ENDO PHARMACEUTICALS HOLDINGS INC
Form 10-K
March 02, 2009
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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, 2008

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: N/A

Securities registered pursuant to Section 12(g) 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**

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 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, 2008 was $2,268,261,974 based on a closing sale price of $24.19 per share as reported on the NASDAQ Global Select Market on June 30, 2008. 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 20, 2009: 116,706,430

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 2009 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, 2008.

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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 net sales, 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 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 many 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;

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

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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 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; and

our ability to successfully integrate Indevus Pharmaceuticals, Inc.

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 (or 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 with market leadership in pain management. We are engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used primarily to treat and manage pain.

We have a portfolio of branded products that includes brand names such as Lidoderm®, Opana® ER and Opana®, Percocet®, Frova®, and Voltaren® Gel. Branded products comprised approximately 93% of our net sales in 2008, with 61% of our net sales coming from Lidoderm®. Our non-branded generic portfolio, which accounted for 7% of net sales in 2008, currently consists of products primarily focused in pain management. We focus on selective generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing.

We have recently acquired a majority position in Indevus Pharmaceuticals, a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. Indevus s approved products include Sanctura® and Sanctura XR for overactive bladder (OAB), which is co-promoted with Allergan, Inc. (Allergan), Vantas® for advanced prostate cancer, Supprelin® LA for central precocious puberty (CPP), Delatestryl® for the treatment of hypogonadism and Valstar for bladder cancer. Indevus also has a core urology and endocrinology portfolio containing multiple compounds in development including Nebido® for hypogonadism, PRO 2000 for the prevention of infection by HIV and other sexually-transmitted pathogens, and the octreotide implant for acromegaly and carcinoid syndrome.

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We have established research and development expertise in analgesics and are expanding our research and development capabilities to enable us to pursue development opportunities outside of pain such as in endocrinology, oncology and urology.

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 of approximately 725 sales representatives in the United States, and through a contracted field force of approximately 275 sales representatives and other sales management positions, we market our branded pharmaceutical products to high-prescribing physicians in pain management, neurology, surgery, anesthesiology, oncology and primary care. 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. (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. Endo Pharmaceuticals Inc. was formed by some members of the then-existing management of DuPont Merck and an affiliate of Kelso & Company who were also parties to the purchase agreement, under which we acquired these initial assets.

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

Our Strategy

Our business strategy is to maximize the future growth of the Company and to strengthen our position as a leading specialty pharmaceutical company by delivering innovative, commercially viable products and technologies to meet unmet medical needs in our existing therapeutic and complementary areas. Execution of our strategy will incorporate the following key elements:

- Developing new products through both an internal and a virtual research and development organization with greater scientific and clinical capabilities;
- Expanding the Company s product line by acquiring new products and technologies in existing therapeutic and complementary areas;
- Increasing revenues and earnings through sales and marketing programs for our innovative product offerings and effectively using the Company s resources; and
- Providing additional resources to support our generics business.

We believe that successful execution of our business strategy will enhance shareholder value.

During 2008, we completed a review of operations to assess our core competencies, cost infrastructure and growth opportunities. As a result of this review, we are pursuing several initiatives to improve the effectiveness of our business operations, reduce expenses and create additional long-term value for our customers and stockholders. In addition to implementing selective personnel reductions, we have decided to change our business structure and reduce our utilization of outside consultants to create a more effective operating model relative to our historical operating model.

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The Company is working to implement this new strategy through the following initiatives:

Refocused sales and marketing programs:

We recently reorganized our commercial group and sales territories to increase the operating efficiency and effectiveness of the Company s sales teams. This reorganization is intended to make the Company s sales representatives more responsive to our customers and better able to allocate time to physicians who may require additional information about the Company s products, particularly Lidoderm®, Opana® ER and Opana®, Voltaren® Gel and Frova®.

New research and development priorities:

Subsequent to the appointment of Dr. Ivan Gergel as executive vice president of research and development in 2008, the Company conducted an in-depth review of its research and development activities. The review included an analysis of the Company s R&D priorities, focus and available resources for current and future projects as well as the commercial potential for each product. As a result of this review, the Company decided to discontinue development of EN3267, Rapinyl™, the sub-lingual, fast-dissolving tablet of fentanyl intended for treatment of breakthrough cancer pain, and EN3269, topical ketoprofen patch, being studied for the treatment of acute pain associated with soft-tissue injuries. In January 2009, the Company announced that by mutual agreement it concluded its research collaboration with Alexza Pharmaceuticals, Inc. to develop an inhaled fentanyl product for the treatment of breakthrough pain using Alexza s Staccato® inhalation technology. Further, in February 2009, the Company decided to discontinue all development activities related to EN3285, an oral rinse being studied for the prevention or delay of oral mucositis (OM) and EN3270 transdermal sufentanil patch for the treatment of moderate-to-severe chronic pain.

The Company also decided to expand its medicinal chemistry, project management and biostatistics competencies to help it conduct preclinical research and more efficiently manage the clinical development of new product candidates by contract research organizations.

Investment in new therapeutic areas:

We believe Endo s pain management products, strong revenue base and sales teams represent strategic assets that can be leveraged to expand the Company s pharmaceutical business beyond the treatment of pain. We are identifying complementary medical specialties where demographic, healthcare and reimbursement trends favor the consideration of new products to address unmet medical needs, such as certain pelvic diseases that are treated by urologists, endocrinologists and oncologists.

This strategy underlies our recent acquisition of Indevus Pharmaceuticals. On March 2, 2009, we announced that approximately 80% of the outstanding shares of Indevus common stock had been tendered into the offer. We expect to acquire the remaining Indevus shares during a subsequent offering period, followed by a merger of a wholly owned subsidiary of Endo with and into Indevus with Indevus surviving. Indevus currently markets products to treat overactive bladder, prostate cancer, hypogonadism and central precocious puberty and is pursuing regulatory approval of drugs to treat hypogonadism and acromegaly. The combined company will market products through three sales forces and have the capability to develop innovative new therapies using a novel drug delivery technology. We believe this acquisition will make Endo a stronger competitor, a more valuable healthcare supplier and a more successful company.

Endo intends to pursue other strategic acquisitions to support the growth of the Company s pain management business and its expansion into other therapeutic specialties, while continuing to make strategic decisions to support and grow our generics business.

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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 recent acquisition of Indevus Pharmaceuticals, we have added several branded products to treat conditions in urology and endocrinology. The Company s branded products include:

Lidoderm® was launched in September 1999. A topical patch product containing lidocaine, Lidoderm® was the first U.S. Food and Drug Administration (FDA)-approved product for the relief of the pain associated with post-herpetic neuralgia.

Opana® ER and Opana® were launched during the second half of 2006. 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® (the immediate-release version) is indicated for the relief of moderate-to-severe acute pain where the use of an opioid is appropriate. Three new additional dosage strengths of Opana® ER were launched in March 2008.

Percocet®, our oxycodone/acetaminophen combination product, and Percodan®, our oxycodone/aspirin combination product, which have been marketed since 1976 and 1950, respectively, are what we consider to be gold standards of pain management based on their long history of demonstrated product safety and effectiveness.

Frova®, for the treatment of migraine headaches in adults, was added to our portfolio of branded products during 2004.

Voltaren® Gel, which was added to our portfolio of branded products in March 2008, is a topical NSAID indicated for the relief of the pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands.

Recently Acquired Indevus Products:

Sanctura® (trospium chloride) was launched by Indevus in August 2004. Sanctura® is indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and urinary frequency. Indevus currently co-promotes Sanctura® in the U.S. with its marketing partner, Allergan, Inc.

Sanctura XR (trospium chloride extended release capsules) is a 60 mg, once-daily formulation of Sanctura®, the only approved quaternary amine compound clinically proven to effectively treat OAB symptoms in as early as one week, with a low incidence of side effects. Indevus currently co-promotes Sanctura XR in the U.S. with its marketing partner, Allergan, Inc.

Supprelin® LA was launched by Indevus in June 2007. Supprelin® LA is 12-month hyrdogel implant for treating central precocious puberty (CPP) or the early onset of puberty in children. Supprelin® LA utilizes Indevus s patented Hydron® Polymer Technology, has been designed to provide the continuous 12-month administration of a controlled dose of histrelin, a GnRH agonist.

Vantas® was launched by Indevus in the U.S. in November 2004. Vantas® is a soft and flexible 12-month hydrogel implant currently marketed in the U.S. that provides histrelin, a luteinizing hormone-releasing hormone (LHRH) agonist, for the palliative treatment of advanced prostate cancer. The product utilizes Indevus s patented Hydron® Polymer Technology that allows for a controlled delivery of medicine over a 12-month period. In November 2005, Vantas® was approved in Denmark, and in March 2006, received approval

for marketing in Canada from Health Canada. Regulatory approval was granted in May 2007 in Germany, Ireland, Italy, Spain and the United Kingdom. As of August 2007, Vantas® was approved in Thailand, Singapore, and Malaysia and approval is pending in Taiwan, Korea, Hong Kong and China. Additionally, Vantas® has been approved and is being marketed in Argentina.

