ENDO PHARMACEUTICALS HOLDINGS INC
Form 10-K
March 01, 2010
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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, 2009

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 ¨ 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, 2009 was $1,603,701,729 based on a closing sale price of $17.92 per share as reported on the NASDAQ Global Select Market on June 30, 2009. 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 19, 2010: 117,286,788

Documents Incorporated by Reference

Portions of the registrant s proxy statement to be filed with the SEC pursuant to Regulation 14A in connection with the registrant s 2010 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, 2009.

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FOR THE YEAR ENDED DECEMBER 31, 2009

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FORWARD LOOKING STATEMENTS

This document contains information that includes or is based on forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements, including estimates of future revenues, future expenses, future net income and future earnings per share, contained in the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations, are subject to risks and uncertainties. Forward-looking statements include the information concerning our possible or assumed results of operations. Also, statements including words such as believes, expects, anticipates, intends, estimates, plan, will, may or similar expressions are forward-looking statements. We these forward-looking statements on our current expectations and projections about the growth of our business, our financial performance and the development of our industry. Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described in Item 1A 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 in this document. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements in this document include those factors described in this document under Item 1A titled Risk Factors, including, among others:

our ability to successfully develop, commercialize and market new products;

timing and results of pre-clinical or clinical trials on new products;

our ability to obtain regulatory approval of any of our pipeline products;

competition for the business of our branded and generic products, and in connection with our acquisition of rights to intellectual property assets;

market acceptance of our future products;

government regulation of the pharmaceutical industry;

our dependence on a small number of products;

our dependence on outside manufacturers for the manufacture of a majority of our products;

our dependence on third parties to supply raw materials and to provide services for certain core aspects of our business;

new regulatory action or lawsuits relating to our use of narcotics in most of our core products;

our exposure to product liability claims and product recalls and the possibility that we may not be able to adequately insure ourselves;

our ability to protect our proprietary technology;

the successful efforts of manufacturers of branded pharmaceuticals to use litigation and legislative and regulatory efforts to limit the use of generics and certain other products;

our ability to successfully implement our acquisition and in-licensing strategy;

regulatory or other limits on the availability of controlled substances that constitute the active ingredients of some of our products and products in development;

the availability of third-party reimbursement for our products;

the outcome of any pending or future litigation or claims by third parties or the government, and the performance of indemnitors with respect to claims for which we have been indemnified;

our dependence on sales to a limited number of large pharmacy chains and wholesale drug distributors for a large portion of our total revenues;

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significant litigation expenses to defend or assert patent infringement claims;

any interruption or failure by our suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us;

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

existing suppliers become unavailable or lose their regulatory status as an approved source, causing an inability to obtain required components, raw materials or products on a timely basis or at commercially reasonable prices;

the loss of branded product exclusivity periods and related intellectual property;

our exposure to securities that are subject to market risk including auction-rate securities that are currently illiquid due to an inactive auction-rate market;

our ability to successfully execute our strategy;

disruption of our operations if our information systems fail or if we are unsuccessful in implementing necessary upgrades or new software; and

our ability to maintain or expand our business if we are unable to retain or attract key personnel and continue to attract additional professional staff.

We do not undertake any obligation to update our forward-looking statements after the date of this Report for any reason, even if new information becomes available or other events occur in the future. You are advised, however, to consult any further disclosures we make on related subjects in our 10-Q and 8-K reports to the Securities and Exchange Commission (referred to as the SEC). Also note that we provide the preceding cautionary discussion of 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 the Private Securities Litigation Reform Act of 1995. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the preceding to be a complete discussion of all potential risks or uncertainties.

PART I

Item 1. *Business*

Overview

We are a specialty pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of branded and generic prescription pharmaceuticals used primarily to treat and manage pain, overactive bladder, prostate and bladder cancer, and the early onset of puberty in children, or central precocious puberty.

We have a portfolio of branded products that includes brand names such as Lidoderm®, Opana® ER and Opana®, Percocet®, Frova®, Voltaren® Gel, Vantas®, Valstar®, and Supprelin® LA. Branded products comprised approximately 91% of our net sales in 2009, with 52% of our revenues coming from Lidoderm®. Our non-branded generic portfolio, which accounted for 9% of net sales in 2009, currently consists of products

primarily focused in pain management. We focus on select generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing.

In the first quarter of 2009, we acquired Indevus Pharmaceuticals (referred to as Indevus), a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. Indevus s approved products included Sanctura® and Sanctura XR® for

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overactive bladder (referred to as OAB), which is promoted by Allergan, Inc. (referred to as Allergan), Vantas® for advanced prostate cancer, Supprelin® LA for central precocious puberty (referred to as CPP), Delatestryl® for the treatment of hypogonadism and Valstar® for bladder cancer. We also acquired from Indevus a core urology and endocrinology portfolio containing multiple compounds in development including Aveed™ for hypogonadism and the octreotide implant for treatment of acromegaly and carcinoid syndrome. All financial information presented herein reflects the operating results of Indevus from February 23, 2009 to December 31, 2009.

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

We enhance our financial flexibility by outsourcing certain of our functions, including manufacturing and distribution. Currently, our primary suppliers of contract manufacturing services are Novartis Consumer Health, Inc. and Teikoku Seiyaku Co., Ltd.

Through a dedicated sales force in the United States consisting of 320 specialty representatives, 365 pharmaceutical sales representatives focusing primarily on pain products, 75 sales representatives focusing primarily on urology and oncology, 27 medical center representatives and a contract sales force of approximately 80 sales representatives, we market our branded pharmaceutical products to high-prescribing physicians in pain management, orthopedics, neurology, rheumatology, surgery, anesthesiology, oncology, urology, endocrinology and primary care, including pediatricians. Our sales force also targets retail pharmacies and other healthcare professionals throughout the United States.

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

Our wholly-owned subsidiary, Endo Pharmaceuticals Inc. (referred to as EPI), commenced operations in 1997 by acquiring certain pharmaceutical products, related rights and assets of The DuPont Merck Pharmaceutical Company, which subsequently became DuPont Pharmaceuticals Company and was thereafter purchased by the Bristol-Myers Squibb Pharma Company in 2001. EPI was formed by certain members of the then-existing management of DuPont Merck and an affiliate of Kelso & Company who were also parties to the purchase agreement under which we acquired these initial assets.

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

Our Competitive Strengths

We believe that we have established a position as a market leader among specialty pharmaceutical companies by capitalizing on our following core strengths:

Established portfolio of branded products. We have assembled a portfolio of branded pharmaceutical 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. The Company s branded products include: Lidoderm®, Opana® ER and Opana®, Percocet®, Frova®, Voltaren® Gel, Supprelin® LA, Vantas®, Hydron® Polymer Technology and Valstar®. A detailed description of each of our products is in this section under our Product Overview .

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Focused Pipeline. As a result of our focused research and development efforts, we believe we have a promising development pipeline and are well-positioned to capitalize on our core development products. Currently, our core development pipeline consists of two New Drug Applications (referred to as NDAs) filed with the Food and Drug Administration (FDA), two products in Phase III trials and three products in Phase II trials. For a more detailed description of our development pipeline, see the Product Overview Products in Development discussion included in this section.

Research and development expertise. Our research and development effort is focused on the development of a balanced, diversified portfolio of innovative and clinically differentiated products. We are continuously seeking opportunities that deepen our penetration in the pain 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 capture both earlier-stage opportunities and pursue other therapeutic areas. We continue to invest in research and development because we believe it is critical to our long-term competitiveness. At December 31, 2009, our research and development and regulatory affairs staff consisted of 153 employees, based in Westbury, New York and at our corporate headquarters in Chadds Ford, Pennsylvania. Our research and development expenses, including upfront and milestone payments were $185.3 million in 2009, $110.2 million in 2008 and $138.3 million in 2007.

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

Drug development is time-consuming, expensive and risky. In the development of human health products, industry practice and government regulations in the U.S. provide for the determination of effectiveness and safety of new molecular entities through preclinical tests and controlled clinical evaluation. Before a new drug may be marketed in the U.S., recorded data on preclinical and clinical experience are included in the NDA which must be submitted to the FDA for the required approval. The process from discovery to regulatory approval often takes ten years or longer. Drug candidates can fail at any stage of the process, and even late-stage product candidates sometimes fail to receive regulatory approval. We believe our investment in research and development, both internally and in collaboration with others, has been productive as demonstrated by our ability to commercialize our research and development efforts by launching a number of new products and product line extensions since our founding in August 1997.

Targeted national sales and marketing infrastructure. We market our branded products directly to physicians through a sales force of approximately 870 representatives in the United States, including a contracted field force of approximately 80 sales representatives. Through our sales force, we market our branded pharmaceutical products to more than 109,000 physicians, which include both specialists and primary care physicians, including pediatricians. We distribute our products principally through independent wholesale distributors, but we also sell directly to retailers, clinics, government agencies, doctors and retail and specialty pharmacies. Our marketing policy is designed to assure that products and relevant, appropriate medical information are immediately available to physicians, pharmacies, hospitals, public and private payers, and appropriate healthcare professionals throughout the United States. We work to gain access to health authority, pharmacy benefit managers (referred to as a PBM) and managed care organizations (referred to as an MCO) formularies (lists of recommended or approved medicines and other products), including Medicare Part D plans and reimbursement lists by demonstrating the qualities and treatment benefits of our products within their approved indications. Our managed markets staff in 2009 consisted of 44 employees.

