutions across our diversified businesses.

Revenues for the year ended December 31, 2010 were \$1.72 billion, a 17.5% increase over 2009, with net income attributable to Endo Pharmaceuticals Holdings Inc. in 2010 of \$259.0 million, or \$2.20 per diluted share, as compared to \$266.3 million or \$2.27 per diluted share in 2009. 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 acquisitions of both HealthTronics and Qualitest, which contributed \$102.1 million and \$30.3 million, respectively, to our total 2010 revenue. Also 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.

#### **Business Environment**

The Company conducts its business within the pharmaceutical 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 third-party manufacturing operations, and research and development of new products. To successfully compete 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. The Company manufactures branded products, which are priced higher than generic products. Generic competition is one of the Company's leading challenges. Similarly, the Company competes with other providers of the 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 exclusivity loss, 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 of 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, 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 United States. 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 United States 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.

The Company has maintained a competitive position in the market and strives to uphold this position, which is dependent on its success in discovering and developing innovative, cost-effective products that serve unmet medical need.

#### 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 United States.

While some provisions of the new healthcare reform law go into effect this year, most of the provisions will not begin to be implemented until 2014 and beyond. Since implementation will be incremental to the enactment date of the law, there are still many challenges and uncertainties ahead. Such a comprehensive reform measure may 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 of the new law. In addition, the Company will continue to monitor attempts to repeal, replace, or defund the U.S. Health 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 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.

The overall impact from healthcare reform reflects a number of uncertainties. Nevertheless, we believe that changes to the Medicaid fee for service program and Medicaid Managed Care plans drove the bulk of our impact in 2010. There are a number of other provisions in the legislation that collectively are expected to have a small impact, including originator AMP for new formulations, the expansion of 340B pricing and the revision of the AMP definition (effective October 1, 2010) to remove physician class of trade. These various elements of healthcare reform adversely impacted our total revenues by approximately \$20 million for the year ending December 31, 2010. Other elements will affect us during 2011. In particular, reducing the size of the donut hole in Medicare Part D coverage by 50% and the payment of an annual fee based on branded prescription drug sales to specific government programs will both have an incremental effect next year. As a result, the overall impact of Healthcare reform in 2011 is expected to increase compared to 2010.

In the United States, 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). Currently, uncertainty exists due to the healthcare reform legislation

currently being considered by Congress. While these proposals have the potential to increase the number of U.S. residents with access to health care services, they also have the potential to impose new costs and increase pricing pressures on the pharmaceutical industry. Virtually all of the proposals seek to reduce significantly the number of uninsured Americans through a combination of private insurance market reforms, mandates on individuals to have health insurance coverage, and premium subsidies to individuals to assist in the purchase of healthcare insurance. Upon obtaining healthcare coverage, previously uninsured individuals are likely to consume more healthcare services, including pharmaceutical products. However, many of the legislative proposals being debated by Congress seek cost savings through additional pricing pressures on prescription products. For example, one proposal being considered would require the Secretary of Health and Human Services to negotiate Medicare Part D prescription drug prices directly with pharmaceutical manufacturers in order to leverage greater savings. Further, proposals to expand coverage to the uninsured may be financed through increased rebates or the imposition of a tax on the pharmaceutical industry. In addition to the federal debate on health care reform, many states are facing substantial budget difficulties due to the downturn in the economy and are expected to seek aggressive cuts or other offsets in healthcare spending. Accordingly, we expect pricing pressures at the federal and state levels to intensify, which could have a material effect on the consolidated results of operations, cash flows and/or financial position.

#### FDA advisory committee

The FDA held a public advisory committee meeting in June 2009 to discuss acetaminophen use in both over-the-counter (OTC) and prescription (Rx) products, the potential for liver injury, and potential interventions to reduce the incidence of liver injury. The panel's recommendations followed the release in May 2009 of an 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 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 NDA's 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.

## Qualitest Acquisition

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 \$769.4 million. In addition, Endo paid \$406.8 million to retire Qualitest's outstanding debt and related interest rate swap on November 30, 2010.

#### HealthTronics Acquisition

On July 2, 2010 (the HealthTronics Acquisition Date), the Company completed its initial tender offer for all outstanding shares of common stock 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. The HealthTronics shares were purchased at a price of \$4.85 per 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.

## Penwest Acquisition

On September 20, 2010 (the Penwest Acquisition Date), the Company completed its tender offer for the outstanding shares of common stock of Penwest, at which time Penwest became a majority-owned subsidiary of the Company. On November 4, 2010, we closed this acquisition immediately following a special meeting of shareholders of Penwest at which they approved the merger. We paid approximately \$171.8 million in aggregate cash consideration. Penwest is now our wholly-owned subsidiary.

# Pipeline Developments

In February 2011, the FDA requested that additional pre-clinical studies, including a carcinogenicity study, be completed prior to the submission of the NDA for the octreotide implant for the treatment of acromegaly. Although this development causes a delay of up to four years in the timing associated with regulatory approval, the Company intends to continue the development of this product and is encouraged by recent preliminary results from its Phase III study.

In addition, the Company recently assessed all of its in-process research and development 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 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 will be expensed in the first quarter of 2011.

In December 2010, the FDA approved Fortesta<sup>TM</sup> Gel for the treatment of Low T, also known as hypogonadism. Endo expects to introduce Fortesta<sup>TM</sup> Gel in the United States in early 2011.

In July 2010, we filed an NDA with the FDA for a new extended-release formulation of oxymorphone, which is a semi-synthetic opioid analgesic intended for the treatment of moderate to severe chronic pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time. The NDA submission is based on a non-clinical and clinical development program designed to demonstrate the crush-resistant properties of this formulation of oxymorphone. In January 2011, we received a complete response letter from the FDA. The FDA issues complete response letters to communicate that its initial review of an NDA or ANDA is complete and that the application cannot be approved in its present form. A complete response also informs applicants of changes that must be made before an application can be approved, with no implication regarding the ultimate approvability of the application. The letter did not require that additional clinical studies be conducted for approval of the NDA. We have begun to address the issue described in the complete response letter and will work closely with the FDA to finalize our response. We are confident that we can address the issue set forth, currently anticipate responding to the FDA by mid 2011 and would expect a six month review cycle once our response is filed.

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, which was recorded as research and development expense for the year ended December 31, 2010. In addition, under the terms of the Impax agreement, Impax could potentially receive 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.

On December 2, 2009, we received a complete response letter from the FDA regarding Aveed<sup>TM</sup>. 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 REMS is not sufficient. We continue to evaluate how best to address the concerns of the FDA and intend to have future additional dialogue with the agency regarding a possible regulatory pathway.

In July 2009, we entered into a License, Development and Supply Agreement (Bioniche Agreement) with Bioniche Life Sciences Inc. and Bioniche Urology Inc. (collectively, Bioniche), whereby we licensed from Bioniche the exclusive rights to develop and market Bioniche's proprietary formulation of Mycobacterial Cell Wall-DNA Complex (MCC), known as Urocidin<sup>TM</sup> in the United States with an option for global rights. We exercised our option for global rights in the first quarter of 2010. Urocidin<sup>TM</sup> 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.

### **Branded Business Activity**

In June 2010, the Company and Penwest settled litigation with both Impax and Sandoz, Inc. (Sandoz) regarding the production and sale of generic formulations of Opana® ER (oxymorphone hydrochloride) Extended Release Tablets CII. The Company and Penwest have agreed to dismiss our suit with prejudice and Impax and Sandoz have agreed to dismiss their counterclaims with prejudice. Under the terms of the settlement, the Company and Penwest have agreed to grant Impax and Sandoz a license to the patents to sell a generic version of Opana® ER on or after January 1, 2013 and September 15, 2012, respectively, and earlier under certain circumstances, and have agreed not to sue Impax or Sandoz under such patents.

## Change in Directors and Executive Officers

On April 28, 2010, Clive A. Meanwell, M.D., Ph.D. notified us of his intent to not stand for reelection as a director of Endo at our 2010 Annual Meeting of Stockholders, so that he may better focus on his other professional responsibilities. Dr. Meanwell served as a director of the Company until the expiration of his term at our 2010 Annual Meeting of Stockholders.

On March 12, 2010, our Board of Directors appointed Julie H. McHugh as our Executive Vice President and Chief Operating Officer.

#### RESULTS OF OPERATIONS

The Company reported net income attributable to Endo Pharmaceuticals Holdings, Inc. for 2010 of \$259.0 million or \$2.20 per diluted share on total revenues of \$1.72 billion compared with net income of \$266.3 million or \$2.27 per diluted share on total revenues of \$1.46 billion for 2009.

# **Consolidated Results Review**

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

# Revenues

Revenues for the year ended December 31, 2010 increased 17.5% 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.

The following table displays our revenues by product category and as a percentage of total revenues for the years ended December 31 (dollars in thousands):

	2010	**	2009	
	\$	%	\$ 10 7	<b>%</b>
Lidoderm®	782,609	46	\$ 763,698	- 52
Opana® ER and Opana®	299,080	17	230,631	16
Percocet <sup>®</sup>	121,347	7	127,090	9
Voltaren® Gel	104,941	6	78,868	5
Frova®	59,299	3	57,924	4
Supprelin® LA	46,910	- 3	27,822	2
Other brands	53,386	3	50,077	4 <u>- 3</u>
Total brands*	1,467,572	86	1,336,110	91
Total generics	146,513	9	124,731	9
Total devices and service revenue	102,144	6		_
Total revenues*	1,716,229	100	\$1,460,841	100

<sup>\* -</sup> Percentages may not add due to rounding.

Lidoderm<sup>®</sup>. Net sales of Lidoderm<sup>®</sup> for the year ended December 31, 2010 increased by \$18.9 million or 2% to \$782.6 million from \$763.7 million in the comparable 2009 period. 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 and Opana®. Net sales of Opana® ER and Opana® for the year ended December 31, 2010 increased by 30% or \$68.4 million to \$299.1 million from \$230.6 million in the comparable 2009 period. The growth in net sales is primarily attributable to continued prescription and market share growth of the products. 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.

Percocet<sup>®</sup>. Net sales of Percocet<sup>®</sup> for the year ended December 31, 2010 decreased by \$5.7 million or 5% to \$121.3 million from \$127.1 million in the comparable 2009 period. The decrease is primarily attributable to decreased volumes during 2010 as compared to 2009, partially offset by price increases.

Voltaren® Gel. Net sales of Voltaren® Gel for the year ended December 31, 2010 increased by \$26.1 million or 33% to \$104.9 million from \$78.9 million in the comparable 2009 period. 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.

*Frova*<sup>®</sup>. Net sales of Frova<sup>®</sup> for the year ended December 31, 2010 increased by \$1.4 million or 2% to \$59.3 million from \$57.9 million in the comparable 2009 period. 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.

Other brands. Net sales of our other branded products for the year ended December 31, 2010 increased by \$3.3 million or 7% to \$53.4 million from \$50.1 million in the comparable 2009 period. This increase is primarily attributable to a full year of royalty revenue from Sanctura® and Sanctura XR® compared to approximately ten months in 2009.

Generics. Net sales of our generic products for the year ended December 31, 2010 increased by \$21.8 million or 17% to \$146.5 million from \$124.7 million in the comparable 2009 period. 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.

Device and service revenues. Device and service revenues were \$102.1 million during the year ended December 31, 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				009	
		\$	% of revenues	Ξ	\$	% 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%
Impairment of other intangible assets		35,000	2%		69,000	5%
Acquisition-related items		18,976	_1%		(93,081)	<u>(6</u> )%
Total costs and expenses*	\$1 ==	,250,863	73% =	\$1	1,070,817	<u>73</u> %

<sup>\* -</sup> Percentages may not add due to rounding.

## Costs of Revenues and Gross Margin

Costs of revenues for the year ended December 31, 2010 increased by \$129.7 million or 35%, to \$504.8 million from \$375.1 million in the comparable 2009 period, primarily due to increased revenues in 2010. Gross profit margins were 71% for the year ended December 31, 2010 compared with 74% during the year ended December 31, 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® ER during

2010 compared to the 2009 period, 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 for the year ended December 31, 2010 increased by 2% to \$547.6 million from \$534.5 million in the comparable 2009 period. 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 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 for the year ended December 31, 2010 decreased by 22% to \$144.5 million from \$185.3 million in the comparable 2009 period. This decrease is primarily a result of lower upfront and milestone payments in 2010, as compared to 2009.

# Impairment of Other Intangible Assets

In May 2010, Teva Pharmaceutical Industries Ltd. terminated the pagoclone 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 annual review of all in-process research and development 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 R&D 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 for the year ended December 31, 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<sup>TM</sup> 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

Acquisition-related items for the year ended December 31, 2010 were \$19.0 million in expense compared to \$93.1 million of income in 2009. Acquisition-related items 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 the comparable 2009 period, 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.

# 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 for the year ended December 31, 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 million of indebtedness the Company incurred in November of 2010. Interest income decreased to \$1.4 million for the year ended December 31, 2010 compared to \$3.5 million in the comparable 2009 period. 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.

#### Other Income, net

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

	2010	2009
Gain on trading securities		•
Loss on auction-rate securities rights	15,659	11,662
Other (income) expense		
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 for the year ended December 31, 2010 increased by 43% to \$133.7 million from \$93.3 million in the comparable 2009 period. 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 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-deductable 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.

### 2011 Outlook

We estimate that our 2011 total revenues will be between \$2.35 billion and \$2.45 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 by new revenues from launching Fortesta™ Gel as well as the full-year effect of our acquisitions of HealthTronics and Qualitest. Cost of revenues as a percent of total revenues is expected to increase when compared to 2010. This increase is expected due to a full year of amortization expense associated with the intangible assets acquired with HealthTronics and Qualitest as well as a full year's change in mix of revenues as a result of the Qualitest, HealthTronics, and Penwest acquisitions. Selling, general and administrative expenses, as a percentage of revenues, are expected to decline in 2011, relative to 2010, reflecting new approaches to customer segmentation and marketing, annualized effects of the prior year's cost reduction efforts and forecasted synergies associated with our 2010 acquisitions. 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 Qualitest'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, 2009 Compared to the Year Ended December 31, 2008

#### Revenues

Revenues for the year ended December 31, 2009 increased 16% to \$1.46 billion from \$1.26 billion in the comparable 2008 period. This increase in revenues is primarily driven by increased sales of Opana® ER and Opana®, and Voltaren® Gel, a topical drug added to our portfolio in March 2008. Additionally, new products from our acquisition of Indevus, included in other brands, accounted for 4% of total revenues at December 31, 2009. Lidoderm® net sales as a percent of total revenues have decreased from 61% of total revenues at December 31, 2008 to 52% of total revenues at December 31, 2009. We expect this trend to continue as we continue to diversify our product portfolio. For the year-ended December 31, 2009, increased sales volume contributed 12% of the total revenue growth while price increases contributed the remaining 4%.

The following table displays our revenues by product category and as a percentage of total revenues for the years ended December 31 (dollars in thousands):

	2009		2008		
	\$	%	\$	%	
Lidoderm®	\$ 763,698	52	\$ 765,097	61	
Opana® ER and Opana®	230,631	16	180,429	14	
Percocet®	127,090	9	129,966	10	
Voltaren® Gel	78,868	5	23,791	2	
Frova®	57,924	4	58,017	5	
Supprelin® LA	27,822	. 2		<del></del>	
Other brands	50,077	3	10,904	1	
Total brands*	1,336,110	91	1,168,204	93	
Total generics	124,731	9	92,332	7	
Total revenues*	\$1,460,841	100	\$1,260,536	100	

<sup>\* -</sup> Percentages may not add due to rounding.

Lidoderm®. Net sales of Lidoderm® for the year ended December 31, 2009 decreased by \$1.4 million to \$763.7 million from \$765.1 million in the comparable 2008 period. The growth of this product has slowed 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 and Opana®. Net sales of Opana® ER and Opana® for the year ended December 31, 2009 increased by 28% or \$50.2 million to \$230.6 million from \$180.4 million in the comparable 2008 period. The growth in net sales is primarily attributable to continued prescription and market share growth of the products, as we continue to drive our promotional efforts through physician targeting. 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.

*Percocet*<sup>®</sup>. Net sales of Percocet<sup>®</sup> for the year ended December 31, 2009 decreased by \$2.9 million or 2% to \$127.1 million from \$130.0 million in the comparable 2008 period.

Voltaren® Gel. Net sales of Voltaren® Gel for the year ended December 31, 2009 increased by \$55.1 million or 232% to \$78.9 million from \$23.8 million in the comparable 2008 period. The Company launched Voltaren® Gel in March 2008. This increase reflects a full year of activity versus a partial year of sales in the comparable 2008 period. Additionally, 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. We believe we are establishing a strong position in the osteoarthritis market with Voltaren® Gel.

*Frova*<sup>®</sup>. Net sales of Frova<sup>®</sup> for the year ended December 31, 2009 remained relatively unchanged at \$57.9 million compared to \$58.0 million in 2008.

Supprelin® LA. Net sales of Supprelin® LA during 2009 were \$27.8 million. The Company began selling Supprelin® LA in February 2009 upon our acquisition of Indevus.

Other brands. Net sales of our other branded products for the year ended December 31, 2009 increased by \$39.2 million or 359% to \$50.1 million from \$10.9 million in the comparable 2008 period. This increase is primarily driven by net sales of Vantas®, acquired from Indevus during 2009. Net sales of Vantas® from the

acquisition date through December 31, 2009 were \$20.0 million. Also contributing to this increase was royalty income, primarily from Sanctura® and Sanctura XR®, of \$9.3 resulting from our acquisition of Indevus in February 2009.

Generics. Net sales of our generic products for the year ended December 31, 2009 increased by \$32.4 million or 35% to \$124.7 million from \$92.3 million in the comparable 2008 period. The 2009 increase was primarily due to a shortage of other competing generic opioids in the market during the first half of 2009. The supply of these generic products has largely returned to normal levels in the second half of 2009.

## Gross Margin, Costs and Expenses

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

	2009				2008		
	Ξ	\$	% o	f revenues	\$	% of revenues	
Cost of revenues	\$	375,058		26%	\$267,235	21%	
Selling, general and administrative		534,523		37%	488,063	38%	
Research and development		185,317		13%	110,211	9%	
Acquisition-related items		(93,081)		(6)%		— %	
Impairment of other intangible assets		69,000		5%	8,083	1%	
Purchased in-process research and development		. —		%	(530)	*%	
Total costs and expenses**	\$1	,070,817		73%	\$873,062	69%	

<sup>\* -</sup> amount less than 1%.

# Costs of Revenues and Gross Margin

Costs of revenues for the year ended December 31, 2009 increased by \$107.9 million or 40%, to \$375.1 million from \$267.2 million in the comparable 2008 period. Gross profit margins were 74% for the year ended December 31, 2009 compared with 79% during the year ended December 31, 2008. The decrease in the gross margin is primarily due to a \$32.1 million increase in intangible asset amortization expense mainly related to the increase in intangible assets acquired as part of the Indevus acquisition during the first quarter of 2009. In addition, cost of revenues includes an additional \$19.3 million for royalties on sales of Opana® ER for the year ended December 31, 2009 compared to \$5.0 million for the comparable 2008 period. Furthermore, as part of our acquisition of Indevus, we were required to fair value the acquired inventories which has resulted in the recognition of an additional \$11.3 million in cost of revenues for the year ended December 31, 2009 which has negatively impacted our gross profit margin.

# Selling, General and Administrative Expenses

Selling, general and administrative expenses for the year ended December 31, 2009 increased by 10% to \$534.5 million from \$488.1 million in the comparable 2008 period. This increase is primarily due to the acquisition of Indevus during the first quarter of 2009 which contributed approximately \$63 million or 13% of the increase. These amounts were partially offset by 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 for the year ended December 31, 2009 increased by 68% to \$185.3 million from \$110.2 million in the comparable 2008 period. Research and development expense reflects the Company's ongoing commitment to clinical research as well as the impact of the Company's external collaborations. The increase in expense for the year ended December 31, 2009 when compared to the same

<sup>\*\* -</sup> Percentages may not add due to rounding.

period in 2008 is primarily attributable to the upfront payments of \$10.0 million and \$20.0 million made to ProStrakan and Bioniche, respectively; and \$34.7 million of upfront and milestone payments made to Grünenthal related to axomadol, all of which were expensed during the year ended December 31, 2009. During 2008, we incurred upfront milestone payments of \$8.9 million.

## Acquisition-Related Items

As a result of our acquisition of Indevus in the first quarter of 2009, we incurred acquisition-related costs of \$35.0 million attributable to transaction fees, professional service fees, employee retention and separation arrangements, and other costs related to the 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.

## Impairment of Other Intangible Assets

During the year ended December 31, 2009, we recorded an impairment charge of \$65.0 million relating to the write-down of our Aveed<sup>TM</sup> indefinite-lived intangible asset and a \$4.0 million write-off of our Pro2000 indefinite-lived intangible asset. As a result of the FDA's response letter received in December of 2009, the Company reassessed the fair value of our Aveed<sup>TM</sup> 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<sup>TM</sup> formulation. The patent should expire no earlier than late 2025. 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. During the year ended December 31, 2008, as a result of our decision to discontinue the development of Rapinyl<sup>TM</sup>, we recorded an impairment charge in the amount of \$8.1 million to write-off the remaining balance of our Rapinyl<sup>TM</sup> intangible asset.

#### Purchased In-Process Research and Development

Purchased in-process research and development in 2008 reflects the reversal of a contingent payment liability originally recorded upon the acquisition of RxKinetix in 2006.

## Interest Expense (Income), net

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

	2009	2008
Interest expense	\$41,247	\$ 18,726
Interest income	(3,529)	(24,833)
Interest expense (income), net	\$37,718	\$ (6,107)

Interest expense for the year ended December 31, 2009 was \$41.2 million compared with \$18.7 million for the comparable period in 2008. This increase is primarily due to interest expense recognized on the Non-recourse notes and the 6.25% Convertible senior notes due July 2009 assumed from Indevus (the Indevus Notes). Additionally, the increase in interest expense reflects a full year of debt discount accretion and interest expense relating to our 1.75% Convertible Senior Subordinated Notes due 2015 (the Convertible Notes) for the year ended December 31, 2009 compared to approximately eight months for the year ended December 31, 2008. Interest income decreased to \$3.5 million for the year ended December 31, 2009 compared to \$24.8 million in the comparable 2008 period. 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 and the yields on those

investments. During the first half of 2008, as a result of uncertainties in the global credit markets, the auction-rate securities market became illiquid and since that time, yields on these securities have decreased significantly.

# Other (Income) Expense, net

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

	2009	2008
Other-than-temporary impairment of auction-rate securities	\$ —	\$ 26,417
Unrealized (gain) loss on trading securities	(15,222)	4,225
Loss (gain) on Auction-Rate Securities Rights	11,662	(27,321)
Other	231	(1,568)
Other (income) expense, net	\$ (3,329)	\$ 1,753
·		

During the fourth quarter of 2008, the Company recorded a \$26.4 million other-than-temporary impairment charge related to certain of its auction-rate securities and upon accepting the UBS Offer of auction-rate securities rights, the Company made a one-time election to transfer these auction-rate securities out of the available-for-sale category and into the trading category. As such, the change in the fair value of these securities is now charged to earnings. During the year ended December 31, 2009, the value of our trading auction-rate securities increased by \$15.2 million. The increases in fair value were partially offset by losses recorded as a result of decreases in the fair value of our auction-rate securities rights totaling \$11.7 million.

## 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.

### Income Tax.

Income tax expense for the year ended December 31, 2009 decreased by 32% to \$93.3 million from \$136.5 million in the comparable 2008 period. The decrease in income tax expense is primarily a result of a decrease in our effective tax rate. Our effective tax rate for the year ended December 31, 2009 decreased to 26.0% from 34.8% in 2008. The decrease in the effective income tax rate is primarily the result of a reduction in the Indevus contingent consideration of \$128.1 million during the year ended December 31, 2009, of which \$115.7 million was non-taxable resulting in a favorable impact on the effective tax rate. The decrease in the Company's effective income tax rate is also attributable to a decrease in the Company's state effective tax rate, which was due primarily to Pennsylvania state income tax law changes enacted in the fourth quarter of 2009 and further integration of Indevus into our state tax profile. These decreases in the Company's effective income tax rate were partially offset by lower tax exempt interest income compared to 2008, the absence of tax benefits realized in 2008 for the reversal of certain of the Company's unrecognized tax contingencies, for the settlement of various tax positions, as well as the transaction costs incurred for the acquisition of Indevus in 2009 which were determined to be non-deductible.

### **Business Segment Results Review**

As a result of our recent acquisitions, the Company has realigned its internal management reporting to reflect a total of three reportable segments. These segments reflect the level at which executive management regularly reviews financial information to assess performance and to make decisions about resources to be allocated.

The three reportable business segments in which the Company now operates include: (1) Branded Pharmaceuticals, (2) Generics and (3) Devices and 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 established products that are included in this operating segment includes Lidoderm<sup>®</sup>, Opana<sup>®</sup> ER and Opana<sup>®</sup>, Percocet<sup>®</sup>, Voltaren<sup>®</sup> Gel, Frova<sup>®</sup>, Supprelin<sup>®</sup> LA, Vantas<sup>®</sup>, Valstar<sup>®</sup>.

### Generics -

This segment is comprised of our legacy Endo non-branded generic portfolio and the portfolio from our newly 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) disorder, immunosuppression, oncology and hypertension markets.

#### **Devices and Services**

The Devices and Services operating segment provides urological services, products, and support systems to urologists, hospitals, surgery centers and clinics across the United States. These services and products are sold through the following five business lines: Lithotripsy services, Prostate treatment services, Radiation therapy services, Anatomical pathology services, and Medical products manufacturing, sales and maintenance. These business lines are discussed in greater detail within Note 5 of the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

In 2010, the Company began to evaluate segment performance based on each segment's adjusted income (loss) before tax. We define adjusted income (loss) before tax as income (loss) before tax before certain upfront and milestone payments to partners, acquisition-related items, cost reduction initiatives, asset impairment charges, amortization of commercial intangible assets related to marketed products, inventory step-up recorded as part of our acquisitions, 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 tax by adding the adjusted income (loss) before tax of each of our reportable segments to corporate unallocated adjusted income (loss) before tax.

Endo refers to adjusted income (loss) before tax in making operating decisions because it believes it provides meaningful supplemental information regarding the Company's operational performance. For instance, Endo believes 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 Endo in its financial and operational decision-making. In addition, Endo has historically reported similar financial measures to its investors and believes that the inclusion of comparative numbers provides consistency in its financial reporting at this time. Further, Endo believes that adjusted income (loss) before tax may be useful to investors as it is aware that certain of its significant stockholders utilize adjusted income (loss) before tax to evaluate its financial performance. Finally, adjusted operating income (loss) 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 its employees, including its executive officers.

There are limitations to using financial measures such as adjusted income (loss) before tax. Other companies in our industry may define adjusted income (loss) before tax differently than we do. As a result, it may be difficult to use adjusted income (loss) before 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 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 operating income and our consolidated income before tax, which are 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.

# Year Ended December 31, 2010 Compared to the Year Ended December 31, 2009

#### Revenues

The following table displays our revenue by reportable segment and as a percentage of total revenues for 2010 and 2009 (dollars in thousands):

the state of the s	2010	2009
Branded Pharmaceuticals	\$1,467,572	\$1,336,110
Generics	146,513	124,731
Devices and Services	102,144	
Total revenues	\$1,716,229	\$1,460,841

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.

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

#### Adjusted income (loss) before tax

The following table displays our adjusted income (loss) before tax by reportable segment and as a percentage of total revenues for 2010 and 2009 (dollars in thousands).

Branded Pharmaceuticals	\$ 757,453	
Generics	24,722	28,557
Devices and Services	35,538	
Corporate unallocated	(194,459)	(174,994)
Total income before income taxes	\$ 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.

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

Corporate unallocated. Corporate unallocated adjusted loss before tax during 2010 increased 11% to \$194.5 million from \$175.0 million in 2009. Corporate unallocated adjusted loss before 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.

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

en e	Twelve Months Ende December 31,	
	2010	2009
Total consolidated adjusted income (loss) before tax	\$623,254	\$496,560
Upfront and milestone payments to partners	(23,850)	(77,099)
Acquisition-related items	(18,976)	93,081
Cost reduction initiatives	(17,245)	(2,549)
Asset impairment charges	(35,000)	(69,000)
Amortization of commercial intangible assets related to marketed products	(83,974)	(62,931)
Inventory step-up	(6,289)	(11,268)
Purchased in-process research and development		_
Non-cash interest expense	(16,983)	(14,719)
Other (expense) income	(239)	3,560
Gain on extinguishment of debt		4,025
Total consolidated income before income tax	\$4 <u>20,698</u>	\$359,660

# Year Ended December 31, 2009 Compared to the Year Ended December 31, 2008

#### Revenues

The following table displays our revenue by reportable segment and as a percentage of total revenues for 2009 and 2008 (dollars in thousands).

	2009	2008
Branded Pharmaceuticals	\$1,336,110	\$1,168,204
Generics	124,731	92,332
Total revenues	\$1,460,841	\$1,260,536

Branded Pharmaceuticals. Net sales during 2009 increased 14% to \$1,336.1 million from \$1,168.2 million in the comparable 2008 period. This increase in revenues is primarily driven by increased sales of Opana® ER and Opana®, and Voltaren® Gel. Additionally, new products from our acquisition of Indevus in February 2009, included in other brands, accounted for 4% of total revenues at December 31, 2009.

Generics. Net sales during 2009 increased 35% to \$124.7 million from \$92.3 million in the comparable 2008 period. The 2009 increase was primarily due to a shortage of other competing generic opioids in the market during the first half of 2009. The supply of these generic products largely returned to normal levels in the second half of 2009.

## Adjusted income (loss) before tax

The following table displays our adjusted income (loss) before tax by reportable segment and as a percentage of total revenues for 2009 and 2008 (dollars in thousands):

	2009	2008
Branded Pharmaceuticals	\$ 642,997	\$ 581,152
Generics		23,163
Corporate unallocated	(174,994)	(130,539)
Total consolidated adjusted income (loss) before tax	\$ 496,560	\$ 473,776

*Branded Pharmaceuticals.* Adjusted income (loss) before tax during 2009 increased 11% to \$643.0 million from \$581.1 million in the comparable 2008 period. This increase was primarily driven by increased net sales.

*Generics*. Adjusted income (loss) before tax during 2009 increased 23% to \$28.6 million from \$23.2 million in the comparable 2008 period. This increase was primarily driven by increased net sales.

Corporate unallocated. Corporate unallocated adjusted loss before tax during 2009 increased 34% to \$175.0 million from \$130.5 million in the comparable 2008 period. This fluctuation was primarily driven by the continued growth of the business in 2009, including the operational costs resulting from the acquisition of Indevus.