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Delatestryl® is a marketed injectable testosterone preparation for the treatment of male hypogonadism. Delatestryl® provides testosterone enanthate, a derivative of the primary endogenous androgen testosterone, for intramuscular injection.

Hydron® Implant is a subcutaneous, retrievable, non-biodegradable, hydrogel reservoir drug delivery device. The Hydron® Implant is designed to provide sustained release of a broad spectrum of drugs continuously, at constant, predetermined rates. The Hydron® Implant is the only soft, flexible, reservoir-based drug delivery system available for parenteral administration. The hydrogel polymer compositions possess flexible, tissue-like characteristics providing excellent biocompatibility and patient comfort. This technology serves as the basis for two currently marketed products of Indevus: Vantas® and Supprelin® LA.

Valstar is a sterile solution of valrubicin for intravesical instillation and is the only product 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 due to a manufacturing problem involving impurity issues in the original formulation and was placed on the FDA Drug Shortages List. In April 2007, Indevus submitted a supplemental New Drug Application (sNDA) to the FDA seeking approval to reintroduce Valstar and in February 2009 obtained FDA approval of its sNDA for Valstar. We intend to begin to market Valstar during the second half of 2009.

Focused Pipeline. During 2008, the Company completed an in-depth review of its research and development activities that included a thorough analysis of the Company s R&D priorities, focus and available resources for current and future projects as well as the commercial potential for each product. As a result of this review, we decided to discontinue development of Rapinyl , the sub-lingual, fast-dissolving tablet of fentanyl intended for treatment of breakthrough cancer pain, and topical ketoprofen patch being studied for the treatment of acute pain associated with soft-tissue injuries. In addition, the Company has recently concluded its research collaboration with Alexza to develop an inhaled fentanyl product for the treatment of breakthrough pain using Alexza s Staccato® inhalation technology. We also decided to discontinue all development activities related to EN3285, our oral rinse for the treatment of oral mucositis obtained through our acquisition of RxKinetix in October 2006 and EN3270 transdermal sufentanil patch for the treatment of moderate-to-severe chronic pain. We plan to pursue and develop new and more commercially viable products and technologies in existing therapeutic and complementary areas.

We have recently entered into three license and collaboration agreements to develop novel treatments for pain and to discover potential treatments for cancer as described below.

In December 2008, we entered into a license agreement and a sponsored research agreement with Harvard University (referred to as the Harvard Agreement). Under the terms of the Harvard Agreement, we obtained the exclusive worldwide rights to a new combination pain-drug-delivery technique that targets pain-sensing neurons without affecting motor neurons. Endo will be responsible for development and commercialization of any drug candidates discovered under the Harvard Agreement.

In February 2009, we entered into a discovery collaboration agreement with Aurigene Discovery Technologies Limited (referred to as the Aurigene Agreement). The Aurigene Agreement is a three-year collaboration to discover novel drug candidates to treat cancer.

In February 2009, we entered into a development, license and supply agreement with Grünenthal GMBH, referred to as Grünenthal, granting us the exclusive right in North America to develop and market Grünethal s investigational drug, axomadol (referred to as the Grünenthal Agreement). Currently in Phase II trials, axomadol is a patented new chemical entity being developed for the treatment of moderate to moderately-severe chronic pain and diabetic peripheral neuropthic pain.

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Also, through the acquisition of Indevus, we have added the following products to our development pipeline:

Nebido® is a long-acting injectable testosterone preparation for the treatment of male hypogonadism. Nebido® is expected to be the first long-acting testosterone preparation available in the U.S. in the growing market for testosterone replacement therapies. Indevus acquired U.S. rights to Nebido® from Schering AG, Germany, in July 2005. In June 2008, Indevus received an approvable letter from the FDA indicating that the NDA may be approved if the Company is able to adequately respond to certain clinical deficiencies related to the product. In September 2008, agreement was reached with the FDA with regard to the additional data and risk management strategy and re-submission (complete response) of the NDA for Nebido® is expected in the first quarter of calendar 2009.

PRO 2000, currently in Phase III clinical trials, is a candidate topical microbicide for the prevention of sexually transmitted infections including infection by the Human Immunodeficiency Virus (HIV), the cause of Acquired Immunodeficiency Syndrome (AIDS). The compound is believed to block the entry of sexually transmitted disease (STD) pathogens into human cells. In addition to its demonstrated activity against HIV infection in laboratory tests and animal models, PRO 2000 has been shown to be active against other STD pathogens such as herpes, chlamydia, and the bacterium that causes gonorrhea. Designed to be applied vaginally prior to sexual intercourse, PRO 2000 promises to offer a discreet safer sex option that can be controlled by women.

Octreotide implant, currently in Phase III clinical trials, utilizes Indevus s patented Hydron® Polymer Technology to deliver six months of octreotide, a long-acting octapeptide that mimics the natural hormone somatostatin to block production of growth hormone (GH), for the treatment of acromegaly.

In addition to the above-mentioned development products, Indevus also has other product candidates in various stages of development.

Research and development expertise. Our research and development effort is focused on the development of a balanced, diversified portfolio of innovative and clinically differentiated products. We are continuously seeking opportunities that deepen our 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, 2008, our research and development and regulatory affairs staff consisted of 156 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 $110.2 million in 2008, $138.3 million in 2007 and $86.6 million in 2006.

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. In addition, many of the research and development activities of products to which we have licensed the marketing rights are performed by our partners.

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 New Drug Application (NDA) 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

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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 August 1997.

Targeted national sales and marketing infrastructure. We market our products directly to physicians through an internal sales force of approximately 725 specialty and office-based representatives and through a contracted field force of approximately 275 sales representatives and other sales management positions, as well as 100 specialty sales representatives through the Indevus acquisition. Through our sales force, we market our branded pharmaceutical products to just over 86,000 physicians, which include both specialists and primary care physicians. We distribute our products principally through independent wholesale distributors, but we also sell directly to retailers, clinics, government agencies and 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 country. We work to gain access to health authority, Pharmacy Benefit Managers (PBMs) and Managed Care Organizations (MCOs) 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 2008 consisted of 41 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 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 The Purdue Frederick Company. We will continue to make strategic decisions to support and grow our generics business.

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 seventeen new products and product line extensions since 1997, and as a result of several successful product launches, have grown our net sales from $108.4 million in 1998 to $1.26 billion in 2008.

Our Industry

According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled $20.8 billion in 2008. This represents an approximately 4% compounded annual growth rate since 2003. Our primary area of focus within this market is analgesics and, specifically, opioid analgesics. In 2008, analgesics were the third most prescribed medication in the United States with over 298 million prescriptions written for this classification.

Opioid analgesics is a segment that comprised approximately 81% of the analgesic prescriptions for 2008 (59% of the pain market). Total U.S. sales for the opioid analgesic segment were $7.5 billion in 2008, representing a compounded annual growth rate of 6% since 2003. 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 168 million prescriptions written in 2008, 41% of the pain market. The U.S. sales for these markets were $13.2 billion with an annual growth rate of 3% since 2003.

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.

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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, in 2000 the population aged 65 and older reached 35 million people and is expected to grow to 40 million people by 2010, 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.

Product Overview

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

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

Products in Development	Active Ingredients(s)	Branding	Status
Nebido®(3)	testosterone undecanoate	Branded	NDA Approvable
PRO 2000(3)	naphthalene sulfonate copolymer	Branded	Phase III
Octreotide implant(3)	octreotide acetate	Branded	Phase III
Axomadol(4)	axomadol	Branded	Phase II

(1) Marketed pursuant to an alliance agreement with Penwest Pharmaceuticals Co.
(2) Licensed marketing rights from Vernalis Development Limited.
(3) Obtained through our acquisition of Indevus Pharmaceuticals, Inc.
(4) Licensed marketing and development rights from Grünenthal GMBH.

Branded Products

Lidoderm®. Lidoderm® was launched in September 1999. A topical patch product containing lidocaine, it 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

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set to expire in 2015. In 2008, 2007 and 2006, Lidoderm® net sales were $765.1 million, $705.6 million and $566.8 million, respectively. Lidoderm® accounted for approximately 61% of our 2008 net sales.

In January 2007, we received a subpoena issued by the United States Department of Health and Human Services, Office of Inspector General (OIG). The subpoena requests documents relating to Lidoderm® (lidocaine patch 5%), focused primarily on the sale, marketing and promotion of Lidoderm®. We are cooperating with the government to provide the requested documents. At this time, we cannot predict or determine the outcome of this matter or reasonably estimate the amount or range of amounts of fines or penalties, if any, that might result from a settlement or an adverse outcome. See Note. 15 Commitment and Contingencies Legal Proceedings , included in the consolidated financial statements in Part IV, Item 15 of this Report.

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. This is the first time oxymorphone is available in an oral, extended-release formulation and is available in 5mg, 7.5 mg, 10mg, 15 mg, 20mg, 30 mg and 40mg 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. Both Opana® ER and Opana® are available by prescription only. Net sales for the year ended December 31, 2008 of Opana® ER and Opana® were $180.4 million. Net sales for 2007 and 2006 were $107.1 million and $6.8 million, respectively. Both of these products were approved by the FDA on June 22, 2006 and became commercially available on July 21, 2006, with active promotion of Endo s sales force beginning in the third quarter 2006. Opana® ER and Opana® accounted for approximately 14% of our 2008 net sales.

