ENDO PHARMACEUTICALS HOLDINGS INC
Form 10-K
February 29, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**
For the fiscal year ended December 31, 2011

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**
For the transition period from to

Commission file number: 001-15989

ENDO PHARMACEUTICALS HOLDINGS INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-4022871**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
100 Endo Boulevard Chadds Ford, Pennsylvania	**19317**
(Address of Principal Executive Offices)	**(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 x 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 x

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every interactive data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months. Yes x No ¨

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

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 x	Accelerated filer ¨	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The aggregate market value of the voting common equity held by non-affiliates as of June 30, 2011 was $4,660,596,549 based on a closing sale price of $40.17 per share as reported on the NASDAQ Global Select Market on June 30, 2011. Shares of the registrant s common stock held by each officer and director and each beneficial owner of 10% or more of the outstanding common stock of the registrant have been excluded since such persons and beneficial owners may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The registrant has no shares of non-voting common stock authorized or outstanding.

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

Documents Incorporated by Reference

Portions of the registrant s proxy statement to be filed with the SEC pursuant to Regulation 14A in connection with the registrant s 2012 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the SEC not later than 120 days after the conclusion of the registrant s fiscal year ended December 31, 2011.

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FOR THE YEAR ENDED DECEMBER 31, 2011

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FORWARD-LOOKING STATEMENTS

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

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

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PART I

Item 1. ***Business***

Overview

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

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

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

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

On a continuous basis, we evaluate and, where appropriate, pursue acquisition opportunities. In particular, we look to continue to enhance our product line by acquiring or licensing rights to additional products and compounds and therefore regularly evaluate selective acquisition and license opportunities. Such acquisitions or licenses may be effected through the purchase of assets, joint ventures and licenses or by acquiring other companies.

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

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

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

Our Strategy

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

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

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

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

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

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

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

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

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

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Our Competitive Strengths

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

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

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

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

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

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

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

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markets. This sales force consists of 450 Endo pharmaceutical sales representatives and 228 sales contracted representatives focusing primarily on pain products, 79 Endo sales representatives focusing primarily on bladder and prostate cancer products, 35 Endo medical center representatives focusing on the treatment of central precocious puberty and 27 Endo account executives focusing on managed markets customers. We also have 361 sales representatives focusing primarily on devices and 39 on services. We market our products and services to primary care physicians and specialty physicians, including those specializing in pain management, orthopedics, neurology, rheumatology, surgery, anesthesiology, urology and pediatric endocrinology. Our sales forces also target retail pharmacies and other healthcare professionals throughout the U.S. We distribute our products principally through independent wholesale distributors, but we also sell directly to retailers, clinics, government agencies, doctors and retail and specialty pharmacies. Our marketing policy is designed to assure that products and relevant, appropriate medical information are immediately available to physicians, pharmacies, hospitals, public and private payers, and appropriate healthcare professionals throughout the U.S. We work to gain access to healthcare authority, pharmacy benefit managers and managed care organizations formularies (lists of recommended or approved medicines and other products), including Medicare Part D plans and reimbursement lists by demonstrating the qualities and treatment benefits of our products within their approved indications.

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

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

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

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

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

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

Our Areas of Focus

Pain Management Market

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

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

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

The growth in this segment has been primarily attributable to:

- increasing physician recognition of the need and patient demand for effective treatment of pain;
- aging population (according to the U.S. Census Bureau, from 2000 to 2010 the population aged 65 and older reached 40 million people, representing 15% growth over this period);
- introduction of new and reformulated branded products; and
- increasing incidence of chronic pain conditions, such as cancer, arthritis and low back pain.

Urology, Endocrinology and Oncology Markets

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

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

Central Precocious Puberty (CPP)

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

Prostate cancer

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

Bladder cancer

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

BCG-refractory CIS bladder cancer

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

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

Testosterone replacement overview

In the U.S. alone, it is estimated that 13.8 million men have low testosterone levels; however, only about 9% are currently being treated. Hypogonadism, or low testosterone, is under diagnosed and under treated. Factors contributing to this include a lack of screening for low testosterone and the perceived risk of prostate cancer associated with current treatment strategies. In the U.S., TRT sales have dramatically increased, from approximately $552 million in 2006 to over $1.6 billion in 2011, representing a compounded annual growth rate of 24% since 2006.

Male incontinence

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

Erectile dysfunction

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

Female incontinence

We estimate over 500 million women worldwide suffer from urinary or fecal incontinence. These diseases can lead to debilitating medical and social problems, ranging from embarrassment to anxiety and depression. There are three types of urinary incontinence: stress, urge, and mixed incontinence (a combination of stress and urge). While stress incontinence is generally caused by a weakening of the pelvic floor and resultant hypermobility of the urethra, urge incontinence is more complex and currently not as well understood. Pads and diapers are often used to contain and absorb leaks, and may be acceptable for controlling mild incontinence. Drug therapy and electrical nerve stimulation are currently used to treat urge incontinence. Incontinence may be treated through exercises to strengthen pelvic floor muscles, or through the injection of collagen or some other bulking agent into the wall of the urethra or bladder neck to narrow the passage. Surgical solutions are generally recommended only when these other therapies are not effective. Our current products in the market treat stress incontinence, which generally results from a weakening of the tissue surrounding the bladder and urethra which can be a result of pregnancy, childbirth and aging.

Pelvic floor repair

Pregnancy, labor, and childbirth are some of the primary causes of pelvic floor prolapse and other pelvic floor disorders. Prolapse and other pelvic floor defects may be treated with a variety of open, laparoscopic, and

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

BPH therapy

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

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

Medical Services Markets

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

Lithotripsy services

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

Prostate treatment services

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

Anatomical pathology services

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

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

Medical products manufacturing, sales and maintenance

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

Information Technology Solutions

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

Products Overview

Branded Pharmaceuticals

The following table summarizes select products in our branded portfolio:

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

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

Lidoderm®. Lidoderm® (lidocaine patch 5%) was launched in September 1999. A topical patch product containing lidocaine, Lidoderm® was the first FDA-approved product for the relief of the pain associated with post-herpetic neuralgia, a condition thought to result after nerve fibers are damaged during a case of Herpes Zoster (commonly known as shingles). Lidoderm® is also currently protected by Orange Book-listed patents for, among other things, a method of treating post-herpetic neuralgia and the composition of the lidocaine-containing patch. The last of these patents is set to expire in 2015. In 2011, 2010 and 2009, Lidoderm® net sales were $825.2 million, $782.6 million and $763.7 million, respectively. Lidoderm® accounted for approximately 30% of our 2011 total revenues.

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

Voltaren® Gel. We launched Voltaren® Gel (diclofenac sodium topical gel 1%) in March 2008 upon closing of the license and supply agreement with Novartis AG and Novartis Consumer Health, Inc. Voltaren® Gel received regulatory approval in October 2007 from the FDA, becoming the first topical prescription treatment for use in treating pain associated with osteoarthritis and the first new product approved in the U.S. for osteoarthritis since 2001. Voltaren® Gel was granted marketing exclusivity in the U.S. as a prescription medicine until October 2010. It is the first prescription topical osteoarthritis treatment to have proven its effectiveness in both the knees and joints of the hands through clinical trials. Voltaren® Gel delivers effective pain relief with a favorable safety profile as its systemic absorption is 94% less than the comparable oral diclofenac treatment. In 2011, 2010 and 2009, net sales of Voltaren® Gel were $142.7 million, $104.9 million and $78.9 million, respectively. Voltaren® Gel accounted for approximately 5% of our 2011 total revenues.

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

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

Supprelin® LA. Supprelin® LA (histrelin acetate) was launched in the U.S. in June 2007. Supprelin® LA is a soft, flexible 12-month hydrogel implant based on our hydrogel polymer technology that delivers histrelin acetate, a gonadotropin releasing hormone (GnRH) agonist and is indicated for the treatment of central precocious puberty (CPP) in children. CPP is the early onset of puberty in young children resulting in the development of secondary sex characteristics and, if left untreated, can result in diminished adult height attainment. The development of these secondary sex characteristics is due to an increase in the secretion of sex hormones, the cause of which is unknown. We market Supprelin® LA in the U.S. through a specialty sales force primarily to pediatric endocrinologists. In 2011, 2010 and 2009, Supprelin® LA net sales were $50.1 million, $46.9 million, and $27.8 million, respectively.

Valstar®. Valstar® (valrubicin) is a sterile solution for intravesical instillation of valrubicin, a chemotherapeutic anthracycline derivative. Valstar® is indicated for intravesical therapy of bacillus Calmette-Guerin (BCG)-refractory carcinoma *in situ* (CIS) of the urinary bladder in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality. Valstar®, originally approved by the FDA in 1998, was withdrawn from the market in 2002 due to a manufacturing problem involving impurity issues in the original formulation and was placed on the FDA Drug Shortages List. In April 2007, the Company

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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®. Net sales of Valstar® were $21.5 million, $14.1 million and $3.4 million in 2011, 2010 and 2009, respectively.

Vantas®. Vantas® (histrelin acetate) was launched in the U.S. in November 2004. Vantas® is a soft, flexible 12-month hydrogel implant based on our hydrogel polymer technology that delivers histrelin acetate, a GnRH agonist and is indicated for the palliative treatment of advanced prostate cancer. We are party to a License, Supply and Distribution Agreement with Orion Corporation (Orion) granting Orion 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 $19.0 million, $17.0 million and $20.0 million in 2011, 2010, and 2009, respectively, primarily in the U.S.

Fortesta® Gel. Fortesta® Gel is a patented two percent (2%) testosterone transdermal gel and is a treatment for men suffering from hypogonadism, also known as low testosterone (Low T). The precision-metered dose delivery system can be accurately customized and adjusted to meet individual patient needs with the appropriate dose. In August 2009, we entered into a License and Supply Agreement (the ProStrakan Agreement) with Strakan International Limited, a subsidiary of ProStrakan Group plc (ProStrakan), for the exclusive right to commercialize Fortesta® Gel in the U.S. 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® Gel. Fortesta® Gel was approved by the FDA in December of 2010. We launched Fortesta® Gel in the first quarter of 2011. Net sales of Fortesta® Gel were $14.9 million in 2011.