Selective focus on generic products. Our generic product portfolio includes products focused on pain management. We develop generic products 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

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characteristics will face a lesser degree of competition and therefore provide longer product life cycles and higher profitability than commodity generic products. We have executed our generic product development strategy successfully to date with products such as morphine sulfate extended-release tablets, which we introduced in November 1998 as a bioequivalent version of MS Contin®, a product of Purdue Pharma, L.P. Additionally, in December of 2009 we received approval of our abbreviated new drug application (referred to as an ANDA) for mycophenolate mofetil capsules (250) mg. Mycophenolate mofetil is a bioequivalent version of Cellcept®, a product of Hoffman-La Roche Ltd. We intend to continue to make strategic decisions to support and grow our generics business in a manner consistent with the characteristics described above.

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. The Company and members of its management team have received FDA approval on more than eighteen new products and product line extensions since 1997, and as a result of several successful product launches, have grown our total revenues from $108.4 million in 1998 to $1.46 billion in 2009.

Our Industry

Pain Management Market

According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled $21.4 billion in 2009. This represents an approximate 6% compounded annual growth rate since 2004. Our primary area of focus within this market is analgesics and, specifically, opioid analgesics. In 2009, analgesics were the third most prescribed medication in the United States with over 305 million prescriptions written for this classification.

Opioid analgesics is a segment that comprised approximately 80% of the analgesic prescriptions for 2009 and represented almost 58% of the overall U.S. pain market. Total U.S. sales for the opioid analgesic segment were $8.1 billion in 2009, representing a compounded annual growth rate of 7% since 2004. 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 with over 174 million prescriptions written in 2009, representing 42% of the U.S. pain market. The U.S. sales for these markets were $13.4 billion with a compound annual growth rate of 5% since 2004.

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 14% growth over this period.);
- introduction of new and reformulated branded products; and
- increasing incidence of chronic pain conditions, such as cancer, arthritis and low back pain.

Urology, Endocrinology and Oncology Markets

Through our acquisition of Indevus as well as other business development activities in 2009, Endo entered the urology, endocrinology and oncology markets, specifically the prostate cancer therapeutic area with Vantas®, the bladder oncology space with Valstar® and Urocidin™, and the central precocious puberty therapeutic area with Supprelin® LA. We also anticipate entering the testosterone replacement therapy (referred to as TRT) market and treating hypogonadism with our development products Aveed® and Fortesta®.

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Central Precocious Puberty (CPP)

In a recent study, the incidence of CPP reported from national registries in the European Union subdivided by gender and age at diagnosis was approximately 1 per 10,000 in girls who were younger than 4 years, thereafter gradually rising to 8 per 10,000 for girls aged 5 to 9 years. The incidence in boys younger than 8 years was approximately 1 per 10,000. Recent market research indicates that girls in the United States are physically maturing at an earlier age than they did 30 years ago, and the number of girls diagnosed with precocious puberty is on the rise. In the U.S., 6,500 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 500 practicing pediatric endocrinologists. In 2008, the market for drugs to treat CPP, reported by IMS Health NSP, was approximately $119 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 200,000 men in the U.S. are diagnosed with prostate cancer and 30,000 die from this disease.

Bladder Cancer Overview

There are more than 500,000 people in the United States alive with a history of bladder cancer, which is the fourth most common cancer among men and the eleventh most common among women in the United States. The American Cancer Society estimated approximately 70,000 new cases of bladder cancer and 14,330 deaths from this disease in the United States in 2009.

Rates of bladder cancer are expected to increase due to the aging population; more than 70% of cases of bladder cancer are diagnosed in people age 65 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

Carcinoma in situ (CIS) of the urinary bladder is a rare form of bladder cancer, affecting about seven of every 100 patients diagnosed with bladder cancer. Standard treatment of CIS of the urinary bladder is transurethral resection of the bladder tumor (TURBT), followed by one or two courses of immunotherapy with the vaccine bacillus Calmette-Guérin (referred to as BCG). About 50 percent of patients will become refractory to BCG therapy. VALSTAR intravesical therapy is the only FDA-approved treatment of carcinoma in situ of the urinary bladder in patients who are refractory to BCG immunotherapy when cystectomy or bladder removal is not an option.

Testosterone Replacement Overview

In the United States alone, it is estimated that 13.8 million men have low testosterone levels; however, only about 9% are currently being treated. Hypogonadism, or low testosterone, is under diagnosed and under treated. Factors contributing to this include a lack of screening for low testosterone and the perceived risk of prostate cancer associated with current treatment strategies. In the United States, testosterone replacement therapy (or TRT) sales have dramatically increased, from approximately $450 million in 2004 to over $1,041 million in 2009, reflecting a growth rate of 28.5%.

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Product Overview

The following table summarizes select products in our marketed portfolio as well as select products in development:

Marketed Products	Active Ingredients(s)	Branding	Status
Lidoderm®	lidocaine 5%	Branded	Marketed
Opana® ER(1)	oxymorphone hydrochloride	Branded	Marketed
Opana®	oxymorphone hydrochloride	Branded	Marketed
Percocet®	oxycodone hydrochloride and acetaminophen	Branded	Marketed
Voltaren® Gel(2)	diclofenac sodium topical gel 1%	Branded	Marketed
Frova®(3)	frovatriptan succinate	Branded	Marketed
Supprelin® LA	histrelin acetate	Branded	Marketed
Vantas®	histrelin acetate	Branded	Marketed
Sanctura XR®(4)	trospium chloride	Branded	Marketed
Sanctura®(5)	trospium chloride	Branded	Marketed
Valstar®	valrubicin	Branded	Marketed
Percodan®	oxycodone hydrochloride and aspirin	Branded	Marketed
Endocet®	oxycodone hydrochloride and acetaminophen	Generic	Marketed
Morphine Sulfate ER	morphine sulfate	Generic	Marketed

Products in Development		Active Ingredients(s)	Branding	Status
Aveed™(6)		testosterone undecanoate	Branded	NDA Filed
Fortesta™(7)		2% testosterone	Branded	NDA Filed
Octreotide implant	acromegaly	octreotide acetate	Branded	Phase III
Urocidin™(8)		mycobacterial cell wall-DNA complex	Branded	Phase III
Axomadol(9)		axomadol phosphate	Branded	Phase II
Octreotide implant	carcinoid syndrome	octreotide acetate	Branded	Phase II

(1) Marketed pursuant to an alliance agreement with Penwest Pharmaceuticals Co.
(2) Licensed marketing rights from Novartis Consumer Health, Inc.
(3) Licensed marketing rights from Vernalis Development Limited.
(4) Licensed marketing and development rights from Supernus Pharmaceuticals Inc.
(5) Licensed marketing and development rights from Madaus GmbH.
(6) Licensed marketing and development rights from BayerSchering Pharma AG.
(7) Licensed marketing and development rights from Strakan International Limited.
(8) Licensed marketing and development rights from Bioniche Life Sciences.
(9) Licensed marketing and development rights from Grünenthal GMBH.

Branded Products

Lidoderm®. Lidoderm® 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 2009, 2008 and 2007, Lidoderm® net sales were $763.7 million, $765.1 million and $705.6 million, respectively. Lidoderm® accounted for approximately 52% of our 2009 total revenues.

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Opana® and Opana® ER. Opana® ER and Opana® were launched during the second half of 2006 and have shown steady prescription growth trends since their launch. Opana® ER is indicated for the relief of moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time. Opana® ER represents the first drug in which oxymorphone is available in an oral, extended-release formulation and is available in 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg and 40 mg tablets. Opana® (the immediate-release version) is indicated for the relief of moderate-to-severe acute pain where the use of an opioid is appropriate and is available in 5mg and 10mg tablets. Opana® ER and Opana® net sales were $230.6 million, $180.4 million, and $107.1 million in 2009, 2008, and 2007, respectively. Opana® ER and Opana® accounted for approximately 16% of our 2009 total revenues.

Percocet®. We consider Percocet® to be a gold standard of pain management. Launched in 1976, Percocet® is approved for the treatment of moderate-to-moderately severe pain. The Percocet® family of products had net sales of $127.1 million, $130.0 million and $121.7 million in the years 2009, 2008 and 2007, respectively. The Percocet® franchise accounted for approximately 9% of our 2009 total revenues.

Voltaren® Gel. We launched Voltaren® Gel in March 2008 upon closing of the license and supply agreement with Novartis AG and Novartis Consumer Health, Inc. Voltaren® Gel (diclofenac sodium topical gel) 1% received regulatory approval in October 2007 from the FDA, becoming the first topical prescription treatment for use in treating pain associated with osteoarthritis and the first new product approved in the U.S. for osteoarthritis since 2001. Voltaren® Gel has been granted marketing exclusivity in the U.S. as a prescription medicine until at least 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 2009 and 2008, net sales of Voltaren® Gel were $78.9 million and $23.8 million, respectively.

Frova®. We began shipping Frova® upon closing of the license agreement with Vernalis in mid-August 2004, and we initiated our promotional efforts in September 2004. Frova® is indicated for the acute treatment of migraine headaches in adults. We believe that Frova® has differentiating features from other migraine products, including the longest half-life in the triptan class and a very low reported migraine recurrence rate in its clinical program. In 2009, 2008 and 2007, Frova® net sales were $57.9 million, $58.0 million and $52.4 million, respectively.

Supprelin® LA. Supprelin® LA was launched in the U.S. in June 2007. Supprelin® LA is a soft, flexible 12-month hydrogel implant based on our patented Hydron Polymer Technology that delivers LHRH (luteinizing hormone-releasing hormone) agonist and is indicated for the treatment of CPP. CPP is the early onset of puberty in young children resulting in the development of secondary sex characteristics and short stature, if left untreated. The development of these secondary sex characteristics is due to an increase in the secretion of sex hormones, the cause of which is unknown. Meetings have been held with various European regulatory authorities to seek scientific advice regarding the strategies for filing marketing applications for Supprelin® LA in Europe. Various strategies are being evaluated and include seeking marketing partners in territories outside of the United States. We market Supprelin® LA in the U.S. through a specialty sales force primarily to pediatric endocrinologists. Net sales of Supprelin® LA were $27.8 million in 2009.