Reconciliation to GAAP. The table below provides reconciliations of our consolidated adjusted income (loss) before income tax to our consolidated operating income and our consolidated income before tax, which are determined in accordance with U.S. GAAP, for the years ended December 31, 2009 and 2008 (in thousands).

	Twelve Months Ended December 31,	
	2009	2008
Total consolidated adjusted income (loss) before tax	\$496,560	\$473,776
Upfront and milestone payments to partners	(77,099)	(8,910)
Acquisition-related items	93,081	
Cost reduction initiatives	(2,549)	(16,375)
Asset impairment charges	(69,000)	(12,680)
Amortization of commercial intangible assets related to marketed products	(62,931)	(30,821)
Inventory step-up	(11,268)	_
Purchased in-process research and development	· <u></u>	530
Non-cash interest expense	(14,719)	(10,372)
Other income (expense)	3,560	(3,320)
Gain on extinguishment of debt	4,025	
Total consolidated income before income tax	\$359,660	\$391,828

#### 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 \$623.7 million at December 31, 2010 compared to \$808.4 million and \$797.2 million at December 31, 2009 and 2008, respectively. Historically, we have generated positive cash flow from operating activities and have had access to broad financial markets that provide liquidity. Cash, cash equivalents and current marketable securities were approximately \$466.2 million at December 31, 2010 compared to \$733.7 million and \$782.2 million at December 31, 2009 and 2008, respectively. Cash and cash equivalents at December 31, 2010, December 31, 2009, and December 31, 2008 primarily consisted of bank deposits, time deposits and money market funds.

In 2011, we expect that sales of our currently marketed branded and generic products as well as our devices and 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 and any regulatory and/or sales milestones that may become due.

Beyond 2011, 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.

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.

On November 30, 2010, we terminated our 2009 Credit Facility and 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 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 is available for working capital, general corporate purposes, up to \$30 million of letters of credit, and up to \$30 million of swing line loans (the Swing Line Loans) on same-day notice. The agreement governing the 2010 Credit Facility (the 2010 Credit Agreement) also permits 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 JP Morgan Chase Bank, as 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 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 2010 Credit Facility contains certain usual and customary covenants, including, but not limited to covenants to maintain a maximum leverage ratio and minimum interest coverage ratio as well as limitations on capital expenditures, asset sales, mergers and acquisitions, indebtedness, liens, dividends, investments and transactions with the Company's affiliates. Borrowings under the 2010 Credit Facility will bear interest at an amount equal to a rate calculated based on the type of borrowing and the Company's Leverage Ratio from time to time. For term loans and revolving loans (other than Swing Line Loans), the Company may 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 will also pay a commitment fee of between 35 to 50 basis points, payable quarterly, on the average daily unused amount of the Revolving Credit Facility based on the Company's Leverage Ratio from time to time.

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 Senior Notes). The Senior 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 United States pursuant to Regulation S under the Securities Act. The Senior 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 Senior Notes offering to partially finance the acquisition of Qualitest, and to pay related fees and expenses.

The Senior Notes bear interest at a rate of 7.00% per year, accruing from November 23, 2010. Interest on the Senior Notes is payable semiannually in arrears on June 15 and December 15 of each year, beginning on June 15, 2011. The Senior Notes will mature on December 15, 2020, subject to earlier repurchase or redemption in accordance with the terms of the indenture governing the Senior Notes. The indenture governing the Senior 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 Senior Notes receiving investment grade credit ratings.

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.

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 2010, the share repurchase plan is set to expire in April 2012. Pursuant to the existing share repurchase program, we purchased approximately 2.5 million shares of our common stock during 2010 at a cost totaling \$59.0 million. We did not purchase any shares of our common stock during the year ended December 31, 2009.

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 earnings per share in future periods. An acquisition may be accretive or dilutive and by its nature, involve numerous risks and uncertainties.

Marketable Securities. Beginning in 2008 and continuing through 2010, 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, 2010, \$18.8 million of our marketable securities portfolio was invested in auction-rate debt securities with ratings of AAA. During 2008, the Board of Directors approved an amended investment policy which seeks to preserve the value of capital, consistent with maximizing return on the Company's investment, while maintaining adequate liquidity and security. The amended investment 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.

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 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 life used for each remaining security, representing time to maturity is eight years.

- 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 on December 31, 2010 was 5.10% and ranged from 5.37% to 6.12% at December 31, 2009. 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 spreads over the base rate for our securities applied to our securities was 218 basis points at December 31, 2010 and ranged from 154 basis points to 410 basis points at December 31, 2009.
- 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.

The following table sets forth the fair value of our long-term auction-rate securities by type of security and underlying credit rating as of December 31, 2010 and December 31, 2009 (in thousands):

		Underlying Credit Rating(1)				
		AAA	À	B2 Ba	a2 Baa3	Total
As of December 31, 2010:				<u></u>		
Underlying security:						
Student loans	· · · · · · · · · · · ·	\$17,332	\$ S	\$— \$-	- \$	\$17,332
Total auction-rate securities included in long-term		<del></del>			<del></del>	<del>-                                    </del>
securities		\$17,332	\$ <del>-</del> \$	<u>\$</u> <u>\$-</u>	_ \$	\$17,332
		Une	derlying Cı	redit Rating	g( <b>1</b> )	
	AAA	A	B2	Ba2	Baa3	Total
As of December 31, 2009:			:			
Underlying security:						41
Student loans	\$130,861	\$51,781	\$9,934	\$7,201	\$7,557	\$207,334
Total auction-rate securities included in long-term						
marketable securities	\$130,861	\$51,781	\$9,934	\$7,201	\$7,557	\$207,334

<sup>(1)</sup> Our auction-rate securities maintain split ratings. For purposes of this table, securities are categorized according to their lowest rating.

During the year ended December 31, 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. 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.

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 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 us 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. As a result, the Company granted to 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. As of June 30, 2010, we exercised the Rights and, on July 1, 2010, received cash for our remaining UBS portfolio at par. Accordingly, as of June 30, 2010, our UBS auctionrate securities were reclassified into a current receivable. The remaining \$18.8 million of our auction-rate securities portfolio, at par-value, is not held in a UBS account and therefore was not subject to the UBS Offer.

As of December 31, 2010, the yields on our long-term auction-rate securities ranged from 0.54% to 0.60%. As of December 31, 2009, the yields on our long-term auction-rate securities ranged from 0.42% to 0.88%. These yields represent the predetermined "maximum" reset rates that occur upon auction failures according to the specific terms within each security's prospectus. As of December 31, 2010 and, 2009, the weighted average yields for our long-term auction-rate securities were 0.57% and 0.73%, respectively. Total interest recognized on our auction-rate securities during the years ended December 31, 2010, 2009 and 2008 was \$0.7 million, \$2.4 million, and \$15.5 million, respectively. The issuers have been making interest payments promptly.

At December 31, 2010, the fair value of our auction-rate securities, as determined by applying the above described discount rate adjustment technique, was approximately \$17.3 million, representing an eight percent (8%), or \$1.5 million discount from their original purchase price or par value. This compares to approximately \$232.6 million, representing a seven percent (7%), or \$16.5 million discount from their original purchase price or par value at December 31, 2009. Had the Company chosen to apply a three or five year term with respect to the liquidity adjustment at December 31, 2010, the resultant discount to the original purchase price or par value would have been \$1.1 million and \$1.8 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.

**Working Capital.** Working capital decreased to \$623.7 million as of December 31, 2010 from \$808.4 million as of December 31, 2009. The components of our working capital for the years ended December 31, are below (in thousands):

	2010	2009	2008
Total current assets			
Less: Total current liabilities	(735,828)	(472,180)	(386,473)
Working capital	\$ 623,706	\$ 808,401	\$ 797,221

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.

Working capital increased slightly from 2008 to 2009 primarily as a result of our first quarter acquisition of Indevus, including the increase in accounts receivable associated with the new Indevus products as well as our deferred tax assets associated with the income tax loss carryforwards and the inclusion of short-term marketable securities and auction-rate securities rights that were classified as long-term assets at December 31, 2008. These amounts were partially offset by the payment of the initial upfront cash consideration for the Indevus transaction, net of cash acquired, of \$250 million.

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

	2010	2009	2008
Net cash flow provided by (used in):	<del></del>		
Operating activities	\$ 453,646	\$ 295,406	\$ 355,627
Investing activities	(896,323)	. , ,	179,807
Financing activities	200,429	(117,128)	(110,066)
Net (decrease) increase in cash and cash equivalents	(242,248)	(67,231)	425,368
Cash and cash equivalents, beginning of period	708,462	775,693	350,325
Cash and cash equivalents, end of period	\$ 466,214	\$ 708,462	\$ 775,693
Current ratio	1.8:1	2.7:1	3.1:1
Days sales outstanding	46	43	40

Net Cash Provided by Operating Activities. 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. Net cash provided by operating activities was \$295.4 million for the year ended December 31, 2009, a 17% decrease from the comparable 2008 period. Significant components of our operating cash flows for the years ended December 31, are as follows (in thousands):

		2009	2008
Cash Flow Data-Operating Activities:	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	. (* - * * ·	
Net income	\$287,020	\$ 266,336	\$255,336
Depreciation and amortization	108,404	80,381	46,445
Stock-based compensation	22,909	19,593	16,934
Change in fair value of acquisition-related contingent consideration	(51,420)	(128.090)	
Impairment of long-lived assets	35,000	69,000	12,680
Loss (gain) on auction-rate securities rights (Gain) loss on trading securities	15,659	11,662	(27,321)
(Gain) loss on trading securities	(15,420)	(15,222)	4,225
Other-than-temporary impairment of available-for-sale securities	· <u> </u>		26,417
Purchased in-process research and development	:	er terrer e <u>Lite</u>	(530)
Changes in assets and liabilities which provided cash	43,672	12,428	4,198
Other, net	7,822	(20,682)	17,243
Net cash provided by operating activities	\$453,646	\$ 295,406	\$355,627
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For the year ended December 31, 2010, changes in net cash provided by operating activities from the year ended December 31, 2009 were primarily driven by increases in net income as a result of increased total revenues, as well as increases (decreases) in non-cash expenses (income) including a \$76.7 million decrease in gains resulting from changes in the fair value of contingent consideration and a \$28.0 million increase in depreciation and amortization.

For the year ended December 31, 2009, significant changes in net cash provided by operating activities from the year ended December 31, 2008 were primarily driven by a \$66.0 million decrease in the cash flow impact of accounts receivable due to a combination of increased revenues and an increase to our average days sales outstanding reflecting the standard payments terms of our UEO products.

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Net Cash (Used in) Provided by Investing Activities. Net cash used in investing activities was \$896.3 million for the year ended December 31, 2010 compared to \$245.5 million used in and \$179.8 million provided by for the years ended December 31, 2009 and 2008, respectively.

The increase in cash used in investing actives 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.

For the year ended December 31, 2009, the Company completed its acquisition of Indevus and paid cash consideration of \$250.4 million, net of cash acquired. In addition, the Company sold \$23.8 million in auction-rate securities and purchased \$12.4 million of capital assets, including property and equipment and licensing rights.

During the year ended December 31, 2008, we collected \$3.3 million in principal payments from Vernalis on our note receivable and \$447.1 million from the sale of available-for-sale securities. These cash inflows were partially offset by the purchase of \$134.2 million of available-for-sale securities, an \$85 million upfront payment to Novartis to obtain the exclusive U.S. marketing rights for the prescription medicine Voltaren® Gel, a \$20 million investment in a privately-held company that is focused on the development of an innovative treatment for certain types of cancer, and \$17.4 million for capital expenditures. Also during 2008, the first dosage of EN 3285 was administered to a patient enrolled in a clinical phase III trial. Accordingly, in March 2008, we paid \$15 million in additional contingent purchase price consideration to the former shareholders of RxKinetix.

Net Cash Provided by (Used in) Financing Activities. Net cash provided by financing activities was \$200.4 million for the year ended December 31, 2010 compared to \$117.1 million and \$110.1 million used in financing activities for the years ended December 31, 2009 and 2008, respectively.

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.

For the year ended December 31, 2009, as a result of our acquisition of Indevus, the Company assumed The Indevus Notes as well as the Non-recourse notes. In 2009, the Company paid approximately \$72 million in outstanding principal to satisfy the Indevus Notes in their entirety and purchased \$48 million of the outstanding Non-recourse notes pursuant to a tender offer.

For the year ended December 31, 2008, in connection with the April 2008 issuance of our Convertible Notes, we received proceeds of approximately \$370.7 million, net of the original purchaser's discount as well as certain other costs of the offering. Concurrently with the issuance of the Convertible Notes, we entered into a privately-negotiated convertible note hedge transaction with affiliates of the initial purchasers. 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. We received approximately \$50.4 million in cash proceeds from the sale of these warrants. 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. We used approximately \$57 million representing a portion of the net proceeds from the Convertible Notes offering to pay the cost of the convertible note hedge transaction, taking into account the proceeds from the warrant transaction, and used the balance of the net proceeds or approximately \$314 million, together with approximately \$11 million of cash on hand, to repurchase a variable number of shares of our common stock pursuant to the accelerated share repurchase agreement entered into as part of our broader share repurchase program. Pursuant to the accelerated share repurchase agreement, the counterparty delivered 11.9 million shares of our common stock to the Company on the day that the note offering closed, April 15, 2008. On August 14, 2008, we received approximately 1.4 million additional shares of our common stock based on the volume weighted average price of our common stock during a specified averaging period set forth by the accelerated share repurchase agreement. In addition to the accelerated share repurchase, beginning in April 2008 we made open market purchases of our common stock as part of our broader share repurchase program. As of December 31, 2008, we purchased approximately 4.5 million shares of our common stock on the open market for a total purchase price of approximately \$99.8 million.

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 pipeline. There can be no assurance that results of any ongoing or future pre-clinical 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.

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. 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 of 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 and Note 14 of 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.

Indevus Acquisition. On February 23, 2009, which we refer to as 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 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™ Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement. The fair value of those potential obligations is \$7.1 million at December 31, 2010.

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® (trospium chloride) and Sanctura XR® (trospium chloride extended release capsules) for the treatment of overactive bladder (OAB); Supprelin® LA (histrelin acetate) for treating central precocious puberty (CPP); Vantas® (histrelin) for the palliative treatment of advanced prostate cancer; Delatestryl® (testosterone enanthate) for the treatment of male hypogonadism; Hydron® Implant, which is used as a drug delivery device and provides for a sustained release of a broad spectrum of drugs continuously; and Valstar® (valrubicin) for therapy of bacillus Calmette-Guerin (BCG)-refractory carcinoma in situ (as CIS) of the bladder.

As of December 31, 2010, primary development products included the following from the Indevus acquistion:

Aveed<sup>TM</sup> (testosterone undecanoate) is expected to be the first long-acting injectable testosterone preparation available in the United States 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® On May 6, 2009, we received notice from the FDA that Nebido® 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 AveedTM 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, 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. 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.

Octreotide, currently in Phase III clinical trials for the treatment of acromegaly, utilizes our patented Hydron® 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). Octreotide is also approved to treat symptoms associated with metastatic carcinoid tumors and vasoactive intestinal peptide secreting adenomas, which are gastrointestinal tumors. In February 2011, the FDA requested additional pre-clinical studies, including a carcinogenicity study, be completed prior to the submission of the NDA for the octreotide implant for the treatment of acromegaly. Although this development causes a delay of up to four years in the timing associated with regulatory approval, the Company intends to continue the development of this product and is encouraged by recent preliminary results from its Phase III study. In addition, the Company recently assessed all of its in-process research and development 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.

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):

	Consideration Transferred
Cash	\$368,034 172,860
Total	\$540,894

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

	February 23, 2009
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
Total identifiable assets	\$ 868,581
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)
Total liabilities assumed	(449,142)
Net identifiable assets acquired	\$ 419,439
Goodwill	\$ 121,455
Net assets acquired	\$ 540,894

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. As of December 31, 2009, our measurement period adjustments were complete.

Of the \$532.9 million of acquired intangible assets, \$255.9 million was assigned to in-process research and development. 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:

	Valuation (in millions)	Amortization Period (in years)
In Process Research & Development:		
Valstar®(1)	\$ 88.0	n/a
Aveed <sup>TM</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
Total	\$255.9	n/a
License Rights:		*
Hydron® Polymer	\$ 22.0	. 10
Vantas®	36.0	10
Sanctura® Franchise	94.0	12
Supprelin® LA	124.0	10
Other	1.0	4
Total	\$277.0	11
Total other intangible assets	\$532.9	

(1) The FDA approved the sNDA for Valstar® subsequent to the Indevus Acquisition Date. Therefore, Valstar® was initially classified as in-process research and development 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.

(3) As part of our annual review of all in-process research and development 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 R&D 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 pretax non-cash impairment charge of \$22.0 million for the year ended December 31, 2010, to write-off, in its entirety, the octreotide – carcinoid syndrome intangible asset.

(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.

(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.

The fair value of the in-process research and development assets and License Rights assets, with the exception of the Hydron® 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 Hydron® 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 Hydron® Polymer Technology is currently used in the following products: Vantas®, Supprelin® LA and octreotide. Thus, we derived the hypothetical royalty income from the projected revenues of those drugs. The fair value of the Hydron® 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 Hydron® 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 Hydron® 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.

HealthTronics Acquisition. On July 2, 2010 (the HealthTronics Acquisition Date), the Company completed its initial tender offer for all outstanding shares of common stock 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. The HealthTronics shares were purchased at a price of \$4.85 per 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 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 2009, 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) photoselective vaporization of the prostate (PVP), (2) trans-urethral needle ablation (TUNA), and (3) trans-urethral microwave therapy (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.

## Radiation therapy services.

HealthTronics provides image guided radiation therapy (IGRT) technical services for cancer treatment centers. Its IGRT technical services may relate to providing the technical (non-physician) personnel to operate a physician practice group's IGRT equipment, leasing IGRT equipment to a physician practice group, providing services related to helping a physician practice group establish an IGRT treatment center, or managing an IGRT treatment center.

## 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 United States. 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 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 Sheet 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):

	July 2, 2010 (As initially reported)	Measurement July 2, period 2010 (As adjustments Adjusted)
Cash and cash equivalents	\$ 6,769	\$ - \$ 6,769
Accounts receivable	33,111	677 33,788
Other receivables	1,006	<b>—</b> 1,006
Inventories	12,399	<b>—</b> 12,399
Prepaid expenses and other current assets	5,204	<b>—</b> 5,204
Deferred income taxes	43,737	3,676 47,413
Property and equipment	30,687	<b>—</b> 30,687
Other intangible assets	65,866	8,458 74,324
Other assets  Total identifiable assets	5,210	5,210
Total identifiable assets	\$203,989	<u>\$ 12,811</u> <u>\$216,800</u>
Accounts payable	\$ (3,084)	\$ (3,084)
Accrued expenses	(11,551)	(8,659) = (20,210)
Deferred income taxes	(20,377)	(3,188) (23,565)
Long-term debt	(44,751)	1,291 (43,460)
Other liabilities	(1,434)	(351) (1,785)
Total liabilities assumed	\$(81,197)	<u>\$(10,907)</u> <u>\$(92,104)</u>
Net identifiable assets acquired	\$122,792	\$ 1,904 \$124,696
Noncontrolling interests	\$ (60,119)	\$ (3,108) \$ (63,227)
Goodwill	\$152,170	\$ 1,204 \$153,374
Net assets acquired	\$214,843	<u>\$ — \$214,843</u>

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 HealthTronics 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 noncontrolling interests 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 HealthTronics Acquisition Date.

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

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rental de la proposición de la companión de la La companión de la companión d	Valuation (in millions)	Period(in years)
Endocare Developed Technology	\$46.3	10
HealthTronics Tradename	14.6	15
Service Contract	13.4	n/a
Total	<u>\$74.3</u>	n/a

The fair value of the developed technology 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 assumed to extend through the patent 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 \$153.4 million of goodwill was assigned to our Devices and Services segment, which was established in July 2010 pursuant to our acquisition of HealthTronics. 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.

The deferred tax assets of \$47.4 million are related primarily to federal net operating loss and credit carryforwards of HealthTronics and its subsidiaries. The deferred tax liabilities of \$23.6 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

The Company recognized \$21.4 million of HealthTronics acquisition-related costs that were expensed for the twelve months ended December 31, 2010. These costs are included in the line item entitled "Acquisitionrelated items" in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

The Bossel Community of the Community of	related Costs
and some for the contract of t	Twelve
was the first of the control of the property of the control of the	
Investment bank fees, includes Endo and Health Tronics	\$ 2,017
Acceleration of outstanding HealthTronics stock-based compensation	7,924
Legal, separation, integration, and other costs	10,988
Acceleration of outstanding HealthTronics stock-based compensation Legal, separation, integration, and other costs	\$20,929

Acquisition-

The amounts of revenue and net loss of Health Tronics included in the Company's Consolidated Statements of Operations from the HealthTronics Acquisition date to December 31, 2010 are as follows (in thousands, except per share data):

; F <sub>1</sub>	E.A.	e e e e e e e e e e e e e e e e e e e	Losses included in the Consolidated Statements of Operations from July 2, 2010 to December 31, 2010
Revenue Net loss Basic ar	e attributable to End ad diluted loss per	do Pharmaceuticals Holdings Inc	\$102,144 \$ (8,098)

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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 and January 1, 2009 for the year ended December 31, 2009. 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 or January 1, 2009, nor are they indicative of any future results.

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·-·	d <sub>W</sub>			Twelve Months Ended December 31,				
* * *						2010		2009
Pro forma consolida	ted results (in	thousar	nds, except p	er		-		
share data):			· • •					A.
Revenue	. 1		· · · · · · · · · · · · · · · · · · ·		\$1.8	314,918	\$1.	646,171
Net income attributab					/ .		· · · /	7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7
Holdings Inc			· · · · · · · · · · · · · · ·	• • • •	\$ 2	64,165	\$	265,282
Basic earnings per sh	are				\$	2.27	\$	2.27
Diluted earnings per s	share				\$	2.24	\$	2.26
and the second s								

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 and 2009, as applicable, together with the consequential tax effects.

**Penwest Acquisition.** On September 20, 2010 (the Penwest Acquisition Date), the Company completed its tender offer for the outstanding shares of common stock of Penwest, at which time Penwest became a majority-owned subsidiary of the Company. On November 4, 2010, we closed this acquisition immediately following a special meeting of shareholders of Penwest at which they approved the merger. We paid approximately \$171.8 million in aggregate cash consideration. Penwest is now our wholly-owned subsidiary.

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 Sheet as of December 31, 2010 reflects the acquisition of Penwest, effective September 20, 2010, the date the Company obtained control of Penwest.

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

<ul> <li>A first transport of the afficiency of the second of the se</li></ul>	in the second of	September 20, 2010 (As initially reported)	Measurement period adjustments	September 20, 2010 (As adjusted)
Cash and cash equivalents		\$ 22,343	\$ —	\$ 22,343
Marketable securities		800	_	800
Accounts receivable		10,885	(19)	10,866
Other receivables		132	(1)	131
inventories	· • • • • • • • • • • • • • • • • • • •	550	11	407
Prepaid expenses and other current assets		716	(223)	493
Deferred income taxes		27,175	3,003	30,178
			(200)	915
Other intangible assets			<del></del>	111,200
Other assets		2,104	· <u>-</u> ·	2,104
Total identifiable assets		\$176,866	\$ 2,571	\$179,437
Accounts payable	أتتنأه بالمتابع لافيات	\$ (229)		\$ (229)
Income taxes payable		(347)	187	(160)
Penwest shareholder liability	eri i va de kirik det. V	(20,815)	20,815	e sek k <del>ala</del> Surik
Accrued expenses	<del>.</del>	(1,455)	(87)	(1,542)
Deferred income taxes		(39,951)	(379)	(40,330)
Other liabilities		(4,403)	(118)	(4,521)
Total liabilities assumed		\$ (67,200)	\$20,418	\$ (46,782)
Net identifiable assets acquired		\$109,666	\$22,989	\$132,655
Goodwill	i e e e e lêgêlêrerê ê erêvel ele bi Lozari	\$ 37,952	\$ 1,159	\$ 39,111
Net assets acquired		\$147,618	\$24,148	\$171,766

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 Penwest 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 intangible assets and deferred 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 Penwest Acquisition Date.

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

	Valuation	Amortization Period (in years)
In Process Research & Development:		
Otsuka	\$ 5.5	n/a
A0001	1.6	n/a
Total	\$ 7.1	n/a
Developed Technology:		
Opana® ER	\$104.1	10
Total	<u>\$104.1</u>	10
Total other intangible assets	<u>\$111.2</u>	n/a
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The fair values of the other intangible 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 the 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 patent life of our purchased technology.

The \$39.1 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.

The deferred tax assets of \$30.2 million are related primarily to federal net operating loss and credit carryforwards of Penwest. The deferred tax liabilities of \$40.3 million are related primarily to the difference between the book basis and tax basis of the identifiable intangible assets.

The Company recognized \$10.7 million of Penwest acquisition-related costs that were expensed for the twelve months ended December 31, 2010. These costs are included in the line item entitled "Acquisition-related items" in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

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	Acquisition-related Costs
	Twelve Months Ended December 31, 2010
Investment bank fees, includes Endo and Penwest  Legal, integration, and other costs	\$ 3,865 6,815
Total	\$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. 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.

### Qualitest Acquisition.

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. (Apax) for approximately \$769.4 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, \$108 million of the purchase price was placed into escrow. One of the escrow amounts is for \$8 million and will be used to fund any working capital adjustments, as defined in the Qualitest Stock Purchase Agreement. We expect this escrow to be settled in 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 United States. Qualitest's product portfolio is comprised of 175 product families in various forms including tablets, capsules, creams, ointments, suppositories, and liquids. This acquisition will enable 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 to December 31, 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):

Prepaid expenses and other current assets Deferred income taxes Property and equipment Other intangible assets  Total identifiable assets  \$1, Accounts payable Accrued expenses Deferred income taxes Long-term debt  \$ (2)	21,828 93,228 1,483 95,000 2,023 63,509 135,807
Accounts receivable Other receivables Inventories Prepaid expenses and other current assets Deferred income taxes Property and equipment Other intangible assets  Total identifiable assets  \$1, Accounts payable Accrued expenses Deferred income taxes Long-term debt	1,483 95,000 2,023 63,509 135,807
Inventories Prepaid expenses and other current assets Deferred income taxes Property and equipment Other intangible assets  Total identifiable assets  \$1, Accounts payable Accrued expenses Deferred income taxes Long-term debt  \$ (2)	95,000 2,023 63,509 135,807
Prepaid expenses and other current assets Deferred income taxes Property and equipment Other intangible assets  Total identifiable assets \$1, Accounts payable Accrued expenses Deferred income taxes Long-term debt  Property and other current assets \$1, \$1, \$2, \$3, \$4, \$5, \$6, \$6, \$6, \$6, \$6, \$6, \$6, \$6, \$6, \$6	2,023 63,509 135,807
Deferred income taxes Property and equipment Other intangible assets  Total identifiable assets  Accounts payable Accrued expenses Deferred income taxes Long-term debt  Property and equipment  \$1,  \$1,  \$1,  \$2,  \$3,  \$4,  \$5,  \$6,  \$6,  \$6,  \$6,  \$6,  \$6,  \$6	63,509 135,807
Property and equipment Other intangible assets  Total identifiable assets  Accounts payable Accrued expenses Deferred income taxes Long-term debt  Other intangible assets  \$1,  \$1,  \$1,  \$1,  \$2,  \$3,  \$4,  \$5,  \$6,  \$6,  \$6,  \$6,  \$6,  \$6,  \$6	135,807
Other intangible assets  Total identifiable assets  \$1,  Accounts payable \$  Accrued expenses  Deferred income taxes  Long-term debt  \$ (4)	
Total identifiable assets \$1,  Accounts payable \$  Accrued expenses  Deferred income taxes (2)  Long-term debt \$1,	0.42 0000 ::
Accounts payable \$ Accrued expenses  Deferred income taxes (2) Long-term debt (4)	843,000
Accrued expenses	255,878
Accrued expenses	(27,422)
Long-term debt	(55,210)
Long-term debt	207,733)
	406,758)
Other liabilities	(9,370)
Total liabilities assumed \$ (	706,493)
Net identifiable assets acquired\$	549,385
	219,986
Net assets acquired	769,371

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 Qualitest 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. 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 Qualitest Acquisition Date.

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

	Valuation (in millions)	Amortization Period (in years)
Developed Technology:		
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
In Process Research & Development:		
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	88.0	n/a
Total	\$198.0	n/a
Tradename:		
Qualitest tradename	\$ 27.0	n/a
Total	\$ 27.0	n/a
Total other intangible assets	\$843.0	n/a

The fair value of the developed technology assets and in-process research and development 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 assumed to extend through the patent life of the purchased technology. 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.

The \$220.0 million of goodwill was assigned to our Generics segment, which was established in November 2010 pursuant to our acquisition of Qualitest. The goodwill recognized is attributable primarily to expected purchasing, manufacturing and distribution synergies as well as their assembled workforce. Approximately \$170.4 million of goodwill is expected to be deductible for income tax purposes.

The deferred tax assets of \$63.5 million are related primarily to federal and state net operating loss and credit carryforwards of Qualitest and its subsidiaries. The deferred tax liabilities of \$207.7 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

The Company recognized \$38.8 million of Qualitest acquisition-related costs that were expensed for the twelve months ended December 31, 2010. These costs are included in the line item entitled "Acquisition-related items" in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	Acquisition-related Costs
	Twelve Months Ended December 31, 2010
Investment bank fees, includes Endo and Qualitest	\$14,215
Legal, separation, integration, and other costs	24,572
Total	\$38,787

The amounts of revenue and net loss of Qualitest included in the Company's Consolidated Statements of Operations from the Qualitest Acquisition date to December 31, 2010 are as follows (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 attributable to Endo Pharmaceuticals Holdings Inc	\$ (3,056)
Basic and diluted net 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 and January 1, 2009 for the year ended December 31, 2009. 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 or January 1, 2009, nor are they indicative of any future results.

	Twelve Months Ended December 31,	
	2010	2009
Pro forma consolidated results (in thousands, except per share data):		•
Revenue	\$2,038,761	\$1,767,873
Net income attributable to Endo Pharmaceuticals		1000
Holdings Inc	\$ 243,710	\$ 257,511
Basic earnings per share	\$ 2.10	\$ 2.20
Diluted earnings per share	\$ 2.07	: \$ 2.19

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 and 2009, as applicable, together with the consequential tax effects.

Convertible Senior Subordinated Notes due 2015. As discussed in Note 18 to the Consolidated Financial Statements in Part IV, Item 15 of this Report, in April 2008, we issued \$379.5 million in aggregate principal

amount of 1.75% Convertible Senior Subordinated Notes due April 15, 2015, which we refer to as 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 semi-annually in arrears on each April 15 and October 15 with the first interest payment having been made on October 15, 2008. The Convertible Notes will mature on April 15, 2015, unless earlier converted or repurchased by us.