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

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

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

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Generics

The following table summarizes select products in our generics portfolio:

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	carisoprodol	Marketed
Hydrocortisone	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
Oxybutynin	oxybutynin	Marketed
Lactulose	lactulose	Marketed
Methylprednisolone	methylprednisolone	Marketed
Perphenazine	perphenazine	Marketed
Lisinopril	lisinopril	Marketed

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

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

Devices

The following table summarizes select products in our devices portfolio:

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

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

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

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

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

Elevate™ Anterior and Posterior Pelvic Floor Repair System. AMS offers the Elevate® transvaginal pelvic floor repair system, for the treatment of pelvic organ prolapse, which may be caused by pregnancy, labor, and childbirth. Using an anatomically designed needle and self-fixating tips, Elevate® allows for safe, simple and precise mesh placement through a single vaginal incision, avoiding an external incision. Elevate® revenue since our June 2011 acquistion of AMS accounted for approximately 1% of our total revenues for 2011.

Monarc® Subfascial Hammock. The Monarc® subfascial hammock is our leading device to treat female stress urinary incontinence, which generally results from a weakening of the tissue surrounding the bladder and urethra which can be a result of pregnancy, childbirth and aging. It incorporates unique helical needles to place a self-fixating, sub-fascial hammock through the obturator foramin. Revenue from Monarc®since our June 2011 acquistion of AMS accounted for approximately 1% of our total revenues for 2011.

Select Products in Development

Branded Pharmaceuticals

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

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

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

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

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

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

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

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

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

Generics

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

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

Devices

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

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

Competition

Branded Pharmaceuticals

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

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

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

The competitive environment of the branded product business requires us continually to seek out technological innovations and to market our products effectively. However, some of our current branded products not only face competition from other brands, but also from generic versions. Generic versions are generally significantly less expensive than branded versions, and, where available, may be required in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies. If competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products can be subject to progressive price reductions or decreased volume of sales, or both. Most new products that we introduce must compete with other products already on the market or products that are later developed by competitors. Manufacturers of generic pharmaceuticals typically invest far less in research and development than research-based pharmaceutical companies and therefore can price their products significantly lower than branded products. Accordingly, when a branded product loses its market exclusivity, it normally faces intense price competition from generic forms of the product. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our products offer not only medical benefits but also cost advantages as compared with other forms of care.

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

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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 Frova®. For a full description of these competitive activities, including the litigation related to Paragraph IV filings, see Note 14. Commitments and Contingencies-Legal Proceeding in the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

Generics

In the generic pharmaceutical market, we face intense competition from other generic drug manufacturers, brand name pharmaceutical companies through authorized generics, existing brand equivalents and manufacturers of therapeutically similar drugs. In the market for generic pharmaceuticals, our competitors, including Teva Pharmaceuticals Industries Ltd, Watson Pharmaceuticals, Mylan Technologies Inc., and Sandoz, Inc., vary depending on product category and dosage strength.

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

As a result of consolidation among wholesale distributors as well as rapid growth of large retail drug store chains, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. This has resulted in customers gaining more purchasing power. Consequently, there is heightened competition among generic drug producers for the business of this smaller and more selective customer base.

Newly introduced generic products with limited or no other generic competition are typically sold at higher selling prices. As competition from other generic products increases, selling prices for all participants typically decline. Consequently, the maintenance of profitable operations in generic pharmaceuticals depends, in part, on our ability to select, develop and launch new generic products in a timely and cost efficient manner and to maintain efficient, high quality manufacturing relationships. New drugs and future developments in improved and/or advanced drug delivery technologies or other therapeutic techniques may provide therapeutic or cost advantages to competing products.

Devices

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

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

Services

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

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

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

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

Seasonality

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

Major Customers

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

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

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

As a result of consolidation among wholesale distributors as well as rapid growth of large retail drug store chains, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. Some wholesale distributors have demanded that pharmaceutical manufacturers, including us, enter into what are referred to as distribution service agreements pursuant to which the wholesale distributors provide the pharmaceutical manufacturers with specific services, including the provision of periodic retail demand information and current inventory levels and other information. To date we have entered into six such agreements.

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

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Patents, Trademarks, Licenses and Proprietary Property

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

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®	Exclusive License	USA
5,962,501	December 16, 2013	Frova®	Exclusive License	USA
5,411,738	May 2, 2012	Lidoderm®	Exclusive License	USA
5,601,838	May 2, 2012	Lidoderm®	Exclusive License	USA
5,827,529	October 27, 2015	Lidoderm®	Exclusive License	USA
5,741,510	March 30, 2014	Lidoderm®	Exclusive License	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
8,075,872	November 20, 2023	Opana® ER	Exclusive License	USA
8,114,383	August 5, 2024	Opana® ER	Exclusive License	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
8,062,652	June 16, 2026	Supprelin® LA	Owned	USA
8,062,209	December 2, 2023	AMS 700®	Owned	USA
7,946,975	February 21, 2030	AMS 700®	Owned	USA
6,554,824	July 24, 2021	GreenLight™ Laser	Owned	USA
6,986,764	July 24, 2021	GreenLight™ Laser	Owned	USA
7,070,556	November 9, 2023	Monarc®	Owned	USA
7,347,812	March 17, 2026	Monarc®	Owned	USA
7,988,615	November 9, 2023	Monarc®	Owned	USA
6,911,003	January 23, 2023	Monarc®	Owned	USA

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

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

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We believe that our patents, the protection of discoveries in connection with our development activities, our proprietary products, technologies, processes and know-how and all of our intellectual property are important to our business. All of our brand products and certain generic products, such as Endocet® and Endodan®, are sold under trademarks. To achieve a competitive position, we rely on trade secrets, non-patented proprietary know-how and continuing technological innovation, where patent protection is not believed to be appropriate or attainable. In addition, as outlined above, we have a number of patent licenses from third parties, some of which may be important to our business. See Note 7. License and Collaboration Agreements in the Consolidated Financial Statements included in Part IV Item 15 of this Annual Report on Form 10-K. There can be no assurance that any of our patents, licenses or other intellectual property rights will afford us any protection from competition.

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

We may find it necessary to initiate litigation to enforce our patent rights, to protect our intellectual property or to determine the scope and validity of the proprietary rights of others. Litigation is costly and time-consuming, and there can be no assurance that our litigation expenses will not be significant in the future or that we will prevail in any such litigation. See Note 14. Commitments and Contingencies-Legal Proceedings in the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

Governmental Regulation

The development, testing, manufacture, holding, packaging, labeling, distribution, marketing, and sales of our products and our ongoing product development activities are subject to extensive and rigorous government regulation. The Federal Food, Drug and Cosmetic Act (FFDCA), the Controlled Substances Act and other federal and state statutes and regulations govern or influence the testing, manufacture, packaging, labeling, storage, record keeping, approval, advertising, promotion, sale and distribution of pharmaceutical products. Noncompliance with applicable requirements can result in fines, recall or seizure of products, total or partial suspension of production and/or distribution, refusal of the government to enter into supply contracts or to approve NDAs and ANDAs, civil penalties and criminal prosecution.

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

Based on scientific developments, post-market experience, or other legislative or regulatory changes, the current FDA standards of review for approving new pharmaceutical products are sometimes more stringent than those that were applied in the past. Some new or evolving review standards or conditions for approval were not applied to many established products currently on the market, including certain opioid products. As a result, the FDA does not have as extensive safety databases on these products as on some products developed more recently. Accordingly, we believe the FDA has recently expressed an intention to develop such databases for certain of these products, including many opioids.

In particular, the FDA has expressed interest in specific chemical structures that may be present as impurities in a number of opioid narcotic active pharmaceutical ingredients, such as oxycodone, which based on certain structural characteristics and laboratory tests may indicate the potential for having mutagenic effects.

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

We cannot determine what effect changes in the FDA s laws or regulations, when and if promulgated, or changes in the FDA s legal or regulatory interpretations, may have on our business in the future. Changes could, among other things, require expanded or different labeling, additional testing, the recall or discontinuance of certain products, additional record keeping and expanded documentation of the properties of certain products and scientific substantiation. Such changes, or new legislation, could have a material adverse effect on our business, financial condition, results of operations and cash flows. In December 2003, Congress passed measures intended to speed the process by which generic versions of brand name drugs are introduced to the market. Among other things, these measures are intended to limit regulatory delays of generic drug applications and penalize companies that reach agreements with makers of brand name drugs to delay the introduction of generic versions. These changes could result in increased generic competition for our branded and generic products and could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, on September 27, 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007 (FDAAA) that re-authorized requirements for testing drug products in children, where appropriate, and included new requirements for post-approval studies or clinical trials of drugs that are known to or that signal the potential to pose serious safety risks, and authority to require risk evaluation and mitigation strategies, or REMS to ensure that the benefits of a drug outweigh the risks of the drug, all of which may increase the time and cost necessary for new drug development as well as the cost of maintaining regulatory compliance for a marketed product.

The evolving and complex nature of regulatory requirements, the broad authority and discretion of the FDA and the generally high level of regulatory oversight results in a continuing possibility that from time to time, we will be adversely affected by regulatory actions despite ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

NDA / BLA Process

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

- Completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA s Good Laboratory Practice, or GLP, regulations;
- Submission to the FDA of an Investigational New Drug (IND) application for human clinical testing, which must become effective before human clinical trials may begin in the U.S.;
- Approval by an independent institutional review board, or IRB, before each trial may be initiated, and continuing review during the trial;
- Performance of human clinical trials, including adequate and well-controlled clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each intended use;
- Submission of an NDA or BLA to the FDA;
- Satisfactory completion of an FDA pre-approval inspection of the product s manufacturing processes and facility or facilities to assess compliance with the FDA s current Good Manufacturing Practice

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

Satisfactory completion of an FDA advisory committee review, if applicable; and

Approval by the FDA of the NDA or BLA.