Vantas®. Vantas® was launched in the U.S. in November 2004. Vantas® is a soft, flexible 12-month hydrogel implant based on our patented Hydron® Polymer Technology that delivers histrelin, a luteinizing hormone-releasing hormone agonist, or LHRH 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 (referred to as Orion) granting them the rights to market Vantas® throughout Europe as well as certain other countries. As of August 2007, Vantas was approved in Thailand, Singapore and Malaysia and approval is pending in Taiwan, Korea, Hong Kong and China. In addition, Teva-Tuteur has received approval for Vantas in Argentina. Net sales of Vantas® were $20.0 million in 2009, primarily in the United States.

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Valstar®. Valstar® a sterile solution for intravesical instillation of valrubicin a chemotherapeutic anthracycline derivative, is the only product currently approved by the FDA for therapy of bacillus Calmette-Guerin (BCG)-refractory carcinoma *in situ* (CIS) of the urinary bladder. Valstar® , originally approved by the FDA in 1998, was withdrawn from the market in 2002 due to a manufacturing problem involving impurity issues in the original formulation and was placed on the FDA Drug Shortages List. In April 2007, a supplemental New Drug Application (sNDA) to the FDA seeking approval to reintroduce Valstar® and in February 2009, the FDA approved this sNDA for Valstar®. In September 2009, we launched Valstar® for the treatment of patients with BCG-refractory CIS of the bladder. We continue to work closely with the manufacturer to build quantities of the product to support the launch of Valstar®. Net sales of Valstar® were $3.4 million in 2009.

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

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

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

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

Other. The balance of our other branded portfolio consists of a number of products, none of which accounted for more than 1% of our total net sales in the 2009 fiscal year.

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Generic Products

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

One of our generic products is an oxycodone hydrochloride and acetaminophen product, Endocet®, which accounted for approximately 6% of our total revenues in 2009. Another of our generic products is morphine sulfate extended-release tablets, which accounted for 2% of our total revenues in 2009. The balance of our generic portfolio consists of a few other products, none of which accounted for more than 1% of our total revenues for 2009.

We principally pursue the development and marketing of generic pharmaceuticals that have one or more barriers to entry. The characteristics of the products that we may target for generic development may include:

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

We believe products with these characteristics will face a lesser degree of competition, therefore providing longer product life cycles and/or higher profitability than commodity generic products. As of December 31, 2009, we have approximately forty projects under development, including fifteen of which are currently the subject of ANDAs on file with the FDA. Thirteen of these fifteen ANDA submissions are expected to have launch dates in the foreseeable future.

Products in Development

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

***Aveed*™.** Aveed™ is a novel, long-acting injectable testosterone preparation for the treatment of male hypogonadism. If approved, Aveed™ would be the first long-acting 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 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 January 2010, the U.S. patent office issued a Notice of Allowance covering the formulation of Aveed™. Accordingly, Aveed s patent should expire no earlier than late 2025.

Male hypogonadism is an increasingly recognized medical condition characterized by a reduced or absent secretion of testosterone from the testes. Reduced testosterone levels can lead to health problems and significantly impair quality of life. Common effects of hypogonadism include decreased sexual desire, erectile dysfunction, muscle loss and weakness, depression, and an increased risk of osteoporosis. In the United States alone, it is estimated that 13.8 million men have low testosterone levels; however, only about 9% are currently being treated.

In June 2008, an approvable letter was received from the FDA indicating that the Aveed™ NDA may be approved if the Company is able to adequately respond to certain clinical deficiencies related to the product. In September 2008, an agreement was reached with the FDA with regard to the additional data and risk management strategy. In March 2009, the FDA accepted for review the complete response submission to the new drug application for Aveed™.

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On December 2, 2009, we received a complete response letter from the FDA regarding Aveed™. In the complete response letter, the FDA has requested information from Endo to address the agency s concerns regarding rare but serious adverse events, including post-injection anaphylactic reaction and pulmonary oil microembolism. The letter also specified that the proposed Risk Evaluation and Mitigation Strategy (referred to as REMS) is not sufficient. The Company is continuing to evaluate how best to address the concerns of the FDA and intends to have future dialogue with the agency regarding a possible regulatory pathway. As a result of the new developments, the Company recorded a $65 million impairment charge during the fourth quarter of 2009. Offsetting this charge is a credit of $125 million, reflecting a reduction in the liability on our balance sheet associated with contingent consideration payable to former Indevus shareholders in the event that the product is approved by the FDA on or before February 23, 2012, under the Nebido Contingent Cash Consideration Agreement entered into in connection with our acquisition of Indevus. The outcome of future communications with the FDA could have a material impact on (1) management s assessment of the overall probability of approval, (2) the timing of such approval, (3) the targeted indication or patient population and (4) the likelihood of additional clinical trials.

Fortesta **.** Fortesta is a patented two percent (2%) testosterone transdermal gel for testosterone replacement therapy in male hypogonadism, which utilizes a metered dose delivery system designed to permit accurate dose adjustment to individual patient requirements. In August 2009, we entered into a License and Supply Agreement (referred to as the ProStrakan Agreement) with Strakan International Limited, a subsidiary of ProStrakan Group plc (referred to as ProStrakan), for the exclusive right to commercialize Fortesta in the U.S.

In October 2009, we received a Complete Response letter from the FDA regarding the NDA for Fortesta . The letter will require us to undertake a re-analysis of the existing clinical samples, and we will need to undertake a wash-off study to evaluate the risk of transference. The Company will continue to work closely with the FDA to address its questions, and we expect to file a complete response in mid-2010. Under the ProStrakan Agreement, the milestone payment to ProStrakan related to FDA approval of Fortesta is reduced the longer such approval takes.

Octreotide implant. The octreotide implant utilizes our patented Hydron® Polymer Technology to deliver six months of octreotide, a long-acting octapeptide that mimics the natural hormone somatostatin to block production of growth hormone (referred to as GH), for the treatment of acromegaly.

Acromegaly is a chronic hormonal disorder that occurs when a tumor of the pituitary gland causes the excess production of GH. It usually affects middle-aged adults and, if untreated, causes enlargement of certain bones, cartilage, muscles, organs and other tissue, leading to serious illness and potential premature death. There are approximately 1,000 new acromegalic patients diagnosed per year and 16,000 total patients in the United States.

In November 2007, positive results from the Phase II trial in patients with acromegaly showed that the octreotide implant effectively suppressed levels of GH and IGF-1 at rates similar to those seen with current FDA approved injectable formulations of octreotide. In addition, the drug was well tolerated. In September 2008, a Phase III clinical trial was initiated. The trial is designed to test the efficacy, safety and tolerability of the octreotide implant in patients with acromegaly. Approximately 34 clinical sites in six countries are participating in the open-label trial. The trial will include approximately 140 patients in the U.S. and Europe and enrollment is expected to be complete in mid-2010.

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

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Urocidin **.** Urocidin is a patented formulation of Mycobacterial Cell Wall-DNA Complex (referred to as MCC) developed by Bioniche Life Sciences Inc. and Bioniche Urology Inc. (collectively referred to as 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 we 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.

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

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.

Competition

The pharmaceutical industry is highly competitive. Our products compete with products manufactured by many other companies in highly competitive markets throughout the United States. Our competitors vary depending upon therapeutic and product categories. Competitors include the major brand name and generic manufacturers of pharmaceuticals doing business in the United States, including Abbott Laboratories, Johnson & Johnson, King Pharmaceuticals, Inc., Mallinckrodt Inc., Pfizer, Inc., Purdue Pharma, L.P., Cephalon, Inc., and Watson Pharmaceuticals, Inc.

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.

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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 of the generic products 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.

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

The Company is aware of certain competitive activities involving Lidoderm® , Opana® ER, and Sanctura XR®. For a full description of these competitive activities, including the litigation related to paragraph IV filings, see Note 14 of the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

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 sell our products directly to a limited number of large pharmacy chains and through a limited number of wholesale drug distributors who, in turn, supply products to pharmacies, hospitals, governmental agencies and physicians. Net sales to customers who accounted for 10% or more of our net sales during the years ended December 31 are as follows:

	2009	2008	2007
Cardinal Health, Inc.	35%	36%	34%
McKesson Corporation	29%	31%	31%
AmerisourceBergen Corporation	16%	15%	15%

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

Patents, Trademarks, Licenses and Proprietary Property

As of February 19, 2010, we held approximately: 50 U.S. issued patents, 40 U.S. patent applications pending, 287 foreign issued patents, and 127 foreign patent applications pending. In addition, as of February 19, 2010, we have licenses for approximately: 70 U.S. issued patents, 31 U.S. patent applications pending, 147 foreign issued patents and 48 foreign patent applications pending.

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

We believe that our patents, the protection of discoveries in connection with our development activities, our proprietary products, technologies, processes and know-how and all of our intellectual property are important to our business. All of our brand products and certain generic products, such as Endocet® and Endodan®, are sold under trademarks. To achieve a competitive position, we rely on trade secrets, non-patented proprietary know-how and continuing technological innovation, where patent protection is not believed to be appropriate or attainable. In addition, as outlined above, we have a number of patent licenses from third parties, some of which may be important to our business. See Note 6 in Part IV Item 15 of this Annual Report on Form 10-K. There can be no assurance that any of our patents, licenses or other intellectual property rights will afford us any protection from competition.

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

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

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Governmental Regulation

The manufacture, development, testing, packaging, labeling, distribution, sales and marketing of our products and our ongoing product development activities are subject to extensive and rigorous regulation at both the federal and state levels. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other federal and state statutes and regulations govern or influence the testing, manufacture, safety, 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 sanctions 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 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 revoke previously granted drug approvals. Product development and approval within this regulatory framework requires a number of years and involves the expenditure of substantial resources.