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 (the Convertible Notes Indenture): (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.

Non-recourse Notes. As discussed in Note 18 to the Consolidated Financial Statements in Part IV, Item 15 of this Report, 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 Non-recourse 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 of Non-recourse notes had been validly tendered and not withdrawn. The Company accepted for payment and purchased these 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 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.

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 of the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

**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, 2010 (in thousands):

	Payment Due by Period						
Contractual Obligations	Total	2011	2012	2013	2014	2015	Thereafter
Lease obligations	\$ 43,811	\$ 12,623	\$ 8,116	\$ 7,124	\$ 6,773	\$ 3,480	\$ 5,695
Debt related payments(1)	1,549,119	75,079	80,734	85,886	89,682	677,351	540,387
Minimum purchase commitments to		*					
Novartis(2)	44,333	14,000	14,000	14,000	2,333	· —.	· ·
Minimum purchase commitments to	- "						
Teikoku(3)	64,000	32,000	32,000	· · ·	· —	<del>-</del>	_
Minimum Voltaren® royalty							
obligations due to Novartis(4)	60,000	15,000	30,000	15,000	_	<u>· · ·</u>	_
Minimum advertising and promotion		r	and the second				• .
spend(5)	6,909	6,909	_			_	
Shire minimum payments(6)	1,500	1,500	· · · · · ·				
Other obligations(7)	5,921	3,562	291	291	291	291	1,195
Total	\$1,775,593	\$160,673	\$165,141	\$122,301	\$99,079	\$681,122	\$547,277

- (1) Includes minimum cash payments related to principal and interest, including commitment fees, associated with our 2010 Credit Facility, Senior Notes, Convertible Notes, and other indebtedness. Since future interest rates on our variable rate borrowings are unknown, for purposes of this contractual obligations table, amounts scheduled above were calculated using the contractual interest rate spread corresponding to our current leverage ratios.
- (2) 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.
- (3) 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.
- (4) 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, Endo has agreed to make certain guaranteed minimum annual royalty payments beginning in the fourth year of the Voltaren® Gel Agreement, subject to certain limitations as defined in the Voltaren® Gel Agreement. 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.
- (5) 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, 2010, the minimum advertising and promotional spending are determined based on a percentage of net sales of the licensed product.
- (6) In April 2008, Indevus entered into an agreement to terminate its manufacturing and supply agreement with Shire Pharmaceuticals Group plc (Shire) related to Vantas<sup>®</sup>. Under this termination agreement, Shire relinquished its right to receive royalties on net sales of Vantas<sup>®</sup> or a percentage of royalties and other consideration received in connection with a sublicense of Vantas<sup>®</sup> selling and marketing rights granted by Shire. The termination agreement provided for Indevus to pay Shire a total of \$5.0 million. The final payment to be made to Shire of \$1.5 million was paid in January 2011.
- (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 more fully described in Note 12 to the Consolidated Financial Statements in Part IV, Item 15 of this Report, on January 1, 2007, we adopted the provisions for accounting for uncertain tax provisions and recorded a \$7.7 million non-current liability representing the Company's unrecognized tax benefits with respect to our uncertain tax positions. As of December 31, 2010, our liability for unrecognized tax benefits amounted to \$47.4 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. We currently have no material operations outside of the United States. As a result, fluctuations in foreign currency exchange rates do not have a material effect on our financial statements.

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

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 United States 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 pharmaceutical products revenues consist of revenues from sales of our 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 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.

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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 five 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. The state of the state and the state of the second and

าว ของ แล้ว และ ความ เมื่อกระบังธรรม ของ และการค้าหลัง Under the DSAs, we received information from our five wholesaler customers about the levels of inventory, they held for our branded products as of December 31, 2010. 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 and services

Our devices and services revenues consist primarily of revenues from sales of our devices and services acquired from HealthTronics. Revenue is recognized for these sales based on the type of product or service sold, as follows:

- Fees for urology treatments. A substantial majority of our devices and 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 must care facilities. The professional fee payable to the physician performing the procedure is generally billed and collected by the physician. We recognize revenue for these services when the services are is: provided. IGRT technical services are billed monthly and the related revenues are recognized as the related services are provided.
- 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. Barrier a Ben in 1811
- 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.

The following table presents the activity and ending balances for our product sales provisions for the last three years (in thousands):

	Returns and Allowances	Rebates	Chargebacks	Other Sales Deductions	Total
Balance at January 1, 2008	\$ 31,198	\$ 81,233	\$ 34,575	\$ 5,157	\$ 152,163
Current year provision	15,596	291,580	345,378	40,641	693,195
Prior year provision	200	(5,763)	(948)	_	(6,511)
Payments or credits	(8,012)	(262,383)	(343,023)	(40,656)	(654,074)
Balance at December 31, 2008	\$ 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 at the state of the sta	(1,287)	(5,749)	1,164	ing <u>— p</u> ir	(5,872)
Payments or credits		(371,074)	(480,963)	(48,450)	(910,128)
Balance at December 31, 2009	\$ 48,274	\$ 124,443	\$ 51,904	\$ 6,060	\$ 230,681
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	*** * <u>-</u>	(4,290)
Payments or credits	(11,752)	(562,636)	(493,345)	(53,542)	(1,121,275)
Balance at December 31, 2010	\$ 65,021	\$ 203,225	\$ 87,820	\$ 15,320	\$ 371,386

#### 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 continually reassess and make the appropriate changes to our estimates and assumptions as new information becomes available to us.

Our estimate for returns and allowances may be impacted by a number of factors, but the principal factor relates to the level of inventory in the distribution channel. When we are aware of an increase in the level of inventory of our products in the distribution channel, we consider the reasons for the increase to determine if the increase may be temporary or other-than-temporary. Increases in inventory levels assessed as temporary will not result in an adjustment to our provision for returns and allowances. Other-than-temporary increases in inventory levels, however, may be an indication that future product returns could be higher than originally anticipated and, accordingly, we may need to adjust our estimate for returns and allowances. Some of the factors that may be an indication that an increase in inventory levels will be temporary include:

- recently implemented or announced price increases for our products; and
- new product launches or expanded indications for our existing products. As the first the second of the second of

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.

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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 (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;
- 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, 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 underperformance 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 2010 and 2009, we did not recognize an impairment charge as a result of our review of long-lived assets.

During the year ended December 31, 2008, as a result of our decision to discontinue the development of Rapinyl<sup>TM</sup>, we recorded an impairment charge of \$8.1 million related to the remaining unamortized portion of our Rapinyl<sup>TM</sup> intangible asset, and \$3.1 million to write off certain other assets related to the development of Rapinyl<sup>TM</sup>. In addition, during the year ended December 31, 2008, we recorded impairment charges totaling \$1.5 million related to the abandonment of certain 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 two to twenty 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 earnings per share to decrease. The value of these licenses is subject to continuing scientific, medical and marketplace uncertainty.

Acquired developed technology is recorded at fair value upon acquisition and amortized using estimated useful lives ranging from ten to twenty years, with a weighted average useful life of approximately 15 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 earnings per share to decrease. The value of these assets is subject to continuing scientific, medical and marketplace uncertainty.

## 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 1st. 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 three operating segments, Branded Pharmaceuticals, Generics, and Devices and Services, we have determined that the Company has six reporting units; (1) Pain, (2) Generics, (3) Urology, Endocrinology and Oncology (UEO), (4) Anatomical Pathology Services, (5) Urology Services, and

(6) Radiation Therapy.

As of January 1, 2011, our annual assessment date, we completed our annual recoverability review. The results of our analyses showed that the fair value of each of our reporting units significantly exceeded their respective carrying values, except for the Urology Services reporting unit, since this was recently acquired in July 2010 as part of the Healthtronics acquisition, and thus no goodwill impairment exists.

Based upon recent market conditions, and 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 estimates of the assumptions that market participants would use in determining the fair value of our reporting units at the measurement dates.

In December 2009, the Company's Phase III clinical trials for Pro2000 provided conclusive results that the drug was not effective. In December 2009, the Company concluded there was no further value or alternative future uses associated with this indefinite-lived asset. Accordingly, we recorded a \$4.0 million pre-tax impairment charge to write-off the Pro2000 intangible asset in its entirety. Additionally, as a result of the FDA's Complete Response letter related to our NDA for Aveed<sup>TM</sup>, the Company performed an impairment review as of December 2, 2009 for the Aveed<sup>TM</sup> indefinite-lived intangible asset.

Although the Company is continuing to evaluate the FDA's findings to better understand the agency's concerns, we were required to estimate the fair value of our Aveed<sup>TM</sup> indefinite-lived intangible asset as of the date we received the Complete Response letter. To estimate fair value we assessed the possible changes to the product's indication and targeted population of eligible recipients, the future probability of regulatory approval, relative timing of commercialization, and estimates of the amount and timing of future cash flows. In January 2010, the Company was notified that the U.S. patent office had issued a Notice of Allowance on a patent covering the Aveed<sup>TM</sup> formulation. Therefore, management considered the likely benefit of patent exclusivity when estimating these future cash flows. To calculate the fair value of the Aveed<sup>TM</sup> intangible asset, the Company used an income approach using a discounted cash flow model considering management's current evaluation of the above mentioned factors. The Company utilized probability-weighted cash flow models using a present value discount factor of 15% which we believe to be commensurate with the overall risk associated with this particular product. The cash flow models included our best estimates of future FDA approval associated with each potential indication and population of eligible recipients. The Company believes that the level and timing of cash flows assumed, discount rate, and probabilities of success appropriately reflect market participant assumptions.

The fair value of the Aveed<sup>TM</sup> intangible asset was determined to be \$35 million. Accordingly, the Company recorded a pre-tax non-cash impairment charge of \$65 million for the year ended December 31, 2009, representing the difference between the carrying value of the intangible asset and its estimated fair value. The impairment charge has been recognized in earnings and is included the Impairment of other intangible assets line item in the Consolidated Statements of Operations. We believe the most subjective assumption in our discounted cash flow model is the probability of regulatory approval. Assessing the probability of achieving the estimated cash flows is challenging particularly as it relates to in-process research and development assets. These probabilities have a material impact on the ultimate fair value of the asset as the probability of regulatory approval is applied directly to our future revenue projections. Although we believe our probabilities of success used in our fair value determination are reasonable, changes in these assumptions would impact the impairment charge as follows: A 500 basis point change in the overall probability of approval would have resulted in a change to the impairment charge of approximately \$5 million.

In 2010, 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 continuing to evaluate how best to address the concerns of the FDA and

intends to have future dialogue with the agency regarding a possible regulatory pathway. 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. Changes in any of these assumptions may result in a further reduction to the estimated fair value of the Aveed<sup>TM</sup> intangible asset resulting in additional and potentially full future impairment charges. Such additional impairment charges could materially impact our results of operations in future periods.

In May 2010, Teva Pharmaceutical Industries Ltd. terminated the pagoclone 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 annual review of all in-process research and development 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 R&D 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 for the year ended December 31, 2010, to write-off, in its entirety, the octreotide – carcinoid syndrome intangible asset.

#### 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 in-process research and development (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.

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 contingent consideration relates to the amounts payable under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement. In the event that the Company receives an approval letter from the FDA with respect to the Aveed<sup>TM</sup> NDA on or before the third anniversary of the time at which we purchased the Indevus Shares in the Offer, then the Company will, subject to the terms described below, (i) pay an additional \$2.00 per Indevus Share to the former stockholders of Indevus, if such approval letter grants the right to market and sell Aveed<sup>TM</sup> immediately and provides labeling for Aveed<sup>TM</sup> that does not contain a "boxed warning" (Aveed<sup>TM</sup> With Label) or alternatively, (ii) pay an additional \$1.00 per Indevus Share, if such approval letter grants the right to market and sell Aveed<sup>TM</sup> immediately and provides labeling for Aveed<sup>TM</sup> that contains a "boxed warning" (Aveed<sup>TM</sup> Without Label). In the event that either an Aveed<sup>TM</sup> With Label approval or an Aveed<sup>TM</sup> Without Label approval has not been obtained prior to the third anniversary of the closing of the Offer, then the Company will not pay, and the former Indevus stockholders will not receive, any payments under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement.

Further, in the event that the Aveed<sup>TM</sup> Without Label approval is received and subsequently, Endo and its subsidiaries publicly report audited financial statements which reflect cumulative net sales of Aveed<sup>TM</sup> of at least \$125.0 million for four consecutive calendar quarters on or prior to the fifth anniversary of the date of the first commercial sale of Aveed<sup>TM</sup> (Aveed<sup>TM</sup> Net Sales Event), then the Company will, subject to the terms described below, pay an additional \$1.00 per Indevus Share to the former stockholders of Indevus. In the event that the Aveed<sup>TM</sup> Net Sales Event does not occur prior to the fifth anniversary of the date of the first commercial sale of Aveed<sup>TM</sup> then the Company will not pay, and former Indevus stockholders will not receive, any additional amounts under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement.

The range of the undiscounted amounts the Company could pay under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement is between \$0 and approximately \$175.0 million. The fair value of the contractual obligation to pay the Aveed™ contingent consideration recognized on the Indevus Acquisition Date was \$133.1 million. We determined the fair value of the obligation to pay the Aveed<sup>TM</sup> contingent consideration based on a probability-weighted income approach. 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. Under the Aveed<sup>TM</sup> Contingent Cash Consideration 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<sup>TM</sup> With Label approval, (2) obtaining an Aveed<sup>TM</sup> 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<sup>TM</sup> should the Aveed<sup>TM</sup> Without Label approval be obtained. The fourth scenario is Aveed<sup>TM</sup> 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<sup>TM</sup>. 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. The fair value of the contractual obligation to pay the Aveed<sup>TM</sup> contingent consideration was \$7.1 million and \$7.5 million at December 31, 2010 and December 31, 2009, respectively. Future changes in any of our assumptions could result in further volatility to the estimated fair value of the acquisition-related contingent consideration. Such additional changes to fair value could materially impact our results of operations in future periods.

Similarly, in the event that an approval letter from the FDA is received with respect to an octreotide NDA, which we refer to as the Octreotide Approval, on or before the fourth anniversary of the closing of the Offer, then

the Company will, subject to the terms described below, pay an additional \$1.00 per Indevus Share to the former stockholders of Indevus (such payment, the Octreotide Contingent Cash Consideration Payment). In the event that an Octreotide Approval has not been obtained prior to the fourth anniversary of the closing of the Offer, then the Company will not pay, and the former Indevus stockholders shall not receive, the Octreotide Contingent Cash Consideration Payment.

The range of the undiscounted amounts the Company could pay under the Octreotide Contingent Cash Consideration Agreement is between \$0 and approximately \$91.0 million. The fair value of the octreotide contractual obligation to pay the contingent consideration recognized on the Indevus Acquisition Date was \$39.8 million. We determined the fair value of the contractual obligation to pay the Octreotide Contingent Consideration Payment based on a probability-weighted income approach. 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. Under the Octreotide Contingent Cash Consideration Agreement, the two scenarios that require consideration are (1) Octreotide Approval 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. The fair value of the contractual obligation to pay the octreotide contingent consideration was determined to be \$0 at December 31, 2010 compared to \$42.5 million at December 31, 2009. Future changes in any of our assumptions could result in further volatility to the estimated fair value of the acquisition-related contingent consideration. Such additional changes to fair value could materially impact our results of operations in future periods.

In addition to the potential contingent payments under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement, the Company has assumed a pre-existing contingent consideration obligation relating to Indevus' acquisition of Valera Pharmaceuticals, Inc. (the Valera Contingent Consideration), which was consummated on April 18, 2007. The Valera Contingent Consideration entitles former Valera shareholders to receive additional Indevus Shares based on an agreed upon conversion factor if FDA approval of the octreotide implant for the treatment for acromegaly is achieved on or before April 18, 2012. Upon Endo's acquisition of Indevus, each Valera shareholder's right to receive additional Indevus Shares was converted into the right to receive \$4.50 per Indevus Share that such former Valera shareholder would have received plus contractual rights to receive up to an additional \$3.00 per Indevus Share that such former Valera shareholder would have received in contingent cash consideration payments under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement. These amounts would only be payable to former Valera shareholders if there were Octreotide Approval. The range of the undiscounted amounts the Company could pay with respect to the Valera Contingent Consideration is between \$0 and approximately \$33.0 million.

The Company is accounting for the Valera Contingent Consideration in the same manner as if it had entered into that arrangement with respect to its acquisition of Indevus. Accordingly, the fair value of the Valera Contingent Consideration recognized on the Indevus Acquisition Date was \$13.7 million. Fair value was estimated based on a probability-weighted discounted cash flow model, or income approach. 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. The fair value of the Valera Contingent Consideration is estimated using the same assumptions used for the Aveed<sup>TM</sup> 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. The fair value of the contractual obligation to pay the Valera Contingent Consideration was determined to be \$0 at December 31, 2010 compared to \$8.5 million at December 31, 2009. Future changes in any of our assumptions could result in further volatility to the estimated fair value of the acquisition-related contingent consideration. Such additional changes to fair value could materially impact our results of operations in future periods.

As of December 31, 2010, the fair value of the Indevus acquisition-related contingent consideration decreased by approximately \$51.4 million from December 31, 2009, 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. The decrease in the liability was recorded as a gain and is included in the Acquisition-related items line item in the accompanying Consolidated Statements of Operations.

As of December 31, 2009, the fair value of the Indevus acquisition-related contingent consideration decreased by approximately \$128.1 million from the acquisition date, primarily reflecting management's assessment of the decreased probability that we will be obligated to make contingent consideration payments under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement within the specified contractual timeframe, as well as the anticipated timeline for the NDA filing and FDA approval of octreotide. The decrease in the liability was recorded as a gain and is included in the Acquisition-related items line item 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). As of December 31, 2010, the range of the undiscounted amounts the Company could pay with respect to the Teva Contingent Consideration is between \$0 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 of the Teva Contingent Consideration recognized on the Qualitest Acquisition Date was \$9.0 million. Fair value was estimated based on a probability-weighted discounted cash flow model, or income approach. 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. The fair value of the contractual obligation to pay contingent consideration was \$9.0 million at December 31, 2010. Future changes in any of our assumptions could result in further volatility to the estimated fair value of the acquisition-related contingent consideration. Such additional changes to fair value could impact our results of operations in future periods.

#### 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.

At December 31, 2010, we had \$399.7 million of gross deferred tax assets, which included federal and state net operating loss carryforwards (NOLs) of approximately \$209.6 million, research and development (R&D) credit carryforwards of \$15.4 million, capital loss carryforwards of \$16.9 million and temporary differences of approximately \$157.8 million. At December 31, 2010, our NOLs and R&D credit carryforwards were related to multiple tax jurisdictions, including federal and various state jurisdictions, which expire at intervals between 2011 and 2029. 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 lessthan-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 R&D credit carryfowards. 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 \$16.9 million at December 31, 2010. In addition, due to our historical losses in certain state jurisdictions and the absence of sources of income, we have established a \$9.0 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.

On January 1, 2007, the Company adopted the provisions for accounting for uncertain tax positions. The provisions apply to all material tax positions in all taxing jurisdictions for all open tax years. The guidance establishes a two-step process for evaluating tax positions. 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.

#### **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 expenses 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 in the future could increase, thereby increasing stock-based compensation expense in future periods. The riskfree 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

Recently Adopted Accounting Pronouncements

The Company adopted new authoritative guidance on variable interests effective January 1, 2010. The amendments change the process for how an enterprise determines which party consolidates a variable interest entity (a VIE) to a primarily qualitative analysis. The party that consolidates the VIE (the primary beneficiary) is defined as the party with (1) the power to direct activities of the VIE that most significantly affect the VIE's economic performance and (2) the obligation to absorb losses of the VIE or the right to receive benefits from the VIE. Upon adoption, reporting enterprises must reconsider their conclusions on whether an entity should be consolidated and should a change result; the effect on net assets will be recorded as a cumulative effect adjustment to retained earnings. This pronouncement did not have a material impact on the Company's consolidated financial statements.

The Company elected to adopt early the new authoritative guidance on revenue recognition effective January 1, 2010. The guidance provides greater ability to separate and allocate arrangement consideration in a multiple element revenue arrangement. In addition, it will require the use of estimated selling price to allocate arrangement considerations, therefore eliminating the use of the residual method of accounting. The Company has elected to prospectively adopt these provisions. Our adoption of this pronouncement did not have a material impact on the Company's consolidated financial statements.

The Company adopted new authoritative guidance on business combinations for acquisitions occurring on or after January 1, 2009. This requires recognition of assets acquired, liabilities assumed, and any noncontrolling interests in the acquiree at the acquisition date, measured at their fair values as of that date. In a business combination achieved in stages, this pronouncement requires recognition of identifiable assets and liabilities, as well as the noncontrolling interests in the acquiree, at the full amounts of their fair values. This pronouncement also requires the fair value of acquired in-process research and development (referred to as IPR&D) to be recorded as indefinite lived intangibles, contingent consideration to be recorded on the acquisition date, and

restructuring and acquisition-related deal costs to be expensed as incurred. In addition, any excess of the fair value of net assets acquired over purchase price and any subsequent changes in estimated contingencies are to be recorded in earnings. See Note 5 for purchase accounting details.

The Company adopted new authoritative guidance on collaborative arrangements which was effective January 1, 2009 and the provisions have been applied retroactively. According to this pronouncement a collaborative arrangement is one in which the participants are actively involved and are exposed to significant risks and rewards that depend on the ultimate commercial success of the endeavor. Payments to or from collaborators are evaluated and presented based on the nature of the arrangement and its terms, the nature of the entity's business, and whether those payments are within the scope of other accounting literature. The nature and purpose of collaborative arrangements are disclosed along with the accounting policies and the classification of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity are accounted for under other accounting literature; however, required disclosure applies to the entire collaborative agreement. This pronouncement did not have a material impact on the Company's consolidated financial statements.

The Company adopted new authoritative guidance on the fair value option for financial assets and financial liabilities which became effective for fiscal years beginning after November 15, 2007. The Standard's objective is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Generally accepted accounting principles have required different measurement attributes for different assets and liabilities that can create artificial volatility in earnings. This authoritative guidance helps to mitigate this type of accounting-induced volatility by enabling companies to report related assets and liabilities at fair value, which would likely reduce the need for companies to comply with detailed rules for hedge accounting. This Standard requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the Company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which the Company has chosen to use fair value on the face of the balance sheet. Upon adoption, we chose not to elect the fair value option for our existing financial assets and liabilities. Therefore, the adoption did not have any impact on our consolidated financial statements. In November 2008, simultaneously with our execution of the agreement with UBS with respect to certain auction-rate securities in UBS accounts, we elected the fair value option for the auction-rate securities rights (See Note 3).

The Company adopted the new authoritative guidance on convertible debt instruments that may be settled in cash or other assets on conversion as of January 1, 2009. The guidance requires that issuers of convertible debt instruments that may be settled in cash or other assets on conversion to separately account for the liability and equity components of the instrument in a manner that will reflect the entity's nonconvertible debt borrowing rate on the instrument's issuance date when interest cost is recognized in subsequent periods. Our Convertible Notes are within the scope of this new guidance. Therefore, we are required to separate the debt portion of our Convertible Notes from the equity portion at their fair value retrospective to the date of issuance and amortize the resulting discount into interest expense over the life of the debt. The provisions of the guidance are to be applied retrospectively to all periods presented upon adoption and became effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The adoption will result in the recognition of approximately \$138.7 million of additional interest expense, on a pre-tax basis, over the life of our Convertible Notes. See Note 18 for further details.

The Company adopted the new authoritative guidance on determining the fair value of a financial asset when the market for that asset is not active for the period ending September 30, 2008. The guidance clarifies the application of fair value measurements when determining the fair value of a financial asset when the market for that asset is not currently active. Additionally, it emphasizes that approaches other than the market approach to determining fair value may be appropriate when it is determined that, as a result of market inactivity, other valuation approaches are more representative of fair value. Other valuation approaches can involve significant assumptions regarding future cash flows. The guidance clarifies that these assumptions must incorporate adjustments for nonperformance and liquidity risks that market participants would consider in valuing the asset in an inactive market. See Note 3 for a further discussion of fair value.

The Company adopted the new authoritative guidance on interim and annual disclosure about fair value of financial instruments which became effective for periods beginning after December 15, 2009. The guidance amends previous authoritative guidance by requiring disclosures with respect to the fair value of financial instruments in interim and annual financial statements. The adoption did not have a material effect on the Company's consolidated results of operations or financial condition; however it did result in enhanced disclosures about fair value of financial instruments in our interim financial statements. See Note 3, Fair Value Measurements, for further discussion.

## Accounting Pronouncements Issued But Not Yet Adopted

In December 2010, the FASB issued authoritative guidance for 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. We expect this fee will be approximately \$11 million in 2011, which will be charged as an operating expense ratably throughout 2011.

In December 2010, the FASB issued authoritative guidance 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 comparative financial statements are presented. It is effective on a prospective basis 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. We will adopt this guidance beginning with business combinations for which the acquisition date is on or after January 1, 2011.

In April 2010, the FASB issued revised authoritative guidance for milestone revenue recognition. The new guidance recognizes the milestone method as an acceptable revenue recognition method for substantive milestones in research or development transactions. It is effective on a prospective basis to milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. We will adopt this guidance beginning with agreements entered into after January 1, 2011. We are currently evaluating the impact of adoption on our consolidated results of operations and financial position.

# 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. 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, 2010 and December 31, 2009, we had no other assets or liabilities that have significant interest rate sensitivity.

#### Investment Risk

At December 31, 2010 and 2009, we had publicly traded equity securities totaling \$6.2 million and \$4.5 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 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, 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. Based on the fair value of the publicly traded equity securities we held at December 31, 2009, 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 \$1.1 million, \$1.8 million and \$2.2 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.

Beginning in 2008 and continuing into 2010, the securities and credit markets have been experiencing severe volatility and disturbance, increasing risk with respect to certain of our financial assets. At December 31, 2008, the Company determined that the market for its auction-rate securities was inactive. That determination was made considering that there are very few observable transactions for the auction-rate securities or similar securities, the prices for transactions that have occurred are not current, and the observable prices for those transactions—to the extent they exist—vary substantially either over time or among market makers, thus reducing the potential usefulness of those observations.

In January 2008, the Company chose to reduce its exposure to auction-rate securities and ceased all purchases of auction-rate securities effective February 1, 2008, prior to when we began to experience failed auctions. There were no realized holding gains or losses resulting from the sales of our auction-rate securities during the twelve months ended December 31, 2008.

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

If uncertainties in the credit and capital markets continue, these markets deteriorate further or we experience any additional cover rating 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, financial condition, and cash flows. 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. However, based on our ability to access our cash and cash equivalents and our other liquid investments, and our expected operating cash flows, we do not expect to be required to sell these securities at a loss. However, there can be no assurance that we will not have to sell these securities at a loss.

#### Foreign Currency Risk

While primarily all of our revenues are within the United States and denominated in U.S. dollars, 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.

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# 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, 2010. 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, 2010.

### (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 HealthTronics, Inc., Penwest Pharmaceuticals Co., and Generics International (US Parent), Inc. (Qualitest) on July 2, 2010, September 20, 2010, and November 30, 2010, 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, 2010 associated with the establishment of internal control over financial reporting with respect to these acquired companies. As of December 31, 2010, Qualitest which, in the aggregate, represents 36.6% and 1.8% of consolidated total assets and consolidated total revenues, respectively, of the Company as of and for the year ended December 31, 2010, has been excluded from management's report of internal control over financial reporting due to the November 30, 2010 closing date and its proximity to the date of management's assessment of the effectiveness of the Company's internal control over financial reporting.

There were no other changes in the Company's internal control over financial reporting during the fourth quarter of 2010 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

#### Item 9B. Other Information

On February 23, 2011, we gave notice to Novartis Consumer Health, Inc. (Novartis) that we would terminate our Master Development and Toll Manufacturing Agreement, as amended, effective February 2014. Pursuant to the terms of this agreement, our requirement to make minimum purchases of approximately \$14 million per year, or pro rata portion thereof, will remain in effect until the effective date of the termination of this agreement.

In February 2011, Edward J. Sweeney elected to resign his position as the Company's Vice President, Controller and Principal Accounting Officer, to become Vice President, Finance effective March 31, 2011. Daniel A. Rudio, age 37, has been appointed as the Company's Vice President, Controller and Principal Accounting Officer effective April 1, 2011. Mr. Rudio joined the Company in November 2006 as Financial Reporting Manager and has held various positions of increasing responsibility, most recently as Senior Director, Finance & Accounting. Prior to joining the Company, Mr. Rudio was a business unit finance manager for the Americas at Rohm and Haas Company where he worked for 4 years in a variety of accounting and finance related positions of increasing responsibility. Before that, Mr. Rudio was a manager at Ernst & Young LLP where he worked from July 1995 to November 2002. Mr. Rudio is a licensed certified public accountant in the Commonwealth of Pennsylvania and holds Bachelor of Science degrees in both accounting and finance from Rutgers University.

#### 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 2011 Annual Meeting of Stockholders (2011 Proxy Statement).

# **Executive Officers**

For information concerning Endo's executive officers, see "Item 1. Business—Executive Officers of the Registrant" and our 2011 Proxy Statement.

#### **Code of Ethics**

The information concerning our Code of Conduct is incorporated herein by reference from our 2011 Proxy Statement.

#### **Audit Committee**

The information concerning our Audit Committee is incorporated herein by reference from our 2011 Proxy Statement.

# **Audit Committee Financial Experts**

The information concerning our Audit Committee Financial Experts is incorporated herein by reference from our 2011 Proxy Statement.

#### Item 11. Executive Compensation

The information required under this Item is incorporated herein by reference from our 2011 Proxy Statement.

# 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, 2010 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 provide that stock options may be granted thereunder to non-employee consultants.

±		• ;	4 4	Column A	Column B	Column C
-Plan Categor	<u>y</u>			Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column A)
<b>Equity</b> cor	npensatio	n plans app	roved by			to Bent Front Days W. Box
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		ticals Holdi				
201	0 Stock Ind	centive Plan		602,880	27.68(1)	10,347,536

<sup>(1)</sup> Excludes shares of restricted stock units outstanding

The other information required under this Item is incorporated herein by reference from our 2011 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 2011 Proxy Statement.

# Item 14. Principal Accountant Fees and Services

Information about the fees for 2010 and 2009 for professional services rendered by our independent registered public accounting firm is incorporated herein by reference from our 2011 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 2011 Proxy Statement.