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

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

Phase II typically involves studies in a small sample of the intended patient population to assess the efficacy of the compound for a specific indication, to determine dose tolerance and the optimal dose range as well as to gather additional information relating to safety and potential adverse effects.

Phase III trials are undertaken to further evaluate clinical safety and efficacy in an expanded patient population at typically dispersed study sites, in order to determine the overall risk-benefit ratio of the compound and to provide an adequate basis for product labeling.

Each trial is conducted in accordance with certain standards under protocols that detail the objectives of the study, the parameters to be used to monitor safety, and efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. In some cases, the FDA allows a company to rely on data developed in foreign countries or previously published data, which eliminates the need to independently repeat some or all of the studies.

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

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

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

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

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

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

On January 14, 2011, the FDA announced in the Federal Register that it was taking steps to reduce the maximum amount of acetaminophen in prescription drug products, to help reduce or prevent the risk of liver injury from an unintentional overdose of acetaminophen. A variety of combination drug products include acetaminophen, such as those that contain the opioids oxycodone hydrochloride or hydrocodone bitartrate and acetaminophen, among others. Under additional authority granted to the FDA by the FDAAA, the FDA notified holders of approved 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

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

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

ANDA Process

FDA approval of an ANDA is required before a generic equivalent of an existing or reference-listed drug can be marketed. The ANDA process is abbreviated in that the FDA waives the requirement of conducting complete preclinical and clinical studies and instead relies principally on bioequivalence studies. Bioequivalence generally involves a comparison of the rate of absorption and levels of concentration of a generic drug in the body with those of the previously approved drug. When the rate and extent of absorption of systemically acting test and reference drugs are the same, the two drugs are considered bioequivalent and regarded as therapeutically equivalent, meaning that a pharmacist can substitute the product for the reference-listed drug. There are other or additional measures the FDA may rely upon to determine bioequivalence in locally acting products, which could include comparative clinical efficacy trials. In May 2007, the FDA began posting to its website, bioequivalence recommendations for individual products in order to provide guidance to generic manufacturers on the specific method of demonstrating bioequivalence.

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

The timing of final FDA approval of ANDA applications depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and whether the manufacturer of the reference listed drug is entitled to one or more statutory exclusivity periods, during which the FDA is prohibited from approving generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date. For example, under the Best Pharmaceuticals for Children Act, if a manufacturer receives and accepts a written request from the FDA to conduct studies on the safety and efficacy of its product in children, the exclusivity of a product is extended by six months past the patent or regulatory expiration date if the manufacturer completes and submits the results of the studies, a so-called pediatric extension.

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

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

Patent and Non-Patent Exclusivity Periods

A sponsor of an NDA is required to identify in its application any patent that claims the drug or a use of the drug subject to the application. Upon NDA approval, the FDA lists these patents in a publication referred to as the Orange Book. Any person that files a Section 505(b)(2) NDA, the type of NDA that relies upon the data in the application for which the patents are listed, or an ANDA to secure approval of a generic version of this first, or listed drug, must make a certification in respect to listed patents. The FDA may not approve such an application for the drug until expiration of the listed patents unless (1) the generic applicant certifies that the listed patents are invalid, unenforceable or not infringed by the proposed generic drug and gives notice to the holder of the NDA for the listed drug of the bases upon which the patents are challenged, and (2) the holder of the listed drug does not sue the later applicant for patent infringement within 45 days of receipt of notice. Under the current law, if an infringement suit is filed, the FDA may not approve the later application until the earliest of: 30 months after submission; entry of an appellate court judgment holding the patent invalid, unenforceable or not infringed; such time as the court may order; or the patent expires.

One of the key motivators for challenging patents is the 180-day market exclusivity period vis a vis other generic applicants granted to the developer of a generic version of a product that is the first to have its application accepted for filing by the FDA and whose filing includes a certification that the applicable patent(s) are invalid, unenforceable and/or not infringed (a Paragraph IV certification) and that prevails in litigation with the manufacturer of the branded product over the applicable patent(s). Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the 2003 Medicare Act, with accompanying amendments to the Hatch Waxman Act (The Drug Price Competition and Patent Term Restoration Act), this marketing exclusivity would begin to run upon the earlier of the commercial launch of the generic product or upon an appellate court decision in the generic company s favor.

In addition, the holder of the NDA for the listed drug may be entitled to certain non-patent exclusivity during which the FDA cannot approve an application for a competing generic product or 505(b)(2) NDA product. If the listed drug is a new chemical entity, in certain circumstances, the FDA may not approve any application for five years; if it is not a new chemical entity, the FDA may not approve a competitive application for three years. Certain additional periods of exclusivity may be available if the listed drug is indicated for use in a rare disease or condition or is studied for pediatric indications.

Medical Device Regulation

Numerous governmental authorities, principally the FDA and comparable foreign regulatory agencies, regulate the development, testing, manufacturing, labeling, marketing, and distribution of our medical devices. In Europe and certain other countries, we comply with the European Union Directives for Medical Devices and certify our compliance with the CE Mark. In other countries outside the U.S., we comply with appropriate local registration and authorization. In the U.S., under the FFDCA, medical devices, such as those manufactured by AMS and HealthTronics are classified into Class I, II, or III depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. Class I includes devices with the least risk and Class III includes those with the greatest risk. Class I medical devices are subject to the FDA s general controls, which include compliance with the applicable portions of the FDA s Quality System Regulation, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA s

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general controls and may also be subject to other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Class III medical devices are subject to the FDA s general controls, special controls, and premarket approval prior to marketing.

HealthTronics currently markets Class I and Class II medical devices, and AMS currently markets Class I, II and III medical devices. If a device is classified as Class I or II, and if it is not exempt, its manufacturer will have to undertake the premarket notification process in order to obtain marketing clearance, also referred to as the 510(k) process. When a 510(k) is required, the manufacturer must submit to the FDA a premarket notification demonstrating that the device is substantially equivalent to either a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or to another commercially available, similar device which was subsequently cleared through the 510(k) process. By regulation, the FDA is required to clear a 510(k) within 90 days of submission of the application. As a practical matter, clearance often takes longer, particularly if a clinical trial is required. A successful 510(k) submission results in FDA permission to market the new device.

Class III devices are approved through a Premarket Approval Application, or PMA, under which the applicant must submit data from adequate and well-controlled clinical trials to the FDA that demonstrate the safety and effectiveness of the device for its intended use(s). All of our marketed devices have been approved or cleared for marketing pursuant to a PMA or the 510(k) process. The FDA also has authority under the FFDCA to require a manufacturer to conduct post-market surveillance of a Class II or Class III device. On January 3, 2012, the FDA ordered manufacturers of transvaginal surgical mesh used for pelvic organ prolapse and of single incision mini-slings for urinary incontinence, such as AMS to conduct post-market safety studies and to monitor adverse event rates relating to the use of these products. These class-wide post-market study orders apply to eighteen AMS pelvic floor repair and mini-sling products. AMS is in the process of complying with these orders. In its orders, the FDA also noted that it is still considering the recommendation of an advisory committee on September 9, 2011, that urogynecological surgical mesh for transvaginal repair of pelvic organ prolapse be reclassified from Class II to Class III.

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

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

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

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

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

Quality Assurance Requirements

The FDA enforces regulations to ensure that the methods used in, and the facilities and controls used for, the manufacture, processing, packing and holding of drugs and medical devices conform to current good manufacturing practices, or cGMP. The cGMP regulations the FDA enforces are comprehensive and cover all aspects of manufacturing operations, from receipt of raw materials to finished product distribution, insofar as they bear upon whether drugs meet all the identity, strength, quality and purity characteristics required of them. The cGMP regulations for devices, called the Quality System Regulation, are also comprehensive and cover all aspects of device manufacture, from pre-production design validation to installation and servicing, insofar as they bear upon the safe and effective use of the device and whether the device otherwise meets the requirements of the FFDCA. To assure compliance requires a continuous commitment of time, money and effort in all operational areas.

The FDA conducts pre-approval inspections of facilities engaged in the development, manufacture, processing, packing, testing and holding of the drugs subject to NDAs and ANDAs. If the FDA concludes that the facilities to be used do not or did not meet cGMP, good laboratory practices or GLP or good clinical practices or GCP requirements, it will not approve the application. Corrective actions to remedy the deficiencies must be performed and are usually verified in a subsequent inspection. In addition, manufacturers of both pharmaceutical products and active pharmaceutical ingredients, or APIs, used to formulate the drug also ordinarily undergo a pre-approval inspection, although the inspection can be waived when the manufacturer has had a passing cGMP inspection in the immediate past. Failure of any facility to pass a pre-approval inspection will result in delayed approval and would have a material adverse effect on our business, results of operations, financial condition and cash flows.

The FDA also conducts periodic inspections of drug and device facilities to assess their cGMP status. If the FDA were to find serious cGMP non-compliance during such an inspection, it could take regulatory actions that could adversely affect our business, results of operations, financial condition and cash flows. Imported API and other components needed to manufacture our products could be rejected by U.S. Customs, usually after conferring with the FDA. In respect to domestic establishments, the FDA could initiate product seizures or request or in some instances require product recalls and seek to enjoin a product s manufacture and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with cGMP requirements, sanctions may be imposed that include preventing that company from receiving the necessary licenses to export its products and classifying that company as an unacceptable supplier , thereby disqualifying that company from selling products to federal agencies.