The current FDA standards of approving new pharmaceutical products are more stringent than those that were applied in the past. These standards 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 addition, the lack of such databases may lead to more requests for post-marketing testing.

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, may indicate the potential for having mutagenic effects. If, after testing, such effects are ultimately demonstrated to exist, more stringent controls of the levels of these impurities may be required for FDA approval of products containing these impurities, such as oxymorphone. Also, 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 regulations or legal interpretations, when and if promulgated, 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 (referred to as 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 pose serious safety risks, and authority to require Risk Evaluation and Mitigation Strategies (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.

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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 Process

FDA approval is typically required before any new drug can be marketed. An NDA 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 NDA must contain complete preclinical and clinical safety and efficacy data or a reference to such data. Before the dosing of a new drug in healthy human subjects or patients may begin, stringent government requirements for preclinical data must be satisfied. The preclinical data, typically obtained from studies in animals, as well as from laboratory studies, are submitted in an Investigational New Drug application, or IND, or its equivalent in countries outside the United States where clinical trials are to be conducted. The preclinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initiation of clinical trials.

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.

Data from preclinical testing and clinical trials are submitted to the FDA in an NDA for marketing approval and to other health authorities as a marketing authorization application. The process of completing clinical trials for a new drug may take several years and require the expenditures of substantial resources. Preparing an NDA 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 or other health authorities may deny an NDA or marketing authorization application if the regulatory criteria are not satisfied, or such authorities may require additional testing or information.

As a condition of approval, the FDA or other regulatory authorities may require further studies, including Phase IV post-marketing studies to provide additional data. In September 2007, Congress passed legislation authorizing FDA to require companies to undertake such studies to assess the risks of drugs known or signaling potential to have serious safety issues. Other post-marketing studies could be used to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested. Also, the FDA or other regulatory authorities require post-marketing reporting to monitor the adverse effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the products.

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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 initiative, the FDA has created a Drug Safety Oversight Board to provide independent oversight and advice to the Center for Drug Evaluation and Research 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. As part of this program, the FDA has also begun publishing a newsletter that contains non-confidential, non-proprietary information regarding post-marketing review of new drug products.

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

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 implemented, 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 (referred to as 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, 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 (referred to as the BPCA). The legislation also contained provisions to expedite new drug development, and collect data and results from clinical trials of drug products more readily available via a registry managed by the National Institutes of Health. These provisions, depending on how they are implemented by FDA, could impact our ability to market existing and new products.

Section 505(b)(2) of the Federal Food Drug and Cosmetic Act provides a procedure for an applicant to seek approval of a drug 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

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systemically acting test and reference drugs are the same, the two drugs are 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 (RLD) 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 seeks and receives 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 debarment and other penalties on individuals and companies that commit certain illegal acts relating to the drug approval process. In some situations, the Generic Act requires 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 provides for temporary denial of approval of applications during the investigation of certain violations that could lead to debarment and also, in more limited circumstances, provides for the suspension of the marketing 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.

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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, this marketing exclusivity would begin to run upon the earlier of the commercial launch of the generic product or upon an appellate court decision in the generic company s favor.

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

Quality Assurance Requirements

The FDA enforces regulations to ensure that the methods used in, and facilities and controls used for, the manufacture, processing, packing and holding of drugs conform with current good manufacturing practices, or cGMP. The cGMP regulations the FDA enforces are comprehensive and cover all aspects of 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. 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 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 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 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. In respect to domestic establishments, the FDA could initiate product seizures or request product recalls and seek to enjoin a product s manufacture and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with cGMP requirements, sanctions may be imposed that include preventing that company from receiving the necessary licenses to export its products and classifying that company as an unacceptable supplier , thereby disqualifying that company from selling products to federal agencies.

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

Following a routine FDA inspection in September 2007 primarily in the area of drug safety, an FDA 483 Inspectional Observation Form was issued to us detailing two observations that were made by the inspector. The observations focused on procedures for handling product complaints and recordkeeping regarding adverse drug

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experiences for the required period of time. We provided to the FDA comprehensive remediation plans which address the issues outlined in the observations along with the timeline for completing the corrective actions. Implementation of the remediation plans was completed in January 2009.

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 or other regulatory authority. 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. Failure to adhere to such requirements can result in regulatory actions that 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, which establishes certain security and record keeping requirements administered by the U.S. Drug Enforcement Administration (referred to as the DEA). The DEA is concerned with the control of registered handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances, with Schedule I and II substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in some of our current products and products in development, including oxycodone, oxymorphone, morphine, sufentanil, fentanyl and hydrocodone, are listed by the DEA as Schedule II or III substances under the Controlled Substances Act of 1970. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation. For example, 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, and we must annually apply to the DEA for procurement quota in order to obtain these substances. As a result, our procurement quota of these active ingredients may not be sufficient to meet commercial demand or complete clinical trials. Any delay or refusal by the DEA in establishing our procurement quota for controlled substances could delay or stop our clinical trials, 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. Facilities that conduct research, manufacture or distribute controlled substances must be registered to perform these activities and 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.

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

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 rebate to

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individual states a percentage of their net sales arising from Medicaid-reimbursed products. 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.

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug Improvement and Modernization Act of 2003. This law, which was fully implemented in January 2006, created a new prescription drug coverage program for people with Medicare through a new system of private market insurance providers. This benefit 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 decrease prices that can be charged by pharmaceutical manufacturers.

Currently, uncertainty exists regarding the healthcare reform legislation currently being considered by Congress. While proposals currently being contemplated have the potential to increase the number of U.S. residents with access to health care services, they also have the potential to impose new costs and decrease prices that can be charged by the pharmaceutical industry.

Service Agreements

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

Manufacturing, Supply and Other Service Agreements

We contract with various third party manufacturers and suppliers to provide us with raw materials used in our products and finished goods. Our most significant agreements are with Novartis Consumer Health, Inc., Novartis AG, Teikoku Seiyaku Co., Ltd., Mallinckrodt Inc., Almac Pharma Services, and Sharp Corporation. In addition, through our agreement with Ventiv Commercial Services, LLC, we maintain a contracted sales force consisting of 80 pharmaceutical representatives. 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, this may have a material adverse effect on our business, financial condition, results of operations and cash flows.

For a complete description of these agreements, see Note 14 of the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

Acquisitions, License and Collaboration Agreements

We continue to seek to enhance our product line and develop a balanced portfolio of differentiated products through selective product acquisitions and in-licensing, or acquiring licenses to products, compounds and technologies from third parties or through company acquisitions. The Company enters into strategic alliances and collaborative arrangements with third parties, which give the Company rights to develop, manufacture, market and/or sell pharmaceutical products, the rights to which are primarily owned by these third parties. These alliances and arrangements can take many forms, including licensing arrangements, co-development and co-marketing agreements, co-promotion arrangements, research collaborations and joint ventures. Such alliances and arrangements enable us to share the risk of incurring all research and development expenses that do not lead to revenue-generating products; however, because profits from alliance products are shared with the 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 6.

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Acquisitions, License and Collaboration Agreements, included in the consolidated financial statements in Part IV, Item 15 of this Annual Report on Form 10-K.

Environmental Matters

Our operations are subject to substantial and evolving federal, state and local environmental laws and regulations concerning, among other matters, the generation, handling, storage, transportation, treatment and disposal of toxic and hazardous substances. We believe that our facilities and the facilities of our third party service providers are in substantial compliance with all provisions of federal, state and local laws concerning the environment and do not believe that future compliance with these provisions will have a material adverse effect on our financial condition or results of operations.

Employees

As of February 19, 2010, we had 1,487 employees, of which 148 are engaged in research and development and regulatory work, 965 in sales and marketing, 34 in quality assurance and 340 in general and administrative capacities. Our employees are not represented by unions, and we believe that our relations with our employees are good.

Executive Officers of the Registrant

Set forth below is information regarding each of our current executive officers, as of February 19, 2010:

Name	Age	Position and Offices
David P. Holveck	64	President and Chief Executive Officer and Director
Alan G. Levin.	47	Executive Vice President, Chief Financial Officer
Ivan Gergel, M.D.	49	Executive Vice President, Research and Development
Caroline B. Manogue	41	Executive Vice President, Chief Legal Officer and Secretary
Edward J. Sweeney	40	Vice President, Controller and Principal Accounting Officer

DAVID P. HOLVECK, 64, was appointed President, Chief Executive Officer, and a Director of Endo in April 2008. Prior to joining Endo, Mr. Holveck was President of Johnson & Johnson Development Corporation and Vice President, Corporate Development of Johnson & Johnson since 2004. Mr. Holveck joined Johnson & Johnson as a company Group Chairman in 1999, following the acquisition of Centocor, Inc., 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 held positions at General Electric Company, Corning Glass Works, and Abbott Laboratories. Mr. Holveck is a member of the Board of Trustees for the Fund for West Chester University, the Board of Directors of the Eastern Technology Council, the Board of Directors of Light Sciences Oncology, Inc. and the Board of Directors of the Pharmaceutical Research and Manufacturers of America (PhRMA).

ALAN G. LEVIN, 47, was appointed Executive Vice President and Chief Financial Officer, on May 5, 2009. Prior to joining Endo, Mr. Levin worked with Texas Pacific Group, a leading private equity firm, and one of its 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*.