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 $130.0 million, $121.7 million and $102.7 million in the years 2008, 2007 and 2006, respectively. The Percocet® franchise accounted for approximately 10% of our 2008 net sales.

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. Net sales of Frova® were $58.0 million in 2008, $52.4 million in 2007 and $40.6 million in 2006.

Voltaren® Gel. We launched Voltaren® Gel in March 2008 upon closing of the license and supply agreement with Novartis. 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. Net sales of Voltaren® Gel were $23.8 million in 2008.

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 2008 fiscal year.

Recently Acquired Indevus Products

Sanctura®. In August 2004, Indevus launched Sanctura®, a muscarinic receptor antagonist for the treatment of OAB. Sanctura® is co-promoted in the U.S. with Allergan, an Indevus marketing partner. Sanctura® is

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indicated for the treatment of OAB with symptoms of urge 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®. Indevus licensed exclusive rights to develop and market Sanctura® in the U.S. from Madaus GmbH (Madaus) in December 1999. In addition, Madaus currently manufactures and sells Indevus commercial quantities of Sanctura® in bulk form. Indevus currently co-promotes Sanctura® in the U.S. with Allergan. To support the commercialization of Sanctura® and as a platform for future growth, Indevus has a sales and marketing infrastructure which includes a specialty sales force who call on urologists and other prescribers specializing in treating patients with OAB.

Sanctura XR™. Sanctura XR™ is a once-daily formulation of Sanctura®, Indevus s 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 Indevus believes provides significant differentiation to the tertiary ammonium compounds currently being marketed for the treatment of OAB. Quaternary ammonium compounds are highly charged and hydrophilic with a limited ability to cross lipid membranes. The formulation of Sanctura XR™ was developed under a development and license agreement with Supernus Pharmaceuticals, Inc. (Supernus), formerly Shire Laboratories, Inc. Indevus completed pharmacokinetic and safety studies with several once-daily formulations, including our lead formulation that was used in our Phase II trial and our Phase III program. In May 2008, Indevus signed a License Agreement with Allergan Inc., a Canadian affiliate of Allergan, Inc., granting Allergan the right to market Sanctura XR™ throughout Canada. Madaus, an Indevus partner, has received marketing approval in October 2008 from their Reference Member State which they designated as Germany.

Vantas®. Indevus launched Vantas® in the U.S. in November 2004. Indevus obtained Vantas® through an acquisition of Valera Pharmaceuticals, Inc. (Valera) in April 2007. Vantas® is a soft, flexible 12-month hydrogel implant based on our patented Hydron® Polymer Technology (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. See Hydron Polymer Technology below for additional information. Mutual Recognition Procedure (MRP) in Germany, Ireland, Italy, Spain and the United Kingdom for marketing authorization began in July 2006. Approval was granted in May 2007. In April 2008, Indevus entered into a License, Supply and Distribution Agreement with Orion Corporation (Orion) granting them the rights to market Vantas® throughout Europe as well as certain other countries. As of August 2007, in conjunction with BioPro Pharmaceutical Inc., an Indevus marketing partner for most countries in Asia, Vantas was approved in Thailand, Singapore and Malaysia and approval is pending in Taiwan, Korea, Hong Kong and China. In addition, a partner Teva-Tuteur has received approval and begun marketing Vantas in Argentina.

Supprelin® LA. Indevus launched Supprelin® LA in the U.S. in June 2007. We obtained Supprelin® LA through our acquisition of Valera. Supprelin® LA 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 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. On May 3, 2007, the FDA approved the NDA for Supprelin® LA. 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 being evaluated include seeking marketing partners in territories outside of the United States. Indevus markets Supprelin® LA in the U.S. through a specialty sales force primarily to pediatric endocrinologists.

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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 is used in BCG-refractory bladder cancer patients who are not candidates for bladder removal (cystectomy).

Valstar, which was removed from the market in the early 2000 s due to manufacturing issues, is currently on the FDA Drug Shortages List. On April 19, 2007, Indevus announced that it had submitted a Supplemental New Drug Application (sNDA) to the FDA seeking approval to reintroduce Valstar in the United States. On December 19, 2007, Indevus announced that it had received a non-approvable letter from the FDA for Valstar related to its chemistry, manufacturing and controls (CMC) NDA supplement submitted to the FDA in May 2007. The letter was received following Indevus s response to an August 2007 approvable letter of its April 2007 sNDA. Indevus believes that the Valstar-specific issues that caused the 2002 withdrawal of the product from the market have been satisfactorily resolved. However, during a recent FDA pre-approval inspection of Indevus s third-party manufacturing facility for Valstar, deficiencies were identified that required resolution prior to final approval. In February 2009, Indevus obtained FDA approval of its sNDA for Valstar. We intend to begin to market Valstar during the second half of 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 Indevus s 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.

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 net sales in 2008. In addition, we sell morphine sulfate extended-release tablets, which accounted for 1% of our total net sales in 2008. The balance of our generic portfolio consists of a few other products, none of which accounted for more than 1% of our total net sales for 2008.

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.

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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.

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 Pharmaceuticals, Inc. on February 23, 2009, are as follows:

Nebido®. Nebido® is a novel, long-acting injectable testosterone preparation for the treatment of male hypogonadism. Nebido® is expected to be the first long-acting testosterone preparation available in the U.S. in the growing market for testosterone replacement therapies. Indevus acquired U.S. rights to Nebido® from Schering AG, Germany, in July 2005. Approved and launched in Europe, Nebido® has a substantial data package which Indevus has leveraged in its U.S. development activities.

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, as well as an increased risk of osteoporosis. Today, there are an estimated four to five million men in the U.S. who suffer from hypogonadism. Of this group, less than ten percent are currently receiving treatment with testosterone replacement therapy.

In January 2008, Indevus announced additional positive results from its Phase III program. Indevus has been exploring additional dosage regimens to determine if it is possible to achieve a more rapid onset of steady state testosterone pharmacokinetics and still satisfy each of the FDA pre-specified criteria for approvability. This Phase III trial, studied a new treatment regimen in which hypogonadal men were given an initial injection of 750 mg of Nebido®, followed 4-weeks later by an additional 750 mg loading injection and then 750 mg injections every 10-weeks thereafter.

The data from this Phase III trial demonstrated a highly effective treatment regimen. In the trial, Nebido® demonstrated a rapid achievement of steady state testosterone levels, minimal excursions outside of the normal range, and an extremely high percentage of patients maintaining a eugonadal (normal) testosterone range. Nebido® met its primary endpoints, a responder analysis based on average testosterone concentrations during the steady state dosing interval and an outlier analysis based on the maximum testosterone concentrations during the steady state dosing interval. As with the original dosing regimen, treatment with Nebido® was well tolerated with this new dosing regimen. The data was filed with the FDA as an addition to the NDA originally filed on August 28, 2007. Indevus requested approval of the 750 mg regimen as it believes this regimen distinguishes itself by providing physicians with the optimal long-term dosing solution for treating their male patients with hypogonadism.

On November 1, 2007, Indevus announced that the FDA accepted for review Indevus s NDA for Nebido®. On June 30, 2008, Indevus announced that it received an approvable letter from the FDA related to the NDA submitted in August 2007. The letter indicated that the application may be approved if Indevus is able to adequately respond to certain clinical deficiencies related to the product.

Indevus announced on September 26, 2008 that it had met with the FDA and an agreement had been reached with regard to the additional data and risk management strategy that will lead to re-submission (complete response) of the NDA for Nebido® in the first quarter of calendar 2009. The re-submission database will include experience from over 14,000 injections in more than 2,600 patients, all of which come from existing clinical trials conducted in the US and post-marketing studies that have been conducted in Europe. The FDA stated that the number of patients and the number of injections of testosterone undecanoate from these studies appear to provide an adequate size database to determine the precise incidence of serious post-injection, oil-based reactions.

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Indevus and the FDA also agreed on an education plan to minimize the risks associated with the clinical use of testosterone undecanoate intramuscular injection, namely, to reduce the incidence and/or severity of the serious oil-based reactions. Further, Indevus and FDA agreed to obtain skin-testing data to characterize an allergic component to the drug or any of its excipients in certain patients. Indevus has also agreed to conduct a large, simple post-marketing study of the safety of Nebido® in approximately 10,000 patients.

PRO 2000. PRO 2000 is a candidate topical microbicide for the prevention of sexually transmitted infections including infection by the Human Immunodeficiency Virus (HIV), the cause of Acquired Immunodeficiency Syndrome (AIDS). The compound is believed to block the entry of sexually transmitted disease (STD) pathogens into human cells. In addition to its demonstrated activity against HIV infection in laboratory tests and animal models, PRO 2000 has been shown to be active against other STD pathogens such as herpes, chlamydia, and the bacterium that causes gonorrhea. Designed to be applied vaginally prior to sexual intercourse, PRO 2000 promises to offer a discreet safer sex option that can be controlled by women.