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

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

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

Other FDA Matters

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

Drug Enforcement Administration

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

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

The DEA limits the availability of the active ingredients used in many of our current products and products in development, as well as the production of these products, and we, or our contract manufacturing organizations, must annually apply to the DEA for procurement and production quotas in order to obtain and produce these substances. As a result, our quotas may not be sufficient to meet commercial demand or complete clinical trials. Moreover, the DEA may adjust these quotas from time to time during the year, although the DEA has substantial

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discretion in whether or not to make such adjustments. Any delay or refusal by the DEA in establishing our quotas, or modification of our quotas, for controlled substances could delay or stop our clinical trials or product launches, or could cause trade inventory disruptions for those products that have already been launched, which could have a material adverse effect on our business, financial position, results of operations and cash flows.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Annual registration is required for any facility that manufactures, tests, distributes, dispenses, imports or exports any controlled substance. The facilities must have the security, control and accounting mechanisms required by the DEA to prevent loss and diversion. Failure to maintain compliance, particularly as manifested in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and cash flows. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could eventuate in criminal proceedings.

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

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

Clinical Laboratory Improvement Amendments of 1988 and State Regulation

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

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

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

Government Benefit Programs

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

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

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

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

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

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

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

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

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Healthcare Fraud and Abuse Laws

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry. For example, in the U.S., there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward past purchases or recommendations. Violations of these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs. These laws are potentially applicable to us as both a manufacturer and a supplier of products reimbursed by federal health care programs. These laws also apply to hospitals, physicians and other potential purchasers of our products.

In particular, the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The term remuneration is not defined in the federal Anti- Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. In addition, the recently enacted U.S. Health Reform Law, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b effective March 23, 2010. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the U.S. Health Reform Law provides that the government may assert that a claim including items or services resulting from a violation of 42 U.S.C. § 1320a-7b constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Moreover, the lack of uniform court interpretation of the Anti-Kickback Statute makes compliance with the law difficult, as virtually any relationship with entities that purchase or refer for our services could implicate the Anti-Kickback Statute.

Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, the OIG issued regulations in July 1991, and periodically since that time, which the OIG refers to as safe harbors. These safe harbor regulations set forth certain provisions which, if met in form and substance, will assure pharmaceutical and medical device companies, healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Additional safe harbor provisions providing similar protections have been published intermittently since 1991. Although full compliance with these provisions ensures against prosecution under the federal Anti- Kickback Statute, the failure of a transaction 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

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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), misrepresentations with respect to the services rendered and causing improper claims to be submitted for allegedly unapproved drugs or other products. Our activities relating to the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products, the sale and marketing of our products and our service arrangements or data purchases, among other activities, may be subject to scrutiny under these laws. For example, a number of cases brought by local and state government entities are pending that allege generally that our wholly owned subsidiary, EPI, and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid. The cost of defending these cases and any other actions that may be brought under the False Claims Act or a similar state law, as well as any sanctions imposed, could adversely affect our financial performance.

Also, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several new federal crimes, including health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

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

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

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

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

Healthcare Privacy and Security Laws

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

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

Service Agreements

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

For a complete description of our manufacturing, supply and other service agreements, see Note 14. Commitments and Contingencies in the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

Acquisitions, License and Collaboration Agreements

We continue to seek to enhance our product line and develop a balanced portfolio of differentiated products through selective product acquisitions and in-licensing, or acquiring licenses to products, compounds and technologies from third parties or through company acquisitions. The Company enters into strategic alliances and collaborative arrangements with third parties, which give the Company rights to develop, manufacture, market and/or sell pharmaceutical products, the rights to which are primarily owned by these third parties. These alliances and arrangements can take many forms, including licensing arrangements, co-development and co-marketing agreements, co-promotion arrangements, research collaborations and joint ventures. Such alliances and arrangements enable us to share the risk of incurring all research and development expenses that do not lead to revenue-generating products; however, because profits from alliance products are shared with the counter-parties to the collaborative arrangement, the gross margins on alliance products are generally lower, sometimes substantially so, than the gross margins that could be achieved had the Company not opted for a development partner. For a full discussion, including agreement terms and status, see our disclosures under Note 7. License and Collaboration Agreements in the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

Environmental Matters

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

Employees

As of February 17, 2012, we have 4,566 employees, of which 438 are engaged in research and development and regulatory work, 1,348 in sales and marketing, 270 in quality assurance and 2,510 in general and administrative capacities. Our employees are not represented by unions and we believe that our relations with our employees are good.

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Executive Officers of the Registrant

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

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

Biographies

Our executive officers are briefly described below:

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

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

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

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

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

We have employment agreements with each of our executive officers.

Available Information

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

You may also read and copy any materials we file with the SEC at the SEC s Public Reference Room that is located at 100 F Street, N.E., Room 1580, NW, Washington, DC 20549. Information about the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330 or 1-202-551-8090. You can also access our filings through the SEC s internet site: *www.sec.gov (intended to be an inactive textual reference only).*

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

Risks related to our business

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

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

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

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

Our branded products face competition from generic versions. Generic versions are generally significantly cheaper than branded versions and, where available, may be required or encouraged in place of the branded version under third party reimbursement programs, or substituted by pharmacies for branded versions by law. The entrance of generic competition to our branded products generally reduces our market share and adversely affects our profitability and cash flows. Generic competition with our branded products has had and will continue to have a material adverse effect on the net sales and profitability of our branded products.

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

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

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

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

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As previously reported, on January 15, 2010, the Company and the holders of the Lidoderm® NDA and relevant patent, Teikoku Seiyaku Co., Ltd., and Teikoku Pharma USA, Inc. (collectively, Teikoku) received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) (a Paragraph IV Notice) from Watson Laboratories, Inc. (Watson) advising of the filing of an Abbreviated New Drug Application (ANDA) for a generic version of Lidoderm® (lidocaine topical patch 5%). The Paragraph IV Notice refers to U.S. Patent No. 5,827,529, which covers the formulation of Lidoderm®, a topical patch to relieve the pain of post herpetic neuralgia launched in 1999. This patent is listed in the FDA s Orange Book and expires in October 2015. As a result of this Notice, on February 19, 2010, the Company and Teikoku filed a lawsuit against Watson in the United States District Court of the District of Delaware. Because the suit was filed within the 45-day period under the Hatch-Waxman Act for filing a patent infringement action, we believe that it triggered an automatic 30-month stay of approval under the Act. This lawsuit was recently heard by the United States District Court of the District of Delaware and concluded on February 14, 2012. We are currently waiting for the court s decision. In October 2010, Teikoku Pharma USA listed U.S. Patent No. 5,741,510 in the FDA Orange Book, and this patent expires in March 2014. On June 30, 2011, the Company and Teikoku filed a second lawsuit against Watson in the United States District Court of the District of Delaware alleging infringement of U.S. Patent Nos. 5,741,510, 6,096,333, and 6,096,334 which cover lidocaine patch formulations and manufacturing processes. The trial relating to this lawsuit has not yet been scheduled.

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

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

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

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

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

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

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

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

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

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

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

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

* Percentages may not add due to rounding.

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

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

Our success, competitive position and future income will depend in part on our ability to obtain patent protection relating to the technologies, processes and products we are currently developing and those we may develop in the future. Our policy is to seek patent protection for technologies, processes and products we own and to enforce the intellectual property rights we own and license. We cannot assure you that patent applications we submit and have submitted will result in patents being issued. If an invention qualifies as a joint invention, the joint inventor or his or her employer may have rights in the invention. We cannot assure you that a third party will not infringe upon, design around or develop uses not covered by any patent issued or licensed to us or that these patents will otherwise be commercially viable. In this regard, the patent position of pharmaceutical compounds and compositions is particularly uncertain. Even issued patents may later be modified or revoked by the U.S. Patent and Trademark Office, or PTO, by analogous foreign offices or in legal proceedings. Moreover, we believe that obtaining foreign patents may be more difficult than obtaining domestic patents because of differences in patent laws and, accordingly, our patent position may be stronger in the U.S. than abroad. Foreign patents may be more difficult to protect and enforce and/or the remedies available may be less extensive than in the U.S. Various countries limit the subject matter that can be patented and limit the ability of a patent owner to enforce patents in the medical field. This may limit our ability to obtain or utilize certain of our patents internationally. Because unissued U.S. patent applications are typically not published for a period of eighteen months and U.S. patent applications filed prior to November 29, 2000 are not disclosed until such patents are issued, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first creator of the inventions covered by our pending patent applications or the first to file patent applications on those inventions. Several drug companies and research and academic institutions have developed technologies, filed patent applications or received patents for technologies that may be related to our business. Others may file patent applications and may receive patents that may conflict

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

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

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

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

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

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

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

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

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

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

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

Goodwill and other intangibles represent a significant portion of our assets. As of December 31, 2011 and 2010, goodwill and other intangibles comprised approximately 69% and 57%, respectively, of our total assets. This provisional measurement of goodwill and other intangibles is subject to change and such changes could be significant. Goodwill and other intangible assets are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually.

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

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

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

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

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including prohibitions on the offer of payment or acceptance of kickbacks or other remuneration for the purchase of our products and services, including inducements to potential patients to request our products and services. Specifically, the federal Anti-Kickback Statute prohibits persons or entities from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Due to recent legislative changes, violations of the Anti-Kickback Statute also carry potential federal False Claims Act liability. Because of the sweeping language of the federal Anti-Kickback Statute, many potentially beneficial business arrangements would be prohibited if the statute were strictly applied. To avoid this outcome, the United States Department of Health and Human Services Office of Inspector General has published regulations known as safe harbors that identify exceptions or exemptions to the statute s prohibitions. Arrangements that do not fit within the safe harbors are not automatically deemed to be illegal, but must be evaluated on a case-by-case basis for compliance with the statute. Additionally, many states have adopted laws similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any third-party payer, not only the Medicare and Medicaid programs, and do not contain identical safe harbors.