IVAN GERGEL, M.D., 49, was appointed Executive Vice President, Research & Development in April 2008. In this role, he has full responsibility for all of the Company s R&D activities, including direct supervision of clinical research, pre-clinical R&D, medical affairs, marketed product development support, regulatory affairs, project management and drug safety and surveillance. Prior to joining Endo, Dr. Gergel was Senior Vice

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President of Scientific Affairs and President of the Forest Research Institute of Forest Laboratories Inc., managing more than 900 physicians, scientists and staff at the Research Institute. Prior to that, Dr. Gergel served as Vice President and Chief Medical Officer at Forest and Executive Vice President of the Forest Research Institute. He joined Forest in 1998 as Executive Director of Clinical Research following nine years at SmithKline Beecham, and was named Vice President of Clinical Development and Clinical Affairs in 1999. Dr. Gergel received his M.D. from the Royal Free Medical School of the University of London and an MBA from the Wharton School. Dr. Gergel is a member of the Board of Directors of Pennsylvania BIO and a member of PhRMA s Research and Development Executive Committee.

CAROLINE B. MANOGUE, 41, has served as Executive Vice President, Chief Legal Officer and Secretary since 2004 and was previously Endo s Senior Vice President, General Counsel and Secretary. Prior to joining Endo in 2000, she was an associate at the law firm Skadden, Arps, Slate, Meagher & Flom LLP in New York City. She has more than 14 years experience in securities and M&A law. Ms. Manogue received her J.D. from Fordham Law School and her B.A. cum laude from Middlebury College. Ms. Manogue is a member of PhRMA s Law Section Executive Committee and the Board of Trustees of the Healthcare Institute of New Jersey.

EDWARD J. SWEENEY, 40, is the Company s Vice President, Controller and Principal Accounting Officer. Mr. Sweeney has been Vice President, Controller since June 2007 after having joined the Company in March 2004 as Director, Financial Reporting. Prior to joining Endo, Mr. Sweeney was a Senior Manager at Ernst & Young LLP, where he worked from September 1991 through March 2004. Mr. Sweeney is a licensed certified public accountant in the Commonwealth of Pennsylvania and holds a BS degree in Accounting from St. Joseph s University.

We have employment agreements with each of our executive officers, except Mr. Sweeney.

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 products and from companies with which we compete to acquire rights to intellectual property assets.

The pharmaceutical industry is intensely competitive, and we face competition across the full range of our activities. If we fail to compete successfully in any of these areas, our business, results of operations, financial condition and cash flows could be adversely affected. Our competitors include many of the major brand name and generic manufacturers of pharmaceuticals, especially those doing business in the United States. In the market for branded pharmaceutical products, our competitors, including Abbott Laboratories, Johnson & Johnson, King Pharmaceuticals Inc., Cephalon, Inc., Pfizer, Inc., Purdue Pharma, L.P., Allergan, Inc., and Watson Pharmaceuticals Inc., vary depending on product category, dosage strength and drug-delivery systems. In addition to product safety, development and efficacy, other competitive factors in the branded pharmaceutical market include product quality

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and price, reputation, service and access to scientific and technical information. It is possible that developments by our competitors will make our products or technologies uncompetitive or obsolete. Because we are smaller than many of our national competitors in the branded pharmaceutical products sector, we may lack the financial and other resources needed to maintain our profit margins and market share in this sector.

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

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

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

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

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

The FDCA Act requires an applicant for a drug that relies, at least in part, on the patent of one of our branded drugs to notify us of their application and potential infringement of our patent rights. Upon receipt of this notice we have 45 days to bring a patent infringement suit in federal district court against the company seeking approval of a product covered by one of our patents. The discovery, trial and appeals process in such suits can take several years. If such a suit is commenced, the FDCA Act provides a 30-month stay on the FDA s approval of the competitor s application. Such litigation is often time-consuming and quite costly and may result in generic competition if such patent(s) are not upheld or if the generic competitor is found not to infringe such 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.

In December 2006, the Division of Bioequivalence, Office of Generic Drugs, Center for Drug Evaluation and Research (referred to as OGD), issued draft guidance making recommendations regarding establishing bioequivalence with our patent-protected product, Lidoderm® (lidocaine topical patch 5%), pursuant to which a

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party could seek ANDA approval of a generic version of that product. In that draft guidance, OGD has recommended a bioequivalence study characterizing the pharmacokinetic profile of lidocaine as well as a skin irritation/sensitization study of any lidocaine-containing patch formulation. This recommendation deviates from our understanding of the applicable regulations and of OGD s past practices, which, for a topically acting product such as Lidoderm®, would require demonstration of bioequivalence through a comparative clinical equivalency study rather than through a pharmacokinetic study.

On December 19, 2006, we submitted a Citizen Petition to the FDA requesting that the FDA apply existing bioequivalence regulations to any ANDA seeking regulatory approval of a generic drug product that references Lidoderm®. We submitted an amendment to that filing in August 2007 in order to provide additional data. Our Citizen Petition emphasizes that the FDA s recommendation deviates from applicable regulations and OGD s past practices, both of which contemplate demonstration of bioequivalence for a topically acting product like Lidoderm® through a comparative clinical efficacy study. We believe blood levels of the active ingredient, lidocaine, cannot properly be used as the key measure in proving bioequivalence. To appropriately assess the efficacy and safety of any generic version of Lidoderm®, we believe that it is critical that the FDA require any ANDA applicant relying on Lidoderm® as its reference listed drug satisfy the regulations by conducting comparative clinical studies demonstrating (1) bioequivalence between the generic version and Lidoderm®, and (2) that the generic version produces the same local analgesic effect as Lidoderm® without producing a complete sensory block, in order to assure that the generic product has the same labeling, efficacy and safety profile as Lidoderm®. The FDA has not acted on our Citizen Petition, and it is unclear whether or not the FDA will agree with our position. In addition to this Petition, on September 28, 2007, we filed comments with the FDA regarding the draft guidance; those comments reiterated our position as set forth in the Citizen Petition, referencing the Citizen Petition and supporting data. The draft guidance remains available and has not been updated or revised since being issued.

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., received a Paragraph IV certification notice under 21 U.S.C. 355(j) from Watson Laboratories, Inc. advising of the filing of an ANDA for a generic version of Lidoderm®. For a complete description of the related legal proceeding see Note 14 of the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

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

The filing of the aforementioned applications, or any other ANDA or Section 505(b)(2) NDA in respect to any of our branded drugs could have an adverse impact on our stock price. Moreover, if the patents covering our branded drugs, including Lidoderm® or Opana® ER, were not upheld in litigation or if a generic competitor is found not to infringe these patents, the resulting generic competition would have a material adverse effect on our business, results of operations, financial condition and cash flows.

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 expense of patent litigation, whether or not we are successful, could have an adverse effect on our business, results of operations, financial condition and cash flows. 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, in either case, whether because of the filing of an ANDA or otherwise, the uncertainties inherent in patent litigation make the outcome of such litigation difficult to predict. The cost of such litigation as well as the ultimate outcome of such litigation, if commenced, 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 displays our revenues by product category and as a percentage of total revenues for the years ended December 31 (dollars in thousands):

	2009		2008		2007	
	$	%	$	%	$	%
Lidoderm®	763,698	52	765,097	61	705,587	65
Opana® ER and Opana®	230,631	16	180,429	14	107,143	10
Percocet®	127,090	9	129,966	10	121,742	11
Voltaren® Gel	78,868	5	23,791	2		
Frova®	57,924	4	58,017	5	52,437	5
Other brands	68,635	5	10,904	1	11,065	1
Total brands	1,326,846	91	1,168,204	93	997,974	92
Total generics	124,731	9	92,332	7	87,634	8
Total royalty and other revenues	9,264	*				
Total revenues	1,460,841	100	1,260,536	100	1,085,608	100

* Amount less than 1%.

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

Our ability to protect our proprietary technology, which is vital to our business, is uncertain.

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

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our products. Litigation to establish the validity of patents, to defend against patent infringement claims of others and to assert patent infringement claims against others can be expensive and time-consuming even if the outcome is favorable to us. If the outcome is unfavorable to us, this could have a material adverse effect on our business. We have taken and may, in the future, take steps to enhance our patent protection, but we cannot assure you that these steps will be successful or that, if unsuccessful, our patent protection will be adequate.

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

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

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

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

Companies may not promote drugs for off-label uses that is, uses that are not described in the product s labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician s choice of treatments, the Federal Food, Drug and Cosmetics Act and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services (referred to as OIG), the FDA, and the Department of Justice (referred to as DOJ) all actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the OIG, the FDA, and DOJ allow companies to engage in truthful, non-misleading, and non-promotional speech concerning their products. The Company has endeavored to establish extensive compliance programs in order to instruct employees as to how to comply with the relevant legal requirements. Nonetheless, the OIG or the FDA 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 civil and administrative remedies, as well as criminal sanctions. In addition, management s attention could be diverted from our business operations and our reputation could be damaged.

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

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

The FDA provides guidelines with respect to appropriate promotion and continuing medical and health education activities. Although we endeavor to follow these guidelines, should it be determined that we have not appropriately followed these guidelines, the government may initiate an action against us which may result in significant liability, including civil and administrative remedies as well as criminal sanctions. Such penalties could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, management s attention could be diverted and our reputation could be damaged.

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

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. Specifically, these anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, or pay any remuneration in exchange for purchasing, leasing or ordering any service or items including the purchase or prescription of a particular drug for which payment may be made under a federal healthcare program. Because of the sweeping language of the federal anti-kickback statute, many potentially beneficial business arrangements would be prohibited if the statute were strictly applied. To avoid this outcome, the U.S. Department of Health and Human Services has published regulations known as safe harbors that identify exceptions or exemptions to the statute s prohibitions. Arrangements that do not fit within the safe harbors are not automatically deemed to be illegal, but must be evaluated on a case-by-case basis for compliance with the statute. We seek to comply with anti-kickback statutes and to fit within one of the defined safe harbors ; we are unaware of any violations of these laws. However, due to the breadth of the statutory provisions and the absence of uniform guidance in the form of regulations or court decisions, there can be no assurance that our practices will not be challenged under anti-kickback or similar laws. Violations of such restrictions may be punishable by civil and/or criminal sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from U.S. federal healthcare programs (including Medicaid and Medicare). Any such violations could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In addition, the FDA has the authority to regulate the claims we make in marketing our prescription drug products to ensure that such claims are true, not misleading, supported by scientific evidence and consistent with the labeled use of the drug. Failure to comply with FDA requirements in this regard could result in, among other things, suspensions of approvals, seizures or recalls of products, injunctions against a product s manufacture, distribution, sales and marketing, operating restrictions, civil penalties and criminal prosecutions.