An estimated 5 million people worldwide were newly infected with HIV in 2004, and 39 million adults and children are thought to be living with HIV infection. The virus s predominant route of transmission worldwide is through heterosexual contact, with women being more susceptible to infection than men. Nearly half of those infected with HIV are now women, and surveys indicate that 100 million women worldwide are concerned about contracting HIV/STDs. More than 400 million new cases of STDs occur worldwide each year, threatening the health and fertility of a growing number of people and increasing the risk of HIV infection. These statistics highlight the vast need for new, safe, effective, female-controlled options for HIV/STD prevention.

Phase I clinical trials, conducted in Europe, found that PRO 2000 was well tolerated by healthy, sexually abstinent women. Findings from an NIH-sponsored Phase I/II trial, conducted in the United States and South Africa, indicate a similarly promising safety profile in healthy, sexually active women. In June 2003, a Phase II clinical trial was initiated in Uganda to assess the safety of PRO 2000 in more than 100 African women. A Phase II/III clinical trial funded by the NIH was initiated in February 2005 and enrolled approximately 3,100 eligible, HIV-uninfected women, all of whom provided written informed consent. On February 9, 2009 Indevus announced results from the NIH-sponsored trial which found that women participating in the trial who received PRO 2000 had an approximately 30% lower risk of acquiring HIV infection than women who received placebo or no vaginal product (approximately 33 percent effectiveness would have been considered statistically significant). The adverse event profile was similar in all arms of the NIH trial, indicating that 0.5% PRO 2000 is safe for vaginal use. A full analysis of the trial data is underway.

A second large trial testing the safety and effectiveness of the 0.5% dose of PRO 2000 is currently underway. This trial is being sponsored by the United Kingdom s Medical Research Council (MRC) and conducted by the Microbicides Development Programme (MDP), an international partnership of researchers established to develop microbicides for the prevention of HIV transmission. Study MDP 301 is a multi-national, randomized, double-blind, placebo-controlled Phase III trial designed to examine the safety and effectiveness of PRO 2000 in preventing HIV infection in women. Approximately 9,400 women have been enrolled at study sites in South Africa, Tanzania, Uganda, and Zambia. Results from this trial are expected in the second half of 2009.

Octreotide implant. The octreotide implant is in development utilizing Indevus s patented Hydron® Polymer Technology to deliver six months of octreotide, a long-acting octapeptide that mimics the natural hormone somatostatin to block production of growth hormone (GH), for the treatment of acromegaly.

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

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Octreotide injections are currently approved treatment to reduce GH levels, as well as levels of insulin-like growth factor (IGF-1), in patients with acromegaly. Octreotide injections have also been approved to treat symptoms associated with metastatic carcinoid tumors and vasoactive intestinal peptide secreting adenomas, which are gastrointestinal tumors.

In 2004, a Phase I / II proof-of-concept clinical study of the implant in 11 acromegaly patients in Brazil was completed. In addition to efficacy and safety assessments, the study evaluated patient pharmacokinetics and the drug release characteristics from the hydron implant. The trial demonstrated reductions in GH and IGF-1 levels in the blood in these patients. During the trial, side effects were generally mild and did not lead to study discontinuations, and included diarrhea, low blood sugar and implant site reactions.

In August 2006, the FDA requested an additional Phase I / II pharmacokinetic study for the octreotide implant. In response, in September 2006, an original Investigational New Drug Application (IND) was submitted with the FDA for the octreotide implant.

In November 2007, positive results from Indevus s Phase II trial in patients with acromegaly were announced. In the recently completed six-month trial, 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, Indevus announced the initiation of a Phase III clinical trial. 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 is expected to enroll approximately 140 patients in the U.S. and Europe.

Axomadol. Axomadol is a patented new chemical entity discovered by Grunenthal and currently in Phase II development for the treatment of moderate to moderately severe chronic pain and diabetic peripheral neuropathic pain.

Other. We also have other 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., The Purdue Frederick Company, 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

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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.

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.

The Company is aware of certain activities involving Opana® ER and Lidoderm®, a summary of which is below.

Opana® ER

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

Lidoderm®

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 Endo s 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 believes 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

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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. To our knowledge, there is no competitive product to Lidoderm® that has been, or is being developed.

On July 25, 2008, the LecTec Corporation filed a complaint in the United States District Court for the Eastern District of Texas against the Company and several other pharmaceutical companies alleging that each of the defendants sells product that infringes one or more claims of patents owned by LecTec. The Company s product Lidoderm® is identified in the complaint. The complaint alleges that Lidoderm® infringes U.S. Patents 5,536,263 and 5,741,510. On September 30, 2008, the Company filed an answer denying infringement and alleging that the patents are invalid. On February 10, 2009, the plaintiff filed a motion for preliminary injunction against the Company. The Company intends to contest this case vigorously. However, we cannot predict the timing or outcome of this litigation.

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, 2008, 2007 and 2006 were as follows:

	2008	2007	2006
Customer A	36%	34%	28%
Customer B	31%	31%	29%
Customer C	15%	15%	15%

In recent years, there have been numerous mergers and acquisitions among wholesale distributors as well as rapid 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. 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 20, 2009, we held approximately: 27 U.S. issued patents, 37 U.S. patent applications pending, 141 foreign issued patents, and 82 foreign patent applications pending. In addition, as of February 20, 2009, we have licenses for approximately: 60 U.S. issued patents, 26 U.S. patent applications pending, 102 foreign issued patents and 37 foreign patent applications pending. The foregoing does not include any of the patents or patent applications owned or licensed by Indevus, of which we acquired majority control on February 23, 2009.

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

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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 18 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 5 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 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 Item 3. Legal Proceedings.

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 NDA 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,

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

We cannot determine what effect changes in 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 new requirements for testing drug products in children and post-approval testing of drugs that pose serious safety risks, all of which may increase the time and cost necessary for new drug development.

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.

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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.

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 Food and Drug Administration (FDA) sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a Risk Evaluation and Mitigation Strategy (REMS) to address whether the benefits of these products continue to outweigh the risks. The FDA has authority to require a REMS under the Food and Drug Administration Amendments Act of 2007 (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 for such 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.

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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 (PDUFA) was reauthorized on September 27, 2007 through passage of the Food and Drug Administration Amendments Act of 2007 (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 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. The legislation also contained provisions to expedite new drug development, collect fees from companies that engage in direct-to-consumer television advertising, 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 (see next section). Approval of Section 505(b)(2) NDAs, like ANDAs, also may be delayed by market exclusivity that covers the reference product. However, despite the similarities, Section 505(b)(2) applications are not permitted when an applicant could submit and obtain approval of an ANDA.

ANDA Process

FDA approval of an ANDA is required before a generic equivalent of an existing or reference-listed drug can be marketed. The ANDA process is abbreviated in that the FDA waives the requirement of conducting complete preclinical and clinical studies and instead relies principally on bioequivalence studies. Bioequivalence generally involves a comparison of the rate of absorption and levels of concentration of a generic drug in the body with those of the previously approved drug. When the rate and extent of absorption of systemically acting test and reference drugs are the same, the two drugs are 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 FDA generally relies upon to determine bioequivalence in locally acting products, including comparative clinical efficacy trials.

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 can substitute the product for the reference-listed drug. Congress enacted pediatric testing legislation in September 2007 which may continue to affect pharmaceutical firms ANDA products. In addition, under that same legislation, ANDA applicants may also be required to formulate abbreviated risk evaluation and mitigation strategies in connection with obtaining approval of their products.

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 listed drug is entitled

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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, the exclusivity of a product is extended by six months past the patent expiration date if the manufacturer undertakes studies FDA requires on the effect of their product in children, 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 Act allows for civil penalties and withdrawal of previously approved applications. We believe neither we nor any of our employees have ever been subject to debarment.

Patent and Non-Patent Exclusivity Periods

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

One of the key motivators for challenging patents is the 180-day market exclusivity period vis a vis other generic applicants granted to the developer of a generic version of a product that is the first to have its application accepted for filing by the FDA and whose filing includes a certification that the applicable patent(s) are invalid, unenforceable and/or not infringed (a Paragraph IV certification) and that prevails in litigation with the manufacturer of the branded product over the applicable patent(s). Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the 2003 Medicare Act, with accompanying amendments to the Hatch Waxman Act, 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

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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 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 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, or 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.

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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 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 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 may result 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 will not be 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 have not been 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 may decrease, and we may be forced to lower prices for our products, which may adversely affect our business and our results of operations.

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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.

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. 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.

Novartis Consumer Health, Inc.

On May 3, 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc. whereby Novartis has agreed to manufacture certain of our commercial products and products in development. We are required to purchase, on an annual basis, a minimum amount of product from Novartis. The purchase price per product is equal to a predetermined amount per unit, subject to periodic adjustments. This agreement had a five-year term, with automatic five-year renewals thereafter. In August 2005, we extended this agreement until 2011. We are required to purchase a minimum of approximately $20 million per year in 2009 and 2010, and approximately $21 million in 2011. Either party may terminate this agreement on three-years notice, effective at any time after the initial five-year term. Either party may also terminate this agreement on account of a material breach by the other. Amounts purchased pursuant to this agreement were $55.4 million, $30.7 million and $40.8 million for the years ended December 31, 2008, 2007 and 2006, respectively.