#### **PART IV**

# Item 15. Exhibits, Financial Statement Schedules

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

- Consolidated Financial Statements: See accompanying Index to Consolidated Financial Statements.
- Consolidated Financial Statement Schedule:

## SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS

#### (in thousands)

Pigo Politores de la sectión de la companya de la c Las sectiones de la companya de la c La companya de la co	Balance at Beginning of Period	Additions, Costs and Expenses	Deductions, Write-offs	Balance at End of Period
Allowance For Doubtful Accounts:	de car	$\phi_{i,j}(t) = -\infty$	ومراف أأعرار	grater
Year Ended December 31, 2008	\$1,465	<u>\$—</u>	<u>\$ —</u>	\$1,465
Year Ended December 31, 2009	\$1,465	\$	\$(442)	\$1,023
Year Ended December 31, 2010 (A	\$1,023	\$855	\$(748)	\$1,130

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.

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<sup>3.</sup> Exhibits: The information called for by this item is incorporated by reference to the Exhibit Index of this Report.

# **SIGNATURES**

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

# ENDO PHARMACEUTICALS HOLDINGS INC. (Registrant)

_	/s/ DAVID P. HOLVECK
Name: Title:	David P. Holveck President and Chief Executive Officer
rue.	(Principal Executive Officer)
_	/s/ Alan G. Levin
Name: Title:	Alan G. Levin Executive Vice President, Chief Financial Officer
Tine:	(Principal Financial Officer)
_	/s/ Edward J. Sweeney
Name:	Edward J. Sweeney
Title:	Vice President, Controller and Principal Accounting Officer (Principal Accounting Officer)

Date: February 28, 2011

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	<u>Title</u>	<u>Date</u>	
/s/ DAVID P. HOLVECK	President and Chief Executive Officer	February 28, 2011	
David P. Holveck			
/s/ Alan G. Levin	Executive Vice President, Chief	February 28, 2011	
Alan G. Levin	Financial Officer		
*	Chairman and Director	February 28, 2011	
Roger H. Kimmel			
*	Director	February 28, 2011	
John J. Delucca			
*	Director	February 28, 2011	
Nancy J. Hutson, Ph.D.			
*	Director	February 28, 2011	
Michael Hyatt			
*	Director	February 28, 2011	
William P. Montague			
*	Director	February 28, 2011	
Joseph C. Scodari			
*	Director	February 28, 2011	
William F. Spengler			
*By: /s/ CAROLINE B. MANOGUE	Attorney-in-fact, pursuant to a Power of	February 28, 2011	
Caroline B. Manogue	Attorney filed with this Report as Exhibit 24		
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# INDEX TO FINANCIAL STATEMENTS

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<sup>-</sup> 2008	F-10

#### 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, 2010. 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, 2010, the Company's internal control over financial reporting is effective based on those criteria.

On November 30, 2010, the Company completed its acquisition of Generics International (US Parent), Inc. (Qualitest). Due to the close proximity of the completion date of the acquisition of Qualitest to the date of management's assessment of the effectiveness of the Company's internal control over financial reporting, management excluded Qualitest from its assessment of internal control over financial reporting. Qualitest, a wholly owned subsidiary of the Company, represents, in the aggregate, 36.6% and 1.8% of consolidated total assets and consolidated total revenues, respectively, of the Company as of and for the year ended December 31, 2010. This acquisition is more fully discussed in Note 5 to our Consolidated Financial Statements for the year ended December 31, 2010.

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, 2010. 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 28, 2011

#### 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, 2010 and 2009, 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, 2010. 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, 2010 and 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010, 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, 2010, 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 28, 2011 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Philadelphia, Pennsylvania February 28, 2011

#### 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, 2010, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. As described in the accompanying Management's Report on Internal Control over Financial Reporting, management excluded from its assessment the internal control over financial reporting at Generics International (US Parent), Inc. (Qualitest), which was acquired on November 30, 2010, and whose financial statements constitute 36.6% and 1.8% of consolidated total assets and consolidated total revenues, respectively, of the consolidated financial statement amounts as of and for the year ended December 31, 2010. Accordingly, our audit did not include the internal control over financial reporting at Generics International (US Parent), Inc. 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, 2010, 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, 2010 of the Company and our report dated February 28, 2011 expressed an unqualified opinion on those financial statements and financial statement schedule.

/s/ DELOITTE & TOUCHE LLP

Philadelphia, Pennsylvania February 28, 2011

# ENDO PHARMACEUTICALS HOLDINGS INC.

# CONSOLIDATED BALANCE SHEETS DECEMBER 31, 2010 AND 2009

(In thousands, except share and per share data)

	2010	2009
ASSETS		
CURRENT ASSETS:	h 466014	A 500 460
Cash and cash equivalents	\$ 466,214	\$ 708,462
Restricted cash	· —	1,515
Marketable securities		25,275
Accounts receivable, net of allowance of \$1,130 and \$1,023 at December 31, 2010 and 2009	547,807	323,501
Inventories	178,805	84,893
Prepaid expenses and other current assets	22,841	17,081
Auction-rate securities rights, at fair value	22,041	15,659
Income taxes receivable	3,143	13,762
Deferred income taxes	140,724	90,433
Total current assets	1,359,534	1,280,581
MARKETABLE SECURITIES	23,509	211,792
PROPERTY AND EQUIPMENT, NET	215,295	
GOODWILL	715,005	302,534
OTHER INTANGIBLES, NET	1,531,760	609,909
OTHER ASSETS	67,286	36,458
TOTAL ASSETS	\$3,912,389	\$2,488,803
LIABILITIES AND STOCKHOLDERS' EQUITY		
CUDDENIT LA DIL TEREC.		•
Accounts payable	\$ 241,114	\$ 176,076
Accrued expenses	469,721	286,606
Current portion of long-term debt	24,993	
Income taxes payable		9,498
Total current liabilities	735,828	472,180
DEFERRED INCOME TAXES	217,334	49,180
ACQUISITION-RELATED CONTINGENT CONSIDERATION	16,050	58,470
LONG-TERM DEBT, LESS CURRENT PORTION, NET	1,045,801	322,534
OTHER LIABILITIES	94,047	89,028
COMMITMENTS AND CONTINGENCIES (NOTE 14)	<i>5</i> 1,0 1 7	05,020
STOCKHOLDERS' EQUITY:		
Preferred Stock, \$0.01 par value; 40,000,000 shares authorized; none issued		
Common Stock, \$0.01 par value; 350,000,000 shares authorized; 136,309,917		
and 134,986,612 shares issued; 116,057,895 and 117,270,309 outstanding at		
December 31, 2010 and 2009, respectively	1,363	1,350
Additional paid-in capital	860,882	817,467
Retained earnings	1,364,297	1,105,291
Accumulated other comprehensive loss	(1,161)	(1,881)
Treasury stock, 20,252,022 and 17,716,303 shares at December 31, 2010 and	(402.700)	(404.016)
December 31, 2009, respectively	(483,790)	(424,816)
Total Endo Pharmaceuticals Holdings Inc. stockholders' equity	1,741,591	1,497,411
Noncontrolling interests	61,738	1 407 411
Total stockholders' equity	1,803,329	1,497,411
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$3,912,389	\$2,488,803

See notes to consolidated financial statements.

# ENDO PHARMACEUTICALS HOLDINGS INC.

# CONSOLIDATED STATEMENTS OF OPERATIONS YEARS ENDED DECEMBER 31, 2010, 2009, AND 2008 (In thousands, except per share data)

	2010	2009	2008
REVENUES:			
Net sales	\$1,601,192	\$1,451,577	\$1,260,536
Device, service and other revenues	115,037	9,264	
TOTAL REVENUES	1,716,229	1,460,841	\$1,260,536
COSTS AND EXPENSES:			
Cost of revenues	504,757	375,058	267,235
Selling, general and administrative	547,605	534,523	488,063
Research and development	144,525	185,317	110,211
Impairment of other intangible assets	35,000	69,000	8,083
Acquisition-related items	18,976	(93,081)	<del>-</del>
Purchased in-process research and development			(530)
OPERATING INCOME	465,366	390,024	387,474
INTEREST EXPENSE (INCOME), NET	46,601	37,718	(6,107)
OTHER (INCOME) EXPENSE, NET	(1,933)	(3,329)	1,753
GAIN ON EXTINGUISHMENT OF DEBT, NET		(4,025)	·
INCOME BEFORE INCOME TAX	420,698	359,660	391,828
INCOME TAX	133,678	93,324	136,492
CONSOLIDATED NET INCOME	\$ 287,020	\$ 266,336	\$ 255,336
Less: Net income attributable to noncontrolling interests	28,014		
NET INCOME ATTRIBUTABLE TO ENDO PHARMACEUTICALS			
HOLDINGS INC.	\$ 259,006	\$ 266,336	\$ 255,336
NET INCOME PER SHARE ATTRIBUTABLE TO ENDO			
PHARMACEUTICALS HOLDINGS INC.:		. ,	
Basic	\$ 2.23	\$ 2.27	\$ 2.07
Diluted	\$ 2.20	\$ 2.27	\$ 2.06
Basic	116,164	117,112	123,248
Diluted	117,951	117,112	123,720
Diffuted	117,531	117,515	123,720

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE INCOME YEARS ENDED DECEMBER 31, 2010, 2009, AND 2008 (In thousands, except share data)

	Total	Noncontrolling Stockholders' Interests Equity	\$1,292,290	14	16,934	7 735	(92)	185	85,782	50,371	(107,607) 41,160	(424,816)		(31,098)	26.417	255,336	\$ 250,655	\$1,207,111	19,593	8,037	(3,693)	767	(225)	266,336	\$ 266,111	\$1,497,411
		Noncontrolling Interests	- \$	ı	1	1		ł	I		1	1		ł			↓	<u> </u>			1			1	<u>,</u>	<u> </u>
	Total Endo Pharmaceuticals Holdings Inc.	Stockholders' Equity	\$1,292,290	14	16,934	7 235	(92)	185	85,782	50,371	(10/,00/) 41,160	(424,816)		(31,098)	26.417	255,336	\$ 250,655	\$1,207,111	19,593	8,037	(3,693)	767	(225)	266,336	\$ 266,111	\$1,497,411
Endo Pharmaceuticals Holdings Inc. Shareholders	Treasury Stock	Number of Shares Amount	 	1	1			1	1		 	(17,716,303) (424,816)		1		 		(17,716,303)\$(424,816)			] ]		1	 		(17,716,303)\$(424,816)
	Accumulated Other	Comprehensive Income (Loss)	\$ 3,025	1			I	1	1	1				(31,098)	26.417			\$ (1,656)	1	l ; l	1		(225)	1		\$ (1,881)
		Ketained Earnings	\$ 583,619		1			1	1					I		255,336		\$ 838,955	1	1			-	266,336		\$1,105,291
Endo P	Additional	Paid-in Capital	\$ 704,305	14	16,934	7 233	(92)	185	85,782	50,371	41,160			I	!	ļ		\$ 793,285	19,593	8,031	(3,693)	[ <del>]</del>		1 .	."	\$ 817,467 \$1,105,291
	Stock	Amount	\$1,341		1	'	1	1	1	1	<b>!</b>	1		1	I	I		\$1,343		9	1	1	i			\$1,350
	Common Stock	Number of Shares	. 134,144,993		1	(1,131)		7,951	1			1			I	1		134,302,004	7 121)	554,827	130 012	716,001	l	1		134,986,612
			BALANCE, JANUARY 1, 2008	Pharma LLC	Compensation related to stock-based awards	Forteiture of restricted stock awards	Tax benefits of stock awards	Common stock issued	Notes due 2015, net of tax of \$56,417	Sale of common stock warrants	Tax benefit of call options	Treasury stock acquired	Comprehensive income: Unrealized gain on securities, net of	tax	reclassification due to offici-trian- temporary impairment	Net income	Total comprehensive income	BALANCE, DECEMBER 31, 2008 134,302,004	Compensation related to stock-based awards	Exercise of options	Tax benefits of stock awards	Treasury stock acquired	Comprehensive income: Unrealized loss on securities, net of tax	Net income	Total comprehensive income	BALANCE, DECEMBER 31, 2009 134,986,612

# CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE INCOME YEARS ENDED DECEMBER 31, 2010, 2009, AND 2008 – (Continued) (In thousands, except share data)

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Shareh
Inc.
Holdings
Pharmaceuticals ]
Endo

					- C					
								Total Endo		
	Common Stock	Stock	Additional		Accumulated Other	Treasury Stock		Pharmaceuticals Holdings Inc		Total
a.	Number of		Paid-in	Retained	Comprehensive	Number of		Stockholders'	Noncontrolling Stockholders	Stockholders'
		Amount	Capitai	Earnings	Income (Loss)	Shares	Amount	Equity	Interests	Equity
Compensation related to stock-based		-	-							:
awards	1		22,909	ļ	1	I		22,909		22.909
Exercise of options	965,013	6	20,874		ł	1	I	20,883		20,883
Tax benefits of stock awards		1	(802)		1	ļ		(802)	}	(802)
Common stock issued	358,292	4	437		ļ	I	1	441		44
Treasury stock acquired	1	I		1		(2,535,719)	(58,974)	(58.974)	l	(58.974)
Noncontrolling interests acquired in business							•			
combinations			1				1	l	63,227	63,227
Distributions to noncontrolling interests	1			ļ		Ĩ	-		(28,870)	(28,870)
Buy-out of noncontrolling interests	1	ŀ	1	1		I	."	1.	(633)	(633)
Comprehensive income:										-
Unrealized loss on securities, net of										
tax	J				720	1	l	720		720
Net income		]	1	259,006		1		259,006	28,014	287,020
Total comprehensive income	:							\$ 259,726	\$ 28,014	\$ 287,740
BALANCE, DECEMBER 31, 2010 136,309,917	136,309,917	\$ 1,363	\$ 860,882	\$ 1,364,297	\$ (1,161)	(20,252,022) \$ (483,790)	(483,790)	\$ 1,741,591	\$ 61,738	\$ 1,803,329

See notes to consolidated financial statements.

### CONSOLIDATED STATEMENTS OF CASH FLOWS YEARS ENDED DECEMBER 31, 2010, 2009 AND 2008 (In thousands)

(III tilousulus)	2010	2009	2008
OPERATING ACTIVITIES:			
Net income	\$ 287,	,	•
Depreciation and amortization Stock-based compensation	108,	,404 80,38 ,909 19,59	
Amortization of deferred financing/debt issuance costs and premium/discount		013 19,50	
Provision for bad debts		855 —	· —
Selling, general and administrative expenses paid in shares of common stock  Deferred income taxes		220 '25 420) (36,39:	
Loss (gain) on disposal of property and equipment	• •	154 (10	5) 143
Change in the fair value of acquisition-related contingent consideration  Loss (gain) on auction-rate securities rights		,420) (128,090 ,659 11,660	
(Gain) loss on trading securities	(15,	420) (15,22)	
(Gain) on extinguishment of debt, net		(4,02	5) —
Impairment of long-lived assets  Purchased in-process research and development	33,	.000 69,000 — —	) 12,680 (530)
Other-than-temporary impairment of available-for-sale securities	t "		26,417
Changes in assets and liabilities which provided (used) cash: Accounts receivable	(84	659) (62,584	3,458
Inventories		894 12,920	(11,428)
Prepaid and other assets Accounts payable		003) 13,554	
Accrued expenses		145 12,068 346 34,112	
Other liabilities	(5.	612) 9,653	3 11,009
Income taxes receivable/payable Note receivable		561 (7,29:	(19,189) (489)
Net cash provided by operating activities	453,	646 295,400	
INVESTING ACTIVITIES:			
Purchases of property and equipment Purchases of available-for-sale securities	(19,	891) (12,41:	(17,428) (134,211)
Proceeds from sales of trading securities	231,	125 23,750	
Proceeds from sales of available-for-sale securities			447,111
Proceeds from sale of property and equipment Principal payments on note receivable		356 —	27 3,333
License fees		400) (4,485	(85,000)
Acquisitions, net of cash acquired Other investments	(1,105,	040) (250,359 473) (2,000	
Net cash (used in) provided by investing activities	(896,		
FINANCING ACTIVITIES:			
Capital lease obligations repayments	.: (	313) (250	
Tax sharing payments to Endo Pharma LLC Tax benefits of stock awards	1.		(671) 307
Deferred financing fees	(13,	563) (5,162	2) —
Exercise of Endo Pharmaceuticals Holdings Inc. Stock Options Principal payments on HealthTronics senior credit facility		883 8,037 000)	2,235
Principal payments on Qualitest debt	(406,	758)	
Principal payments on debt Net proceeds from issuance of debt	(61, 786,	559) (120,470 576	)) — 370,740
Proceeds from other indebtedness, net		696 —	370,740
Purchase of hedge on convertible senior subordinated notes due 2015			(107,607)
Purchase of common stock	(58,	974) —	50,371 (424,816)
Distributions to noncontrolling interests	(28,	870) —	
Buy-out of noncontrolling interests, net of contributions  Net cash provided by (used in) financing activities	200,	633) <u>—</u> 429 (117,128	(110,066)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(242,		
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	708,		
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 466,	<u>\$ 708,462</u>	\$ 775,693
SUPPLEMENTAL INFORMATION:			
Interest paid	\$ 22,		
Income taxes paid	\$ 143,	<u>\$ 126,431</u>	\$ 142,660
SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES: Purchase of property and equipment financed by capital leases	\$	689 \$ 235	\$ 798
Accrual for purchases of property and equipment		793 \$ 2,635	\$ 4,211
Settlement of note receivable	\$	_ \$ _	\$ (46,667)
Acquisition of license rights Transfer of securities from available-for-sale to trading	\$	_	\$ 90,657 \$ 228,633
See notes to consolidated financial statements.	•	•	
	ſ		

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS YEARS ENDED DECEMBER 31, 2010, 2009 AND 2008

### NOTE 1. DESCRIPTION OF BUSINESS

Endo Pharmaceuticals Holdings Inc., together with its subsidiaries, (the Company or we) is a United States-based, specialty healthcare solutions company focused on high-value branded products and generics as well as 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 medical devices, primarily for the urology community. On September 20, 2010, we acquired a majority interest in Penwest Pharmaceuticals Co., a drug development company. Additionally, on November 30, 2010, we acquired Qualitest, a privately-held generics company in the U.S.

### 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.

Use of Estimates—Management uses estimates and assumptions in preparing financial statements in accordance with U.S. generally accepted accounting principles. Those estimates and assumptions affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and the reported revenues and expenses. Actual results could vary from the estimates that were assumed in preparing the consolidated financial statements.

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 revenues during the years ended December 31 are as follows:

	<u>2010</u>	2009	2008
Cardinal Health, Inc.	33%	35%	36%
McKesson Corporation	28%	29%	31%
AmerisourceBergen Corporation.	15%	16%	15%

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:

	2010	2009	2008	
Lidoderm®	46%	52%	61%	
Opana® ER and Opana®	17%	16%	14%	
Percocet®	7%	9%	10%	

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 for further details).

### Revenue Recognition—

Net sales. Our net 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.

Devices and services. Our fees for urology and pathology services are recorded when the procedure is performed and are based on contracted rates. Management fees from limited partnerships are recorded monthly when earned. Image guided radiation therapy (IGRT) technical services are billed monthly and the related revenues are recognized as the related services are provided.

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 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.

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, 2010, 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.

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.

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.

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.

At December 31, 2010, \$18.8 million of our marketable securities portfolio is invested in auction-rate securities with underlying ratings of AAA. As explained in Note 3, the fair value of these securities, as

determined using a valuation model, was \$17.3 million, \$1.5 million less than their original par value of approximately \$18.8 million. Due to the continuing changes and uncertainty in the credit markets, it is possible that the valuation of auction-rate securities will further fluctuate in the near term.

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 79% and 80% of our trade accounts receivable balance represent amounts due from three customers at December 31, 2010 and 2009, respectively.

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 and Equipment—Property 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 45 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 two to twenty 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.

Developed Technology—Acquired developed technology is recorded at fair value upon acquisition and amortized using estimated useful lives ranging from ten to twenty years, with a weighted average useful life of approximately 15 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 earnings per share to decrease. The value of these assets is subject to continuing scientific, medical and marketplace uncertainty.

Impairment of Long-Lived Assets—Long-lived assets, which includes property and equipment, and other intangible assets, are assessed for impairment whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows generated by that asset. In the event the carrying 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 —The fair value of in-process research and development (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 six 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 \$44.3 million, \$56.9 million and \$50.9 million for the years ended December 31, 2010, 2009 and 2008, 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.

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 part of our

consideration for the Indevus and Qualitest 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, 2010, 2009 and 2008 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—As of December 31, 2010, our operations are organized into three reportable segments: Branded Pharmaceuticals, Generics, and Devices and Services. The Generics and Devices and Services segments were established during the year ended December 31, 2010 pursuant to changes in the organization of our business resulting from the acquisitions of Qualitest and HealthTronics, respectively. A summary of our net revenues to external customers and adjusted income (loss) before income tax for each of our segments is found in Note 6 to the Consolidated Financial Statements.

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, 2010.

Convertible Senior Subordinated Notes—We accounted for the issuance of our 1.75% Convertible Senior Subordinated Notes due April 2015 (the Convertible Notes) in accordance with the guidance regarding the accounting for convertible debt instruments that may be settled in cash upon conversion, which among other items, specifies that contracts issued or held by an entity that are both (1) indexed to the entities own 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. 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 Sheet.

### Recently Adopted Accounting Pronouncements

The Company adopted new authoritative guidance on variable interests effective January 1, 2010. The amendments change the process for how an enterprise determines which party consolidates a variable interest

entity (a VIE) to a primarily qualitative analysis. The party that consolidates the VIE (the primary beneficiary) is defined as the party with (1) the power to direct activities of the VIE that most significantly affect the VIE's economic performance and (2) the obligation to absorb losses of the VIE or the right to receive benefits from the VIE. Upon adoption, reporting enterprises must reconsider their conclusions on whether an entity should be consolidated and should a change result; the effect on net assets will be recorded as a cumulative effect adjustment to retained earnings. This pronouncement did not have a material impact on the Company's consolidated financial statements.

The Company elected to adopt early the new authoritative guidance on revenue recognition effective January 1, 2010. The guidance provides greater ability to separate and allocate arrangement consideration in a multiple element revenue arrangement. In addition, it will require the use of estimated selling price to allocate arrangement considerations, therefore eliminating the use of the residual method of accounting. The Company has elected to prospectively adopt these provisions. Our adoption of this pronouncement did not have a material impact on the Company's consolidated financial statements.

The Company adopted new authoritative guidance on business combinations for acquisitions occurring on or after January 1, 2009. This requires recognition of assets acquired, liabilities assumed, and any noncontrolling interests in the acquiree at the acquisition date, measured at their fair values as of that date. In a business combination achieved in stages, this pronouncement requires recognition of identifiable assets and liabilities, as well as the noncontrolling interests in the acquiree, at the full amounts of their fair values. This pronouncement also requires the fair value of acquired in-process research and development (referred to as IPR&D) to be recorded as indefinite lived intangibles, contingent consideration to be recorded on the acquisition date, and restructuring and acquisition-related deal costs to be expensed as incurred. In addition, any excess of the fair value of net assets acquired over purchase price and any subsequent changes in estimated contingencies are to be recorded in earnings. See Note 5 for purchase accounting details.

The Company adopted new authoritative guidance on collaborative arrangements which was effective January 1, 2009 and the provisions have been applied retroactively. According to this pronouncement a collaborative arrangement is one in which the participants are actively involved and are exposed to significant risks and rewards that depend on the ultimate commercial success of the endeavor. Payments to or from collaborators are evaluated and presented based on the nature of the arrangement and its terms, the nature of the entity's business, and whether those payments are within the scope of other accounting literature. The nature and purpose of collaborative arrangements are disclosed along with the accounting policies and the classification of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity are accounted for under other accounting literature; however, required disclosure applies to the entire collaborative agreement. This pronouncement did not have a material impact on the Company's consolidated financial statements.

The Company adopted new authoritative guidance on the fair value option for financial assets and financial liabilities which became effective for fiscal years beginning after November 15, 2007. The Standard's objective is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Generally accepted accounting principles have required different measurement attributes for different assets and liabilities that can create artificial volatility in earnings. This authoritative guidance helps to mitigate this type of accounting-induced volatility by enabling companies to report related assets and liabilities at fair value, which would likely reduce the need for companies to comply with detailed rules for hedge accounting. This Standard requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the Company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which the Company has chosen to use fair value on the face of the balance sheet. Upon adoption, we chose not to elect the fair value option for our existing financial assets and liabilities. Therefore, the adoption did not have any impact on our consolidated financial statements. In November 2008; simultaneously with our

execution of the agreement with UBS with respect to certain auction-rate securities in UBS accounts, we elected the fair value option for the auction-rate securities rights (See Note 3).

The Company adopted the new authoritative guidance on convertible debt instruments that may be settled in cash or other assets on conversion as of January 1, 2009. The guidance requires that issuers of convertible debt instruments that may be settled in cash or other assets on conversion to separately account for the liability and equity components of the instrument in a manner that will reflect the entity's nonconvertible debt borrowing rate on the instrument's issuance date when interest cost is recognized in subsequent periods. Our Convertible Notes are within the scope of this new guidance. Therefore, we are required to separate the debt portion of our Convertible Notes from the equity portion at their fair value retrospective to the date of issuance and amortize the resulting discount into interest expense over the life of the debt. The provisions of the guidance are to be applied retrospectively to all periods presented upon adoption and became effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The adoption results in the recognition of approximately \$138.7 million of additional interest expense, on a pre-tax basis, over the life of our Convertible Notes. See Note 18 for further details.

The Company adopted the new authoritative guidance on determining the fair value of a financial asset when the market for that asset is not active for the period ending September 30, 2008. The guidance clarifies the application of fair value measurements when determining the fair value of a financial asset when the market for that asset is not currently active. Additionally, it emphasizes that approaches other than the market approach to determining fair value may be appropriate when it is determined that, as a result of market inactivity, other valuation approaches are more representative of fair value. Other valuation approaches can involve significant assumptions regarding future cash flows. The guidance clarifies that these assumptions must incorporate adjustments for nonperformance and liquidity risks that market participants would consider in valuing the asset in an inactive market. See Note 3 for a further discussion of fair value.

The Company adopted the new authoritative guidance on interim and annual disclosure about fair value of financial instruments which became effective for periods beginning after December 15, 2009. The guidance amends previous authoritative guidance by requiring disclosures with respect to the fair value of financial instruments in interim and annual financial statements. The adoption did not have a material effect on the Company's consolidated results of operations or financial condition; however it did result in enhanced disclosures about fair value of financial instruments in our interim financial statements. See Note 3, Fair Value Measurements for further discussion.

### Accounting Pronouncements Issued But Not Yet Adopted

In December 2010, the FASB issued authoritative guidance for 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. We expect this fee will be approximately \$11 million in 2011, which will be charged as an operating expense ratably throughout 2011.

In December 2010, the FASB issued authoritative guidance 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 comparative financial statements are presented. It is effective on a prospective basis 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. We will adopt this guidance beginning with business combinations for which the acquisition date is on or after January 1, 2011.

In April 2010, the FASB issued revised authoritative guidance for milestone revenue recognition. The new guidance recognizes the milestone method as an acceptable revenue recognition method for substantive

milestones in research or development transactions. It is effective on a prospective basis to milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. We will adopt this guidance beginning with agreements entered into after January 1, 2011. We are currently evaluating the impact of adoption on our consolidated results of operations and financial position.

### 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 and our debt obligations. 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 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):

		20	10		2009			
	Car	rying Amount	<u>. 1</u>	Fair Value	Carry	ying Amount	Fair	Value
Current assets:		;		- 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1		· ,		
Auction-rate securities	\$		\$		\$	25,275	\$ 2	25,275
Auction-rate securities rights		<del></del>	. / *:	. —		15,659		15,659
Long-term assets:								
Auction-rate securities		17,332		17,332		207,334	20	07,334
Equity securities	٠.	6,177		6,177		4,458		4,458
Equity and cost method investments		34,677		N/A		30,236		N/A
	\$	58,186		÷.	\$	282,962		•
Current liabilities:						:		
Current portion of long-term debt	\$	(24,993)	\$	(24,993)	\$		\$	
Long-term liabilities:		, ,					·	
Acquisition-related contingent								
consideration	\$	(16,050)	\$	(16,050)	\$	(58,470)	\$ (5	58,470)
Term Loan Due 2015, less current portion,								
net		(377,500)		(380,038)				
7.00% Senior Notes Due 2020, net		(386,716)		(403,308)		<del></del> .		
1.75% Convertible Senior Subordinated								
Notes Due 2015, net		(278,922)		(324,257)	(	260,279)	(27	77,651)
Minimum Voltaren® Gel royalties due to								
Novartis		(38,922)		(38,922)		(49,996)	(4	19,996)
Other long-term debt, less current portion		(2,663)	11	(2,663)		(62,255)	(6	51,896)
	\$6	1,125,766)	<u>\$</u>	1,190,231)	\$6	431,000)	\$(44	18,013)
			<u>Ψ(</u>		Ψ(	121,000	Ψ(-1-	(0,013)

Equity securities consist of publicly traded common stock the value 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 represents amounts payable to the former Indevus shareholders under contingent cash consideration agreements relating to the development of Aveed<sup>TM</sup> (see Note 5 for further details) as well as contingent cash consideration related to the acquisition of Qualitest, which occurred in November 2010 (see Note 7 for further details). These amounts are required to be measured at fair value on a recurring basis. The fair values of our Term Loan Facility due 2015 and our 7.00% Senior Notes due 2020 (the

Senior 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 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 2010 and 36% in 2009 that were based on historic volatility of the Company's common stock and other factors. The fair value of our Non-recourse notes at December 31, 2009, included within other long-term debt in the table above, was determined using an income approach (present value technique) consistent with the methodology used as of February 23, 2009.

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. The Company is not aware of any events or circumstances that would have a significant effect on the fair value of this Novartis AG liability. We believe the carrying amount of this minimum royalty guarantee at December 31, 2010 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, 2010. 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 our \$23.6 million of cost method investments.

As of December 31, 2010, the Company held certain assets and liabilities that are required to be measured at fair value on a recurring basis, including money market funds, available-for-sale securities, and acquisition-related contingent consideration. 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.