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

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lawsuits, including class action lawsuits, related to OxyContin® misuse or abuse. On June 7, 2005, we began commercial sale of our oxycodone extended-release tablets, 10mg, 20mg, 40mg and 80mg strengths, each bioequivalent versions of OxyContin®. Pursuant to a settlement agreement with Purdue, all sales of our oxycodone extended-release tablets ceased as of December 31, 2006. However, we may be subject to litigation similar to the OxyContin® suits related to any narcotic-containing product that we market.

The FDA or 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 REMS, restrictions on prescription and sale of these products and mandatory reformulation of our products in order to make abuse more difficult. On September 27, 2007, Congress passed legislation authorizing the FDA to require companies to undertake post-approval studies in order to assess known or signaled potential serious safety risks and to make any labeling changes necessary to address safety risks. Congress also empowered the FDA to require companies to formulate REMS to ensure a drug s benefits outweigh its risks. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse. In either case, any such new regulations or requirements may be difficult and expensive for us to comply with, may delay our introduction of new products, may adversely affect our total revenues and may have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

Federal, state and local governmental authorities in the United States, principally the FDA, impose substantial requirements on the development, manufacture, labeling, sale, distribution, marketing, advertising, promotion and introduction of therapeutic pharmaceutical products through lengthy and detailed laboratory and clinical testing and other costly and time-consuming procedures. The submission of an NDA or ANDA to the FDA alone does not guarantee that the FDA will grant approval to market the product. Satisfaction of FDA requirements typically takes a number of years, varies substantially based upon the type, complexity and novelty of the pharmaceutical product and 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 for which a company may seek to market a product. The FDA actively enforces regulations prohibiting marketing of products for unapproved uses. The FDA also requires companies to undertake post-approval surveillance regarding their drug products and to report any adverse events. Failure to comply with applicable regulatory requirements in this regard can result in, among other things, suspensions or withdrawals of approvals, seizures or recalls of products, injunctions against a product s manufacture, distribution, sales and marketing, operating restrictions, civil penalties and criminal prosecutions. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals. The effect of government regulation may be to delay marketing of our new products for a considerable period of time, to impose costly procedures upon our activities and to furnish a competitive advantage to larger companies that compete against us.

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

The current FDA standards of approving new pharmaceutical products are more stringent than those that were applied in the past. These standards 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.

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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, Congress enacted 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.

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 enforce their statutory authority and regulations using administrative remedies as well as civil and criminal sanctions.

The FDA regulates the facilities and procedures used to manufacture pharmaceutical products in the United States or for sale in the United States. Such facilities must be registered with the FDA and all products made in such facilities must be manufactured in accordance with current good manufacturing practices, or cGMP, regulations enforced by the FDA. Compliance with cGMP regulations requires the dedication of substantial resources and requires significant expenditures. The FDA periodically inspects our third party manufacturing facilities and procedures to assure compliance. The FDA may cause a recall or withdrawal of product approvals if regulatory standards are not maintained. The FDA approval to manufacture a drug is site-specific. In the event an approved manufacturing facility for a particular drug is required by the FDA to cease or curtail operations, or otherwise becomes inoperable, or the manufacturing contract applicable thereto terminates, obtaining the required FDA approval to manufacture such drug at a different manufacturing site could result in production delays, which could adversely affect our business, results of operations, financial condition and cash flow.

The stringent DEA regulations on our use of controlled substances include restrictions on their use in research, manufacture, distribution and storage. A breach of these regulations could result in imposition of civil penalties, refusal to renew or action to revoke necessary registrations, or other restrictions on operations involving controlled substances. See also The DEA limits the availability of the active ingredients used in many of our current products and products in development and, as a result, our procurement quota may not be sufficient to meet commercial demand or complete clinical trials.

We cannot determine what effect changes in regulations or legal interpretations, when and if promulgated, may have on our business in the future. 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 of these products. On February 6, 2009, the FDA sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a REMS to ensure that the benefits of the drugs continue to outweigh the risks. The FDA has authority to require a REMS under the FDAAA when necessary to address whether the benefits of these products continue to outweigh the risks. On September 27, 2007, Congress

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enacted new requirements for testing drug products in children, which may increase the time and cost necessary for new drug development. In addition, 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 certain types of 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. See If generic manufacturers use litigation and regulatory means to obtain approval for generic versions of our branded drugs, our sales may suffer. 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.

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 are advisory in nature and the FDA is not bound to follow these recommendations. At this time, the FDA has not made any decisions regarding acetaminophen-containing products, but has stated that it is reviewing the recommendations of the advisory committee, all available safety and efficacy data as well as public input before making a final decision. Therefore it is unclear what actions the FDA may take in response to the panel s recommendations. Implementation by the FDA of certain specific panel recommendations could result in (1) a black box warning on the labels of prescription acetaminophen combination products or (2) the removal of several products from the marketplace including certain, or even all, strengths of Percocet® and Endocet®. The recommendation does not change the safety and efficacy of Percocet® and Endocet®, which remain FDA approved. Endo remains committed to working with the FDA so that these products are prescribed in the best interest of patients, and we will continue to closely monitor this issue. Any action taken by the FDA to implement certain of the recommendations of the panel, or take other measures to address concerns raised by the panel, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

Before obtaining regulatory approvals for the sale of any of our products, other than generic products, we must demonstrate through preclinical studies and clinical trials that the product is safe and effective for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product. Even promising results from preclinical and early clinical studies do not always accurately predict results in later, large scale trials. A failure to demonstrate safety and efficacy would result in our failure to obtain regulatory approvals.

The rate of patient enrollment sometimes delays completion of clinical studies. There is substantial competition to enroll patients in clinical trials and such competition has delayed clinical development of our products in the past. Delays in planned patient enrollment can result in increased development costs and delays in regulatory approval. In addition, we rely on collaboration partners that may control or make changes in trial protocol and design enhancements that may also delay clinical trials. We cannot assure you that we will not experience delays or undesired results in these or any other of our clinical trials.

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We cannot assure you that the FDA or other regulatory agencies will approve any products developed by us, on a timely basis, if at all, or, if granted, that such approval will not subject the marketing of our products to certain limits on indicated use. Any limitation on use imposed by the FDA or delay in or failure to obtain FDA approvals of products developed by us would adversely affect the marketing of these products and our ability to generate product revenue, as well as adversely affect the price of our common stock.

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

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

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

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

Acquisitions, such as the recent Indevus acquisition, 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 consolidated financial statements may be impacted in future periods based on the accuracy of our valuation of the Indevus business.

Accounting for our acquisition of Indevus involved a complex and subjective valuation of the assets and liabilities of Indevus, which have been recorded in the Company s consolidated financial statements pursuant to authoritative guidance for business combinations. Differences between the inputs and assumptions used in the valuation and actual results could have a significant impact on our consolidated financial statements in future periods.

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

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

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

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

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

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

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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.

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

Our generic products compete with branded products and with generic versions made by or for other manufacturers, such as Mallinckrodt Inc. and Watson Pharmaceuticals, Inc. When additional versions of one of our generic products enter the market, we generally lose market share and our selling prices and margins on the product decline. Because we are smaller than many of our full-line competitors in the generic pharmaceutical products sector, we may lack the financial and other resources needed to maintain our profit margins and market share in this sector.

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

Pharmaceutical companies that produce patented brand products are increasingly employing a range of legal and regulatory strategies to delay the introduction of competing generics and certain other products to which we do not have a right of reference to all necessary preclinical and clinical data. Opposing such measures 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 Federal Food, Drug and Cosmetic Act, where we rely on information to which we do not have a right of reference. Once the FDA accepts our ANDA or Section 505(b)(2) NDA, we are required to notify the brand manufacturer of this fact. The brand manufacturer then has 45 days from the receipt of the notice in which to sue us 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 our favor (including through appeal to any federal Court of Appeals) or expiration of the patent(s).

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

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

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

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

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

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug Improvement and Modernization Act (Medicare Modernization Act) of 2003. The Medicare Modernization Act created a new prescription drug coverage program for people with Medicare through a new system of private market insurance providers; the program began in January 2006. This new benefit has resulted in an increased use of formularies (listings of prescription drugs approved for use) such that, in the event a Medicare beneficiary s medications are not listed on the applicable formulary, such Medicare beneficiary may not receive reimbursement for such medications. Moreover, once these formularies are established, Medicare is not obligated to pay for drugs omitted from a formulary, and the cost of these non-covered drugs will not be counted towards the $3,600 annual out-of-pocket beneficiary deductible established by the Medicare Modernization Act. Further, since 2006, Medicare prescription drug program beneficiaries are not permitted to purchase private insurance policies, known as Medigap policies, to cover the cost of off-formulary medications. If our products are or become excluded from these formularies, demand for our products might decrease and we may be forced to lower prices for our products, which may adversely affect our business, financial condition, results of operations and cash flows.