Pursuant to the March 2008 Voltaren® Gel license and supply agreement with Novartis AG and Novartis Consumer Health, Inc., (referred to as the Voltaren® Gel Agreement), Endo has agreed to purchase from Novartis all of its requirements for Voltaren® Gel during the entire term of the Voltaren® Gel Agreement. The price of product purchased under the Voltaren® Gel Agreement is fixed for the first year and subject to annual changes based upon changes in the producer price index and raw materials as set forth in the Voltaren® Gel Agreement. Amounts purchased pursuant to the Voltaren® Gel Agreement were $23.4 million for the year ended December 31, 2008.

As part of the Voltaren® Gel Agreement, we also agreed to fund certain advertising and promotion of Voltaren® Gel (A&P Expenditures), subject to certain thresholds set forth in the Voltaren® Gel Agreement. Amounts incurred by Endo for such A&P Expenditures were $9.4 million for the year ended December 31, 2008. In 2009, we agreed to spend $15.6 million on A&P Expenditures. Subsequent to 2009, the minimum A&P Expenditures set forth in the Voltaren® Gel Agreement are determined based on a percentage of net sales of Voltaren® Gel.

The initial term of the Voltaren® Gel Agreement will expire on June 30, 2013. Endo has the option to extend the Voltaren® Gel Agreement for two successive one (1) year terms (each referred to as a Renewal Term) beyond the initial term. The Voltaren® Gel Agreement will remain in place after the first two Renewal Terms unless either party provides written notice of non-renewal to the other party at least six (6) months prior to the expiration of any Renewal Term after the first Renewal Term or the Voltaren® Gel Agreement is otherwise terminated in accordance with its terms. Among other standard and customary termination rights granted under the Voltaren® Gel Agreement, the Voltaren® Gel Agreement can be terminated by either party upon reasonable written notice, if either party has committed a material breach that has not been remedied within ninety (90) days from the giving of

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written notice. Endo may terminate the Voltaren® Gel Agreement by written notice upon the occurrence of several events, including the launch in the United States of a generic to Voltaren® Gel. Novartis may terminate the Voltaren® Gel Agreement upon reasonable written notice (1) if Endo fails to deliver a set percentage of the minimum details in any given six (6) month period under the Voltaren® Gel Agreement; or (2) on or after the launch in the United States of an OTC equivalent product by Novartis, its affiliates or any third party that does not result in the declassification of Voltaren® Gel as a prescription product, following which net sales in any six-month period under the Voltaren® Gel Agreement are less than a certain defined dollar amount.

Teikoku Seiyaku Co., Ltd.

Under the terms of our agreement with Teikoku, a Japanese manufacturer, Teikoku manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. We also have an option to extend the supply area to other territories. The agreement contains certain provisions requiring Teikoku to qualify an additional manufacturing site, at our request, should we meet certain defined purchasing levels for a defined period of time. On April 24, 2007, we amended this agreement. The material components of the Amended Agreement are as follows:

- We agreed to purchase a minimum number of patches per year through 2012, representing the noncancelable portion of the Amended Agreement.

- Teikoku agreed to fix the supply price of Lidoderm® for a period of time after which the price will be adjusted at future dates certain based on a price index defined in the Amended Agreement. Since future price changes are unknown, we have used prices currently existing under the Amended Agreement, and estimated our minimum purchase requirement to be approximately $32 million per year through 2012. The minimum purchase requirement shall remain in effect subsequent to 2012, except that Endo has the right to terminate the Amended Agreement after 2012, if we fail to meet the annual minimum requirement.

- Following cessation of our obligation to pay royalties to Hind Healthcare Inc. (Hind) under the Sole and Exclusive License Agreement dated as of November 23, 1998, as amended, between Hind and Endo, we will pay to Teikoku annual royalties based on our annual net sales of Lidoderm®.

- The Amended Agreement will expire on December 31, 2021, unless terminated in accordance with its terms. Either party may terminate this Agreement, upon thirty (30) days written notice, in the event that Endo fails to purchase the annual minimum quantity for each year after 2012 (e.g., 2013 through 2021) upon thirty (30) days written notice. Notwithstanding the foregoing, after December 31, 2021, the Amended Agreement shall be automatically renewed on the first day of January each year unless (i) we and Teikoku agree to terminate the Amended Agreement upon mutual written agreement or (ii) either we or Teikoku terminates the Amended Agreement with 180-day written notice to the other party, which notice shall not in any event be effective prior to July 1, 2022.

Amounts purchased pursuant to this agreement were $152.2 million, $152.3 million, and $142.2 million for the years ended December 31, 2008, 2007 and 2006, respectively.

Mallinckrodt Inc.

Under the terms of our agreement with Mallinckrodt, Mallinckrodt manufactures and supplies to us narcotic active drug substances, in bulk form, and raw materials for inclusion in our controlled substance pharmaceutical products. There is no minimum annual purchase commitment under this agreement. However, we are required to purchase a fixed percentage of our annual requirements of each narcotic active drug substance from Mallinckrodt. The purchase price for these substances is equal to a fixed amount, adjusted on an annual basis. The initial term of this agreement is July 1, 1998 until June 30, 2013, with an automatic renewal provision for unlimited successive one-year periods. Either party may terminate this agreement for a material breach. Amounts purchased pursuant to this agreement were $15.8 million, $16.5 million, and $15.3 million for the years ended December 31, 2008, 2007 and 2006, respectively.

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Almac Pharma Services

Under the terms of our agreement with Almac Pharma Services (Almac), a European manufacturer, Almac manufactures Frova® at its Ireland facility for commercial sale by us in the United States. The agreement with Almac will expire on January 1, 2010, unless terminated sooner in accordance with its terms and can be extended beyond January 1, 2010 upon mutual agreement by both parties. If no agreement as to any extension or termination is reached six months prior to the end of the term, then the agreement will automatically renew for a period of twelve months. Almac has agreed to fix the supply price of Frova® for a period of time after which the price will be adjusted at future dates certain based on a price index defined in the agreement, subject to an annual maximum increase.

Sharp Corporation

Under the terms of our agreement with Sharp Corporation (Sharp), a U.S. manufacturer, Sharp performs certain services for Endo including the packaging and labeling of Lidoderm® at its facility in Allentown, Pennsylvania, for commercial sale by us in the United States. The Sharp agreement will expire on March 1, 2011, subject to renewal for additional one-year periods upon mutual agreement by both parties. Endo has the right to terminate the Sharp agreement at any time upon ninety (90) days written notice. Amounts purchased pursuant to the Sharp agreement were $5.3 million, $5.1 million and $5.0 million for the years ended December 31, 2008, 2007 and 2006, respectively.

Ventiv Commercial Services, LLC

On May 15, 2008, we entered into a services agreement with Ventiv Commercial Services, LLC (Ventiv), (referred to as the Ventiv Agreement). Under the terms of the Ventiv Agreement, Ventiv will provide to Endo certain sales and marketing services through a contracted field force of approximately 275 sales representatives and other sales management positions, collectively referred to as the Ventiv Field Force. The Ventiv Field Force will promote primarily Voltaren® Gel and will be required to perform a minimum number of face-to-face one-on-one discussions with physicians and other healthcare practitioners for the purpose of promoting Voltaren® Gel and other Endo products within their respective approved indications during each year of the Ventiv Agreement, subject to certain provisions.

Under the terms of the Ventiv Agreement, we incurred a one-time implementation fee that we recognized in selling, general, and administrative expense in the second quarter of 2008. In addition, each month we are required to pay Ventiv a monthly fixed fee during the term of the Ventiv Agreement based on a pre-approved budget. Included in the fixed monthly fee are certain costs such as the Ventiv sales representative and district manager salaries, Ventiv field force travel, and office and other expenses captured on routine expense reports, as well as a fixed management fee. If the Ventiv Agreement is terminated prior to the completion of the first twelve months of Detailing (as defined in the Ventiv Agreement), Endo is obligated to pay Ventiv the remaining unpaid portion of the fixed management fee. During the term of the Ventiv Agreement, Ventiv will also be eligible to earn a performance-based bonus equal to the fixed management fee during each year of the Ventiv Agreement. This performance-based bonus is payable upon the achievement of certain conditions, including the number of Voltaren® Gel tubes sold and the number of Details achieved.

The Ventiv Agreement is effective April 1, 2008 and will expire on June 30, 2010. Among other standard and customary termination rights granted under the Ventiv Agreement, we may terminate the Ventiv Agreement at our sole discretion at any time upon 120 days written prior notice to Ventiv, at which time we may be required to pay Ventiv a termination fee of up to $1 million. In January 2009, we agreed to certain changes to the Ventiv Agreement allowing for modifications to certain provisions, including the modification to the termination rights such that Endo is now permitted to terminate the Ventiv Agreement at our sole discretion at any time upon 60 days written prior notice. The Ventiv Agreement can also be terminated by either party upon reasonable written notice, if either party has committed a material breach that has not been remedied within thirty (30) days from the giving of written notice.

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General

In addition to the manufacturing and supply agreements described above, we have agreements with (1) UPS Supply Chain Solutions, Inc. (f/d/b/a Livingston Healthcare Services, Inc.) for customer service support, warehouse and distribution services and certain financial functions that expires in 2010 and (2) Kunitz and Associates Inc. for assistance with adverse event reporting. Although we have no reason to believe that these agreements will not be honored, failure by any of these third parties to honor their contractual obligations may have a materially adverse effect on our business, financial condition, results of operations and cash flows.