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

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

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

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

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

Many of our core products contain narcotic ingredients. Misuse or abuse of such drugs can lead to physical or other harm. For example, in the past, reportedly widespread misuse or abuse of OxyContin®, 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, referred to herein as the DEA, may impose new regulations concerning the manufacture, storage, transportation and sale of prescription narcotics. Such regulations may include new labeling requirements, the development and implementation of formal Risk Evaluation and Mitigation Strategy, or REMS, restrictions on prescription and sale of these products and mandatory reformulation of our products in order to make abuse more difficult. On September 27, 2007, Congress passed legislation authorizing the FDA to require companies to undertake post-approval studies in order to assess known or signaled potential serious safety risks and to make any labeling changes necessary to address safety risks. Congress also empowered the FDA to require companies to formulate REMS to ensure a drug s benefits outweigh its risks. On April 19, 2011, the FDA issued letters to manufacturers of long-acting and extended-release opioid drug products requiring them to develop and submit to the FDA a post-market REMS plan to ensure that training is provided to prescribers of these products, and that information is provided to prescribers that they can use in counseling patients about the risks and benefits of opioid drug use. We received a REMS notification letter from the FDA to develop the REMS education and training program for prescribers for our Opana® ER, morphine sulfate ER, and oxycodone ER drug products. On December 9, 2011, the FDA approved our interim REMS for Opana® ER, while a class-wide REMS is being developed by an Industry Working Group. The Obama administration has also released a comprehensive action plan to reduce prescription drug abuse, which may include proposed legislation to amend existing controlled substances laws to require health care practitioners who request DEA registration to prescribe controlled substances to receive training on opioid prescribing practices as a condition of registration. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse. In either case, any such new regulations or requirements may be difficult and expensive for us to comply with, may delay our introduction of new products, may adversely affect our total revenues and may have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

Federal and state governmental authorities in the U.S., principally the FDA, impose substantial requirements on the development, manufacture, holding, labeling, marketing, advertising, promotion, distribution and sale of therapeutic pharmaceutical and medical device products through lengthy and detailed laboratory and clinical testing and other costly and time-consuming procedures.

With respect to pharmaceutical products, the submission of an NDA or ANDA to the FDA with supporting clinical safety and efficacy data, for example, does not guarantee that the FDA will grant approval to market the product. Meeting the FDA s regulatory requirements to obtain approval to market a drug product typically takes many years, varies substantially based upon the type, complexity and novelty of the pharmaceutical product, and the application process is subject to uncertainty. The NDA approval process for a new product varies in time, generally requiring a minimum of 10 months, but could also take several years from the date of application. The timing for the ANDA approval process for generic products is difficult to estimate and can vary significantly.

NDA approvals, if granted, may not include all uses (known as indications) for which a company may seek to market a product. The FDA also requires companies to undertake post-approval surveillance regarding their drug products and to report adverse events.

With respect to medical devices, such as those manufactured by HealthTronics and AMS, before a new medical device, or a new use of, or claim for, an existing product can be marketed, it must first receive either premarket clearance under Section 510(k) of the FFDCA, or premarket approval, or PMA, from the FDA, unless an exemption applies. In the 510(k) premarket clearance process, the FDA must determine that the proposed device is substantially equivalent to a device legally on the market, known as a predicate device, with respect to intended use, technology and safety and effectiveness to clear the proposed device for marketing. Clinical data is sometimes required to support a showing of substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device for its intended use based, in part, on extensive data including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Both the 510(k) and PMA processes can be expensive and lengthy and entail significant user fees. HealthTronics currently commercialized products have received premarket clearance under Section 510(k) of the FFDCA. AMS s currently commercialized products have received premarket clearance or PMA from the FDA under Section 510(k) or 515 of the FFDCA.

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

On October 20, 2008, the FDA issued a Public Health Notification regarding potential complications associated with transvaginal placement of surgical mesh to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). The notification provides recommendations and encourages physicians to seek specialized training in mesh procedures, to advise their patients about the risks associated with these procedures and to be diligent in diagnosing and reporting complications.

In July 2011, FDA issued an update to the October 2008 Public Health Notification regarding mesh to further advise the public and the medical community of the potential complications associated with transvaginal placement of surgical mesh to treat POP and SUI. In this July 2011 update, the FDA maintained that adverse events are not rare, as previously reported, and questioned the relative effectiveness of transvaginal mesh as a treatment for POP as compared to non-mesh surgical repair. The July 2011 notification continued to encourage physicians to seek specialized training in mesh procedures, to consider and to advise their patients about the risks associated with these procedures and to be diligent in diagnosing and reporting complications. FDA also convened an advisory panel which met on September 8-9, 2011 to further address the safety and effectiveness of

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

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

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

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

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

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

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

The extent to which and how the FDA will implement some or all of its planned action items and draft guidance is unknown at this time. If implemented, these actions could have a significant effect on the cost of applying for and maintaining applications under the 510(k) clearance mechanism, and on the criteria required for achieving clearance for additional uses of existing devices or new 510(k) devices. Further, some new or evolving review standards or conditions for approval or clearance were not applied to many established products currently on the market, including certain opioid products. As a result, the FDA does not have as extensive safety databases on these products as on some products developed more recently. Accordingly, we believe the FDA has recently expressed an intention to develop such databases for certain of these products, including many opioids.

In particular, the FDA has expressed interest in specific chemical structures that may be present as impurities in a number of opioid narcotic active pharmaceutical ingredients, such as oxycodone, which based on certain structural characteristics and laboratory tests may indicate the potential for having mutagenic effects.

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

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

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

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societies, practice management groups or patient or trade organizations to recommend or publish guidance or guidelines related to the use of our products, which may lead to reduced sales of our products.

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

The FDA regulates the facilities, processes and procedures used to manufacture and market pharmaceutical and medical products in the U.S. Manufacturing facilities must be registered with the FDA and all products made in such facilities must be manufactured in accordance with current good manufacturing practices (cGMP), regulations enforced by the FDA. Compliance with cGMP regulations requires the dedication of substantial resources and requires significant expenditures. The FDA periodically inspects both our third party and owned manufacturing facilities and procedures to assure compliance. The FDA may cause a suspension or withdrawal of product approvals if regulatory standards are not maintained. In the event an approved manufacturing facility for a particular drug or medical device is required by the FDA to curtail or cease operations, or otherwise becomes inoperable, or a third party contract manufacturing facility faces manufacturing problems, obtaining the required FDA authorization to manufacture at the same or a different manufacturing site could result in production delays, which could adversely affect our business, results of operations, financial condition and cash flow.

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

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

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

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The stringent DEA regulations on our use of controlled substances include restrictions on their use in research, manufacture, distribution and storage. A breach of these regulations could result in imposition of civil penalties, refusal to renew or action to revoke necessary registrations, or other restrictions on operations involving controlled substances. Failure to comply with applicable legal requirements subjects the Qualitest facilities to possible legal or regulatory action, including shutdown, which may adversely affect their ability to supply us with product. Were we not able to manufacture products at the Qualitest facilities because of regulatory, business or any other reasons, the manufacture and marketing of these products would be interrupted. This could have a negative impact on our business, results of operation, financial condition, cash flows and competitive position. See also the risk described under the caption The DEA limits the availability of the active ingredients used in many of our current products and products in development and, as a result, our procurement quota may not be sufficient to meet commercial demand or complete clinical trials.

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

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

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

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

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

Before obtaining regulatory approvals for the sale of any of our new product candidates, we must demonstrate through preclinical studies and clinical trials that the product is safe and effective for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product. Likewise, we may not be able to demonstrate through clinical trials that a product candidate s therapeutic benefits outweigh its risks. Even promising results from preclinical and early clinical studies do not always accurately predict results in later, large scale trials. A failure to demonstrate safety and efficacy could or would result in our failure to obtain regulatory approvals.

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

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

Before obtaining regulatory approvals for certain generic products, we must conduct limited clinical or other trials to show comparability to the branded products. A failure to obtain satisfactory results in these trials would prevent us from obtaining required regulatory approvals.

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

We regularly evaluate selective acquisitions and look to continue to enhance our product line by acquiring rights to additional products and compounds. Such acquisitions may be carried out through the purchase of assets, joint ventures and licenses or by acquiring other companies. However, we cannot assure you that we will be able to complete acquisitions that meet our target criteria on satisfactory terms, if at all. In particular, we may not be able to identify suitable acquisition candidates, and we may have to compete for acquisition candidates.

Our competitors may have greater resources than us and therefore be better able to complete acquisitions or may cause the ultimate price we pay for acquisitions to increase. If we fail to achieve our acquisition goals, our growth may be limited.

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

- fail to accomplish our strategic objectives;
- not be successfully combined with our operations;
- not perform as expected; and
- expose us to cross border risks.

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

Further, if we are unable to maintain, on commercially reasonable terms, product, compound or other licenses that we have acquired, our ability to develop or commercially exploit our products may be inhibited.

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

Our future revenues and profitability will depend, to a significant extent, upon our ability to successfully commercialize new branded and generic pharmaceutical products in a timely manner. As a result, we must continually develop, test and manufacture new products, and these new products must meet regulatory standards and receive requisite regulatory approvals. Products we are currently developing may or may not receive the regulatory approvals necessary for us to market them. Furthermore, the development and commercialization process is time-consuming and costly, and we cannot assure you that any of our products, if and when developed and approved, can be successfully commercialized. Some of our collaboration partners may decide to make substantial changes to a product s formulation or design, may experience financial difficulties or have limited financial resources, any of which may delay the development, commercialization and/or marketing of new products. In addition, if a co-developer on a new product terminates our collaboration agreement or does not perform under the agreement, we may experience delays and, possibly, additional costs in developing and marketing that product.

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

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

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

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

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

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

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

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

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

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

We may be the subject of product liability claims or product recalls, and we may be unable to obtain or maintain insurance adequate to cover potential liabilities.