From time to time, state Medicaid programs review our products to assess whether such products should be subject to a prior authorization process, which processes vary state-by-state but generally require physicians prescribing the products to answer several questions prior to the product being dispensed. The institution of a prior authorization process may adversely impact the sales of the related product in the state and depending on the state, may adversely affect our business and results of operations. On February 20, 2008, in connection with its Clinical Drug Review Program, the Pharmacy and Therapeutics Committee of the New York State Department of Health reviewed our product Lidoderm® and recommended that it be subject to a prior authorization process. As a result, on July 31, 2008, the New York State Department of Health placed Lidoderm® in its Clinical Drug Review Program, which is a specific program within its prior authorization program. There can be no assurance that such a process, or the institution 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 third party payers do not provide adequate coverage and reimbursement levels for users of our products, the market acceptance of these products could be adversely affected. In addition, the following factors could significantly influence the purchase of pharmaceutical products, which would result in lower prices and a reduced demand for our products that might force us to reduce the price of these products to remain competitive:

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

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On February 17, 2009, President Obama signed into law the American Recovery and Reinvestment Act of 2009, which appropriates $1.1 billion to fund comparative effectiveness research (referred to as CER) relating to healthcare treatments. Although the concept of CER now has significant momentum, numerous unresolved and potentially contentious issues remain, and stakeholders are following implementation of this new law closely. Depending on whether and, if so, how CER is implemented, CER could possibly present regulatory, and reimbursement issues under certain circumstances. On February 26, 2009, President Obama released his fiscal 2010 budget, which included approximately $43 billion in new revenue from biopharmaceutical companies. The impact of the President s proposed budget on the Company s business, financial condition, results of operations and cash flows is not yet known. President Obama released his fiscal year (FY) 2011 budget which proposes $3.8 trillion in spending. The President s budget serves as an important marker for policy proposals and the Administration s preferences. The FY 2011 budget includes a $743 billion allowance for health insurance reform. This allowance demonstrates the Administration s commitment to enacting fundamental reforms to the U.S. health care delivery system, which may have an impact on the Company s business.

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

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

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

We and other pharmaceutical companies are defendants in a number of lawsuits filed by local and state government entities, alleging generally that we and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid. We intend to defend these lawsuits vigorously. Depending on developments in the litigation however, as with all litigation, there is a possibility that we will suffer adverse decisions or verdicts of substantial amounts, or that we will enter into monetary settlements in one or more of these actions as we recently did with a number of New York counties. See Legal proceedings in Note 14 of the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K. Any unfavorable outcomes as a result of such litigation could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Government regulations regarding reporting and payment obligations are complex and we are continually evaluating the methods we use to calculate and report the amounts owed with respect to Medicaid and other government pricing programs. Our calculations are subject to review and challenge by various government agencies and authorities and it is possible that any such review could result either in material changes to the method used for calculating the amounts owed to the pertinent government agency (or agencies), or to the amounts themselves. In addition, because our processes for these calculations and our judgments supporting these calculations involve, and will continue to involve, subjective decisions, these calculations are subject to the risk of errors. As noted above, any governmental agency that commences an action, if successful, could impose,

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based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal healthcare programs (including Medicaid and Medicare). Some of the applicable laws impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments and even in the absence of such ambiguity a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. Any such penalties or sanctions could have a material adverse effect on our business, financial position, results of operations and cash flows, and could cause the market value of our common stock to decline.

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

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

We 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. Net sales to customers who accounted for 10% or more of our net sales during the years ended December 31 were as follows:

	2009	2008	2007
Cardinal Health, Inc.	35%	36%	34%
McKesson Corporation	29%	31%	31%
AmerisourceBergen Corporation	16%	15%	15%

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 net sales, profitability and cash flows could be materially and adversely affected.

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

Third party manufacturers currently manufacture substantially all of our products pursuant to contractual arrangements. Certain of our manufacturers currently constitute the sole source of one or more of our products. Because of contractual restraints and the lead-time necessary to obtain FDA approval, and possibly DEA registration, of a new manufacturer, replacement of any of these manufacturers may be expensive and time consuming and may cause interruptions in our supply of products to customers. As a result, any such delay could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Because all 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,

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interruptions in our supply of products or lapses in quality could adversely impact our margins, profitability and cash flows. We are reliant on our third party manufacturers to maintain the facilities at which they manufacture our products in compliance with FDA, DEA, state and local regulations. If they fail to maintain compliance with FDA, DEA or other critical regulations, they could be ordered to cease manufacturing which would have a material adverse impact on our business, results of operations, financial condition and cash flows. In addition to FDA and DEA regulation, violation of standards enforced by the Environmental Protection Agency (referred to as the EPA), and the Occupational Safety and Health Administration (referred to as OSHA), and their counterpart agencies at the state level, could slow down or curtail operations of third party manufacturers.

We have entered into minimum purchase requirement contracts with some of our third party manufacturers. In May 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc. pursuant to which Novartis Consumer Health Inc. has agreed to manufacture certain of our commercial products in addition to products in development. As of December 31, 2009, we are required to purchase a minimum of approximately $20 million in 2010 and approximately $21 million of product from Novartis Consumer Health Inc. in 2011.

We also have a long-term contract with Teikoku Seiyaku Co., Ltd. (referred to as Teikoku), under which Teikoku manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. We agreed to purchase a minimum number of patches per year from Teikoku through 2012, representing the noncancelable portion of the Teikoku agreement. Teikoku has agreed to fix the supply price of Lidoderm® for a period of time after which the price will be adjusted at future set dates based on a price index defined in the Teikoku agreement. Since future price changes are unknown, we have used prices currently existing under the Teikoku agreement, and estimated our minimum purchase requirement to be approximately $32 million per year through 2012. The minimum purchase requirement shall remain in effect subsequent to 2012, except that we have the right to terminate the Teikoku agreement after 2012, if we fail to meet the annual minimum requirement.

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

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

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

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

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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.

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.

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

Furthermore, the DEA limits the availability of the active ingredients used in many of our current products and products in development and, as a result, our procurement quota of these active ingredients may not be sufficient to meet commercial demand or complete clinical trials. We must annually apply to the DEA for procurement quota in order to obtain these substances. Any delay or refusal by the DEA in establishing our procurement quota for controlled substances could delay or stop our clinical trials, 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.

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 expense of patent litigation, whether or not we are successful, could have an adverse effect on our business, results of operations, financial condition and cash flows. 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, in either case, whether because of the filing of an ANDA or otherwise, the uncertainties inherent in patent litigation make the outcome of such litigation difficult to predict. The cost of such litigation as well as the ultimate outcome of such litigation, if commenced, could have a material adverse effect on our business, results of operations, financial condition 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, 2009, $232.6 million of our marketable securities portfolio was invested in A, Aa, AAA, B, Ba and Baa 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. Pursuant to the Rights (described below), we may require UBS AG to purchase certain auction rate securities beginning on June 30, 2010.

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The underlying assets of our auction-rate securities are student loans. Student loans are insured by either the Federal Family Education Loan Program (referred to as FFELP), or a combination of FFELP and other monoline insurers such as Ambac Assurance Corp. (referred to as AMBAC) and MBIA Insurance Corp (referred to as MBIA). As of February 19, 2010, MBIA was rated Ba3 by Moody s and BB- by Standard and Poor s. AMBAC was rated Ca by Moody s and CC by Standard and Poor s.

Throughout 2009, the auction-rate securities market has continued to be inactive. If credit and capital markets deteriorate further or we experience any additional ratings downgrades on any investments in our portfolio (including on our auction-rate securities), we may incur additional impairments in future periods, which could negatively affect our financial condition, cash flow or reported earnings.

Any of these events could materially affect our results of operations and our financial condition. In the event we need to access these funds, we could be required to sell these securities at an amount below our original purchase value. However, based on our ability to access our cash and cash equivalents and our other liquid investments, and our expected operating cash flows, we do not expect to be required to sell these securities at a loss. However, there can be no assurance that we will not have to sell these securities at a loss.

In the event UBS AG becomes insolvent, UBS may not meet its obligations under the Rights.

On November 10, 2008, the Company accepted an offer (referred to as the UBS Offer) made by UBS AG (referred to as UBS) of auction-rate securities rights (referred to as the Rights) to the Company and other clients of UBS Securities LLC and UBS Financial Services Inc. (collectively referred to as the UBS Entities), pursuant to which the Company is entitled to sell to UBS all auction-rate securities held by the Company as of February 13, 2008 in a UBS account (referred to as the Eligible Auction-Rate Securities). The Rights permit the Company to require UBS to purchase the Eligible Auction-Rate Securities for a price equal to original par value plus any accrued but unpaid dividends or interest beginning on June 30, 2010 and ending on July 2, 2012 (referred to as the Expiration Date). Further, under the terms of the UBS Offer, the Company granted to the UBS Entities the sole discretion and right to sell or otherwise dispose of, and/or enter orders in the auction process with respect to the Eligible Auction-Rate Securities on the Company s behalf until the Expiration Date, without prior notification, so long as the Company receives a payment of par value plus any accrued but unpaid dividends or interest upon any sale or disposition.

As of December 31, 2009, we had Eligible Auction-Rate Securities with original par value of $230.3 million, representing 92% of our total auction-rate securities portfolio at par. The remaining eight percent (8%), or $18.8 million at par, of our auction-rate securities portfolio are not held in a UBS account and therefore are not subject to the UBS Offer.

The Rights are not secured by any assets of UBS. As a result, if UBS becomes insolvent in the future, UBS may become unable to meet its obligations under the Rights and may not purchase Eligible Auction Rate Securities from us.

Furthermore, pursuant to the terms of the Offer and related settlement, we are eligible for no net cost loans for an amount up to 75% of the market value of the Eligible Auction-Rate Securities at the time of the loan. In the event UBS becomes insolvent, secured creditors of UBS may be able to attach their secured interests to our no net cost loans. We have not yet entered into any loan arrangement with UBS.