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 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 Company s alliance partners, 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. Below is a brief summary of our most significant existing third party collaboration and license agreements. For a full discussion, including agreement terms and status, see our disclosures under Note 5. Acquisitions, License and Collaboration Agreements, included in the consolidated financial statements in Part IV, Item 15 of this Report.

Commercial Products

Novartis AG

On March 4, 2008, we entered into a license and supply agreement (referred to as the Voltaren® Gel Agreement) with and among Novartis AG and Novartis Consumer Health, Inc. (referred to as Novartis), to obtain the exclusive U.S. marketing rights for the prescription medicine Voltaren® Gel (diclofenac sodium topical gel) 1% (referred to as Voltaren® Gel or Licensed Product). Voltaren® Gel received regulatory approval in October 2007 from the FDA, becoming the first topical prescription treatment for use in treating pain associated with osteoarthritis and the first new product approved in the U.S. for osteoarthritis since 2001. Voltaren® Gel has been granted marketing exclusivity in the U.S. as a prescription medicine until at least October 2010.

Hind Healthcare Inc.

In November 1998, Endo entered into a license agreement (referred to as the Hind License Agreement) with Hind Healthcare Inc., or Hind, for the sole and exclusive right to develop, use, market, promote and sell Lidoderm® in the United States. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico.

Penwest Pharmaceuticals Co.

In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals Co. to exclusively co-develop opioid analgesic products for pain management, using Penwest s patent-protected proprietary technology, for commercial sale worldwide. On April 2, 2002, we amended and restated this strategic alliance agreement between the parties (the 2002 Agreement) to provide, among other things, that this collaboration would cover only the opioid analgesic product, oxymorphone ER, now known as Opana® ER. In January 2007, the Company and Penwest entered into an amendment (the 2007 Amendment) to the 2002

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Agreement. Under the terms of the 2007 Amendment, Endo and Penwest agreed to restructure the 2002 Agreement to provide that royalties payable to Penwest for U.S. sales of Opana® ER will be calculated based on net sales of the product rather than on operating profit, and to change certain other provisions of the 2002 Agreement.

Vernalis Development Limited

In July 2004, we entered into a license agreement and a loan agreement with Vernalis Development Limited, or Vernalis, under which Vernalis agreed to license exclusively to us rights to market Frova® (frovatriptan succinate) in North America. Launched in the U.S. in June 2002, Frova® is indicated for the acute treatment of migraine headaches in adults. The license agreement with Vernalis was amended in February 2008.

Products in development

In December 2008, we entered into a license agreement and a sponsored research agreement with Harvard University (referred to as the Harvard Agreement). Under the terms of the Harvard Agreement, we obtained the exclusive worldwide rights to a new combination pain-drug-delivery technique that targets pain-sensing neurons without affecting motor neurons. Endo will be responsible for development and commercialization of any drug candidates discovered under the Harvard Agreement. Under the terms of the Harvard Agreement, we made an upfront payment of $2.0 million and may pay up to an additional $16.5 million in clinical, regulatory and approval milestones. In addition, we agreed to provide research funding with respect to these products of approximately $2.0 million over the three-year life of the sponsored research agreement. Harvard will also receive payments from Endo based on a percentage of Endo s annual net sales of licensed products commercialized under the Harvard Agreement. Endo may terminate the Harvard Agreement upon 60 days prior written notice without penalty.

In February 2009, we entered into a discovery collaboration agreement with Aurigene Discovery Technologies Limited (referred to as the Aurigene Agreement). The Aurigene Agreement is a three-year collaboration to discover novel drug candidates to treat cancer. Endo has agreed to provide discovery research funding of approximately $3.0 million over the first three years of the Aurigene Agreement. Endo will be responsible for all clinical development and commercialization of drug candidates that advance into human testing. We also may be required to make additional clinical, regulatory and approval milestones of up to $29.8 million and commercial milestone payments of up to an additional $32.5 million based on cumulative net sales of products commercialized under the Aurigene Agreement. The Aurigene Agreement includes an initial three-year discovery research program, which may be terminated by Endo at our sole discretion upon 60 days prior written notice without penalty. The Aurigene Agreement will expire in its entirety if Endo does not select any development product candidates by the end of the discovery research program or upon satisfaction and/or expiration of Endo s obligations to make the milestone payments. Subsequent to the initial discovery research program, Endo may terminate the Aurigene Agreement at our sole discretion upon 30 days prior written notice without penalty.

In February 2009, we entered into a development, license and supply agreement with Grünenthal GMBH, referred to as Grünenthal, granting us the exclusive right in North America to develop and market Grünethal s investigational drug, axomadol (referred to as the Grünenthal Agreement). Currently in Phase II trials, axomadol is a patented new chemical entity being developed for the treatment of moderate to moderately-severe chronic pain and diabetic peripheral neuropthic pain. Under the terms of the Grünenthal Agreement, Endo will pay Grünenthal approximately 22.4 million euros up-front, and possibly additional clinical, regulatory and approval milestones of up to an additional 21.7 million euros and possibly development and commercial milestone payments of up to an additional $68 million. In addition, Grünenthal will receive payments from Endo based on a percentage of Endo s annual net sales of the product in the United States and Canada. The Grünenthal Agreement will expire in its entirety on the date of (i) the 15th anniversary of the first commercial sale of the product; or (ii) the expiration of the last issued patent claiming or covering the product, or (iii) the expiration of exclusivity

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granted by the FDA for the product, whichever occurs later. Among other standard and customary termination rights granted under the Grünenthal Agreement, we may terminate the Grünenthal Agreement at our sole discretion at any time upon 90 days written prior notice to Grünenthal and payment of certain penalties.

Other

In December 2007, we entered into a license, development and supply agreement with an undisclosed third party collaborative partner for the exclusive clinical development and commercialization rights in Canada and the United States for a certain technology to be utilized in our various product development activities.

We have also entered into certain other collaboration agreements with third parties for the development of pain management and other products. Potential payments pursuant to these contracts could total up to approximately $3.1 million. These agreements require us to share in the development costs of such products and grant marketing rights to us for such products. During the years ended December 31, 2008 and 2007, amounts expensed to research and development under these agreements was approximately $4.8 million and $1.4 million, respectively.

We have also licensed from universities and other companies rights to certain technologies or intellectual property generally in the field of pain management. We are generally required to make upfront payments as well as other payments upon successful completion of regulatory or sales milestones. In addition, these agreements generally require us to pay royalties on sales of the products arising from these agreements. These agreements generally permit Endo to terminate the agreement with no significant continuing obligation.

In July 2008, the Company made a $20 million investment in a privately-held company focused on the development of an innovative treatment for certain types of cancer. In exchange for our $20 million payment, we received an equity interest in the privately-held company and the rights to negotiate an exclusive worldwide development and commercialization arrangement with respect to a certain technology for use in a specified indication.

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.

Summary of Recent Events

In December 2008, we entered into a license agreement and a sponsored research agreement with Harvard University (referred to as the Harvard Agreement). Under the terms of the Harvard Agreement, we obtained the exclusive worldwide rights to a new combination pain-drug-delivery technique that targets pain-sensing neurons without affecting motor neurons.

On January 29, 2009, the Company announced that by mutual agreement it concluded its research collaboration with Alexza Pharmaceuticals, Inc.to develop an inhaled fentanyl product for the treatment of breakthrough pain using Alexza s Staccato® inhalation technology. The product, Staccato®fentanyl (AZ-003/EN-3284), has completed Phase I clinical testing and will be returned to Alexza. In 2007, Endo licensed exclusive rights to develop and commercialize AZ-003 in North America.

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In February 2009, we entered into a discovery collaboration agreement with Aurigene Discovery Technologies Limited (referred to as the Aurigene Agreement). The Aurigene Agreement is a three-year collaboration to discover novel drug candidates to treat cancer.

On February 23, 2009, BTB Purchaser Inc. (Purchaser), a Delaware corporation and a wholly-owned subsidiary of Endo Pharmaceuticals Holdings Inc., a Delaware corporation (Parent), completed its initial tender offer (the Offer) for all outstanding shares of common stock, par value $0.001 per share (the Shares), of Indevus Pharmaceuticals, Inc., a Delaware corporation (Indevus), at a price of $4.50 per Share, net to the seller in cash (less any required withholding taxes and without interest), plus contractual rights to receive up to an additional $3.00 per Share in contingent cash consideration payments (the Offer Price), pursuant to the terms of the Agreement and Plan of Merger, dated as of January 5, 2009, by and among Parent, Purchaser and Indevus (as amended, the Merger Agreement). The initial Offer period expired at 5:00 p.m., New York City time, on February 20, 2009. Indevus was advised by the depositary for the Offer that, as of that date, a total of approximately 61.4 million Shares were validly tendered and not withdrawn (including Shares delivered through notices of guaranteed delivery), representing approximately 77.972% of the Shares outstanding. On February 23, 2009, Parent announced that Purchaser had accepted for payment in accordance with the terms of the Offer all Shares that were validly tendered and not withdrawn prior to the expiration of the Offer. On that same day, Purchaser paid $276.1 million in aggregate initial cash consideration for the Shares tendered to the depositary and Parent entered into the Nebido Contingent Cash Consideration Agreement and the Octreotide Contingent Consideration Agreement (each as defined in the Merger Agreement), providing for the payment of up to an additional $3.00 per Share in contingent cash consideration payments, in accordance with the terms of the Offer.