Our business exposes us to potential liability risks that arise from the testing, manufacturing, marketing and sale of our products. In addition to direct expenditures for damages, settlement and defense costs, there is a possibility of adverse publicity as a result of product liability claims. Product liability is a significant commercial risk for us. Some plaintiffs have received substantial damage awards in some jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. In addition, it may be necessary for us to voluntarily or mandatorily recall or withdraw products that do not meet approved specifications or which subsequent data demonstrate may be unsafe or ineffective, which would also result in adverse publicity as well as in costs connected to the recall and loss of revenue.

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

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

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

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

We cannot assure you that a product liability claim or series of claims brought against us would not have a material adverse effect on our business, financial condition, results of operations and cash flows. If any claim is brought against us, regardless of the success or failure of the claim, we cannot assure you that we will be able to obtain or maintain product liability insurance in the future on acceptable terms or with adequate coverage against potential liabilities or the cost of a recall. Additionally, we may be limited by the surviving insurance policies of our recently acquired subsidiaries.

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

On October 20, 2008, the FDA issued a Public Health Notification regarding potential complications associated with transvaginal placement of surgical mesh to treat POP and SUI. The notification provides recommendations and encourages physicians to seek specialized training in mesh procedures, to advise their patients about the risks associated with these procedures and to be diligent in diagnosing and reporting complications.

In July 2011, FDA issued an update to the October 2008 Public Health Notification regarding mesh to further advise the public and the medical community of the potential complications associated with transvaginal placement of surgical mesh to treat POP and SUI. In this July 2011 update, the FDA maintained that adverse events are not rare, as previously reported, and questioned the relative effectiveness of transvaginal mesh as a treatment for POP as compared to non-mesh surgical repair. The July 2011 notification continued to encourage physicians to seek specialized training in mesh procedures, to consider and to advise their patients about the risks associated with these procedures and to be diligent in diagnosing and reporting complications.

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

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

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

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

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

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

Our ability to commercialize our products depends, in part, on the extent to which reimbursement for the costs of these products is available from government healthcare programs, private health insurers and others. We cannot be certain that, over time, third party payment for our products will be adequate for us to maintain price levels sufficient for realization of an appropriate return on our investment. Government payors, private insurers and other third party payers are increasingly attempting to contain healthcare costs by (1) limiting both coverage and the level of reimbursement (including adjusting co-pays) for products approved for marketing by the FDA, (2) refusing, in some cases, to provide any coverage for uses of approved products for indications for which the FDA has not granted marketing approval and (3) requiring or encouraging, through more favorable reimbursement levels or otherwise, the substitution of generic alternatives to branded products.

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

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

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

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

- the trend toward managed healthcare in the U.S.;
- the growth of organizations such as HMOs and managed care organizations;
- legislative proposals to reform healthcare and government insurance programs; and
- price controls and non-reimbursement of new and highly priced medicines for which the economic therapeutic rationales are not established.

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

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

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

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

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

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including prohibitions on the offer of payment or acceptance of kickbacks or other remuneration in return for the purchase of our products. Sanctions for violating these laws include criminal penalties and civil sanctions and possible exclusion from the Medicare, Medicaid, and other government healthcare programs. There can be no assurance that our practices will not be challenged under these laws in the future or that such a challenge would not have a material adverse effect on our business or results of operations.

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

We are subject to provisions that require us to enter into a Medicaid Drug Rebate Agreement and a 340B Pharmaceutical Pricing Agreement as a condition for having our products eligible for payment under Medicare Part B and Medicaid. We have entered into such agreements. In addition, we are required to report certain pricing information to the Centers for Medicare and Medicaid Services on a periodic basis to allow for accurate determination of rebates owed under the Medicaid Drug Rebate Agreement, ceiling prices under the 340B program and certain other government pricing arrangements, and reimbursement rates for certain drugs paid under Medicare Part B.

We and other pharmaceutical companies are defendants in a number of lawsuits filed by local and state government entities, alleging generally that we and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable by state Medicaid programs, which are partially funded by the federal government. In addition, a predecessor entity of Qualitest and other pharmaceutical companies are defendants in a federal False Claims Act lawsuit brought by a *qui tam* relator alleging the submission (or the causing of the submission) of false claims for payments to be made through state Medicaid reimbursement programs for unapproved drugs or non-drugs. We intend to vigorously defend these lawsuits to which we are a party. Depending on developments in the litigation however, as with all litigation, there is a possibility that we will suffer adverse decisions or verdicts of substantial amounts, or that we will enter into monetary settlements in one or more of these actions as we recently did with a number of New York counties. Any unfavorable outcomes as a result of such litigation could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

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

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

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

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

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

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

Revenues from these customers are included within our Branded Pharmaceuticals and Generics segments. If we were to lose the business of any of these customers, or if any were to experience difficulty in paying us on a timely basis, our total revenues, profitability and cash flows could be materially and adversely affected.

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

Third party manufacturers currently manufacture a significant amount of our products pursuant to contractual arrangements. Certain of our manufacturers currently constitute the sole source of our products. For example, Teikoku is our sole source of Lidoderm® and Grünenthal is our sole source of our new formulation of Opana® ER, designed to be crush-resistant. Because of contractual restraints and the lead-time necessary to obtain FDA approval, and possibly DEA registration, of a new manufacturer, replacement of any of these manufacturers may be expensive and time consuming and may cause interruptions in our supply of products to customers. As a result, any such delay could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Because most of our products are manufactured by third parties, we have a limited ability to control the manufacturing process or costs related to this process. Increases in the prices we pay our manufacturers, interruptions in our supply of products or lapses in quality could adversely impact our margins, profitability and cash flows. We are reliant on our third party manufacturers to maintain the facilities at which they manufacture our products in compliance with FDA, DEA, state and local regulations. If they fail to maintain compliance with FDA, DEA or other critical regulations, they could be ordered to cease manufacturing which would have a material adverse impact on our business, results of operations, financial condition and cash flows. For example, in December 2011, Novartis Consumer Health, Inc. s Lincoln, Nebraska manufacturing facility was temporarily shut down to facilitate its implementation of certain manufacturing process improvements. These improvements are intended to address the possibility of rare instances of errors in the packaging of the tablets, potentially resulting in product mix-ups. The temporary supply disruption is not related to the efficacy or safety of Endo s products. As a result, there will be a short-term supply constraint of Opana® ER and certain other Endo analgesic products manufactured at this facility, including Opana®, Voltaren® Gel, oxymorphone hydrochloride, Percocet®, Percodan®, Endocet®, Endodan®, morphine sulfate ER and Zydone®. Additionally, if any facility that manufactures our products experiences a natural disaster such as the recent earthquakes in Japan or the recent tornados in Alabama, we could experience a material adverse impact on our business, results of operations, financial condition and cash flows. In addition to FDA and DEA regulation, violation of standards enforced by the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA) and their counterpart agencies at the state level, could slow down or curtail operations of third party manufacturers.

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

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

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In addition, we may consider entering into additional manufacturing arrangements with third party manufacturers. In each case, we will incur significant costs in obtaining the regulatory approvals and taking the other steps necessary to begin commercial production by these manufacturers. If the market for the products manufactured by these third parties substantially contracts or disappears, we will continue to be financially obligated under these contracts, an obligation which could have a material adverse effect on our business.

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

We rely on third parties to supply all raw materials used in our products. In addition, we rely on third party suppliers, distributors and collaboration partners to provide services for certain core aspects of our business, including manufacturing, warehousing, distribution, customer service support, medical affairs services, clinical studies, sales and other technical and financial services. All third party suppliers and contractors are subject to FDA, and very often DEA, requirements. Our business and financial viability are dependent on the continued supply by these third party suppliers, the regulatory compliance of these third parties, and on the strength, validity and terms of our various contracts with these third party manufacturers, distributors and collaboration partners. Any interruption or failure by our suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, we have entered into minimum purchase requirement contracts with some of our third party raw material suppliers. If the market for the products that utilize these raw materials substantially contracts or disappears, we will continue to be financially obligated under these contracts and meeting such obligations could have a material adverse effect on our business.

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

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

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

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

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If our manufacturing facilities fail to comply with regulatory requirements or encounter other manufacturing difficulties, it could adversely affect their ability to supply products to us. All facilities and manufacturing processes used for the manufacture of pharmaceutical products and medical devices must be operated in conformity with cGMP and, in the case of controlled substances, DEA regulations. Compliance with the FDA s cGMP and DEA requirements applies to both drug products seeking regulatory approval and to approved drug products. In complying with cGMP requirements, pharmaceutical manufacturing facilities must continually expend significant time, money and effort in production, record-keeping and quality assurance and control so that their products meet applicable specifications and other requirements for product safety, efficacy and quality. Failure to comply with applicable legal requirements subjects our manufacturing facilities to possible legal or regulatory action, including shutdown, which may adversely affect their ability to supply us with product. Were we not able to manufacture products at our manufacturing facilities because of regulatory, business or any other reasons, the manufacture and marketing of these products would be interrupted. This could have a material adverse impact on our business, results of operation, financial condition, cash flows and competitive position.