The Company's financial assets and liabilities measured at fair value on a recurring basis at December 31, 2010 and December 31, 2009, were as follows (in thousands):

			Fair Valu	e Measurements at	Reporting Date U	Jsing
December 31, 2010		· • ·	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:	,				1 112	
Money market funds	· · · · · · · · · · · · · · · ·		. \$149,318	\$—	\$	\$149,318
Auction-rate securities		·		_	17,332	17,332
Equity securities			. 6,177	<del>_</del> _		6,177
Total	·		\$155,495	\$	\$ 17,332	\$172,827
Liabilities:		•			13. 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
Acquisition-related continge	ent consideration	n – long-term		<u> </u>	(16,050)	(16,050)
Total			. \$ —	<del>\$</del>	\$(16,050)	\$(16,050)
· . *				<del></del>	<del></del>	
			Fair Value	e Measurements at	Reporting Date U	sing
			Quoted Prices in	3	Reporting Date U	sing
e de la companya de l			Quoted Prices in Active Markets	Significant Other	Significant	sing
December 31, 2009	en ekur Georgia		Quoted Prices in	3	1 (44.)	Sing Total
December 31, 2009 Assets:			Quoted Prices in Active Markets for Identical	Significant Other Observable	Significant Unobservable	
Assets: Money market funds		· · · · · · · · · · · · · · · · · · ·	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable	Significant Unobservable	Total
Assets:			Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable	Significant Unobservable Inputs (Level 3)	
Assets:  Money market funds		• • • • • • • • • • • • • • • • • • • •	Quoted Prices in Active Markets for Identical Assets (Level 1) . \$279,772 . 25,275	Significant Other Observable	Significant Unobservable Inputs (Level 3)	<b>Total</b> \$279,772
Assets:  Money market funds Auction-rate securities		• • • • • • • • • • • • • • • • • • • •	Quoted Prices in Active Markets for Identical Assets (Level 1) . \$279,772 . 25,275	Significant Other Observable	Significant Unobservable Inputs (Level 3) \$ — 207,334	Total \$279,772 232,609
Assets:  Money market funds	s		Quoted Prices in Active Markets for Identical Assets (Level 1)  \$279,772 25,275 4,458	Significant Other Observable	Significant Unobservable Inputs (Level 3) \$ — 207,334	Total \$279,772 232,609 15,659
Assets:  Money market funds	s		Quoted Prices in Active Markets for Identical Assets (Level 1) \$279,772 25,275 	Significant Other Observable	Significant Unobservable Inputs (Level 3)  \$ 207,334	Total \$279,772 232,609 15,659 4,458
Assets:  Money market funds  Auction-rate securities  Auction-rate securities rights  Equity securities	S		Quoted Prices in Active Markets for Identical Assets (Level 1)  \$279,772 25,275 4,458 \$309,505	Significant Other Observable	Significant Unobservable Inputs (Level 3)  \$ 207,334	Total \$279,772 232,609 15,659 4,458

### 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 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 has become 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.

At December 31, 2010 and 2009, the Company determined that the market for its auction-rate securities was still inactive. That determination was made considering that there are very few observable transactions for the auction-rate securities or similar securities, the prices for transactions that have occurred are not current, and the observable prices for those transactions – to the extent they exist – vary substantially either over time or among market makers, thus reducing the potential usefulness of those observations. In addition, the current lack of liquidity prevents the Company from comparing our securities directly to securities with quoted market prices.

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, 2010. Further, 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.

The UBS Offer was made pursuant to agreements in principle entered into by the UBS Entities with the Securities and Exchange Commission, the New York Attorney General, the Texas State Securities Board and other state regulatory agencies represented by North American Securities Administrators Association, and a settlement agreement with the Massachusetts Securities Division to settle investigations brought by each of these agencies against the UBS Entities relating to the sale and marketing of auction-rate securities. The alleged conduct underlying these investigations suggested that the UBS Entities marketed auction-rate securities as cash alternatives but failed to adequately disclose liquidity risk.

On November 10, 2008, the Company accepted the UBS Offer. As a result, the Company granted to 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. The fair values of our Term Loan Facility due 2015 and our 7.00% Senior Notes due 2020 (the Senior 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.

Acceptance of the UBS Offer constituted a substantive change in facts and circumstances that altered the Company's view that it intended to hold the impaired securities until their anticipated recovery. Accordingly, we could no longer assert that we had the intent to hold the auction-rate securities until anticipated recovery. As a result, during the fourth quarter of 2008, we recognized an other-than-temporary impairment charge recorded in earnings. The charge was measured as the difference between the par value and fair value of the auction-rate securities on November 10, 2008. Previously recognized declines in fair value associated with the Eligible Auction-Rate Securities that were determined to be temporary were transferred out of other comprehensive income and charged to earnings as part of the impairment charge.

Acceptance of the UBS Offer created an enforceable legal right by and between the Company and UBS. The UBS Offer was a legally separate contractual agreement and was non-transferable. The Rights were not readily convertible to cash and did not provide for net settlement. Accordingly, the Rights did not meet the definition of a derivative instrument and were treated as a freestanding financial instrument.

Subsequent Accounting for Auction-Rate Securities and Auction-Rate Securities Rights

Acceptance of the UBS Offer constituted a substantive change in facts and circumstances that altered the Company's view that it intended to hold the illiquid securities until their scheduled maturity date. As a result of the change, we recognized an other than temporary impairment charge as of December 31, 2008 of approximately \$26.4 million that is included in Other (income) expense, net in the Consolidated Statements of Operations.

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, and additional expense of \$4.2 million during the year ended December 31, 2008, and were recorded in Other (income) expense, net in the Consolidated Statements of Operations.

As a result of our fair value election for our auction-rate securities rights, the fair value of the auction-rate securities rights were re-measured each reporting period with the corresponding changes in fair value reported in earnings. Since the auction-rate securities rights were freestanding financial instruments, they did not affect the separate determination of the fair value of the Eligible Auction-Rate Securities. However, in management's view, the auction-rate securities rights acted as an economic hedge against further fair value changes in the Eligible Auction-Rate Securities. On June 30, 2010, our auction-rate securities rights were exercised. Accordingly, the related asset was written off with a corresponding charge to earnings of \$15.7 million for the year ended December 31, 2010. At December 31, 2009, the fair value of our auction-rate securities rights was \$15.7 million. The changes in fair value during 2009 resulted in a loss of \$11.7 million during the year ended December 31, 2009. These amounts were recognized in earnings and included in other (income) expense, 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 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 life used for each remaining security, representing time to maturity is eight years.
- 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 on December 31, 2010 was 5.10% and ranged from 5.37% to 6.12% at December 31, 2009. 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 spreads over the base rate for our securities applied to our securities was 218 basis points at December 31, 2010 and ranged from 154 basis points to 410 basis points at December 31, 2009.
- 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, 2010, the fair value of our auction-rate securities, as determined by applying the above described discount rate adjustment technique, was approximately \$17.3 million, representing an eight percent (8%), or \$1.5 million discount from their original purchase price or par value. This compares to approximately \$232.6 million, representing a seven percent (7%), or \$16.5 million discount from their original purchase price or par value at December 31, 2009. 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, 2010 and 2009 were reduced by approximately \$1.5 million and \$16.5 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 this 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 \$0.4 million loss and a \$0.6 million gain in shareholders' equity in accumulated other comprehensive loss as of December 31, 2010, and 2009, 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

The Company has 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 the auction-rate securities rights. Specifically, the Company used the discount rate adjustment technique to determine an indication of fair value.

The values of the Rights at December 31, 2009 were estimated as the value of a portfolio designed to approximate the cash flows of the UBS Agreement. The portfolio consists of a bond issued by UBS that will mature equal to the face value of the auction-rate securities, a series of payments that will replicate the coupons of the auction-rate securities, and a short position in the callable auction-rate security. If the UBS agreement is in the money on the exercise date, then both the UBS agreement and the replicating portfolio will be worth the difference between the par value of the auction-rate securities and the market value of the auction-rate securities. If the UBS agreement is out of the money on the exercise date, then both the replicating portfolio and the UBS agreement will have no value.

For purposes of valuing the UBS bond, management selected a required rate of return for a UBS obligation based on market factors including relevant credit default spreads. The rate of return for the auction-rate securities is determined as described above under "Valuation of the Auction-Rate Securities" and is used to determine the present value of the coupons of the auction-rate security.

At June 30, 2010, the fair value of our auction-rate securities rights were adjusted to \$0 due to the Rights being exercised and the associated UBS securities being sold as of June 30, 2010. For comparable 2009 periods, the Company chose to use a four-year term to adjust for the lack of liquidity on the auction-rate securities as we believe it is the point within the range that is most representative of fair value. Accordingly, the same term was used when valuing the Rights. We believe we have appropriately reflected our best estimate of the assumptions that market participants would use in pricing the asset in a current transaction to sell the asset at the measurement date.

The following table presents changes to the Company's financial assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the twelve months ended December 31, 2010 (in thousands):

	Unobservable Inputs (Level 3)					
en de la companya de La companya de la co	Auction-rate Securities	Auction-rate Securities Rights	Total			
Balance at January 1, 2010	\$ 207,334	\$ 15,659	\$ 222,993			
Securities sold or redeemed		· _ ·	(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 loss included in other comprehensive loss	(372)		(372)			
Balance at December 31, 2010	\$ 17,332	<u> </u>	\$ 17,332			

		Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
		Acquisition-related Contingent Consideration
Liabilities:		
Balance at January 1, 2010	· · · · · · · · · · · · · · · · · · ·	 \$(58,470)
Amounts acquired or issued .		 (9,000)
Transfers in and/or (out) of Le	vel 3	 _
Changes in fair value recorded	in earnings	 51,420
Balance at December 31, 2010		<u>\$(16,050)</u>

The following table presents changes to the Company's financial assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the twelve months ended December 31, 2009 (in thousands):

	Fair Value Measurements Using Significa Unobservable Inputs (Level 3)			
	Auction-rate Securities	Auction-rate Securities Rights	Total	
Balance at January 1, 2009	\$234,005	\$ 27,321	\$261,326	
Securities sold or redeemed	(17,250)	·	(17,250)	
Securities purchased or acquired	_	. · · · · · · · · · · · · · · · · · · ·	<del></del>	
Transfers in and/or (out) of Level 3	(25,275)		(25,275)	
Changes in fair value recorded in earnings	15,222	(11,662)	3,560	
Unrealized gain included in other comprehensive loss	632	· · <u> </u>	632	
Balance at December 31, 2009	\$207,334	\$ 15,659	\$222,993	

en e	Using Significant Unobservable Inputs (Level 3)
	Acquisition-related Contingent Consideration
Liabilities:	41
Balance at January 1, 2009	\$ —
Amounts acquired or issued	(186,560)
Transfers in and/or (out) of Level 3	
Changes in fair value recorded in earnings	128,090
Balance at December 31, 2009	\$ (58,470)

Fair Value Messurem

At December 31, 2010 and 2009, the fair value of the Company's trading securities was \$0 and \$214.9 million, respectively. The following is a summary of available-for-sale securities held by the Company as of December 31, 2010 and 2009 (in thousands):

	Available-for-sale			
en e	Amortized Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Value
December 31, 2010:				
Money market funds	\$149,318	<b>\$</b> —	s \$ <sub>0</sub> —	\$149,318
Total included in cash and cash equivalents	\$149,318	<del></del>	<u> </u>	\$149,318
Auction-rate securities	18,800		(1,468)	17,332
Equity securities	5,564	613.	. —	6,177
Long-term available-for-sale securities	\$ 24,364	\$613	\$(1,468)	\$ 23,509
Total available-for-sale securities	\$173,682	\$613	\$(1,468)	\$172,827
	<del></del>	3 ====		· <del>===</del>
		Available	e-for-sale	
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Value
December 31, 2009:				
Money market funds	\$279,772	<b>\$</b> —	\$ —	\$279,772
Total included in cash and cash equivalents	\$279,772	· · · · · · · · · · · · · · · · · · ·	\$ —	\$279,772
Auction-rate securities	18,800	· ·	(1,096)	17,704
Equity securities	5,564		(1,106)	4,458
Long-term available-for-sale securities	\$ 24,364	<del></del>	\$(2,202)	\$ 22,162
Total available-for-sale securities	\$304,136	\$	\$(2,202)	\$301,934

During the year ended December 31, 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, 2010 and 2009. 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.

The following table sets forth the fair value of our long-term auction-rate securities by type of security and underlying credit rating as of December 31, 2010 (in thousands):

	Underlying Credit Rating(1)					
90 <b>-</b>	AAA	A	B2	Ba2	Baa3	Total
Underlying security: Student loans	\$17,332	<u>\$—</u>	<b>\$</b>	<u>\$—</u>	<u>\$—_</u>	\$17,332
Total auction-rate securities included in long-term marketable securities			\$ <u>\$—</u> -		<u>\$—</u>	\$17,332

<sup>(1)</sup> Our auction-rate securities maintain split ratings. For purposes of this table, securities are categorized according to their lowest rating.

The following table sets forth the fair value of our long-term auction-rate securities by type of security and underlying credit rating as of December 31, 2009 (in thousands):

	Underlying Credit Rating(1)					
	AAA	A	B2	Ba2	Baa3	Total
Underlying security:						
Student loans	\$130,861	\$51,781	\$9,934	\$7,201	\$7,557	<u>\$207,334</u>
Total auction-rate securities included in long-term						
marketable securities	\$130,861	\$51,781	\$9,934	\$7,201	\$7,557	\$207,334

<sup>(1)</sup> Our auction-rate securities maintain split ratings. For purposes of this table, securities are categorized according to their lowest rating.

As of December 31, 2010, the yields on our long-term auction-rate securities ranged from 0.54% to 0.60%. These yields represent the predetermined "maximum" reset rates that occur upon auction failures according to the specific terms within each security's prospectus. As of December 31, 2010, the weighted average yield for our long-term auction-rate securities was 0.57%. Total interest recognized on our auction-rate securities and variable rate demand obligations during the year ended December 31, 2010, 2009 and 2008 was \$0.7 million, \$2.4 million, and \$15.5 million, respectively. Further, the issuers have been making interest payments promptly.

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, 2010		December 31, 2010 December 31	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Available-for-sale debt securities:				
Due in less than 1 year		\$ —	\$	<b>\$</b> _ —
Due in 1 to 5 years	_	_		
Due in 5 to 10 years		. <u>/ ~ .</u> .		· · ·
Due after 10 years	18,800	17,332	18,800	17,704
Equity securities	5,564	6,177	5,564	4,458
Total	\$24,364	\$23,509	\$24,364	<u>\$22,162</u>

The Company's financial assets measured at fair value on a nonrecurring basis at December 31, 2010, were as follows (in thousands):

	Fair Value Meas			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Loss
Assets:				
Pagoclone indefinite-lived intangible asset	\$	<b>\$</b> —	\$8,000	\$(13,000)
Total	<u>\$—</u>	<u>\$</u>	\$8,000	\$(13,000)

The Company's financial assets measured at fair value on a nonrecurring basis at December 31, 2009, were as follows (in thousands):

	Fair Value Mea	ing Date Using		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Loss
Assets:				
Aveed <sup>TM</sup> indefinite-lived intangible asset	\$	<b>\$</b>	\$35,000	\$(65,000)
Total	<u>\$—</u>	<u>\$—</u>	\$35,000	\$(65,000)

See Note 9 for a discussion of these impairments. As required, we also performed an impairment analysis on all other indefinite-lived intangible assets as of January 1, 2011 and January 1, 2010. None of our other indefinite-lived intangible assets were determined to be impaired.

### **NOTE 4. INVENTORIES**

Inventories are comprised of the following for the years ended December 31 (in thousands):

	2010	2009
Raw materials	\$ 45,957	\$ 8,510
Work-in-process	34,208	25,799
Finished goods		
Total	\$178,805	\$84,893

### **NOTE 5. ACQUISITIONS**

### Indevus Pharmaceuticals, Inc.

On February 23, 2009 (the Indevus Acquisition Date), the Company completed its initial tender offer (the Offer) for all outstanding shares of common stock of Indevus. Through purchases in subsequent offer periods, the exercise of a top-up option and a subsequent merger (the 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 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, pursuant to the terms of the Agreement and Plan of Merger, dated as of January 5, 2009. Accordingly, the Company paid

approximately \$368 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 Merger Agreement), providing for the payment of up to an additional \$3.00 per Indevus Share in contingent cash consideration payments, in accordance with the terms of the Offer. The total cost to acquire all outstanding Indevus Shares pursuant to the Offer and the Merger could be up to an additional approximately \$267 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.

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 Merger, Indevus was renamed Endo Pharmaceuticals Solutions Inc.

Approved products assumed in the acquisition included Sanctura® (trospium chloride) and Sanctura XR® (trospium chloride extended release capsules) for the treatment of overactive bladder (OAB); Supprelin® LA (histrelin acetate) for treating central precocious puberty (CPP); Vantas® (histrelin) for the palliative treatment of advanced prostate cancer; Delatestryl® (testosterone enanthate) for the treatment of male hypogonadism; Hydron® Implant utilized as a drug delivery device providing for a sustained release of a broad spectrum of drugs continuously and Valstar® (valrubicin) for therapy of bacillus Calmette-Guerin (BCG)-refractory carcinoma in situ (referred to as CIS) of the bladder.

Primary development products include the following:

- Aveed<sup>TM</sup> (testosterone undecanoate) 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® which the Company acquired the U.S. rights to from Schering AG, Germany, in July 2005. On May 6, 2009, we received notice from the FDA that Nebido® was unacceptable as a proprietary name for testosterone undecanoate. In August 2009, we received approval from FDA to use the name Aveed™. The contingent cash consideration agreement relating to the product, which we have historically referred to as the Nebido® Contingent Cash Consideration Agreement, will now be referred to as the AveedTM Contingent Cash Consideration Agreement throughout this Report. 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 REMS is not sufficient. In 2010, 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. 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.
- Octreotide, currently in Phase III clinical trials for the treatment of acromegaly, utilizes our patented Hydron® 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). Octreotide is also approved to treat symptoms associated with metastatic carcinoid tumors and vasoactive intestinal peptide secreting adenomas, which are gastrointestinal tumors. In February 2011, the FDA requested additional pre-clinical studies, including a carcinogenicity study, be completed prior to the submission of the NDA for the octreotide implant for the treatment of acromegaly. Although this development causes a delay of up to four years in the timing associated with regulatory approval, the Company intends to continue the development of this product and is encouraged by recent preliminary results from its Phase III study. In addition, the Company recently assessed all of its in-process research and

development 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.

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 operating results of Indevus from February 23, 2009 to December 31, 2010 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheets as of December 31, 2010 and December 31, 2009 reflect 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):

and the control of t The control of the control of	Consideration Transferred
Cash	\$368,034
Contingent consideration	172,860
Total	\$540,894

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As of December 31, 2010 and 2009, the fair value of the Indevus contingent consideration is \$7.1 million and \$58.5 million, respectively.

The contingent consideration relates to the amounts payable under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement. In the event that the Company receives an approval letter from the FDA with respect to the Aveed<sup>TM</sup> NDA on or before the third anniversary of the time at which we purchased the Indevus Shares in the Offer, then the Company will, subject to the terms described below, (i) pay an additional \$2.00 per Indevus Share to the former stockholders of Indevus, if such approval letter grants the right to market and sell Aveed<sup>TM</sup> immediately and provides labeling for Aveed<sup>TM</sup> that does not contain a "boxed warning" (Aveed<sup>TM</sup> With Label) or alternatively, (ii) pay an additional \$1.00 per Indevus Share, if such approval letter grants the right to market and sell Aveed<sup>TM</sup> immediately and provides labeling for Aveed<sup>TM</sup> that contains a "boxed warning" (Aveed<sup>TM</sup> Without Label). In the event that either an Aveed<sup>TM</sup> With Label approval or an Aveed<sup>TM</sup> Without Label approval has not been obtained prior to the third anniversary of the closing of the Offer, then the Company will not pay, and the former Indevus stockholders will not receive, any payments under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement.

Further, in the event that the Aveed<sup>TM</sup> Without Label approval is received and subsequently, Endo and its subsidiaries publicly report audited financial statements which reflect cumulative net sales of Aveed<sup>TM</sup> of at least \$125.0 million for four consecutive calendar quarters on or prior to the fifth anniversary of the date of the first commercial sale of Aveed<sup>TM</sup> (Aveed<sup>TM</sup> Net Sales Event), then the Company will, subject to the terms described below, pay an additional \$1.00 per Indevus Share to the former stockholders of Indevus. In the event that the Aveed<sup>TM</sup> Net Sales Event does not occur prior to the fifth anniversary of the date of the first commercial sale of Aveed<sup>TM</sup> then the Company will not pay, and former Indevus stockholders will not receive, any additional amounts under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement.

The range of the undiscounted amounts the Company could pay under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement is between \$0 and approximately \$175.0 million. The fair value of the contractual obligation to pay the Aveed<sup>TM</sup> contingent consideration recognized on the Indevus Acquisition Date was \$133.1 million. We determined the fair value of the obligation to pay the Aveed<sup>TM</sup> contingent consideration based on a probability-weighted income approach. 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. Under the Aveed<sup>TM</sup>

Contingent Cash Consideration 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<sup>TM</sup> With Label approval, (2) obtaining an Aveed<sup>TM</sup> 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<sup>TM</sup> should the Aveed<sup>TM</sup> Without Label approval be obtained. The fourth scenario is Aveed<sup>TM</sup> 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<sup>TM</sup>. 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. The fair value of the contractual obligation to pay the Aveed<sup>TM</sup> contingent consideration was \$7.1 million and \$7.5 million at December 31, 2010 and December 31, 2009, respectively. Future changes in any of our assumptions could result in further volatility to the estimated fair value of the acquisition-related contingent consideration. Such additional changes to fair value could materially impact our results of operations in future periods.

Similarly, in the event that an approval letter from the FDA is received with respect to an octreotide NDA (such approval letter, the Octreotide Approval) on or before the fourth anniversary of the closing of the Offer, then the Company will, subject to the terms described below, pay an additional \$1.00 per Indevus Share to the former stockholders of Indevus (such payment, the Octreotide Contingent Cash Consideration Payment). In the event that an Octreotide Approval has not been obtained prior to the fourth anniversary of the closing of the Offer, then the Company will not pay, and the former Indevus stockholders shall not receive, the Octreotide Contingent Cash Consideration Payment.

The range of the undiscounted amounts the Company could pay under the Octreotide Contingent Cash Consideration Agreement is between \$0 and approximately \$91.0 million. The fair value of the octreotide contractual obligation to pay the contingent consideration recognized on the Indevus Acquisition Date was \$39.8 million. We determined the fair value of the contractual obligation to pay the Octreotide Contingent Consideration Payment based on a probability-weighted income approach. 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. Under the Octreotide Contingent Cash Consideration Agreement, the two scenarios that require consideration are (1) Octreotide Approval 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. The fair value of the contractual obligation to pay the octreotide contingent consideration was determined to be \$0 at December 31, 2010 compared to \$42.5 million at December 31, 2009. Future changes in any of our assumptions could result in further volatility to the estimated fair value of the acquisition-related contingent consideration. Such additional changes to fair value could materially impact our results of operations in future periods.

In addition to the potential contingent payments under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement, the Company has assumed a pre-existing contingent consideration obligation relating to Indevus' acquisition of Valera Pharmaceuticals, Inc. (the Valera Contingent Consideration), which was consummated on April 18, 2007. The Valera Contingent Consideration entitles former Valera shareholders to receive additional Indevus Shares based on an agreed upon conversion factor if FDA approval of the octreotide implant for the treatment for acromegaly is achieved on or before April 18, 2012. Upon Endo's acquisition of Indevus, each Valera shareholder's right to receive additional Indevus Shares was converted into the right to receive \$4.50 per Indevus Share that such former Valera shareholder would have received plus contractual rights to receive up to an additional \$3.00 per Indevus Share that such former Valera shareholder would have received in contingent cash consideration payments under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement. These amounts would only be payable to former Valera shareholders if there were Octreotide Approval. The range of the undiscounted amounts the Company could pay with respect to the Valera Contingent Consideration is between \$0 and approximately \$33.0 million.

The Company is accounting for the Valera Contingent Consideration in the same manner as if it had entered into that arrangement with respect to its acquisition of Indevus. Accordingly, the fair value of the Valera Contingent Consideration recognized on the Indevus Acquisition Date was \$13.7 million. Fair value was estimated based on a probability-weighted discounted cash flow model, or income approach. 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. The fair value of the Valera Contingent Consideration is estimated using the same assumptions used for the Aveed<sup>TM</sup> 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. The fair value of the contractual obligation to pay the Valera Contingent Consideration was determined to be \$0 at December 31, 2010 compared to \$8.5 million at December 31, 2009. Future changes in any of our assumptions could result in further volatility to the estimated fair value of the acquisition-related contingent consideration. Such additional changes to fair value could materially impact our results of operations in future periods.

As of December 31, 2010, the fair value of the Indevus acquisition-related contingent consideration decreased by approximately \$51.4 million from December 31, 2009, 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. The decrease in the liability was recorded as a gain and is included in the Acquisition-related items line item in the accompanying Consolidated Statements of Operations.

As of December 31, 2009, the fair value of the Indevus acquisition-related contingent consideration decreased by approximately \$128.1 million from the acquisition date, primarily reflecting management's assessment of the decreased probability that we will be obligated to make contingent consideration payments under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement within the specified contractual timeframe, as well as the anticipated timeline for the NDA filing and FDA approval of octreotide. The decrease in the liability was recorded as a gain and is included in the Acquisition-related items line item in the accompanying Consolidated Statements of Operations.

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

	February 23, 2009
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
Total identifiable assets	\$ 868,581
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)
Total liabilities assumed	(449,142)
Net identifiable assets acquired	\$ 419,439
Goodwill	\$ 121,455
Net assets acquired	\$ 540,894

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. As of December 31, 2009, our measurement period adjustments were complete.

Of the \$532.9 million of acquired intangible assets, \$255.9 million was assigned to in-process research and development. 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:

			Valuation (in millions)	Amortization Period (in years)
In-Process Research & Developi				
				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
			\$255.9	n/a
License Rights:		-		1.0
Hydron <sup>®</sup> Polymer			\$ 22.0	10
Vantas <sup>®</sup>			36.0	10
			94.0	12
Supprelin® LA			124.0	10
Other			1.0	4 🚉
Total			\$277.0	11
Total other intangible as	sets	•••••	\$532.9	

<sup>(1)</sup> The FDA approved the sNDA for Valstar® subsequent to the Indevus Acquisition Date. Therefore, Valstar® was initially classified as in-process research and development and subsequently transferred to License Rights upon obtaining FDA approval and is being amortized over a 15 year useful life.

<sup>(2)</sup> 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.

<sup>(3)</sup> As part of our annual review of all in-process research and development 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 R&D 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 for the year ended December 31, 2010, to write-off, in its entirety, the octreotide – carcinoid syndrome intangible asset.

<sup>(4)</sup> 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.

<sup>(5)</sup> 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.

The fair value of the in-process research and development assets and License Rights assets, with the exception of the Hydron® 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 Hydron® 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 Hydron® Polymer Technology is currently used in the following products: Vantas®, Supprelin® LA and octreotide. Thus, we derived the hypothetical royalty income from the projected revenues of those drugs. The fair value of the Hydron® Polymer Technology also includes an existing royalty payable by the Company to certain third party partners based on the net sales derived from drugs that use the Hydron® 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 Hydron® 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, 2010 and 2009, we recorded \$51.4 million and \$93.1 million in income for Indevus acquisition-related items. These amounts are included Acquisition-related items in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	Acquisition-related items			
	Year ended December 31, 2010	February 23, 2009 to December 31, 2009		
Investment bank fees, includes Endo and				
Indevus	\$ —	\$ 13,030		
Legal, separation, integration, and other				
items	<del>-</del>	21,979		
Changes in fair value of acquisition-related				
contingent consideration	(51,420)	(128,090)		
Total	\$(51,420)	\$ (93,081)		
	<del></del>			

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):

		e de la francia		February 23, 2009 to December 31, 2009
Net loss			*****	 \$(107,779)
Basic and	diluted loss per	share		 \$ (0.92)

The following supplemental pro forma information presents the financial results as if the acquisition of Indevus had occurred January 1, 2009 for the year ended December 31, 2009 and on January 1, 2008 for the year ended December 31, 2008. 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 of Indevus been completed on January 1, 2009, nor are they indicative of any future results.

	December 31,			
	_	2009		2008
Pro forma consolidated results (in thousands, except per share data):				
Revenue	\$1	,471,141	\$1	,326,717
Net income	\$	243,336	\$	192,826
Basic net income per share	\$	2.08	\$	1.56
Diluted net income per share	\$	2.07	\$	1.56

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of Indevus to reflect a different revenue recognition model, the additional depreciation and amortization that would have been charged assuming the fair value adjustments to property, plant and equipment, intangible assets, unfavorable leases and current and long-term debt, had been applied on January 1, 2009 or 2008, as applicable, together with the consequential tax effects.

### 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. The 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 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 2009, 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) photoselective vaporization of the prostate (PVP), (2) trans-urethral needle ablation (TUNA), and (3) trans-urethral microwave therapy (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.

### Radiation therapy services.

HealthTronics provides image guided radiation therapy (IGRT) technical services for cancer treatment centers. Its IGRT technical services may relate to providing the technical (non-physician) personnel to operate a physician practice group's IGRT equipment, leasing IGRT equipment to a physician practice group, providing services related to helping a physician practice group establish an IGRT treatment center, or managing an IGRT treatment center.

### 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 United States. 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 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 Sheet 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):

	July 2, 2010 (As initially reported)	Measurement period adjustments	July 2, 2010 (As Adjusted)
Cash and cash equivalents	\$ 6,769	* \$ —	\$ 6,769
Accounts receivable	33,111	677	33,788
Other receivables	1,006	_	1,006
Inventories	12,399	-	12,399
Prepaid expenses and other current assets	5,204	_	5,204
Deferred income taxes	43,737	3,676	47,413
Property and equipment	30,687	_	30,687
Other intangible assets	65,866	8,458	74,324
Other assets	5,210		5,210
Total identifiable assets	\$203,989	\$ 12,811	\$216,800
Accounts payable	\$ (3,084)	\$ —	\$ (3,084).
Accrued expenses	(11,551)	(8,659)	(20,210)
Deferred income taxes	(20,377)	(3,188)	(23,565)
Long-term debt	(44,751)	1,291	(43,460)
Other liabilities	(1,434)	(351)	(1,785)
Total liabilities assumed	\$(81,197)	\$(10,907)	\$ (92,104)
Net identifiable assets acquired	\$122,792	\$ 1,904	\$124,696
Noncontrolling interests	\$ (60,119)	\$ (3,108)	\$ (63,227)
Goodwill	\$152,170	\$ 1,204	\$153,374
Net assets acquired	\$214,843	<u>\$</u>	\$214,843

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 HealthTronics 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 noncontrolling interests 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 HealthTronics Acquisition Date.

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		15
Service Contract	 13.4	n/a
Total	 \$74.3	n/a

The fair value of the developed technology 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 assumed to extend through the patent 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 \$153.4 million of goodwill was assigned to our Devices and Services segment, which was established in July 2010 pursuant to our acquisition of HealthTronics. 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.