On February 23, 2009, Parent also announced that Purchaser had commenced a subsequent offering period for all remaining untendered Shares. The subsequent offering period expired at 5:00 p.m., New York City time, on February 27, 2009. Indevus was advised by the depositary for the Offer that, as of the expiration of the subsequent offering period, an additional 2,238,757 Shares were validly tendered and not withdrawn, which together with the 61,358,944 Shares previously tendered represents approximately 80% of the Shares outstanding. On March 2, 2009, the Parent announced that it has extended the subsequent offering period until 5:00 p.m. New York City time on Friday, March 13, 2009.

The offering period may be extended in accordance with the terms of the Merger Agreement and the applicable rules and regulations of the Securities and Exchange Commission. Any such extension will be followed by a public announcement no later than 9:00 a.m., New York City time, on the next business day after the subsequent offering period was scheduled to expire. The same Offer Price per Share offered in the initial offering period of the Offer will be paid during the subsequent offering period. Purchaser will immediately accept for payment all Shares validly tendered during this subsequent offering period, and payment will be made promptly after acceptance, in accordance with the terms of the Offer. Procedures for tendering Shares during the subsequent offering period are the same as during the initial offering period with two exceptions: (1) Shares cannot be delivered by the guaranteed delivery procedure, and (2) pursuant to Rule 14d-7(a)(2) promulgated under the Securities Exchange Act of 1934, as amended, Shares tendered during the subsequent offering period may not be withdrawn. Indevus supports the Purchaser s decision to pursue the subsequent offering period.

The $286.2 million in initial cash consideration payable to holders of Shares tendered during the initial and subsequent offer period through February 27, 2009, has been, and any cash payable to holders of Shares tendered during the extended subsequent offering period and for Shares to be converted into the right to receive the Offer Price upon the merger of Purchaser with and into Indevus pursuant to the Merger Agreement, whereby Indevus will become a wholly owned subsidiary of Parent (the Merger), will be provided by cash on hand at Parent and its subsidiaries.

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The results of operations of Indevus Pharmaceuticals will be reflected in our consolidated statements of operations beginning on February 23, 2009.

In February 2009, we entered into a development, license and supply agreement with Grünenthal GMBH, referred to as Grünenthal, granting us the exclusive right in North America to develop and market Grünethal s investigational drug, axomadol (referred to as the Grünenthal Agreement). Currently in Phase II trials, axomadol is a patented new chemical entity being developed for the treatment of moderate to moderately-severe chronic pain and diabetic peripheral neuropthic pain.

Employees

As of December 31, 2008, we had 1,216 employees, of which 156 are engaged in research and development and regulatory work, 845 in sales and marketing, 24 in quality assurance and 191 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 27, 2009:

Name	Age	Position and Offices
David P. Holveck	63	President and Chief Executive Officer and Director
Nancy J. Wysenski	51	Chief Operating Officer
Ivan Gergel, M.D.	48	Executive Vice President, Research and Development
Caroline B. Manogue	40	Executive Vice President, Chief Legal Officer and Secretary
Edward J. Sweeney	39	Vice President, Controller and Principal Accounting Officer (Principal Financial Officer)

DAVID P. HOLVECK, 63, 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 and the Board of Directors of the Eastern Technology Council, the Board of Directors of Light Sciences Oncology, Inc., and effective February 23, 2009, the Board of Directors of Indevus Pharmaceuticals, Inc.

NANCY J. WYSENSKI, 51, was appointed Chief Operating Officer on September 6, 2007. Ms. Wysenski, a 25-year pharmaceutical industry veteran, was most recently the President and CEO of EMD Pharmaceuticals, Inc., the U.S. subsidiary of German-based Merck KGaA for more than seven years. Prior to joining and co-founding EMD, Ms. Wysenski, was the Senior Vice President of Operations at NetGenics, a start-up company specializing in sequencing software for use in drug discovery. Earlier, Ms. Wysenski held a number of positions of increasing scope and responsibility at Astra Merck, where she rose to Vice President of Sales. During her tenure at Astra Merck, she also served on the company s operating board. Ms. Wysenski began her pharmaceutical industry career in 1984 at Merck Human Health as a sales representative following a successful career in nursing. On February 23, 2009, Ms. Wysenski was appointed to the Board of Directors of Indevus Pharmaceuticals, Inc.

IVAN GERGEL, M.D., 48, 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

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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 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. On February 23, 2009, Mr. Gergel was appointed to the Board of Directors of Indevus Pharmaceuticals, Inc.

CAROLINE B. MANOGUE, 40, 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. At Endo, she is responsible for all aspects of the Company s legal function, including securities law, litigation, intellectual property and commercial law, as well as advising as to compliance with current laws and existing pharmaceutical company guidelines relating to, among other things, clinical, sales and marketing practices. In her capacity as Secretary, she is responsible for corporate governance matters and reports directly to the Board of Directors. 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.

EDWARD J. SWEENEY, 39, in his capacity as the Company s Vice President, Controller, serves as the Company s 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

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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., The Purdue Frederick Company, 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 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, or the FDCA Act, the FDA can approve an abbreviated new drug application, or ANDA, for a generic version of a branded drug and what is referred to as a Section 505(b)(2) new drug application, or 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

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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, or OGD, issued draft guidance making recommendations regarding establishing bioequivalence with our patent-protected product, Lidoderm® (lidocaine topical patch 5%), pursuant to which a party could seek ANDA approval of a generic version of that product. In that draft guidance, OGD has recommended a bioequivalence study characterizing the pharmacokinetic profile of lidocaine as well as a skin irritation/sensitization study of any lidocaine-containing patch formulation. This recommendation deviates from our understanding of the applicable regulations and of OGD s past practices, which, for a topically acting product such as Lidoderm®, would require demonstration of bioequivalence through a comparative clinical equivalency study rather than through a pharmacokinetic study.

On December 19, 2006, we submitted a Citizen Petition to the FDA requesting that the FDA apply existing bioequivalence regulations to any ANDA seeking regulatory approval of a generic drug product that references Lidoderm®. We submitted an amendment to that filing in August 2007 in order to provide additional data. Our 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 this 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 FDA regarding the draft guidance; those comments reiterated our position as set forth in the Petition, referencing the Petition and supporting data. The draft guidance remains available and has not been updated or revised since being issued.

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 15 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, particularly Lidoderm®, 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 net sales, gross profit, operating income, net income 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 net sales come from a small number of products.

The following table displays our net sales by product category and as a percentage of total net sales for the years ended December 31, 2008, 2007 and 2006 (dollars in thousands):

	Year Ended December 31					
	2008		2007		2006	
	$	%	$	%	$	%
Lidoderm®	765,097	61	705,587	65	566,785	62
Opana® ER and Opana®	180,429	14	107,143	10	6,845	1
Percocet®	129,966	10	121,742	11	102,707	11
Frova®	58,017	5	52,437	5	40,564	5
Voltaren® Gel	23,791	2				
Other brands	10,904	1	11,065	1	14,027	1
Total brands	1,168,204	93	997,974	92	730,928	80
Total generics	92,332	7	87,634	8	178,731	20
Total net sales	1,260,536	100	1,085,608	100	909,659	100

The FDA granted Lidoderm® orphan drug status for the treatment of the pain associated with post herpetic neuralgia, which meant, generally, that no other lidocaine-containing product could have been approved for this indication prior to March 19, 2006. While the orphan drug exclusivity period for Lidoderm® has expired, that product is covered by patents through 2015, and any party seeking approval for a generic version of Lidoderm® in spite of our patent rights would be obligated to notify us of the filing of an application with the FDA.

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 net sales, 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. Patent applications in the United States are maintained in secrecy until at least 18 months after the filing of the application with the PTO and, since publication of discoveries in the scientific or patent literature tends to lag 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

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

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

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

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

We may incur significant liability if it is determined that we are promoting 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 (OIG) and FDA both 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 and the FDA allow companies to engage in truthful, non-misleading, and non-promotional speech concerning their products. Although we believe that all of our communications regarding all of our products are in compliance with the relevant legal requirements, the OIG or the FDA may disagree, and 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, the FDA or the OIG may disagree, and we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. 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. 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.

Most 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 risk minimization action plans, which may prove difficult or expensive to comply with, and we and other pharmaceutical companies may face lawsuits.

Most 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

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its labeling. In addition, we believe that Purdue, the manufacturer of OxyContin®, faces or did face numerous lawsuits, including class action lawsuits, related to OxyContin® misuse or abuse. 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 U.S. Drug Enforcement Administration, or DEA, may impose new regulations concerning the manufacture, storage, transportation and sale of prescription narcotics. Such regulations may include new labeling requirements, the development and implementation of formal risk minimization action plans, 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 risk evaluation and mitigation strategies 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 net sales 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,

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

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

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

In addition, on September 27, 2007, through passage of the Food and Drug Administration Amendments Act of 2007, 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 risk evaluation and mitigation strategies 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

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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 Food and Drug Administration (FDA) sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of the drugs continue to outweigh the risks. The FDA has authority to require a REMS under the Food and Drug Administration Amendments Act of 2007 (FDAAA) when necessary to address whether the benefits of these products continue to outweigh the risks. On September 27, 2007, Congress 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.