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

The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in some of our current products and products in development, including oxycodone, oxymorphone, morphine, fentanyl, and hydrocodone, are listed by the DEA as Schedule II or III substances under the Controlled Substances Act of 1970. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation. For example, generally, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Furthermore, the DEA limits the availability of the active ingredients used in many of our current products and products in development, as well as the production of these products and, and we, or our contract manufacturing organizations, must annually apply to the DEA for procurement and production quotas in order to obtain and produce these substances. As a result, our procurement and production quotas may not be sufficient to meet commercial demand or to complete clinical trials. Moreover, the DEA may adjust these quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Any delay or refusal by the DEA in establishing our quotas, or modification of our quotas, for controlled substances could delay or result in the stoppage of our clinical trials or product launches, or could cause trade inventory disruptions for those products that have already been launched, which could have a material adverse effect on our business, financial position, results of operations and cash flows.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- FDA approval or disapproval of any of the drug applications we have submitted;
- the success or failure of our clinical trials;
- new data or new analyses of older data that raises potential safety or effectiveness issues concerning our approved products;
- competitors announcing technological innovations or new commercial products;
- introduction of generic substitutes for our products, including the filing of ANDAs with respect to generic versions of our branded products, such as Lidoderm®;
- developments concerning our or others proprietary rights, including patents;

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competitors publicity regarding actual or potential products under development;

regulatory developments in the U.S. and foreign countries, or announcements relating to these matters;

period-to-period fluctuations in our financial results;

new legislation in the U.S. relating to the development, sale or pricing of pharmaceuticals;

a determination by a regulatory agency that we are engaging or have engaged in inappropriate sales or marketing activities, including promoting the off-label use of our products;

litigation; and

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

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

Our business depends on the efficient and uninterrupted operation of our computer and communications systems and networks, hardware and software systems and our other information technology. If our systems were to fail or we are unable to successfully expand the capacity of these systems, or we are unable to integrate new technologies into our existing systems, our operations and financial results could suffer.

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

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

The regulatory approval process outside the U.S. varies depending on foreign regulatory requirements, and failure to obtain regulatory approval in foreign jurisdictions would prevent the marketing of our products in those jurisdictions.

We have worldwide intellectual property rights to market many of our products and product candidates. We intend to seek approval of and market certain of our products outside of the U.S. To market our products in the European Union and other foreign jurisdictions, we must obtain separate regulatory authorization and comply with numerous and varying regulatory requirements. Approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing that product in those countries. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process includes all of the risks associated with obtaining FDA approval set forth herein and approval by the FDA does not ensure approval by the regulatory authorities of any other country, nor does the approval by foreign regulatory authorities in one country ensure approval by regulatory authorities in other foreign countries or the FDA. If we fail to comply with these regulatory requirements or obtain and maintain required approvals, our target market will be reduced and our ability to generate revenue from abroad will be adversely affected.

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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 branded pharmaceutical companies and generic pharmaceutical companies are facing increased government scrutiny in both the U.S. and abroad.

We are involved in numerous patent litigations in which generic companies challenge the validity or enforceability of our products listed patents and/or the applicability of these patents to the generic applicant s products. Likewise, our generics business is also involved in patent litigations in which we challenge the validity or enforceability of innovator companies listed patents and/or their applicability to our generic products. Therefore, settling patent litigations has been and is likely to continue to be part of our business. Parties to such settlement agreements in the U.S., including us, are required by law to file them with the FTC and the Antitrust Division of the Department of Justice for review. The FTC has publicly stated that, in its view, some of these settlement agreements violate the antitrust laws and has brought actions against some brand and generic companies that have entered into such agreements. Accordingly, we may receive formal or informal requests from the FTC for information about a particular settlement agreement, and there is a risk that the FTC may commence an action against us alleging violation of the antitrust laws. Any adverse outcome of these actions or investigations could have a significant adverse effect on our business, financial condition and results of operations. In addition, some members of Congress have proposed legislation that would limit the types of

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

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

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

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

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively (effective January 1, 2010);
- extension of Medicaid prescription drug rebates to drugs dispensed to enrollees in certain Medicaid managed care organizations (effective March 23, 2010);
- an increase in the additional Medicaid rebates for new formulations of oral solid dosage forms of innovator drugs;
- the revision of the average manufacturers price, or AMP, definition to remove the retail pharmacy class of trade (effective October 1, 2010);
- expansion of the types of institutions eligible for the Section 340B discounts for outpatient drugs provided to hospitals meeting the qualification criteria under Section 340B of the Public Health Service Act of 1944 (effective January 1, 2010) (340B Pricing);
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition of the manufacturer s outpatient drugs to be covered under Medicare Part D (effective January 1, 2011);
- an annual fee payable to the federal government (which is not deductible for U.S. income tax purposes) based on our prior-calendar-year share relative to other companies of branded prescription drug sales to specified government programs (effective January 1, 2011, with the total fee to be paid each year by the pharmaceutical industry increasing annually through 2019);
- a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the U.S., with limited exceptions (effective January 1, 2013);
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting any transfer of value made or distributed to physicians and teaching hospitals and reporting any investment interests held by physicians and their immediate family members during each calendar year (beginning in 2012, with reporting starting in 2013);

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the need to comply with applicable FDA and foreign regulations relating to cGMP and medical device approval or certification requirements, and with state licensing requirements;
- the need for special non-governmental certifications and registrations regarding product safety, product quality and manufacturing procedures in order to market products in the European Union, i.e. EN ISO certifications;
- the fact that in some foreign countries, medical device sales are strongly determined by the reimbursement policies of statutory and private health insurance companies, i.e., if insurance companies decline reimbursement for HealthTronics or AMS s products, sales may be adversely affected;
- potential product liability claims for any defective goods that are distributed; and
- the need for research and development expenditures to develop or enhance products and compete in the equipment markets.

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

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

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

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

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

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

AMS derives a significant portion of its net sales from operations in international markets. Since our June 2011 acquisition of AMS, 32.6% of our AMS subsidiary s 2011 total revenues were to customers outside the U.S. Some of these sales were to governmental entities and other organizations with extended payment terms. A number of factors, including differing economic conditions, changes in political climate, differing tax structures, changes in diplomatic and trade relationships, and political or economic instability in the countries where AMS does business, could affect payment terms and AMS s ability to collect foreign receivables. We have little influence over these factors and changes could have a material adverse impact on our business. In addition, foreign sales are influenced by fluctuations in currency exchange rates, primarily the Euro, Canadian dollar, Australian dollar, and Great Britain pound. Increases in the value of the foreign currencies relative to the U.S. dollar would positively impact our earnings and decreases in the value of the foreign currencies relative to the U.S. dollar would negatively impact our earnings.

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

The sale and shipping of AMS s products and services across international borders is subject to extensive U.S. and foreign governmental trade regulations, such as various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act, export control laws, customs and import laws, and anti-boycott laws. Our failure to comply with applicable laws and regulations could result in significant criminal, civil and administrative penalties, including, but not limited to, imprisonment of individuals, fines, denial of export privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities.

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In addition, some countries in which AMS sells products are, to some degree, subject to political, economic and/or social instability. AMS s international sales operations expose us and our representatives, agents and distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- the imposition of additional U.S. and foreign governmental controls or regulations;
- the imposition of costly and lengthy new export licensing requirements;
- the imposition of U.S. and/or international sanctions against a country, company, person or entity with whom the company does business that would restrict or prohibit continued business with the sanctioned country, company, person or entity;
- economic instability or disruptions, including local and regional instability, or disruptions due to natural disasters, such as severe weather and geological events;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of new trade restrictions;
- imposition of restrictions on the activities of foreign agents, representatives and distributors;
- scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;
- pricing pressure that we may experience internationally;
- laws and business practices favoring local companies;
- difficulties in enforcing or defending intellectual property rights; and
- exposure to different legal and political standards due to our conducting business in several foreign countries.

We cannot provide assurance that one or more of these factors will not harm our business and we are experiencing fluidity in regulatory and pricing trends as a result of healthcare reform. Any material decrease in AMS s international sales would adversely impact AMS s results of operations and financial condition.

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

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

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

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

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

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

Our substantial indebtedness may:

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

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

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

Covenants in our debt agreements restrict our business in many ways.

The indentures governing the notes and the agreements governing the 2011 Credit Facility and other outstanding indebtedness subject us to various covenants that limit our ability and/or our restricted subsidiaries ability to, among other things:

- incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;
- issue redeemable stock and preferred stock;

pay dividends or distributions or redeem or repurchase capital stock;

prepay, redeem or repurchase debt;

make loans, investments and capital expenditures;

enter into agreements that restrict distributions from our subsidiaries;

sell assets and capital stock of our subsidiaries;

enter into certain transactions with affiliates; and

consolidate or merge with or into, or sell substantially all of our assets to, another person.

A breach of any of these covenants could result in a default under our indebtedness, including the 2011 Credit Facility and/or the notes.

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

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

their earnings;

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

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

business and tax considerations; and

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

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

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

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

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

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

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

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

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delay capital expenditures or seek to raise additional capital, any of which could have a material adverse effect on our operations. There can be no assurance that we will be able to accomplish any of these alternatives on terms acceptable to us, or at all. Our ability to restructure or refinance our indebtedness, including the notes, will depend on the condition of the capital markets and our financial condition at such time. Any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. In addition, the terms of existing or future debt agreements, including the indentures governing the notes, may restrict us from adopting any of these alternatives. Any failure to make scheduled payments of interest or principal on our outstanding indebtedness would likely result in a reduction of our credit rating, which could negatively impact our ability to incur additional indebtedness on commercially reasonable terms or at all. The failure to generate sufficient cash flow or to achieve any of these alternatives could materially adversely affect the value of our notes, our business, financial condition and other results of operations, and our ability to pay the amounts due under the notes and our other indebtedness.

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

If there were an event of default under any of the agreements relating to our outstanding indebtedness, the holders of the defaulted debt could cause all amounts outstanding with respect to that debt to be due and payable immediately and our lenders could terminate all commitments to extend further credit. The instruments governing our debt contain cross-default or cross-acceleration provisions that may cause all of the debt issued under such instruments to become immediately due and payable as a result of a default under an unrelated debt instrument. An event of default or an acceleration under one debt agreement could cause a cross-default or cross-acceleration of other debt agreements. Upon acceleration of certain of our other indebtedness, holders of the notes could declare all amounts outstanding under the notes immediately due and payable. We cannot assure you that our assets or cash flow would be sufficient to fully repay borrowings under our outstanding debt instruments if the obligations thereunder were accelerated upon an event of default. Further, if we are unable to repay, refinance or restructure our secured debt, the holders of such debt could proceed against the collateral securing that indebtedness. We have pledged substantially all of our assets as collateral under the 2011 Credit Facility. If the lenders under the 2011 Credit Facility accelerate the repayment of borrowings, we may not have sufficient assets to repay the obligations outstanding under the 2011 Credit Facility and our other indebtedness, including the notes. Furthermore, our borrowings under the 2011 Credit Facility are expected to be at variable rates of interest and expose us to interest rate risk. If interest rates increase, our debt service obligations on the variable rate indebtedness would increase even though the amount borrowed remains the same, and our net income would decrease. For a description of our indebtedness, see Note 18. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

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

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

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

None.