The deferred tax assets of \$47.4 million are related primarily to federal net operating loss and credit carryforwards of HealthTronics and its subsidiaries. The deferred tax liabilities of \$23.6 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

The Company recognized \$20.9 million of HealthTronics acquisition-related costs that were expensed for the twelve months ended December 31, 2010. These costs are included in the line item entitled "Acquisition-related items" in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	Acquisition-related Costs
	Twelve Months Ended December 31, 2010
Investment bank fees, includes Endo and HealthTronics	\$ 2,017
Acceleration of outstanding HealthTronics stock-based compensation	7,924
Legal, separation, integration, and other costs	10,988
Total	\$20,929

The amounts of revenue and net loss of HealthTronics included in the Company's Consolidated Statements of Operations from the HealthTronics Acquisition date to December 31, 2010 are as follows (in thousands, except per share data):

	Revenue and Losses included in the Consolidated Statements of Operations from July 2, 2010 to December 31, 2010
Revenue	\$102,144 \$ (8,098) \$ (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 and January 1, 2009 for the year ended December 31, 2009. 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 or January 1, 2009, nor are they indicative of any future results.

	Twelve Months Ended December 31,			
		2010		2009
Pro forma consolidated results (in thousands, except per share data):				
Revenue	\$1	,814,918	\$1	,646,171
Net income attributable to Endo Pharmaceuticals Holdings Inc	\$	264,165	\$	265,282
Basic earnings per share	\$	2.27	\$	2.27
Diluted earnings per share	\$	2.24	\$	2.26

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 and 2009, as applicable, together with the consequential tax effects.

### 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, at which time Penwest became a majority-owned subsidiary of the Company. On November 4, 2010, we closed this acquisition immediately following a special meeting of shareholders of Penwest at which they approved the merger. We paid approximately \$171.8 million in aggregate cash consideration. Penwest is now our wholly-owned subsidiary.

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 Sheet 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):

	September 20, 2010 (As initially reported)	Measurement period adjustments	September 20, 2010 (As adjusted)
Cash and cash equivalents	\$ 22,343	\$ —	\$ 22,343
Marketable securities	800		800
Accounts receivable	10,885	(19)	10,866
Other receivables	132°	(1)	131
Inventories	396	11	407
Prepaid expenses and other current assets	716	(223)	493
Deferred income taxes	27,175	3,003	30,178
Property and equipment	1,115	(200)	915
Other intangible assets	111,200		111,200
Other assets	2,104		2,104
Total identifiable assets	\$176,866	\$ 2,571	\$179,437
Accounts payable	\$ (229)	\$ —	\$ (229)
Income taxes payable	(347)	187	(160)
Penwest shareholder liability	(20,815)	20,815	<del>_</del> _
Accrued expenses	(1,455)	(87)	(1,542)
Deferred income taxes	(39,951)	(379)	(40,330)
Other liabilities	(4,403)	(118)	(4,521)
Total liabilities assumed	<u>\$ (67,200)</u>	\$20,418	\$ (46,782)
Net identifiable assets acquired	\$109,666	\$22,989	\$132,655
Goodwill	\$ 37,952	\$ 1,159	\$ 39,111
Net assets acquired	\$147,618	\$24,148	\$171,766

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 Penwest 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 intangible assets and deferred 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 Penwest Acquisition Date.

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

	Valuation	Amortization Period (in years)
In Process Research & Development:		7
Otsuka	\$ 5.5	n/a
A0001	1.6	n/a
Total	\$ 7.1	n/a
Developed Technology:	<del>=</del>	-
Opana® ER	\$104.1	10
Total	\$104.1	. 10
Total other intangible assets	\$111.2	n/a

The fair values of the in-process research and development 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 assumed to extend through the patent life of our purchased technology.

The \$39.1 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.

The deferred tax assets of \$30.2 million are related primarily to federal net operating loss and credit carryforwards of Penwest. The deferred tax liabilities of \$40.3 million are related primarily to the difference between the book basis and tax basis of the identifiable intangible assets.

The Company recognized \$10.7 million of Penwest acquisition-related costs that were expensed for the twelve months ended December 31, 2010. These costs are included in the line item entitled "Acquisition-related items" in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	Acquisition-related Costs
•	Twelve Months Ended December 31, 2010
Investment bank fees, includes Endo and Penwest	\$ 3,865
Legal, integration, and other costs	6,815
Total	\$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. 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.

### **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 \$769.4 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, \$108 million of the purchase price was placed into escrow. One of the escrow amounts is for \$8 million and will be used to fund any working capital adjustments, as defined in the Qualitest Stock Purchase Agreement. We expect this escrow to be settled in 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 United States. Qualitest's product portfolio is comprised of 175 product families in various forms including tablets, capsules, creams, ointments, suppositories, and liquids. This acquisition will enable 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 to December 31, 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
Cash and cash equivalents Accounts receivable Other receivables Inventories Prepaid expenses and other current assets Deferred income taxes Property and equipment	\$ 21,828 93,228 1,483 95,000 2,023 63,509 135,807
Other intangible assets  Total identifiable assets	843,000 \$1,255,878
Accounts payable Accrued expenses Deferred income taxes Long-term debt Other liabilities	\$ (27,422) (55,210) (207,733) (406,758) (9,370)
Total liabilities assumed  Net identifiable assets acquired  Goodwill	\$ (706,493) \$ 549,385 \$ 219,986
Net assets acquired	\$ 769,371

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 Qualitest Acquisition Date. 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. 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 Qualitest Acquisition Date.

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

	Valuation (in millions)	Amortization Period (in years)
Developed Technology:		
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

	Valuation (in millions)	Period (in years)
In Process Research & Development:		
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	88.0	n/a
Total	\$198.0	n/a
Tradename:		
Qualitest tradename	\$ 27.0	n/a
Total	\$ 27.0	n/a
Total other intangible assets	\$843.0	n/a

A mortization

The fair value of the developed technology assets and in-process research and development 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 assumed to extend through the patent life of the purchased technology. 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.

The \$220.0 million of goodwill was assigned to our Generics segment, which was established in November 2010 pursuant to our acquisition of Qualitest. The goodwill recognized is attributable primarily to expected purchasing, manufacturing and distribution synergies as well as their assembled workforce. Approximately \$170.4 million of goodwill is expected to be deductible for income tax purposes.

The deferred tax assets of \$63.5 million are related primarily to federal and state net operating loss and credit carryforwards of Qualitest and its subsidiaries. The deferred tax liabilities of \$207.7 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

The Company recognized \$38.8 million of Qualitest acquisition-related costs that were expensed for the twelve months ended December 31, 2010. These costs are included in the line item entitled "Acquisition-related items" in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	Acquisition-related Costs
	Twelve Months Ended December 31, 2010
Investment bank fees, includes Endo and Qualitest	\$14,215
Legal, separation, integration, and other costs	24,572
Total	<u>\$38,787</u>

The amounts of revenue and net loss of Qualitest included in the Company's Consolidated Statements of Operations from the Qualitest Acquisition date to December 31, 2010 are as follows (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  Net loss attributable to Endo Pharmaceuticals Holdings	\$30,323
Inc	\$ (3,056)
Basic and diluted net 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 and January 1, 2009 for the year ended December 31, 2009. 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 or January 1, 2009, nor are they indicative of any future results.

		onths Ended ober 31,
and the state of t	2010	2009
Pro forma consolidated results (in thousands, except per share data):		
Revenue	\$2,038,761	\$1,767,873
Inc	\$ 243,710 \$ 2.10 \$ 2.07	\$ 257,511 \$ 2.20 \$ 2.19

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 and 2009, as applicable, together with the consequential tax effects.

### NOTE 6. SEGMENT RESULTS

As a result of our recent acquisitions, the Company has realigned its internal management reporting to reflect a total of three reportable segments. These segments reflect the level at which executive management regularly reviews financial information to assess performance and to make decisions about resources to be allocated.

The three reportable business segments in which the Company now operates include: (1) Branded Pharmaceuticals, (2) Generics and (3) Devices and 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 established products that are included in this operating segment includes Lidoderm®, Opana® ER and Opana®, Percocet®, Voltaren® Gel, Frova®, Supprelin® LA, Vantas®, and Valstar®.

#### Generics

This segment is comprised of our legacy Endo non-branded generic portfolio and the portfolio from our newly 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) disorder, immunosuppression, oncology and hypertension markets.

## **Devices and Services**

The Devices and Services operating segment provides urological services, products and support systems to urologists, hospitals, surgery centers and clinics across the United States. These services and products are sold through the following five business lines: Lithotripsy services, Prostate treatment services, Radiation therapy services, Anatomical pathology services, and Medical products manufacturing, sales and maintenance. These business lines are discussed in greater detail within Note 5.

In 2010, the Company began to evaluate segment performance based on each segment's adjusted income (loss) before tax. We define adjusted income (loss) before tax as income (loss) before tax before certain upfront and milestone payments to partners, acquisition-related items, cost reduction initiatives, asset impairment charges, amortization of commercial intangible assets related to marketed products, inventory step-up recorded as part of our acquisitions, 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 tax by adding the adjusted income (loss) before tax of each of our reportable segments to corporate unallocated adjusted income (loss) before tax.

The following represents selected information for the Company's reportable segments for the years ended December 31, 2010, 2009 and 2008 (in thousands):

and the second of the second o	Twelve Months Ended December 31,				r 31,	
	_	2010		2009		2008
Net revenues to external customers		v .		٠.		
Branded Pharmaceuticals	\$	1,467,572	\$	1,336,110	\$	1,168,204
Generics		146,513		124,731	,	92,332
Devices and Services		102,144				<u> </u>
Total consolidated net revenues to external customers	\$	1,716,229	\$	1,460,841	\$	1,260,536
				1 1 1		A
Adjusted income (loss) before tax						1 -
Branded Pharmaceuticals	\$	757,453	\$	642,997	\$	581,152
Generics	•	24,722		28,557		23,163
Devices and Services		35,538				· · · <u>—</u>
Corporate unallocated	_	(194,459)	1	(174,994)		(130,539)
Total consolidated adjusted income (loss) before tax	\$	623,254	\$	496,560	\$	473,776

The table below provides reconciliations of our consolidated adjusted income (loss) before income tax to our consolidated operating income and our consolidated income before tax, which are determined in accordance with U.S. generally accepted accounting principles (GAAP), for the years ended December 31, 2010, 2009 and 2008 (in thousands):

±	Twelve Months Ended December 31,					
		2010		2009		2008
Total consolidated adjusted income (loss) before tax	\$	623,254	\$	496,560	\$	473,776
Upfront and milestone payments to partners		(23,850)		(77,099)		(8,910)
Acquisition-related items		(18,976)		93,081		
Cost reduction initiatives		(17,245)		(2,549)		(16,375)
Asset impairment charges		(35,000)		(69,000)		(12,680)
Amortization of commercial intangible assets related						
to marketed products		(83,974)		(62,931)		(30,821)
Inventory step-up		(6,289)		(11,268)		· <del></del>
Purchased in-process research and development		<del></del>				530
Non-cash interest expense		(16,983)		(14,719)		(10,372)
Other (expense) income		(239)		3,560		(3,320)
Gain on extinguishment of debt				4,025		<u>.                                    </u>
Total consolidated income before income tax	\$	420,698	\$	359,660	\$	391,828

The following represents additional selected financial information for our reportable segments (in thousands):

	Twelve Months Ended December 31, 2010					
		2010		2009		2008
Depreciation expense: Branded Pharmaceuticals Generics Devices and Services Corporate unallocated  Total depreciation expense	1,676 6,000 2,894	\$	13,400 822 - 2,628 16,850		10,255 508 - 2,214 12,977	
Amortization expense:  Branded Pharmaceuticals  Generics  Devices and Services  Total amortization expense	\$ .	78,647 3,068 2,860 84,575	\$ 	63,531 — — — 63,531	\$ 	33,468

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.

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 regulatory approval in October 2007 from the U.S. Food and Drug Administration (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, subject to certain limitations including the launch of a generic to the Licensed Product in the United States. 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. No royalty payments were payable to Novartis during 2010 and 2009. 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, Endo is required to incur a minimum amount of annual advertising and promotional expenses on the commercialization of the Licensed Product, subject to certain limitations. 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 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 United States, (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 United States 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 United States 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 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 United States 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 United States 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 United States. 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, Endo pays Hind nonrefundable royalties based on net sales of Lidoderm®. Royalties are 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 is 10% of net sales through the shorter of (1) the expiration of the last licensed patent or (2) November 20, 2011, including a minimum royalty of at least \$500,000 per year. During 2010, 2009, and 2008, we recorded \$86.8 million, \$84.9 million, and \$84.8 million for these royalties to Hind, respectively, which we recorded as a reduction to net sales. At December 31, 2010 and 2009, \$23.0 million and \$22.8 million, respectively, is recorded as a royalty payable and included in accounts payable in the accompanying balance sheets. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico.

# Penwest Pharmaceuticals Co.

In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals Co. (Penwest) to exclusively co-develop opioid analgesic products for pain management, using Penwest's patent-protected proprietary technology, for commercial sale worldwide. On April 2, 2002, we amended and restated this agreement between the parties (the 2002 Agreement) to provide, among other things, that this collaboration would cover only the opioid analgesic product, oxymorphone ER, now known as Opana® ER. In September 2010, we acquired Penwest, which effectively eliminated this third party relationship. See Note 5 for discussion of our Penwest Acquisition. We recorded, in cost of revenues, royalties to Penwest under the 2002 Agreement of \$29.8 million, \$19.3 million, and \$5.0 million during the years ended December 31, 2010, 2009, and 2008, respectively.

# Valeant Canada Ltd

In June 2009, the Company entered into a License Agreement with Valeant Canada Ltd (Valeant) granting Valeant a license to market Opana® and Opana® ER in Canada, Australia and New Zealand. Opana® ER, the extended release formulation of oxymorphone, was jointly developed by Penwest and Endo. Prior to Endo's acquisition of the majority of common stock of Penwest, under the terms of the collaboration agreement between Penwest and Endo, the two companies have shared equally in the proceeds received from Valeant for Opana®

ER. The license agreement with Valeant also includes rights to Opana®, the immediate release formulation of oxymorphone developed by Endo. Under the terms of the License Agreement, Valeant made an upfront payment to Endo and may make future payments if certain sales milestones are reached. In addition, Valeant has agreed to pay royalties ranging from 10%-20% on net sales of Opana® ER and Opana® in each of the three countries, subject to royalty reductions upon patent expiry or generic entry.

# 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.

Under the terms of the License Agreement we would have been required to make a \$40 million milestone payment upon FDA approval for the short-term prevention of menstrual migraine indication. In September 2007, the FDA issued to the Company and our development partner Vernalis, a "not approvable" letter pertaining to our supplemental new drug application (sNDA) for Frova® for the additional indication of short-term prevention of menstrual migraine. In April 2008, Endo notified the FDA of the withdrawal of the sNDA without prejudice to refiling as afforded under 21 CFR 314.65 for Frova® 2.5 mg tablets. Frova® is approved and marketed for the acute treatment of migraine with or without aura in adults.

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 the product Frova® in Canada, under the Canadian Trademark.

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® less than \$85 million. Prior to this amendment, royalties were payable by us to Vernalis on all net sales of Frova® in the United States. 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.

### Allergan/Esprit

In September 2007, Indevus (now, Endo Pharmaceuticals Solutions Inc.) entered into an Amended and Restated License, Commercialization and Supply Agreement with Esprit Pharma, Inc (Esprit), which modified the obligations of each party and superseded all previous agreements (the Allergan Agreement). In October, 2007, Allergan, Inc. (Allergan) acquired Esprit resulting in Esprit being a wholly-owned subsidiary of Allergan. Under the Allergan Agreement, we received the right to receive a fixed percentage of net sales for the term of the

Allergan Agreement, subject to increasing annual minimum royalties. Aggregate minimum royalties for the remainder of the Allergan Agreement amount to approximately \$88.5 million through December 31, 2014, provided there is no product adverse event, as defined in the Allergan Agreement. Commencing January 1, 2010, Allergan has the right to reduce, subject to quarterly and annual restrictions, royalty payments by \$20 million in the aggregate. The Company may also receive a payment of \$20 million related to a long-term commercialization milestone related to generic competition on December 31, 2013. Lastly, all third-party royalties paid by the Company as a result of existing licensing, manufacturing and supply agreements associated with sales of Sanctura® and Sanctura XR® will be reimbursed to the Company by Allergan up to six percent (6%) of net sales. The Allergan Agreement expires on the later of the twelfth annual anniversary of the launch of Sanctura XR® or February 1, 2025, the date of the last to expire patent covering Sanctura XR® in the United States. Either party may also terminate the Allergan Agreement in the event of a material breach by the other party. In August 2008, Indevus assigned its rights to receive a fixed percentage of net sales and \$20 million related to a long-term commercialization milestone related to generic competition to the holders of the Non-recourse notes (see Note 18).

In May 2008, together with Madaus AG, Indevus licensed to Allergan the exclusive right to develop, manufacture, and commercialize Sanctura XR® in Canada. As a result, the Company could receive milestones upon the achievement of certain sales thresholds of up to \$2 million. In addition, any third-party royalties owed by the Company on net sales in Canada will be reimbursed by Allergan. This agreement will expire after the later of the expiration of the last applicable patent or our third party royalty obligation, which is currently expected to be November 4, 2024, after which Allergan will have a fully-paid license.

### Madaus

In November 1999, Indevus entered into an agreement with Madaus to license the exclusive rights to develop and market certain products, including Sanctura® in the United States. In November 2006, Indevus entered into (i) a License and Supply Agreement and (ii) an amendment to its original 1999 license agreement with Madaus (collectively, the Madaus Agreements). In March 2010, Endo amended the Madaus Agreements. Under the amended Madaus Agreements, (a) Madaus has licensed the rights to sell Sanctura XR® in all countries outside of the U.S. (the Madaus Territory) except Canada, Japan, Korea and China (the Joint Territory), (b) Madaus has agreed to pay a fee based on the number of capsules of Sanctura XR sold in the Madaus Territory through December 9, 2015 and (c) Endo has agreed to pay a fee based on the number of capsules of Sanctura XR® sold in the U.S. through the earlier of August 23, 2014 or upon generic formulations achieving a predetermined market share. In exchange, Madaus (a) agreed to make certain immaterial payments upon the achievement of certain commercial milestones and pay royalties of 5% of net sales based on future sales of Sanctura XR® in the Madaus Territory and (b) agreed to reimburse Endo for any amounts due to Supernus (see Supernus below) related to the development or commercialization in the Madaus territory. The Company and Madaus will share the development and commercialization costs in the countries in the Joint Territory. If either party decides not to pursue development and commercialization of Sanctura XR® in any country in the Joint Territory, the other party has the right to independently develop and commercialize Sanctura XR® in that country. The term of the Madaus Agreement for Sanctura XR® extends until the expiration, on a country-by-country basis, of all royalty obligations owed to the Company from Madaus which ceases upon the last to expire applicable patent in the Madaus Territory. Either party may terminate the amended Madaus Agreement in the event of a material breach by the other party.

### Supernus

In March 2003, Indevus entered into a Development and License Agreement (the Supernus Agreement) with Supernus Pharmaceuticals, Inc. (Supernus) pursuant to which Supernus agreed to develop Sanctura XR® and granted exclusive, worldwide rights under certain Supernus patents and know-how to Indevus. The Supernus agreement includes potential future development and commercialization milestone payments from the Company to Supernus, including royalties based on sales of Sanctura XR®, and potential future development and

commercialization milestone payments for up to an aggregate of \$2.4 million upon the launch of Sanctura XR® in certain geographic areas. In addition, the Supernus agreement includes potential future development and commercialization milestone payments for up to an aggregate of \$4.5 million upon the launch of new formulations and over-the-counter products. The Company is responsible for all development costs and the commercialization of Sanctura XR® under the Supernus agreement. The Supernus agreement continues until the earlier of, in any particular country, (i) the last date on which the manufacture, use or sale of licensed product in such country would infringe a valid claim of a licensed patent in such country but for the license granted by the agreement; or (ii) twelve years from the date of first commercial sale of licensed product in such country. Either party may also terminate this agreement in the event of a material breach by the other party or by mutual consent.

# The Population Council

The Company markets its products utilizing the hydrogel polymer technology pursuant to an agreement between Indevus 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® and any polymer implant containing an 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® or any other polymer implant containing an LHRH analog and 5% for other implants.

# Orion Corporation

In April 2008, Indevus entered into a License, Supply and Distribution Agreement (the 2008 Orion Agreement) with Orion Corporation (Orion) granting Orion the rights to market Vantas® in Europe and in certain other countries outside of Europe. Vantas® is currently approved for the treatment of advanced prostate cancer in Denmark, the United Kingdom and other European countries, and the Company is seeking additional European approvals through the mutual recognition procedure. In 2010, the Company received \$2.8 million from Orion for marketing authorizations in the Benelux countries, Finland, France, Norway and Sweden and could receive, upon the achievement of sales thresholds, an aggregate amount of \$11.2 million. Additionally, the Company will supply Vantas® to Orion at a pre-determined transfer price subject to annual minimum purchase requirements.

In January 2011, the 2008 Orion Agreement was amended, effective December 2010, to reduce minimum purchase obligations, to modify pricing provisions, and to change certain other provisions. The 2008 Orion Agreement, as amended, expires in April 2023, unless earlier terminated by either party in the event of a material breach by the other party. The 2008 Orion Agreement will automatically renew for one-year periods, subject to the right of either party to terminate the agreement at any time effective at the end of the initial fifteen-year term or any subsequent one-year renewal period thereafter with at least six months prior written notice to the other party.

## 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), for the exclusive right to commercialize Fortesta<sup>TM</sup> Gel in the U.S. (the ProStrakan Agreement). Fortesta<sup>TM</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.

In October 2009, we received a Complete Response letter from the FDA regarding the NDA for Fortesta<sup>TM</sup> Gel. The FDA issues Complete Response letters to communicate that their initial review of an NDA or

abbreviated new drug application (ANDA) is complete and that the application cannot be approved in its present form. A Complete Response also informs applicants of changes that must be made before an application can be approved, with no implication regarding the ultimate approvability of the application.

Following the July 1, 2010 complete response to the FDA, the Company received FDA approval in December 2010. As of December 31, 2010, the Company has accrued and capitalized the one-time approval milestone to ProStrakan for \$12.5 million. ProStrakan could potentially receive up to approximately \$175.0 million in additional payments linked to the achievement of future commercial milestones related to Fortesta<sup>TM</sup> Gel. We are amortizing this intangible asset into cost of revenues on a straight-line basis over its estimated useful life.

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.

### Products in Development

## Grünenthal GMBH

In February 2009, we entered into a Development, License and Supply Agreement (the Grünenthal Agreement) with Grünenthal GMBH (Grünenthal), granting us the exclusive right in North America to develop and market Grünenthal's investigational drug, axomadol. Currently in Phase II trials, axomadol is a patented new chemical entity being developed for the treatment of moderate to moderately-severe chronic pain and diabetic peripheral neuropathic pain. Under the terms of the Grünenthal Agreement, Endo paid Grünenthal approximately \$9.4 million upfront and an additional \$25.2 million in 2009 upon the achievement of certain milestones. We could be obligated to pay additional clinical, regulatory and approval milestone payments of up to approximately 6.3 million Euros (approximately \$8.4 million at December 31, 2010) and possibly development and commerce milestone payments of up to an additional \$68 million. In addition, Grünenthal will receive payments from Endo based on a percentage of Endo's annual net sales of the product in the United States and Canada. The Grünenthal Agreement will expire in its entirety on the date of (i) the 15th anniversary of the first commercial sale of the product; or (ii) the expiration of the last issued patent claiming or covering the product, or (iii) the expiration of exclusivity granted by the FDA for the product, whichever occurs later. Among other standard and customary termination rights granted under the Grünenthal Agreement, we may terminate the Grünenthal Agreement at our sole discretion at any time upon ninety (90) days' written prior notice to Grünenthal and payment of certain penalties.

In December 2007, we entered into a license, development and supply agreement with Grünenthal for the exclusive clinical development and commercialization rights in Canada and the United States for a new oral formulation of long-acting oxymorphone, which is designed to be crush resistant. Under the terms of this agreement Grünenthal is responsible for development efforts to conduct pharmaceutical formulation development and will manufacture any such product or products which obtain FDA approval. Endo is responsible for conducting clinical development activities and for all development costs incurred to obtain regulatory approval. Under the terms of the agreement, we paid approximately \$4.9 million for the successful completion of a clinical milestone, which was recorded as research and development expense for the year ended December 31, 2010. Additional payments of approximately 59.2 million Euros (approximately \$78.5 million at December 31, 2010) may become due upon achievement of 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.

# 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, which was recorded as research and development expense for the year ended December 31, 2010. In addition, under the terms of the Impax agreement, Impax could potentially receive 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<sup>TM</sup>, in the U.S. with an option for global rights. We exercised our option for global rights in the first quarter of 2010. Urocidin<sup>TM</sup> 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, which was recorded as research and development expense. During 2010, Endo paid Bioniche milestone payments of \$4.0 million 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 \$29.0 million in additional payments linked to the achievement of future clinical, regulatory, and commercial milestones related to two separate indications for Urocidin<sup>TM</sup>. Bioniche will manufacture Urocidin<sup>TM</sup> and receive a transfer price for supply based on a percentage of Endo's annual net sales of Urocidin<sup>TM</sup>. Endo may terminate the Bioniche Agreement upon 180 days' prior written notice.

# **BayerSchering**

In July 2005, Indevus 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 Aveed<sup>TM</sup> (the BayerSchering Agreement). The Company is responsible for the development and commercialization of Aveed<sup>TM</sup> in the United States. 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<sup>TM</sup>. Indevus also agreed to pay to BayerSchering 25% of net sales of Aveed<sup>TM</sup> to cover both the cost of finished product and royalties. The BayerSchering Agreement expires ten years from the first commercial sale of Aveed<sup>TM</sup>. 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<sup>TM</sup> for a supply price based on net sales of Aveed<sup>TM</sup>. 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<sup>TM</sup>.

# Sanofi-Aventis

In February 1994, Indevus licensed from Rhone-Poulenc Rorer, S.A., now Aventis Pharma S.A. (Sanofi-Aventis), exclusive, worldwide rights for the manufacture, use and sale of pagoclone under patent rights and know-how related to the drug, except that Indevus granted Sanofi-Aventis an option to sublicense, under certain conditions, rights to market pagoclone in France. Indevus paid Sanofi-Aventis a license fee and agreed to make milestone payments based on clinical and regulatory developments, and to pay royalties based on net sales

through the expiration of the composition of matter patent. If sublicensed, the Company would pay to Sanofi-Aventis a portion of receipts from the sublicensee in lieu of payments. Under the terms of the agreement with Sanofi-Aventis, the Company is responsible for all costs of developing, manufacturing, and marketing pagoclone. This agreement expires with respect to each country upon the last to expire applicable patent. Additionally either party may also terminate this agreement in the event of a material breach by the other party. The Company could owe an additional \$11.1 million if certain clinical and regulatory development milestones are achieved, as well as royalties on net sales or a percentage of royalties it receives if the product is sublicensed.

# 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 Hydron® Polymer Technology. Hydron Technologies retained an exclusive, worldwide license to manufacture, market or use products composed of, or produced with the use of, the Hydron® 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 Hydron® 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 Hydron® Polymer Technology and Hydron Technologies is obligated to purchase them from the Company. In the event the Company withdraws from the business of manufacturing the Hydron® Polymer Technology, the Company will assign all of its right and interest in the Hydron trademark to Hydron Technologies. 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.

## 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, to 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 2011 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 will be expensed in the first quarter of 2011.

# Teva Pharmaceutical Industries Ltd

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. As of December 31, 2010, the maximum amount we could be obligated to pay under the Teva Agreement is \$12.5 million.

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.

In July 2008, the Company made a \$20 million investment in a privately-held company focused on the development of an innovative treatment for certain types of cancer. In exchange for our \$20 million payment, we received an equity interest in the privately-held company. The Company's \$20 million payment resulted in an ownership interest of less than 20% of the outstanding voting stock of the privately-held company. In addition, Endo and other equity holders have provided a line of credit totaling \$25 million, of which Endo committed to fund \$3 million. During 2010, \$2.5 million has been funded by Endo under the line-of credit which would be converted into equity of the privately-held company upon certain events. During January of 2011, an additional payment of \$0.3 million was subsequently funded under the same commitment. Based on the equity ownership structure, Endo does not have the ability to exert significant influence over the privately-held company. Pursuant to authoritative accounting guidance, our investment constitutes a variable interest in this privately-held company. We have determined that Endo is not the primary beneficiary and therefore have not consolidated the assets, liabilities, and results of operations of the privately-held company into our Condensed Consolidated Financial Statements. Accordingly, Endo is accounting for this investment under the cost method. As of December 31, 2010, our investment in the privately-held company was \$22.5 million, representing our maximum exposure to loss.

# NOTE 8. PROPERTY AND EQUIPMENT

Property and equipment is comprised of the following for the years ended December 31 (in thousands):

	2010	2009
Buildings and land	\$ 88,871	\$ — <u> </u>
Machinery and equipment	90,503	17,331
Leasehold improvements	25,995	22,567
Computer equipment and software	51,208	40,681
	1.952	1,222
Assets under capital leases	11,286	8,094
Furniture and fixtures	13,818	7,758
Assets under construction		<del></del>
	283,633	97,653
Less accumulated depreciation	(68,338)	(50,124)
Total		<u>\$ 47,529</u>

Depreciation expense was \$23.8 million, \$16.9 million, and \$13.0 million for the years ended December 31, 2010, 2009, and 2008, respectively.

### NOTE 9. GOODWILL AND OTHER INTANGIBLES

For the year ended December 31, 2010, changes in the carrying amount of Goodwill consisted of the following (in thousands):

•	Carrying Amount
Balance at December 31, 2009	\$302,534
Acquisition of HealthTronics (Note 5)	153,374
Acquisition of Penwest (Note 5)	39,111
Acquisition of Qualitest (Note 5)	
Balance at December 31, 2010	\$715,005

As a result of the HealthTronics, Penwest, and Qualitest acquisitions, Endo recorded goodwill of approximately \$412.5 million in 2010. In allocating the goodwill from the acquisitions, Endo determined that the a portion of the goodwill derived from the transactions was assignable to each reporting unit due to the value associated with the forecasted synergies related to the acquisitions.

As of January 1, 2011, our annual assessment date, we tested each of our six reporting units for impairment. The results of our analyses showed that no goodwill impairments exist.