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

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wholesalers and retailers will place competitive pressures on drug manufacturers, including us. If we lose any of these customer accounts, or if our relationship with them were to deteriorate, our business could also be materially and adversely affected. Orders for our products may increase or decrease depending on the inventory levels held by our major customers. Significant increases and decreases in orders from our major customers could cause our operating results to vary significantly from quarter to quarter.

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

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

Property, product liability, directors and officers and general liability insurance represent significant costs to us. Since the events of September 11, 2001, and due to an increased focus on corporate governance in the United States, and product liability lawsuits related to pharmaceuticals, liability and other types of insurance have become more difficult and costly to obtain. Unanticipated additional insurance costs could have a material adverse effect on our results of operations and cash flows. There can be no assurance that we will be able to maintain our existing insurance policies or obtain new policies in meaningful amounts or at a reasonable cost. Any failure to obtain or maintain any necessary insurance coverage could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

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

We 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, 2009, goodwill and other intangibles comprised approximately 37% of our total assets. Goodwill and other intangible assets are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually.

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

We are a holding company with no operations.

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

Our revenues and operating results may fluctuate in future periods and we may fail to meet expectations, which may cause the price of our common stock 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 price of our common stock 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. For example, in 2010, we have assumed that our sales of Lidoderm®, Opana® ER, Voltaren® Gel, Supprelin® LA and Valstar® will grow over the course of the year, but there can be no assurance that sales of these products will grow at the rates anticipated, or at all.

Our stock price may be volatile, and your investment in our common stock 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 the twelve months ended December 31, 2009, our stock traded between $15.75 and $26.14 per share. The following factors, in addition to other risk factors described in this section, may cause the market price of our common stock 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;
- competitors publicity regarding actual or potential products under development;
- regulatory developments in the United States and foreign countries, or announcements relating to these matters;

period-to-period fluctuations in our financial results;

new legislation in the United States relating to the development, sale or pricing of pharmaceuticals;

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

litigation; and

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

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If our stockholders sell substantial amounts of our common stock, the market price of our common stock may fall.

If our stockholders sell substantial amounts of our common stock, including shares issued upon the exercise of outstanding options, the market price of our common stock may fall. These sales also may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate.

Of the 6,635,782 shares that may be issued upon the exercise of options or vesting of restricted stock units outstanding as of December 31, 2009, 2,005,355 were vested, exercisable and eligible for sale.

We have not paid, and may not pay, dividends and therefore, unless our stock appreciates in value, investors in our stock may not benefit from holding our stock.

We have not paid any cash dividends since our inception. The payment of cash dividends is subject to the discretion of our Board of Directors and will be dependent on many factors, including our earnings, capital needs and general financial condition. Further, in October of 2009, we established a three-year senior secured revolving credit facility (referred to as the Credit Facility) with JP Morgan Chase Bank, Barclay s Capital and certain other lenders. Subject to certain limitations, we are permitted to pay dividends under the Credit Facility. We anticipate that, for the foreseeable future, we will retain our earnings in order to finance investments in our business. As a result, investors in our stock may not be able to benefit from owning our stock unless the shares that these investors acquire appreciate in value.

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

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

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

From time to time, studies or clinical trials on various aspects of pharmaceutical products are conducted by academics or others, including government agencies. The results of these studies or trials, when published, may have a dramatic effect on the market for the pharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our products compete could adversely affect our sales, the prescription trends for our products and the reputation of our products. In the event of the publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our products compete, our business, financial condition, results of operations and cash flows could be materially adversely affected. In addition, on September 27, 2007, Congress enacted requirements that the results of studies and clinical trials be provided by the investigator to the National Institutes of Health (referred to as NIH) for inclusion in a publicly-available database registry of clinical trials. There is an exception for clinical research performed on behalf of a sponsor who has not yet submitted an NDA in connection with the drug being studied; however, it is unclear what impact the potential publication of clinical research data for our products will have.

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

Campaigns by significant investors to effect changes at publicly traded companies have increased in recent years. In August 2007, affiliates of D.E. Shaw & Co., L.P., which collectively currently beneficially own approximately 8.3 million shares of our outstanding common stock, sent letters to our Board of Directors

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suggesting, among other things, that the Company begin a process of evaluating strategic alternatives and explore a recapitalization. In April 2008, we reached an agreement with the D. E. Shaw group, pursuant to which Endo s Board of Directors nominated William F. Spengler at the 2008 Annual Meeting of Stockholders to serve as a member of the Company s Board of Directors. Mr. Spengler is an independent unaffiliated person who was recommended by D.E. Shaw to our Board of Directors. The D. E. Shaw group agreed to vote all of its shares in favor of the election of each of the Board s nominees at our 2008 Annual Meeting of Stockholders. At the 2008 Annual Meeting of Stockholders, the Company stockholders elected Mr. Spengler as a director of the Company. The D.E. Shaw group is no longer subject to any restrictions with respect to its shares in the Company.

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

We are dependent upon the ability of Allergan to perform its obligations with respect to sales of Sanctura® and Sanctura XR®, and Allergan s failure to successfully market and commercialize Sanctura® and Sanctura XR® may delay repayment of the Non-recourse Notes, and delay or prevent our receipt of future revenue from sales of Sanctura® and Sanctura XR®. Royalties under the Allergan Agreement may not be sufficient for our subsidiary to meet its payment obligations.

Two of our products Sanctura® and Sanctura XR® are treatments for OAB marketed by Allergan. Under the terms of our agreement with Allergan (which we refer to as the Allergan Agreement), Allergan is responsible for all U.S. marketing and sales activities relating to Sanctura® and Sanctura XR®, and Allergan is obligated to pay royalties based on net sales of Sanctura® and Sanctura XR®. Royalty payments in respect of net sales of Sanctura® and Sanctura XR® in the U.S. are entirely dependent on the actions, efforts and success of Allergan, over whom neither we nor our subsidiary Ledgemont Royalty Sub LLC, have control. Neither we nor our subsidiary, Ledgemont Royalty Sub LLC, can ensure that Allergan effectively maximizes the potential sales of Sanctura® and Sanctura XR®.

In August 2008, Indevus transferred to its wholly-owned subsidiary, Ledgemont Royalty Sub LLC, all of its rights under the Allergan Agreement. Ledgemont Royalty Sub LLC issued $105.0 million in aggregate principal amount of Non-recourse Notes, which were secured by the assets of Ledgemont Royalty Sub LLC, including the rights to receive royalty payments from Allergan relating to future sales of Sanctura® and Sanctura XR® in the U.S. under the Allergan Agreement. As of December 31, 2009, $57 million in aggregate principal amount of Non-recourse Notes are outstanding.

Ledgemont Royalty Sub LLC is entitled to receive certain minimum royalties under the Allergan Agreement; however, such minimum royalties may not be sufficient for Ledgemont Royalty Sub LLC to meet its payment obligations under the Non-recourse Notes. If Allergan is not successful with respect to Sanctura® and Sanctura XR® , and royalties paid to Ledgemont Royalty Sub LLC are not in excess of these minimum amounts, Ledgemont Royalty Sub LLC may not be able to meet its payment obligations under the Non-recourse Notes. In addition, Allergan s obligation to pay minimum royalties may be reduced, suspended or eliminated following certain adverse events pertaining to regulatory non-compliance, generic competition, lack of product supply and other events. Any such reduction, suspension or elimination of royalties could result in Ledgemont Royalty Sub LLC receiving significantly reduced or no royalties under the Allergan Agreement, in which case, Ledgemont Royalty Sub LLC may not be able to meet its payment obligations under the Non-recourse Notes.

An event of default under the Non-recourse Notes will occur if Ledgemont Royalty Sub LLC is unable to meet its interest payment obligations under the Non-recourse Notes from royalty payments received from Allergan, unless any interest payment shortfalls are satisfied in accordance with the terms of the indenture governing the Non-recourse Notes. An interest payment shortfall may be satisfied by capital contributions from the Company, however no assurances can be made that the Company will exercise this right, and this right may not be exercised more than six times over the life of the Non-recourse Notes and no more than three consecutive times. Based on current expectations, it is reasonably possible that we may exceed the maximum number of

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times we can fund the capital account to satisfy an interest payment shortfall as early as November 2010. In the event the Company determines not to, or is no longer permitted to make capital contributions to Ledgemont Royalty Sub LLC to satisfy interest payment shortfalls and the Company does not redeem the Non-recourse Notes, an event of default under the indenture governing the Non-recourse Notes will occur.

Upon the occurrence of an event of default under the indenture, the noteholders will have the right to accelerate the obligations of Ledgemont Royalty Sub LLC to pay amounts outstanding under the Non-recourse Notes and may exercise their remedies under the indenture, including assuming all rights to future payments from Allergan. The loss of our right to receive royalties from Allergan under the Allergan Agreement could adversely affect our business and results of operations.

In certain circumstances, we may lose the potential to receive future royalty payments after the Non-recourse Notes are repaid in full or we may be required to pay damages for breaches of representations, warranties or covenants under certain of the Non-recourse Note financing agreements.

In connection with the transfer of rights under the Allergan Agreement from Indevus to Ledgemont Royalty Sub LLC and the issuance of the Non-recourse Notes, Indevus made certain representations, warranties and covenants to Ledgemont Royalty Sub LLC, and Ledgemont Royalty Sub LLC made certain representations, warranties and covenants to the holders of the Non-recourse Notes. If there is a breach of these representations, warranties or covenants, such breach could trigger an event of default under the indenture governing the Non-recourse Notes. Upon the occurrence of an event of default under the indenture, the noteholders may have the right to accelerate the obligations of Ledgemont Royalty Sub LLC to pay amounts outstanding under the Non-recourse Notes and may exercise their remedies under the indenture, including assuming all rights to future payments from Allergan. The loss of our right to receive royalties from Allergan under the Allergan Agreement could adversely affect our business and results of operations.

The regulatory approval process outside the U.S. v