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

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

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

Item 3. ***Legal Proceedings***

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

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

None

PART II

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

Market Information. Our common stock is traded on the NASDAQ Global Select Market under the symbol ENDP . The following table sets forth the quarterly high and low share price information for the periods indicated. The prices shown represent quotations between dealers, without adjustment for retail markups, markdowns or commissions, and may not represent actual transactions.

	Endo Common Stock	
	High	**Low**
Year Ending December 31, 2011		
1st Quarter	$ 38.51	$ 32.14
2nd Quarter	$ 44.53	$ 36.65
3rd Quarter	$ 42.09	$ 26.76
4th Quarter	$ 36.41	$ 26.02
Year Ending December 31, 2010		
1st Quarter	$ 24.85	$ 19.19
2nd Quarter	$ 24.29	$ 19.58
3rd Quarter	$ 34.26	$ 21.30
4th Quarter	$ 38.20	$ 32.80

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

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

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

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

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

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

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

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

The consolidated financial data presented below have been derived from our audited financial statements. The selected historical consolidated financial data presented below should be read in conjunction with Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations and Item 8. Financial Statements and Supplementary Data. The selected data in this section is not intended to replace the consolidated financial statements. The information presented below is not necessarily indicative of the results of our future operations. Certain prior year amounts have been reclassified to conform to the current year presentation.

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

Cash dividends declared per share	$	$	$	$	$

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

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

The following Management s Discussion and Analysis of Financial Condition and Results of Operations (MD&A) describes the principal factors affecting the results of operations, liquidity and capital resources, and critical accounting estimates at Endo. This discussion should be read in conjunction with our audited Consolidated Financial Statements and related notes thereto. Except for the historical information contained in this Report, including the following discussion, this Report contains forward-looking statements that involve risks and uncertainties. See Forward-Looking Statements beginning on page 1 of this Report.

EXECUTIVE SUMMARY

About the Company

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

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

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2011 A Year in Review

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

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

Business Environment

The Company conducts its business within the pharmaceutical, devices, and healthcare services industries, which are highly competitive and subject to numerous government regulations. Many competitive factors may significantly affect the Company s sales of its products and services, including efficacy, safety, price and cost-effectiveness, marketing effectiveness, product labeling, quality control and quality assurance at our and our third-party manufacturing operations, and research and development of new products. To compete successfully for business in the healthcare industry, the Company must demonstrate that its products and services offer medical benefits as well as cost advantages. Currently, most of the Company s products compete with other products already on the market in the same therapeutic category, and are subject to potential competition from new products that competitors may introduce in the future. Generic competition is one of the Company s leading challenges. Similarly, the Company competes with other providers with respect to the devices and services we offer, as well as providers of alternative treatments.

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

The healthcare industry is subject to various government-imposed regulations authorizing prices or price controls that have and will continue to have an impact on the Company s sales. The U.S. Congress and some state legislatures have considered a number of proposals and have enacted laws that could result in major changes in the current healthcare system, either nationally or at the state level. Driven in part by budget concerns,

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Medicaid access and reimbursement restrictions have been implemented in some states and proposed in many others. In addition, the Medicare Prescription Drug Improvement and Modernization Act provides outpatient prescription drug coverage to senior citizens in the U.S. This legislation has had a modest favorable impact on the Company as a result of an increase in the number of seniors with drug coverage. At the same time, there continues to be a potential negative impact on the U.S. pharmaceutical business that could result from pricing pressures or controls.

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

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

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

Healthcare Reform

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

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

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

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

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

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

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

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

Governmental Regulation

The development, testing, manufacture, holding, packaging, labeling, distribution, marketing, and sales of our products and our ongoing product development activities are subject to extensive and rigorous government regulation. The Federal Food, Drug and Cosmetic Act (FFDCA), the Controlled Substances Act and other federal and state statutes and regulations govern or influence the testing, manufacture, packaging, labeling, storage, record keeping, approval, advertising, promotion, sale and distribution of pharmaceutical products. Noncompliance with applicable requirements can result in fines, recall or seizure of products, total or partial suspension of production and/or distribution, refusal of the government to enter into supply contracts or to approve NDAs and ANDAs, civil penalties and criminal prosecution.

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

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

Based on scientific developments, post-market experience, or other legislative or regulatory changes, the current FDA standards of review for approving new pharmaceutical products are sometimes more stringent than those that were applied in the past. Some new or evolving review standards or conditions for approval were not applied to many established products currently on the market, including certain opioid products. As a result, the

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FDA does not have as extensive safety databases on these products as on some products developed more recently. Accordingly, we believe the FDA has recently expressed an intention to develop such databases for certain of these products, including many opioids.

In particular, the FDA has expressed interest in specific chemical structures that may be present as impurities in a number of opioid narcotic active pharmaceutical ingredients, such as oxycodone, which based on certain structural characteristics and laboratory tests may indicate the potential for having mutagenic effects.

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

We cannot determine what effect changes in the FDA s laws or regulations, when and if promulgated, or changes in the FDA s legal or regulatory interpretations, may have on our business in the future. Changes could, among other things, require expanded or different labeling, additional testing, the recall or discontinuance of certain products, additional record keeping and expanded documentation of the properties of certain products and scientific substantiation. Such changes, or new legislation, could have a material adverse effect on our business, financial condition, results of operations and cash flows. In December 2003, Congress passed measures intended to speed the process by which generic versions of brand name drugs are introduced to the market. Among other things, these measures are intended to limit regulatory delays of generic drug applications and penalize companies that reach agreements with makers of brand name drugs to delay the introduction of generic versions. These changes could result in increased generic competition for our branded and generic products and could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, on September 27, 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007 (FDAAA) that re-authorized requirements for testing drug products in children, where appropriate, and included new requirements for post-approval studies or clinical trials of drugs that are known to or that signal the potential to pose serious safety risks, and authority to require risk evaluation and mitigation strategies, or REMS to ensure that the benefits of a drug outweigh the risks of the drug, all of which may increase the time and cost necessary for new drug development as well as the cost of maintaining regulatory compliance for a marketed product.

The evolving and complex nature of regulatory requirements, the broad authority and discretion of the FDA and the generally high level of regulatory oversight results in a continuing possibility that from time to time, we will be adversely affected by regulatory actions despite ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

Pipeline Developments

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

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

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

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

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

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

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

Change in Directors and Executive Officers

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

Corporate Headquarters Lease

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

RESULTS OF OPERATIONS

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

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Consolidated Results Review

Year Ended December 31, 2011 Compared to the Year Ended December 31, 2010

Revenues

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

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

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

* Percentages may not add due to rounding.

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

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

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

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

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

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

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

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

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

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

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

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Gross Margin, Costs and Expenses

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

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

* Percentages may not add due to rounding.

Costs of Revenues and Gross Profit Margin

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

Selling, General and Administrative Expenses

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

Research and Development Expenses

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

We invest in research and development because we believe it is important to our long-term competitiveness. As a percent of revenues, R&D expense was approximately 7%, 8% and 13% in 2011, 2010 and 2009, respectively. The variation in R&D expense as a percent of revenues is primarily due to upfront and milestone payments to third party collaborative partners included in R&D expense totaling $19.1 million or 1% of revenue, $23.9 or 1% of revenue million and $77.1 million or 5% of revenue in 2011, 2010 and 2009, respectively. In addition to upfront and milestone payments, total research and development expenses include the costs of discovery research, preclinical development, early- and late-clinical development and drug formulation, as well as clinical trials, medical support of marketed products, other payments under third-party collaborations and contracts and other costs. Research and development spending also includes enterprise-wide costs which support

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

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

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

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

The Company s pharmaceutical research and development efforts are also focused on the goal of developing a balanced, diversified portfolio of innovative and clinically differentiated generic products across a wide range of therapeutic areas. We generally focus on selective generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. We believe products with these characteristics will face a lesser degree of competition and therefore provide longer product life cycles and higher profitability than commodity generic products. For the years ended December 31, 2011, 2010 and 2009, the Company s direct R&D expense related to generics was $29.1 million, $17.5 million and $24.2 million, respectively.

FDA approval of an abbreviated new drug application (ANDA) is required before a generic equivalent of an existing or reference-listed drug can be marketed. As of December 31, 2011, we have approximately 50 ANDAs under active FDA review in multiple therapeutic areas. The timing of final FDA approval of ANDA applications depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and whether the manufacturer of the reference listed drug is entitled to one or more statutory exclusivity periods, during which the FDA is prohibited from approving generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date.

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

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

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

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

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

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

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

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

Asset Impairment Charges

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

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

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

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

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

Acquisition-Related Items, net

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

Interest Expense, net

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

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

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

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

Loss (Gain) on Extinguishment of Debt

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

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

Other Income, net

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

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

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

Income Tax

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

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

Net income attributable to noncontrolling interests

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

2012 Outlook

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

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

Revenues

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

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

	2010		2009	
	$	%	$	%
Lidoderm®	782,609	46	$ 763,698	52
Opana® ER	239,864	14	171,979	12
Voltaren® Gel	104,941	6	78,868	5
Percocet®	121,347	7	127,090	9
Frova®	59,299	3	57,924	4
Supprelin® LA				