Based upon recent market conditions, and 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, 2010 and December 31, 2009, respectively (in thousands):

	December 31, 2010	December 31, 2009
Indefinite-lived intangibles:		
In-process research and development	\$ 271,000	\$ 100,900
Tradenames	27,000	·
Total indefinite-lived intangibles	\$ 298,000	\$ 100,900
Definite-lived intangibles:		
Licenses (weighted average life of 10 years)	638,142	625,242
Less accumulated amortization	(185,706)	(116,233)
Licenses, net	\$ 452,436	\$ 509,009
Tradenames (weighted average life of 15 years)	14,600	
Less accumulated amortization	(486)	
Tradenames, net	\$ 14,114	<u> </u>
Developed technology (weighted average life of 15 years)	768,400	
Less accumulated amortization	(14,614)	· · · <u> </u>
Developed technology, net	\$ 753,786	<u>\$</u>
Service contract	13,424	·
Less accumulated amortization		
Service contract, net	\$ 13,424	<u> </u>
Total definite-lived intangibles, net (weighted average life of 13	* *	1.
years)	\$1,233,760	\$ 509,009
Other intangibles, net	\$1,531,760	\$ 609,909

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, 2009	\$ 726,142
HealthTronics acquisition	74,324
Penwest acquisition	111,200
Qualitest acquisition	843,000
Milestone resulting from FDA approval of	
Fortesta <sup>TM</sup>	12,500
Octreotide impairment	(22,000)
Pagoclone impairment	(13,000)
Other	400
Balance at December 31, 2010	\$1,732,566

As part of our annual review of all in-process research and development 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 \$9 million related to 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 R&D 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 for the year ended December 31, 2010, to write-off, in its entirety, the octreotide – carcinoid syndrome intangible asset.

In May 2010, following the completion of the pagoclone phase IIb study, Teva terminated their agreement with the Company whereby Teva had agreed to fund all future development and commercialization costs of pagoclone in exchange for exclusive worldwide rights. As a result of this termination, all rights to pagoclone were returned to us. As a result of this triggering event, we assessed the product's indication and targeted population of eligible recipients, the future probability of regulatory approval, relative timing of commercialization, and estimates of the amount and timing of future cash flows. To calculate the fair value of the pagoclone intangible asset, the Company used an income approach using a discounted cash flow model considering management's current evaluation of the above mentioned factors. The Company utilized a probability-weighted cash flow model using a present value discount factor of 17% which we believe to be commensurate with the overall risk associated with this particular product. The cash-flow model included our best estimates of future FDA approval associated with the indication and population of eligible recipients. The Company presently believes that the level and timing of cash flows assumed, discount rate, and probabilities of success appropriately reflected market participant assumptions. The fair value of the pagoclone intangible asset was determined to be \$8.0 million. Accordingly, the Company recorded a pre-tax non-cash impairment charge of \$13.0 million during 2010, representing the difference between the carrying value of the intangible asset and its estimated fair value. The impairment charge was recognized in earnings and included the Impairment of other intangible assets line item in the Condensed Consolidated Statements of Operations. Changes in any of our assumptions may result in a further reduction to the estimated fair value of the pagoclone intangible asset and could result in additional and potentially full future impairment charges of up to \$8.0 million.

As a result of the FDA's Complete Response letter related to our NDA for Aveed™ in 2009 (see Note 5 for further details), the Company performed an impairment review for the Aveed<sup>TM</sup> intangible asset and concluded that it is required, under generally accepted accounting principles, to record a pre-tax, non-cash impairment charge to write-down the asset to its estimated fair value. In the complete response letter, the FDA requested information to address the agency's concerns regarding rare but serious adverse events, including post-injection anaphylactic reaction and pulmonary oily microembolism. The letter also specified that our proposed Risk Evaluation and Mitigation Strategy with respect to the product is not sufficient. We believe that significant regulatory uncertainty currently exists with respect to the timing, label and regulatory path forward for AveedTM, and accordingly determined that a review for asset impairment was appropriate. Although the Company is continuing to evaluate the FDA's findings to better understand the agency's concerns, we were required to estimate the fair value of our Aveed<sup>TM</sup> indefinite-lived intangible asset as of the date we received the Complete Response letter. To estimate fair value we assessed the possible changes to the product's indication and targeted population of eligible recipients, the future probability of regulatory approval, relative timing of commercialization, and estimates of the amount and timing of future cash flows. In January 2010, the Company was notified that the U.S. patent office had issued a Notice of Allowance on a patent covering the Aveed<sup>TM</sup> formulation. Therefore, management considered the likely benefit of patent exclusivity when estimating these future cash flows. To calculate the fair value of the Aveed<sup>TM</sup> intangible asset, the Company used an income approach using a discounted cash flow model considering management's current evaluation of the above mentioned factors. The Company utilized probability-weighted cash flow models using a present value discount factor of 15% which we believe to be commensurate with the overall risk associated with this particular product. The cash-flow models included our best estimates of future FDA approval associated with each potential indication and population of eligible recipients. The Company believes that the level and timing of cash flows assumed, discount rate, and probabilities of success appropriately reflect market participant assumptions.

The fair value of the Aveed<sup>TM</sup> intangible asset was determined to be \$35 million. Accordingly, the Company recorded a pre-tax non-cash impairment charge of \$65 million for the year ended December 31, 2009, representing the difference between the carrying value of the intangible asset and its estimated fair value. The impairment charge has been recognized in earnings and included the Impairment of other intangible assets line item in the Consolidated Statements of Operations. Changes in any of these assumptions may result in a further reduction to the estimated fair value of the Aveed<sup>TM</sup> intangible asset resulting in additional and potentially full future impairment charges. Such additional impairment charges could materially impact our results of operations in future periods.

In December of 2009, the Company's Phase III clinical trials for Pro2000 provided conclusive results that the drug was not effective. In December 2009, the Company concluded there was no further value or alternative future uses associated with this indefinite-lived asset. Accordingly, we recorded a \$4 million impairment charge to write-off the Pro2000 intangible asset in its entirety.

On November 11, 2009, we reached a settlement with LecTec Corporation on outstanding patent litigation. Endo made a one-time, \$23 million payment for the exclusive license to two patents for use in the field of prescription pain medicines and treatment. As part of this settlement, both Hind Healthcare Inc. and Teikoku Seiyaku Co., Ltd. (Teikoku) were each contractually required to fund their share of this settlement. Accordingly, we recorded an intangible asset representing the portion of our net payment attributable to the license. The remaining \$1.3 million was charged to expense within selling, general, and administrative, representing our estimate of the portion of our net payment attributable to the settlement. Effective October 1, 2010, we granted Teikoku non-exclusive license rights with respect to the applicable patents.

Amortization expense was \$84.6 million, \$63.5 million, and \$33.5 million for the years ended December 31, 2010, 2009, and 2008, respectively. As of December 31, 2010, estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2010 is as follows (in thousands):

2011	:	\$147,344
2012		\$147,081
2013		\$105,308
2014		
2015		\$ 92,200

#### **NOTE 10. ACCRUED EXPENSES**

Accrued expenses are comprised of the following for each of the years ended December 31 (in thousands):

	2010	2009
Chargebacks		
Returns and allowances	65,021	48,274
Rebates	203,225	124,443
Other sales deductions	15,320	6,060
Other	98,335	55,925
Total	\$469,721	\$286,606

# NOTE 11. OTHER (INCOME) EXPENSE, NET

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

	2010	2009	2008
Other-than-temporary impairment of auction-rate securities	\$	<del></del>	\$ 26,417
(Gain) loss on trading securities	(15,420)	(15,222)	4,225
Loss (gain) on auction-rate securities rights	15,659	11,662	(27,321)
Other (income) expense	(2,172)	231	(1,568)
Other (income) expense, net	\$ (1,933)	\$ (3,329)	\$ 1,753

# **NOTE 12. INCOME TAXES**

Income tax consists of the following for each of the years ended December 31 (in thousands):

	2010	2009	2008
Current:			
Federal	\$128,793	\$116,372	\$124,862
State	22,451	17,036	8,639
	151,244	133,408	133,501
Deferred:		-	
Federal	(8,139)	(18,621)	2,582
State	(6,871)	(5,884)	(743)
	(15,010)	(24,505)	1,839
Excess tax benefits of stock options exercised	(1,051)	(3,689)	(92)
Valuation allowance	(1,505)	(11,890)	1,244
Total income tax	\$133,678	\$ 93,324	\$136,492

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):

	2010	2009	2008
Federal income tax at the statutory rate	\$147.245	\$125,888	\$137,144
Noncontrolling interests	(9,805)		<u>—</u>
State income tax, net of federal benefit	8,447	6,729	6.227
Research and development credit	(3,667)	(2,915)	(2,124)
Orphan drug credit	(904)		
Uncertain tax positions	1,148	1,574	(550)
Effect of permanent items:		,	
Changes in contingent consideration	(15,673)	(40,503)	
Transaction-related expenses	9,612	3,256	
Tax exempt interest income	(237)	(855)	(6,068)
Other	(2,488)	150	1,863
Total income tax	\$133,678	\$ 93,324	\$136,492

In order to conform to current year presentation, state taxes related to Research and Development credits, permanent items and Uncertain tax positions as of December 31, 2009, as well as state taxes related to permanent

items and Uncertain tax positions as of December 31, 2008, 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):

the control of the co	2010	2009
Deferred tax assets:	*.	
Accrued expenses	\$ 100,068	\$ 67,953
Compensation related to stock options	18,328	15,693
Purchased in-process research and development	1,820	2,943
Net operating loss carryforward	209,618	122,558
Capital loss carryforward	16,914	11,235
Research and development credit carryforward	15,371	11,604
Uncertain tax positions	17,383	17,795
Other-than-temporary impairment of auction-rate securities	550	6,135
Prepaid royalties	9,115	12,354
Other	10,543	11,722
Total gross deferred income tax assets	399,710	279,992
Deferred tax liabilities:		•
Property, equipment, and intangibles	(434,013)	(199,612)
Convertible debt—non cash interest expense	(8,171)	(10,469)
Auction-rate securities rights	_	(5,817)
Other	(7,859)	(5,601)
Total gross deferred income tax liabilities	(450,043)	(221,499)
Valuation allowance	(26,277)	(17,240)
Net deferred income tax (liability) asset	\$ (76,610)	\$ 41,253

As of December 31, 2010, the Company recorded a valuation allowance of \$0.4 million related to the unrealized holding loss on available-for-sale auction-rate securities, the offset of which was recorded in accumulated other comprehensive loss, a component of stockholders' equity.

In order to conform to current year presentation, deferred tax assets related to intangible assets totaling \$23.8 million as of December 31, 2009 have been reclassified from deferred tax assets to deferred tax liabilities and are now included as an offset to deferred tax liabilities in the Property, equipment, and intangibles line in the table above. This change does not impact the total 2009 net deferred tax asset balance.

On January 1, 2007, the Company adopted the provisions for accounting for uncertain tax positions, which became effective for fiscal years beginning after December 15, 2006. The new standard created a single model to address uncertainty in tax positions and clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. The provisions apply to all material tax positions in all taxing jurisdictions for all open tax years. The standard establishes a two-step process for evaluating tax positions. 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. During the years ended December 31, 2010 and 2009, interest and penalties included in income tax expense totaled \$1.0 million and \$2.1 million, respectively.

A reconciliation of the change in the uncertain tax benefits (UTB) balance from January 1, 2008 to December 31, 2010 is as follows (in thousands):

	Unrecognized Tax Benefit Federal, State, and Foreign Tax
UTB Balance at January 1, 2008	\$ 10,980
Gross additions for current year positions	5,200
Gross additions for prior period positions	17,091
Gross reductions for prior period positions	(11,758)
Decrease due to settlements	(559)
Decrease due to lapse of statute of limitations	(1,650)
UTB Balance at December 31, 2008	\$ 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
Accrued interest and penalties	8,226
Total UTB balance including accrued interest and penalties	\$ 47,407
Current portion (included in accrued expenses)	\$ 180
Non-current portion (included in other liabilities)	\$ 47,227

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 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 jurisdiction, 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's U.S. federal income tax returns for tax years 2003 through 2008 are currently under routine examination by the IRS. In general, the Company is no longer subject to U.S. federal, state and local income tax examinations by tax authorities for years before 2003. The Company believes that it has adequately provided 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, 2010 is \$47.4 million, including interest and penalties, of which \$21.6 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, 2010 or our financial position as of December 31, 2010. 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 the 2010 Credit Facility and our Senior Notes. See Note 18 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, 2010, no shares of Preferred Stock have been issued.

## Stock-Based Compensation

# Endo Pharmaceuticals Holdings Inc. 2000, 2004, 2007, and 2010 Stock Incentive Plans

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 expired during 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 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). Approximately 18.4 million shares were reserved for future issuance upon exercise of options granted or to be granted under the 2004, 2007, and 2010 Stock Incentive Plans. As of December 31, 2010, stock options, restricted stock awards and restricted stock units have been granted under the Stock Incentive Plans.

# **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 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.

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).

	2010	2009	2008
Selling, general and administrative expenses	\$19,229	\$17,211	\$15,492
Research and development expenses	3,680	2,382	1,442
Total stock-based compensation expense	\$22,909	\$19,593	\$16,934

#### **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. 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 2000, 2004, 2007, and 2010 Stock Incentive Plans for the three-year period ended December 31, 2010 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, January 1, 2008	4,336,052	\$24.24		
Granted	1,371,253	\$24.78		4.
Exercised	(150,191)	\$14.88		
Forfeited	(834,753)	\$28.10		
Expired	(62,979)	\$29.11		
Outstanding, December 31, 2008	4,659,382	\$23.95		
Granted	2,216,544	\$19.30	, ,	
Exercised	(554,827)	\$14.48	* E/	
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	; · · · <u></u>	
Outstanding, December 31, 2010	5,891,400	\$22.60	7.60	\$79,141,959
Vested and expected to vest, December 31, 2010	5,453,882	\$22.64	7.50	\$73,014,084
Exercisable, December 31, 2010	1,887,649	\$24.32	5.50	\$22,083,003

The total intrinsic value of options exercised during the years ended December 31, 2010, 2009, and 2008 was \$9.0 million, \$3.6 million, and \$1.4 million, respectively. The weighted-average grant date fair value of the stock options granted during the years ended December 31, 2010, 2009, and 2008 was \$7.66, \$7.47, and \$9.48 per option, respectively, determined using the following assumptions:

1.5		 			. '	2010	2009	2008
Average expected ter	m (years)	 		:		5.25	5.22	4.92
Risk-free interest rate	e	 				2.4%	2.0%	2.8%
Dividend vield		 				$0.00^{\circ}$	0.00	0.00
Expected volatility .		 	• • • • • •			34%	40%	39%

The weighted average remaining requisite service period of the non-vested stock options is 2.5 years. As of December 31, 2010, the total remaining unrecognized compensation cost related to non-vested stock options amounted to \$41.5 million. This unrecognized compensation cost does not include the impact of any future stock-based compensation awards.

The following table summarizes information about stock options outstanding under our 2000, 2004, 2007, and 2010 Stock Incentive Plans at December 31, 2010:

# 2000, 2004, 2007, and 2010 Stock Incentive Plans Options Outstanding

Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Exercisable Weighted Average Exercise Price	Range of Exercise Prices
5,891,400	7.60	\$22.60	1,887,649	\$24.32	\$9.29-36.70

# **Restricted Stock Awards**

During the year ended December 31, 2007, the Company began granting restricted stock awards to non-employee directors of the Company. 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.

A summary of our restricted stock activity during the years ended December 31, 2010, 2009 and 2008 is presented below:

	Shares	Weighted Average Fair Value Per Share	Aggregate Intrinsic Value
Non-vested, January 1, 2008	13,572	\$29.84	
Forfeited Vested	(1,131) (6,786)	\$ — \$29.84 \$29.84	\$175,622
Non-vested, December 31, 2008 Granted	5,655	\$29.84 \$ —	
Forfeited Vested Vested	(1,131) (4,524)	\$29.84 \$29.84	\$ 92,832
Non-vested, December 31, 2009		\$	
Forfeited Vested	_	\$ — \$ —	· ·
Non-vested, December 31, 2010		<u>\$</u>	<u>* — </u>

As of December 31, 2010, there was no unrecognized compensation cost related to non-vested restricted stock awards.

# **Restricted Stock Units**

During the years ended December 31, 2010, 2009, and 2008, 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, 2010, 2009, and 2008 is presented below:

	Number of Shares	Aggregate Intrinsic Value
Outstanding, January 1, 2008		
Granieu	620.206	2
Fortested	(01 0/3)	
Vested	()1,0 is)	1
Outstanding, December 31, 2008		
Granted	1 133 186	
Portelled	(86 286)	
Vested	(118.012)	
Outstanding, December 31, 2009		<del></del>
Granted	1,4//,241	
Forfeited	(357 546)	
Vested	(319 532)	
Outstanding, December 31, 2010		\$79,651,134

The weighted average remaining requisite service period of the non-vested restricted stock units is 2.46 years. The weighted-average grant date fair values of the restricted stock units granted during the years ended December 31, 2010, 2009, and 2008 were \$21.39, \$19.43, and \$25.09 per unit, respectively. As of December 31, 2010, the total remaining unrecognized compensation cost related to non-vested restricted stock units amounted to \$20.9 million. This unrecognized compensation cost does not include the impact of any future stock-based compensation awards.

### **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, 2010 totaled 163,000. As of December 31, 2010, there was approximately \$3.5 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 2010, the share repurchase plan is set to expire in April 2012.

As described in Note 18, we entered into a privately-negotiated \$325.0 million accelerated share repurchase agreement as part of our broader share repurchase program described above. Pursuant to the accelerated share repurchase agreement, we purchased approximately 11.9 million shares of our common stock on April 15, 2008. On August 14, 2008, Endo received approximately 1.4 million additional shares of our common stock based on the volume-weighted average price of our common stock during a specified averaging period set forth by the accelerated share repurchase agreement. In addition to the accelerated share repurchase, beginning in April 2008, we made open market purchases of our common stock as part of our broader share repurchase program. As of December 31, 2008, we purchased approximately 4.5 million shares of our common stock on the open market for a total purchase price of approximately \$99.8 million. We did not purchase any shares of our common stock during the year ended December 31, 2009. During the year ended December 31, 2010, pursuant to the existing share repurchase program, we purchased approximately 2.5 million shares of our common stock totaling \$59.0 million.

# NOTE 14. COMMITMENTS AND CONTINGENCIES

# 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 and finished goods. 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, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

### Novartis Consumer Health, Inc.

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 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 that we would terminate this agreement effective February 2014. As of December 31, 2010, we are required to purchase a minimum of approximately \$14 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 \$54.9 million, \$51.5 million, and \$32.0 million for the years ended December 31, 2010, 2009, and 2008, respectively.

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 \$27.1 million, \$13.1 million, and \$23.4 million for the years ended December 31, 2010, 2009, and 2008, 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. 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.

Amounts incurred by Endo for such A&P Expenditures were \$18.0 million, \$15.6 million, and \$9.4 million for the years ended December 31, 2010, 2009, and 2008, respectively.

# 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 United States. 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 \$32 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<sup>®</sup>.
- 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 the product at a fixed price for a period of time after which the price will be adjusted at future dates certain 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 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.

Amounts purchased pursuant to this agreement, as amended, were \$172.3 million, \$152.9 million, and \$156.9 million for the years ended December 31, 2010, 2009, and 2008, respectively.

#### 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 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 is July 1, 1998 until June 30, 2013, with an automatic renewal provision for unlimited successive one-year periods. Either party may terminate the Mallinckrodt agreement in the event of a material breach by the other party. Amounts purchased pursuant to this agreement were \$26.1 million, \$20.7 million, and \$15.8 million for the years ended December 31, 2010, 2009, and 2008, 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. The Noramco Agreement will expire on December 31, 2011, with automatic renewal provisions for unlimited successive one-year periods. Either party may terminate the Noramco Agreement in the event of a material breach by the other party or at a designated time prior to its termination date. Amounts purchased from Noramco were \$13.9 million, \$3.2 million, and \$4.2 million for the years ended December 31, 2010, 2009, and 2008, 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 United States. The Sharp Agreement will expire on March 1, 2011, 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 \$6.9 million, \$6.3 million, and \$5.3 million for the years ended December 31, 2010, 2009, and 2008, respectively. On December 6, 2010, the parties amended the Sharp Packaging and Labeling agreement, effective December 1, 2010, extending the agreement until March 1, 2015.

## Ventiv Commercial Services, LLC

On May 15, 2008, we entered into a services agreement (the 2008 Ventiv Agreement) with Ventiv Commercial Services, LLC (Ventiv). Under the terms of the 2008 Ventiv Agreement, Ventiv provided to Endo certain sales and marketing services through a contracted field force and other sales management positions, collectively referred to as the 2008 Ventiv Field Force. The 2008 Ventiv Field Force promoted primarily Voltaren® Gel and was required to perform a minimum number of face-to-face one-on-one discussions with physicians and other healthcare practitioners for the purpose of promoting Voltaren® Gel and other Endo products within their respective approved indications during each year of the 2008 Ventiv Agreement, subject to certain provisions.

Under the terms of the 2008 Ventiv Agreement, we incurred a one-time implementation fee that we recognized in selling, general, and administrative expense in the second quarter of 2008. In addition, each month we were required to pay Ventiv a monthly fixed fee during the term of the 2008 Ventiv Agreement based on a pre-approved budget. Included in the fixed monthly fee were certain costs such as the Ventiv sales representative and district manager salaries, 2008 Ventiv Field Force travel, and office and other expenses captured on routine expense reports, as well as a fixed management fee. Ventiv was also eligible to earn a performance-based bonus equal to the fixed management fee during each year of the 2008 Ventiv Agreement. This performance-based bonus was payable upon the satisfaction of certain conditions, including the sale of a minimum number of Voltaren® Gel tubes and a minimum number of Details achieved.

In May 2009, we amended the 2008 Ventiv Agreement to change certain provisions including a reduction in the 2008 Ventiv Field Force from 275 to 80 sales representatives effective June 1, 2009. On September 30, 2010, the term of the Ventiv Agreement, which was originally set to expire on August 10, 2010, was extended until the first to occur of the following: (i) Endo and Ventiv entering into the new services agreement or (ii) November 30, 2010. On November 24, 2010, Endo and Ventiv terminated the 2008 Ventiv Agreement and entered into a new services agreement (the 2010 Ventiv Agreement).

Under the terms of the 2010 Ventiv Agreement, Ventiv will provide 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 2010 Ventiv Field Force. The 2010 Ventiv Field Force is 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® Gel, Lidoderm®, Frova®, Opana® ER, and other Endo products within their respective approved indications during each year of the 2010 Ventiv Agreement, subject to certain provisions.

Under the terms of the 2010 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 are required to pay Ventiv a monthly fixed fee during the term of the 2010 Ventiv Agreement based on a pre-approved budget. Ventiv is also eligible to earn a performance-based bonus equal to the fixed management fee during each year of the 2010 Ventiv Agreement. This performance-based bonus is payable upon the satisfaction of certain conditions, including the sale of a minimum number of Voltaren® Gel tubes and a minimum number of Details achieved. The 2010 Ventiv Agreement shall expire on October 1, 2011, unless extended by Endo.

The expenses incurred with respect to Ventiv under both the 2008 Ventiv Agreement and the 2010 Ventiv Agreement were \$10.9 million, \$21.6 million, and \$19.2 million for the years ended December 31, 2010, 2009, and 2008, 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 United States. 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 \$2 million.

#### 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.

# **Milestones and Royalties**

See Note 7 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**

In the ordinary course of its business, the Company is involved in various claims and legal proceedings, including product liability, intellectual property, and commercial litigation. 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.

# Withdrawal of Redux, Legal Proceedings, Insurance Claims, and Related Contingencies

In September 1997, Indevus 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 of Redux, Indevus was named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions in federal and state courts relating to the use of Redux and other weight loss drugs. Fewer than 50 cases are still pending against Indevus and/or the Company. In May 2001, Indevus entered into the AHP Indemnity and Release Agreement with Wyeth pursuant to which Wyeth agreed to indemnify Indevus against certain classes of product liability cases filed against Indevus related to Redux and Indevus agreed to dismiss Redux related claims against Wyeth. Under the terms of the AHP Indemnity and Release Agreement, Wyeth has agreed to indemnify Indevus for claims brought by plaintiffs who initially opted out of Wyeth's national class action settlement of diet drug claims and claimants alleging primary pulmonary hypertension. In addition, Wyeth has agreed to fund all future legal costs of Indevus related to the defense of Redux-related product liability cases. Also, pursuant to the AHP Indemnity and Release Agreement, Wyeth agreed to fund additional insurance coverage to supplement Indevus' existing product liability insurance. The Company believes the total insurance coverage, including the additional insurance coverage funded by Wyeth, is sufficient to address the potential remaining Redux product liability exposure. However, there can be no assurance Redux claims will not exceed the amount of insurance coverage available to the Company and Wyeth's indemnification obligations under the AHP Indemnity and Release Agreement. If such insurance coverage and Wyeth indemnification is not sufficient to satisfy Redux-related claims, the payment of amounts to satisfy such claims may have a material adverse effect on the Company's business, results of operations, financial condition or cash flows. Prior to the effectiveness of the AHP Indemnity and Release Agreement, Redux-related defense costs of Indevus were paid by, or subject to reimbursement from, Indevus' product liability insurers. To date, there have been no Redux-related product liability settlements or judgments paid by Indevus or their insurers. en al facto de trochia de la factoria de la compansión de

If the Company incurs additional product liability defense and other costs subject to claims on the Reliance product liability policy up to the \$5.0 million limit of the policy, the Company will have to pay such costs without expectation of reimbursement and will incur charges to operations for all or a portion of such payments.

# Department of Health and Human Services Subpoena

In January 2007, the Company received a subpoena issued by the United States Department of Health and Human Services, Office of Inspector General (OIG). The subpoena requests documents relating to Lidoderm<sup>®</sup> (lidocaine patch 5%), focused primarily on the sale, marketing and promotion of Lidoderm<sup>®</sup>. The Company is cooperating with the government. At this time, the Company cannot predict or determine the outcome of the above matter 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.

#### Pricing Litigation

A number of cases brought by local and state government entities are pending 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.

The federal court cases have been consolidated in the United States District Court for the District of Massachusetts under the Multidistrict Litigation Rules as In re: *Pharmaceutical Industry Average Wholesale Price Litigation*, MDL 1456. The following previously reported cases are pending in MDL 1456 and have been consolidated into one consolidated complaint: City of New York v. Abbott Laboratories, Inc., et al.; County of

Albany v. Abbott Laboratories, Inc., et al.; County of Allegany v. Abbott Laboratories, Inc., et al.; County of Broome v. Abbott Laboratories, Inc., et al.; County of Cattaraugus v. Abbott Laboratories, Inc., et al.; County of Cayuga v. Abbott Laboratories, Inc., et al.; County of Chautauqua v. Abbott Laboratories, Inc., et al.; County of Chemung v. Abbott Laboratories, Inc., et al., County of Chemango v. Abbott Laboratories, Inc., et al., County of Columbia v. Abbott Laboratories, Inc., et al.; County of Cortland v. Abbott Laboratories, Inc., et al.; County of Dutchess v. Abbott Laboratories, Inc., et al.; County of Essex v. Abbott Laboratories, Inc., et al.; County of Fulton v. Abbott Laboratories, Inc., et al.; County of Genesee v. Abbott Laboratories, Inc., et al.; County of Greene v. Abbott Laboratories, Inc., et al.; County of Herkimer v. Abbott Laboratories, Inc., et al.; County of Jefferson v. Abbott Laboratories, Inc., et al.; County of Lewis v. Abbott Laboratories, Inc., et al.; County of Madison v. Abbott Laboratories, Inc., et al.; County of Monroe v. Abbott Laboratories, Inc., et al.; County of Niagara v. Abbott Laboratories, Inc., et al.; County of Oneida v. Abbott Laboratories, Inc., et al.; County of Onondaga v. Abbott Laboratories, Inc., et al.; County of Ontario v. Abbott Laboratories, Inc., et al.; County of Orleans v. Abbott Laboratories, Inc., et al., County of Putnam v. Abbott Laboratories, Inc., et al., County of Rensselaer v. Abbott Laboratories, Inc., et al.; County of Rockland v. Abbott Laboratories, Inc., et al.; County of St. Lawrence v. Abbott Laboratories, Inc., et al.; County of Saratoga v. Abbott Laboratories, Inc., et al.; County of Schuyler v. Abbott Laboratories, Inc., et al.; County of Seneca v. Abbott Laboratories, Inc., et al.; County of Steuben v. Abbott Laboratories, Inc., et al.; County of Suffolk v. Abbott Laboratories, Inc., et al.; County of Tompkins v. Abbott Laboratories, Inc., et al., County of Ulster v. Abbott Laboratories, Inc., et al., County of Warren v. Abbott Laboratories, Inc., et al.; County of Washington v. Abbott Laboratories, Inc., et al.; County of Wayne v. Abbott Laboratories, Inc., et al., County of Westchester v. Abbott Laboratories, Inc., et al., County of Wyoming v. Abbott Laboratories, Inc., et al.; and County of Yates v. Abbott Laboratories, Inc., et al.

In addition, a previously reported case originally filed in the Southern District of New York, County of Orange v. Abbott Laboratories, Inc., et al., has been transferred to the MDL and consolidated with the cases listed above.

On January 22, 2010, without admitting any liability or wrongdoing, EPI and the plaintiffs reached an agreement in principle to resolve the foregoing federal cases brought by New York City and the New York counties on terms that are not material to the Company's business, results of operations, financial condition or cash flows.

On November 3, 2010, the State of Louisiana submitted its Third Amending Petition for Damages and Jury Demand in the previously-filed case of State of Louisiana v. Abbott Laboratories, Inc., et al., No. 596164. That Petition names EPI as a defendant. The Petition also names numerous other pharmaceutical companies and contains allegations similar to the allegations in the cases described above. The case is pending in the 19th Judicial District, Parish of East Baton Rouge.

There is a previously reported case pending in the MDL against EPI and numerous other pharmaceutical companies: State of Iowa v. Abbott Laboratories, Inc., et al., Civ. Action No. 4:07-cv-00461. On June 25, 2010, without admitting any liability or wrongdoing, EPI and the plaintiff reached an agreement in principle to resolve this case brought by the State of Iowa on terms that are not material to the Company's business, results of operations, financial condition or cash flows.

Three previously reported cases, County of Erie v. Abbott Laboratories, Inc., et al., originally filed in the Supreme Court of the State of New York, Erie County, County of Oswego v. Abbott Laboratories, Inc., et al., originally filed in the Supreme Court of the State of New York, Oswego County, and County of Schenectady v. Abbott Laboratories, Inc., et al., originally filed in the Supreme Court of the State of New York, Schenectady County, have been coordinated by the New York Litigation Coordinating Panel in the Supreme Court of the State of New York, Erie County. Without admitting any liability or wrongdoing, EPI and the plaintiffs have reached an agreement in principle to resolve these cases brought by the County of Erie, the County of Oswego and the County of Schenectady on terms that are not material to the Company's business, results of operations, financial condition or cash flows.

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.

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., Civ. Action No. 070913719.

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.

# Paragraph IV Certifications on Lidoderm®

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. (Teikoku) received a Paragraph IV Certification Notice under 21 U.S.C. 355(i) from Watson Laboratories, Inc. advising of the filing of an Abbreviated New Drug Application (ANDA) for a generic version Lidoderm® (lidocaine topical patch 5%). The Paragraph IV Certification 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, Teikoku Seiyaku Co., Ltd. and Teikoku Pharma USA, Inc. filed a lawsuit against Watson Laboratories, Inc, 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. On March 4, 2010, Watson filed an Answer and Counterclaims, claiming U.S. Patent No. 5,827,529 is invalid or not infringed. In October 2010, Teikoku Pharma USA listed U.S. Patent No. 5,741,510 in the FDA's Orange Book, and this patent expires in March 2014. This patent has not yet been challenged. Endo intends, and has been advised by Teikoku that they too intend, to 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. 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 January 2011, the Company and Teikoku received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) 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 Certification 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. The Company is currently reviewing the details of this notice from Mylan and intends, and has been advised by Teikoku that it too intends, to pursue all available legal and regulatory pathways in defense of Lidoderm®. 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, it may be able to launch its generic version of Lidoderm® prior to the applicable patents' expirations in 2014 and 2015.

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

On December 14, 2007, the Company received a notice from Impax Laboratories, Inc. (Impax) advising of the FDA's apparent acceptance for substantive review, as of November 23, 2007, of Impax's amended ANDA for a generic version of Opana® ER (oxymorphone hydrochloride extended-release tablets CII). Impax's letter included notification that it had filed Paragraph IV certifications with respect to Penwest's U.S. Patent Nos. 7,276,250, 5,958,456 and 5,662,933, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire in 2023, 2013 and 2013, respectively.

On June 16, 2008, the Company received a notice from Impax that it had filed an amendment to its ANDA containing Paragraph IV certifications for the 7.5 mg, 15 mg and 30 mg strengths of oxymorphone hydrochloride extended release tablets. The Company and Penwest timely filed lawsuits against Impax in the United States District Court for the District of Delaware in connection with Impax's ANDAs.

On June 8, 2010, the Company and Penwest settled all of the Impax litigation relating to Opana® ER. Both sides dismissed their respective claims and counterclaim with prejudice. Under the terms of the settlement, Impax agreed not to challenge the validity or enforceability of Penwest's patents relating to Opana® ER. The Company and Penwest agreed to grant Impax a license permitting the production and sale of generic Opana® ER for 5, 10, 20, 30 and 40 mg tablets commencing on January 1, 2013 or earlier under certain circumstances. Such license is exclusive for 5, 10, 20, 30 and 40 mg tablets of generic Opana® ER for which Impax obtains first applicant status as described in 21 U.S.C. Section 355(j)(5)(B)(iv), for the period beginning on January 1, 2013 or earlier under certain circumstances, and such exclusivity ends upon expiration or forfeit of the 180-day period described in 21 U.S.C. Section 355(j)(5)(B)(iv) for such dosage strength. Such license is also subject to any agreements executed by us and/or Penwest and any third party holding an ANDA referencing Opana® ER as of or prior to June 8, 2010.

In February 2008, the Company received a notice from Actavis South Atlantic LLC (Actavis), advising of the filing by Actavis of an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) for a generic version of Opana® ER (oxymorphone hydrochloride extended-release tablets CII).

On or around June 2, 2008, the Company received a notice from Actavis that it had filed an amendment to its ANDA containing Paragraph IV certifications for the 7.5 mg and 15 mg dosage strengths of oxymorphone hydrochloride extended release tablets. On or around July 2, 2008, the Company received a notice from Actavis that it had filed an amendment to its ANDA containing a Paragraph IV certification for the 30 mg dosage strength. The Company and Penwest timely filed lawsuits against Actavis in the United States District Court for the District of New Jersey.

On February 20, 2009, the Company and Penwest settled all of the Actavis litigation relating to Opana® ER. Under the terms of the settlement, Actavis agreed not to challenge the validity or enforceability of Penwest's patents relating to Opana® ER. The Company and Penwest agreed to grant Actavis a license permitting the production and sale of generic Opana® ER 7.5 and 15 mg tablets on July 15, 2011, or earlier under certain circumstances. The Company and Penwest also granted Actavis a license to produce and market other strengths of Opana® ER generic commencing on the earlier of July 15, 2011 and the date on which any third party commences commercial sales of a generic form of the drug.

On July 14, 2008, the Company received a notice from Sandoz, Inc. (Sandoz), advising of the filing by Sandoz of an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in 5 mg, 10 mg, 20 mg and 40 mg dosage strengths.

On November 20, 2008, the Company received a notice from Sandoz that it had filed an amendment to its ANDA containing Paragraph IV certifications for the 7.5 mg, 15 mg and 30 mg dosage strengths of oxymorphone hydrochloride extended release tablets. The Company and Penwest timely filed lawsuits against Sandoz in the United States District Court for the District of Delaware.

On June 8, 2010, the Company and Penwest settled all of the Sandoz litigation relating to Opana® ER. Both sides dismissed their respective claims and counterclaim with prejudice. Under the terms of the settlement, Sandoz agreed not to challenge the validity or enforceability of Penwest's patents relating to Opana® ER. The Company and Penwest agreed to grant Sandoz a license permitting the production and sale of all strengths of Opana® ER commencing on September 15, 2012, or earlier under certain circumstances.

On September 12, 2008, the Company received a notice from Barr Laboratories, Inc. (Barr), advising of the filing by Barr of an ANDA containing a Paragraph IV certification under 21/U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in a 40 mg dosage strength. On September 15, 2008,

the Company received a notice from Barr that it had filed an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in 5 mg, 10 mg, and 20 mg dosage strengths. On June 2, 2009, the Company received a notice from Barr that it had filed an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in 7.5 mg, 15 mg, and 30 mg dosage strengths. The Company and Penwest timely filed lawsuits against Barr in the United States District Court for the District of Delaware in connection with Barr's ANDA.

On April 12, 2010, the Company and Penwest settled all of the Barr litigation relating to Opana® ER. Under the terms of the settlement, Barr agreed not to challenge the validity or enforceability of Penwest's patents relating to Opana® ER. The Company and Penwest agreed to grant Barr a license permitting the production and sale of all strengths of Opana® ER commencing on September 15, 2012, or earlier under certain circumstances.

On January 20, 2010, the Company received a notice from Watson Laboratories, Inc. (Watson) advising of the filing by Watson of an ANDA containing a Paragraph IV certification under 21 U.S.C. section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in a 40 mg dosage strength. On March 19, 2010, the Company received a notice from Watson advising of the filing by Watson of an ANDA containing a Paragraph IV certification under 21 U.S.C. section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in 5, 7.5,10, 15, 20, and 30 mg dosage strengths. The Company and Penwest timely filed lawsuits against Watson in the U.S. District Court for the District of New Jersey in connection with Watson's ANDA. The lawsuit alleges infringement of an Orange Book-listed U.S. patent that covers the Opana® ER formulation.

On October 4, 2010, the Company and Penwest settled all of the Watson litigation relating to Opana<sup>®</sup> ER. Under the terms of the settlement, Watson agreed not to challenge the validity or enforceability of Penwest's patents relating to Opana<sup>®</sup> ER. The Company and Penwest agreed to grant Watson a license permitting the production and sale of all strengths of Opana<sup>®</sup> ER commencing on September 15, 2012, or earlier under certain circumstances.

On December 29, 2009, the Company received a notice from Roxane Laboratories, Inc. (Roxane) advising of the filing by Roxane of an ANDA containing a Paragraph IV certification under 21 U.S.C. section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in a 40 mg dosage strength. The notice refers to Penwest's U.S. Patent Nos. 5,662,933, 5,958,456 and 7,276,250, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire in 2013, 2013, and 2023, respectively. Subsequently, on January 29, 2010, the Company and Penwest filed a lawsuit against Roxane in the U.S. District Court for the District of New Jersey in connection with Roxane's ANDA. The lawsuit alleges infringement of an Orange Book-listed U.S. patent that covers the Opana® ER formulation. 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.

We intend to 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 Certifications on Sanctura XR®

On June 2, 2009, the Company's subsidiary, Endo Pharmaceuticals Solutions, Inc. (Endo Solutions), received a notice from Watson advising that Watson had filed a certification with the FDA under 21 C.F.R. Section 314.95(c)(1) in conjunction with ANDA 91-289 for approval to commercially manufacture and sell generic versions of Sanctura XR® trospium chloride extended release capsules. The Paragraph IV Certification Notice alleged that U.S. Patent No. 7,410,978, listed in the Orange Book for Sanctura XR® is invalid and/or will not be infringed by the commercial manufacture, use, or sale of Watson's generic product. This patent expires February 1, 2025 and is owned by Supernus Pharmaceuticals, Inc. and licensed to Endo Solutions.

In response to Watson's notice letter, on July 13, 2009, Endo Solutions and its partners Supernus Pharmaceuticals, Inc. (Supernus) and Allergan filed a lawsuit against Watson in the United States District Court for the District of Delaware alleging infringement of U.S. Patent No. 7,410,978 by Watson's ANDA. 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. We intend, and have been advised by Supernus and Allergan that they too intend, to contest this case vigorously. However, there can be no assurance that we will be successful. 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.

On November 4, 2009, the Company received a Paragraph IV Certification Notice under 21 U.S.C. Section 355(j) from Sandoz advising the Company that Sandoz had filed an ANDA for a generic version of Sanctura XR® trospium chloride extended release capsules. The Paragraph IV Certification Notice alleges that U.S. Patent No. 7,410,978, listed in the Orange Book for Sanctura XR® is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Sandoz's generic product. This patent expires February 1, 2025 and is owned by Supernus Pharmaceuticals, Inc. and licensed to Endo Solutions.

In response to Sandoz's Certification Notice, on November 19, 2009, Supernus, Endo Solutions and Allergan filed a lawsuit against Sandoz in the United States District Court for the District of Delaware alleging infringement of U.S. Patent No. 7,410,978 by Sandoz's ANDA. 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. We intend, and have been advised by Supernus and Allergan that they too intend, to contest this case vigorously. However, there can be no assurance that we will be successful. 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.

On April 26, 2010, the Company received a Paragraph IV Certification Notice under 21 U.S.C. Section 355(j) from Paddock Laboratories, Inc. (Paddock) advising the Company that Paddock had filed an ANDA for a generic version of Sanctura XR® trospium chloride extended release capsules. The Paragraph IV Certification Notice alleges that U.S. Patent No. 7,410,978, listed in the Orange Book for Sanctura XR® is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Paddock's generic product. This patent expires February 1, 2025 and is owned by Supernus Pharmaceuticals, Inc. and licensed to Endo Solutions.

In response to Paddock's Certification Notice, on June 9, 2010, Supernus, Endo Solutions and Allergan filed a lawsuit against Paddock in the United States District Court for the District of Delaware alleging infringement of U.S. Patent No. 7,410,978 by Paddock's ANDA. 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. We intend, and have been advised by Supernus and Allergan that they too intend, to contest this case vigorously. However, there can be no assurance that we will be successful. 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.

During the second half of 2010, Watson, Sandoz, and Paddock filed additional Paragraph IV certifications pertaining to U.S. Patent Nos. 7,763,635 (the '635 patent), 7,759,359 (the '359 patent), 7,781,448 (the '448 patent), and 7,781,449 (the '449 patent). In each case, Supernus, Allergan, and Endo Solutions filed complaints alleging infringement of the '448 and '449 patents by each defendant and infringement by Sandoz of the '635 and '359 patents as well.

On September 21, 2010, the court consolidated the suits against Sandoz and Paddock into the original suit filed against Watson. Trial in these cases is currently set to commence on May 2, 2011.

## MCP Cases

Qualitest Pharmaceuticals (Qualitest), along with several other pharmaceutical manufacturers, has been named as a defendant 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. Trials in certain of these actions have been scheduled for 2011. 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.

# 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.

#### 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 leases as of December 31, 2010 are as follows (in thousands):

	Operating Leases
2011	12,247
2012	
2013	7,002
2014	6,665
2015	
Thereafter	5,695
Total minimum lease payments	\$42,911

Expense incurred under operating leases was \$17.2 million, \$12.2 million, and \$8.7 million for the years ended December 31, 2010, 2009, and 2008, respectively.

# NOTE 15. SAVINGS AND INVESTMENT PLAN AND DEFERRED COMPENSATION PLANS

On September 1, 1997, we established a defined contribution Savings and Investment 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. Contributions by us amounted to \$9.8 million, \$8.3 million, and \$7.2 million for the years ended December 31, 2010, 2009, and 2008, respectively.

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 and up to 100% of restricted stock units granted, with payout to occur as elected either in lump sum or installments. Under the 401(k) Restoration Plan the participant may defer the amount of base salary and bonus that would have been deferrable under the Company's Savings and Investment Plan (up to 50% of salary and bonus) if not for the qualified plan statutory limits on deferrals and contributions, 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 after separation from service either in lump sum or installments as elected by the participant.

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. Payment occurs after separation from service either in lump sum or installments as elected by the participant.

#### **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):

	2010	2009	2008
Numerator:	- *		100
Net income attributable to Endo Pharmaceuticals Holdings Inc. common			4
stockholders	\$259,006	\$266,336	\$255,336
Denominator:			
For basic per share data—weighted average shares	116,164	117,112	123,248
Dilutive effect of common stock equivalents	1,202	403	472
Dilutive effect of 1.75% Convertible Senior Subordinated Notes	585	<u> </u>	
For diluted per share data—weighted average shares	117,951	117,515	123,720
Basic net income per share attributable to Endo Pharmaceuticals Holdings Inc	\$ 2.23	\$ 2.27	\$ 2.07
Diluted net income per share attributable to Endo Pharmaceuticals Holdings			
Inc	\$ 2.20	\$ 2.27	\$ 2.06

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 were only included in the dilutive earnings 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 figure 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 warrant agreements on diluted weighted average shares. As a result, the purchases of the convertible note hedges are excluded because their impact would be anti-dilutive. The treasury

stock method will be 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 shares excluded from the calculation of diluted earnings per share as the inclusion of such shares would be anti-dilutive for the years ended December 31 (in thousands):

	2010	2009	2008
Weighted average shares excluded:			· <del></del>
1.75% Convertible senior subordinated notes due 2015 and warrants(1)	25,408	25,993	25,993
Employee stock-based awards	2,721	4,681	3,596
		30,674	29,589

<sup>(1)</sup> Amounts represent the potential total dilution that could occur if our Convertible Notes and warrants were converted to shares of our common stock in excess of the amounts of related dilution included in our calculations of diluted earnings per share.

### NOTE 17. COST OF REVENUES

The components of cost of revenues for the years ended December 31 (in thousands) were as follows:

	2010	2009	2008
Cost of net sales	\$451,096	\$375,058	\$267,235
Cost of device, service and other revenues	53,661		···
Total cost of revenues	\$504,757	\$375,058	\$267,235

#### NOTE 18. DEBT

The components of our total indebtedness for the years ended December 31 (in thousands), were as follows:

	2010	2009
7.00% Senior Notes due 2020	400,000 (13,284)	
7.00% Senior Notes due 2020, net	\$ 386,716	\$ —
1.75% Convertible Senior Subordinated Notes due 2015	379,500	379,500
Notes due 2015	(100,578)	(119,221)
1.75% Convertible Senior Subordinated Notes due 2015, net	\$ 278,922	\$ 260,279
2010 Credit Facility, Term Loan due 2015, net  16% Non-recourse notes due 2024, net  Other long-term debt, net	\$ 400,000 \$ — \$ 5,156	\$ — \$ 62,255 \$ —
Total long-term debt, net	\$1,070,794	\$ 322,534
Less current portion	\$ 24,993	\$ —
Total long-term debt, less current portion, net	\$1,045,801	\$ 322,534

#### 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. No amounts were drawn under the 2009 Credit Facility in 2009 or 2010.

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 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 is available for working capital and general corporate purposes. The agreement governing the 2010 Credit Facility (the 2010 Credit Agreement) also permits 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 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 2010 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 2010 Credit Facility will bear 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 may 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 will also pay a commitment fee of between 35 to 50 basis points, payable quarterly, on the average daily unused amount of the Revolving Credit Facility. As of the date of this filing, the Company has not drawn any amounts under the 2010 Credit Facility.

Financing costs of \$16.5 million paid to establish the 2010 Credit Facility were deferred and are being 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, 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.

We recognized \$5.4 million of interest expense related to our 2010 Credit Facility and 2009 Credit Facility for the year ended December 31, 2010.

### 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 Senior Notes) at an issue price of 99.105%. The Senior 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 Senior 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 Senior Notes is payable semiannually in arrears on June 15 and December 15 of each year, beginning on June 15, 2011. The Senior 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 Senior 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:

Payment Dates (between indicated dates)	Redemption Percentage
From December 15, 2015 to and including December 14, 2016	
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 Senior Notes at a specified redemption price set forth in the Indenture, plus accrued and unpaid interest and additional interest, if any. If the Company experiences certain change of control events, it must offer to repurchase the Senior 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 Senior Notes receiving investment grade credit ratings.

We recognized \$3.1 million of interest expense related to our Senior Notes for the year ended December 31, 2010.

# 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 semi-annually 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.

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 (the Indenture): (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 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 earnings per share to the extent that the price of our common stock exceeds the strike price of the warrants at exercise.

As part of our broader share repurchase program described in Note 13, we also entered into a privately-negotiated accelerated share repurchase agreement with the same counterparty. We used approximately \$314 million of the net proceeds from the Convertible Notes, together with approximately \$11 million of cash on hand, to repurchase a variable number of shares of our common stock pursuant to the accelerated share repurchase agreement entered into as part of our broader share repurchase program. Pursuant to the accelerated share repurchase agreement, the counterparty delivered 11.9 million shares of our common stock to the Company on the day that the Convertible Note offering closed, April 15, 2008. On August 14, 2008, Endo received approximately 1.4 million additional shares of our common stock based on the volume-weighted average price of our common stock during a specified averaging period set forth by the accelerated share repurchase agreement.

The Company has reserved previously authorized shares of common stock for issuance pursuant to the aforementioned Convertible Notes transaction, the convertible note hedge transaction, and the warrant.

We accounted for the call options, warrants, and accelerated share repurchase agreement in accordance with the guidance regarding the accounting for convertible debt instruments that may be settled in cash upon conversion. 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 our Consolidated Balance Sheets as of December 31, 2010 and 2009. The common stock acquired through the accelerated share repurchase agreement has been included in treasury stock in our Consolidated Balance Sheets as of December 31, 2010 and 2009.

As discussed in Note 2, on January 1, 2009 the Company retrospectively adopted the provisions of the authoritative guidance relating to the accounting for convertible debt instruments. The guidance requires that issuers of convertible debt instruments that may be settled in cash or other assets on conversion to separately account for the liability and equity components of the instrument in a manner that will reflect the entity's nonconvertible debt borrowing rate on the instrument's issuance date when interest cost is recognized in subsequent periods.

As a result of our adoption, we separated the debt portion of our Convertible Notes from the equity portion at their fair value retrospective to the date of issuance and are amortizing the resulting discount into interest expense over the life of the Convertible Notes.

In order to determine the fair value of the debt portion and equity portion of our Convertible Notes, we first attempted to use a market approach by identifying prices and other relevant information generated by market

transactions at or near the issuance date of our Convertible Notes, that involved comparable companies issuing nonconvertible debt with similar embedded features (other than the conversion feature). We were unable to identify any such transactions. As a result, the Company determined that an expected present value technique, or income approach that maximizes the use of observable market inputs is the preferred approach to measure the fair value of the debt and equity components of our Convertible Notes. Specifically, the Company used an income approach known as the binomial lattice model.

To calculate the fair value of the debt and equity components of our Convertible Notes, the Company constructed a binomial lattice to model future changes in the equity value of the Company, and a convertible bond lattice for the Convertible Notes, which incorporated certain inputs and assumptions, including scheduled coupon and principal payments, the conversion feature inherent in the Convertible Notes, and a stock price volatility of 36% that was based on historic volatility of the Company's common stock and other factors.

An implied credit spread of 6.12% was calculated based on the results of the convertible bond lattice described above. The fair value of the debt component was then calculated by discounting the coupon and principal payments of the Convertible Notes with a risk free interest rate of 2.97% and the implied credit spread of 6.12%, which collectively represent the Company's estimated nonconvertible debt borrowing rate of 9.09%. As a result of this analysis, the fair value of the debt component of our Convertible Notes was determined to be \$237.3 million on the date of issuance.

As a result of the retrospective adoption, we recorded an adjustment to our Consolidated Balance Sheet as of April 15, 2008 to separate the debt and equity components of our Convertible Notes. This adjustment resulted in a reclassification out of Convertible Senior Subordinated Notes Due 2015 into Additional Paid-In Capital of \$142.2 million, which represents the fair value of the equity component of our Convertible Notes on the date of issuance.

In addition, we were required to reclassify the portion of the initial purchaser's discount and certain other costs of the offering that were attributable to the equity component of our Convertible Notes. The initial purchaser's discount and certain other costs of the offering were originally recorded as a contra-liability account applied to the face amount of the Convertible Notes and were being amortized to interest expense utilizing the effective interest method. Upon adoption, we recorded an adjustment out of the contra-liability account and into Additional Paid-In Capital of \$3.3 million, which represents the portion of the original purchaser's discount and certain other costs of the offering that are relate to the equity component of our Convertible Notes.

The adoption resulted in the recognition of an additional \$10.4 million of interest expense and a reduction to our income tax expense of \$4.0 million for the year ended December 31, 2008. Accordingly, we recorded a \$6.4 million adjustment to beginning retained earnings in our December 31, 2009 Consolidated Balance Sheet.

The carrying values of the debt and equity components of our Convertible Notes at December 31, 2010 and December 31, 2009 are as follows (in thousands):

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Principal amount of Convertible Notes	\$ 379,500	\$ 379,500
Unamortized discount related to the debt component(1)		(119,221)
Net carrying amount of the debt component	\$ 278,922	\$ 260,279
Carrying amount of the equity component	\$ 142,199	\$ 142,199
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<sup>(1)</sup> 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 \$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. During the year ended December 31, 2009, we recognized \$23.8 million of interest expense related to our Convertible Notes, \$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.

#### Convertible Notes Due July 2009

As a result of our acquisition of Indevus, the Company assumed Indevus' 6.25% Convertible Senior Notes due July 2009 (the Indevus Notes). Pursuant to the Indenture governing the Indevus Notes, within 30 days of the effective date of the Merger, holders of the Indevus Notes had the right to tender their notes for the principal amount of the Indevus Notes plus any accrued and unpaid interest. During this 30-day period, approximately \$3.6 million in aggregate principal amount of Indevus Notes were tendered and the Company paid this amount in April 2009.

The Notes matured on July 15, 2009. Accordingly, the Company paid the remaining \$68.3 million in outstanding principal to satisfy the Notes in their entirety.

#### Non-recourse Notes

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.

#### Other Debt

In connection with our acquisition of HealthTronics, we assumed \$40 million in outstanding debt drawn under the HealthTronics Senior Credit Facility. The Company repaid those amounts, including unpaid interest, on July 2, 2010 and the HealthTronics Senior Credit Facility was terminated as a result of the acquisition.

Upon our acquisition of HealthTronics, we also assumed \$4.6 million in notes related to equipment purchased by HealthTronics' limited partnerships, which indebtedness we believe will be repaid from the cash flows of the partnerships. Since our acquisition in July of 2010, our partnerships repaid certain of these notes and financed additional purchases of equipment by obtaining additional similar notes. The carrying amount of our partnership's notes associated with the purchase of equipment is \$5.2 million at December 31, 2010. These notes bear interest at either a fixed rate of five to eight percent or LIBOR or prime plus a certain premium and are due over the next four years.

#### Maturities

Maturities on long-term debt for each of the next five years as of December 31, 2010 are as follows (in thousands):

	December 31, 2010
2011	. \$ 24,993
2012	. 34,246
2013	. 40,344
2014	. 45,154
2015	260,033

# NOTE 19. SUBSEQUENT EVENTS

### Long-Term Incentive Compensation

In early 2011, long-term incentive compensation in the form of approximately 1.4 million stock options, 0.7 million restricted stock units and 0.2 million performance shares were granted to employees. Stock options will generally vest over four years and expire ten years from the date of the grant. Restricted stock units will vest over four 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 \$45.1 million.

# NOTE 20. QUARTERLY FINANCIAL DATA (UNAUDITED)

	<u> </u>	Qua	rter Ended	e e f
	March 31,	June 30,	September 30,	December 31,
2010(1)	(i	in thousands,	except per share o	lata)
Total revenues	\$364,412	\$396,524	\$444,103	\$511,190
Gross profit	\$270,339	\$289,308	\$310,183	\$341,642
Net income attributable to Endo Pharmaceuticals Holdings	\$106,307	\$ 93,605	\$115,932	\$149,522
Inc	\$ 60,355	\$ 51,460	\$ 54,206	\$ 92,985
Holdings Inc. (basic)	\$ 0.51	\$ 0.44	\$ 0.47	\$ 0.80
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

	Quarter Ended			
,	March 31,	June 30,	September 30,	December 31,
	(i	in thousands,	except per share o	lata)
			the first section	
2009(2)				ľ
Total revenues	\$335,300	\$373,108	\$361,027	\$391,406
Gross profit	\$252,291	\$278,039	\$263,720	\$291,733
Operating income	\$ 77,466	\$ 64,916	\$ 84,314	\$163,328
Net income attributable to Endo Pharmaceuticals Holdings				
Inc	\$ 39,037	\$ 30,029	\$ 49,422	\$147,848
Net income per share attributable to Endo Pharmaceuticals		•	1	
Holdings Inc. (basic)	\$ 0.33	\$ 0.26	\$ 0.42	\$ 1.26
Net income per share attributable to Endo Pharmaceuticals				
Holdings Inc. (diluted)	\$ 0.33	\$ 0.26	\$ 0.42	\$ 1.25
Weighted average shares (basic)	116,822	117,158	117,207	117,261
Weighted average shares (diluted)	117,209	117,350	117,643	117,859

Quarter Ended

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, 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 costs (income) 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 pagoclone 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.
- (2) Operating income for the year ended December 31, 2009 was impacted by milestone payments to collaborative partners of \$9.4 million, \$21.0 million, \$30.7 million and \$16.0 million in the first, second, third and fourth quarters, respectively. Operating income for the year ended December 31, 2009 was also impacted by (1) the Indevus acquisition-related costs (income) of \$26.4 million, \$35.0 million, (\$20.2) million and (\$134.3) million during the first, second, third and fourth quarters, respectively (2) impairment charges of \$69.0 million relating to Pro2000 and Aveed™ during the fourth quarter (3) inventory step-up of \$1.6 million, \$3.6 million, \$5.9 million and \$0.2 million during the first, second, third and fourth quarters, respectively and (4) amortization expense relating to developed technology assets of \$11.4 million, \$15.6 million, \$16.7 million and \$19.2 million during the first, second, third and fourth quarters, respectively.

# **Exhibit Index**

Exhibit No.	<u>Title</u>
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 3.2 of the Form 10-K for the Year ended December 31, 2009 filed with the Commission on March 1, 2010)
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
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)

Exhibit No.	Title
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
10.16	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)
10.17*	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.)
10.17.1*	First Amendment, effective January 16, 2007, to the Supply Agreement by and between Vintage Pharmaceuticals, LLC and Noramco, Inc.
10.17.2*	Second Amendment, effective May 7, 2008, to the Supply Agreement by and between Vintage Pharmaceuticals, Inc. and Noramco, Inc.
10.17.3*	Third Amendment, effective December 22, 2008, to the Supply Agreement by and between Vintage Pharmaceuticals, LLC and Noramco, Inc.
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)
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)
10.27	Executive Employment Agreement between Endo and Ivan Gergel, M.D., dated as of April 29, 2008 (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated March 25, 2009)
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)
10.29	Auction-Rate Securities Rights Agreement, dated November 10, 2008, by and between Endo Pharmaceuticals and UBS AG (incorporated herein by reference to Exhibit 10.29 to the Form 10-K for the year ended December 31, 2008 filed with the Commission on March 2, 2009)

Exhibit No.	<u>Title</u>
10.30	Employment Agreement, dated as of April 1, 2008, by and between Endo and David P. Holveck (incorporated herein by reference to Exhibit 10.30 of the Current Report on Form 8-K dated March 12, 2008)
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, dated November 24, 2010 and effective as of October 1, 2010, 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)
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)

Exhibit No.	<u>Title</u>
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.
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)
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)
10.50	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)

Exhibit No.	<u>Title</u>
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 <sup>TM</sup> ) 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
10.60	Form of Stock Option Grant Agreement under the 2010 Stock Incentive Plan
	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)
	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)
	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)
·	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)
	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)

Exhibit No.	<u>Title</u>
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)
10.89	Credit Agreement dated as of October 16, 2009 among Endo Pharmaceuticals Holdings Inc., the lenders named therein, JPMorgan Chase Bank, N.A., as administrative agent, Barclays Capital as syndication agent, and J.P. Morgan Securities Inc. and Barclays Capital as Joint Bookrunners and Joint Lead Arrangers (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated October 22, 2009)
10.89.1	Credit Facility Amendment dated as of October 25, 2010 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)
10.89.2	Credit Agreement dated as of November 30, 2010 among Endo Pharmaceuticals Holdings Inc., the lenders named therein, Barclays Bank PLC, as documentation agent, and J.P. Morgan Securities LLC and RBC Capital Markets as Joint Bookrunners and Joint Lead Arrangers
10.89.3	Pledge and Security Agreement dated as of November 30, 2010 by and among Endo Pharmaceuticals Holdings Inc., the lenders named therein and JPMorgan Chase Bank N.A. as administrative agent
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)
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)

Exhibit No.	<u>Title</u>
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)
10.100	Credit Agreement, dated as of December 29, 2009, among HealthTronics, Inc., the lenders party thereto, JPMorgan Chase Bank, National Association, as Administrative Agent, J.P. Morgan Securities, Inc., as Arranger, and Bank of America, N.A., as Syndication Agent (incorporated by reference to Exhibit 10.1 to HealthTronics' Current Report on Form 8-K filed with the Securities and Exchange Commission on December 29, 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)
10.103	Registration Rights Agreement dated November 23, 2010 among the Company, J.P. Morgan Securities LLC, as Representative of the initial purchasers of the 7.00% Senior Notes due 2020 (the Initial Purchasers), and the guarantors named therein (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the Commission on November 24, 2010)
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 financial statements from the Endo Pharmaceuticals Holdings Inc. Annual Report on Form 10-K for the year ended December 31, 2010 formatted in Extensive Business Reporting Language (XBRL): (i) consolidated balance sheets, (ii) consolidated statements of operations, (iii) consolidated statements of stockholders' equity and comprehensive income, (iv) consolidated statements of cash flows, and (v) the notes to the consolidated financial statements.

<sup>\*</sup> 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.

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