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 for pain management products, 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.

In September 2007, we received a non-approvable letter from the FDA identifying deficiencies and asking for additional information pertaining to our supplemental New Drug Application (sNDA) for Frova® (frovatriptan succinate) 2.5 mg tablets for the short-term (six days per menstrual cycle) prevention of menstrual migraine (MM). We evaluated the points raised in the FDA notification, and we have determined that the appropriate course of action is to withdraw this sNDA without prejudice to refiling as afforded under 21 CFR 314.65. We notified the FDA of this withdrawal on April 7, 2008.

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.

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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 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.

There are risks associated with our recent acquisition of Indevus Pharmaceuticals, Inc., including but not limited to our ability to integrate the business into ours.

On February 23, 2009, BTB Purchaser Inc. (Purchaser), a Delaware corporation and a wholly-owned subsidiary of Endo Pharmaceuticals Holdings Inc., a Delaware corporation (Parent), completed its initial tender offer (the Offer) for all outstanding shares of common stock, par value $0.001 per share (the Shares), of Indevus Pharmaceuticals, Inc., a Delaware corporation (Indevus), at a price of $4.50 per Share, net to the seller in cash (less any required withholding taxes and without interest), plus contractual rights to receive up to an additional $3.00 per Share in contingent cash consideration payments (the Offer Price), pursuant to the terms of the Agreement and Plan of Merger, dated as of January 5, 2009, by and among Parent, Purchaser and Indevus (as amended, the Merger Agreement). The initial Offer period expired at 5:00 p.m., New York City time, on February 20, 2009. Indevus was advised by the depositary for the Offer that, as of that date, a total of approximately 61,358,944 Shares were validly tendered and not withdrawn (including Shares delivered through notices of guaranteed delivery), representing approximately 77.972% of the Shares outstanding. On February 23, 2009, Parent announced that Purchaser had accepted for payment in accordance with the terms of the Offer all Shares that were validly tendered and not withdrawn prior to the expiration of the Offer. On that same day, Purchaser paid $276,115,248 in aggregate initial cash consideration for the Shares tendered to the depositary and Parent entered into the Nebido Contingent Cash Consideration Agreement and the Octreotide Contingent Consideration Agreement (each as defined in the Merger Agreement), providing for the payment of up to an additional $3.00 per Share in contingent cash consideration payments, in accordance with the terms of the Offer.

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On February 23, 2009, Parent also announced that Purchaser had commenced a subsequent offering period for all remaining untendered Shares. On March 2, 2009, the Parent announced that Purchaser had commenced another subsequent offering period for all remaining untendered Shares until March 13, 2009 in accordance with the terms of the Merger Agreement and applicable rules and regulations of the Securities and Exchange Commission. The same Offer Price per Share offered in the initial offering period of the Offer will be paid during the subsequent offering period. Purchaser will immediately accept for payment all Shares validly tendered during this subsequent offering period, and payment will be made promptly after acceptance, in accordance with the terms of the Offer. Procedures for tendering Shares during the subsequent offering period are the same as during the initial offering period with two exceptions: (1) Shares cannot be delivered by the guaranteed delivery procedure, and (2) pursuant to Rule 14d-7(a)(2) promulgated under the Securities Exchange Act of 1934, as amended, Shares tendered during the subsequent offering period may not be withdrawn. Indevus supports the Purchaser s decision to pursue the subsequent offering period.

If a significant number of Indevus stockholders validly assert appraisal rights, a Delaware court might disagree with Endo s valuation and award the Indevus stockholders a significantly higher price than Endo intended to pay for Indevus shares, which could raise the cost to the Company of acquiring Indevus.

Following the completion of the pending subsequent offering period, the Company intends to merge its wholly owned subsidiary, BTB Purchaser Inc., with and into Indevus. Indevus stockholders who did not tender their Indevus shares into the tender offer will receive in the merger the right to receive the same consideration per share as if such holder had tendered its shares into the Offer. Under Section 262 of the Delaware General Corporation Law, Indevus stockholders who have not tendered their shares into the tender offer and who have not voted in favor of the merger will have certain rights to demand appraisal of, and to receive payment in cash of the fair value of their Indevus shares. Indevus stockholders who perfect these rights by complying with the procedures set forth in Section 262 of the Delaware General Corporation Law will have the fair value of their shares determined by the Delaware Court of Chancery and will be entitled to receive a cash payment equal to such fair value. The fair value as determined by the Court could be more than the consideration paid by BTB Purchaser in the Offer, which could raise the cost to the Company of acquiring Indevus stock. If a significant number of Indevus stockholders validly assert these appraisal rights, a Delaware court might disagree with the Company s valuation and award the Indevus stockholders a significantly higher price than the Company intended to pay for Indevus shares.

Our consolidated financial statements may be impacted in future periods based on the accuracy of our valuation of the Indevus business.

Accounting for our recent acquisition of Indevus will involve a complex and subjective valuation of the assets and liabilities of Indevus, which will be recorded in the Company s consolidated financial statements pursuant to Financial Accounting Standards Board Statement No. 141(R). 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.

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

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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 risk evaluation and mitigation strategies 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 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.

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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.

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.

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On December 8, 2003, President Bush signed into law the 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 may result 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 will not be 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 and results of operations.

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.

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 (CER) relating to healthcare treatments. Although the concept of CER now has significant momentum, numerous unresolved and potentially contentious issues remain, and stakeholders should follow 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 as the Company s business, financial condition, results of operations and cash flows is not yet known.

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

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

Government regulations regarding reporting and payment obligations are complex and we are continually evaluating the methods we use to calculate and report the amounts owed with respect to Medicaid and other government pricing programs. Our calculations are subject to review and challenge by various government agencies and authorities and it is possible that any such review could result either in material changes to the method used for calculating the amounts owed to the pertinent government agency (or agencies), or to the amounts themselves. In addition, because our processes for these calculations and our judgments supporting these calculations involve, and will continue to involve, subjective decisions, these calculations are subject to the risk of errors. As noted above, any governmental agency that commences an action, if successful, could impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal healthcare programs (including Medicaid and Medicare). Some of the applicable laws impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments and even in the absence of such ambiguity a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. Any such penalties or sanctions could have a material adverse effect on our business, financial position, results of operations and cash flows, and could cause the market value of our common stock to decline.

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

Even if we obtain regulatory approvals, uncertainty exists as to whether the market will accept our products. A number of factors may limit the market acceptance of our products, including the timing of regulatory approvals and market entry relative to competitive products, the availability of alternative products, the price of our products relative to alternative products, the availability of third party reimbursement and the extent of marketing efforts by third party distributors or agents that we retain. We cannot assure you that our products will receive market acceptance in a commercially viable period of time, if at all. We cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position, results of operations and cash flows may be

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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, 2008, 2007 and 2006 were as follows:

	2008	2007	2006
Customer A	36%	34%	28%
Customer B	31%	31%	29%
Customer C	15%	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 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, 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, or EPA, and the Occupational Safety and Health Administration, or OSHA, and their counterpart agencies at the state level, could slow down or curtail operations of third party manufacturers.

We have entered into minimum purchase requirement contracts with some of our third party manufacturers. In May 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc., or Novartis, pursuant to which Novartis has agreed to manufacture certain of our commercial products in addition to products in development. As of December 31, 2008, we are required to purchase a minimum of approximately $20 million per year in 2009 and 2010, and approximately $21 million of product from Novartis in 2011.

We also have a long-term contract with Teikoku Seiyaku Co., Ltd., or 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,

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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 suppliers. If the market for the products that utilize these raw materials substantially contracts or disappears, we will continue to be financially obligated under these contracts and meeting such obligations could have a material adverse effect on our business.

We are dependent upon third parties to provide us with various estimates as a basis for our financial reporting. While we undertake certain procedures to review the reasonability 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

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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, 2008, $240.5 million of our marketable securities portfolio was invested in A, AA, and AAA rated investments in auction-rate debt securities. Auction-rate securities are long-term variable rate bonds tied to short-term interest rates. After the initial issuance of the securities, the interest rate on the securities is reset periodically, at intervals established at the time of issuance (e.g., every seven, twenty-eight, or thirty-five days; every six months; etc.). In an active market, auction-rate securities are bought and sold at each reset date through a competitive bidding process, often referred to as a Dutch auction . Auctions are successful when the supply and demand of securities are in balance. Financial institutions brokering the auctions would also participate in the auctions to balance the supply and demand. Beginning in the second half of 2007, auctions began to fail for specific securities and in mid-February 2008 auction failures became common, prompting market participants, including financial institutions, to cease or limit their exposure to the auction-rate market. Given the current negative liquidity conditions in the global credit markets, the auction-rate securities market has become inactive. Consequently, our auction-rate securities are currently illiquid through the normal auction process.

The underlying assets of our auction-rate securities are student loans. Student loans are insured by either the Federal Family Education Loan Program, or FFELP, or a combination of FFELP and other monocline insurers such as Ambac Assurance Corp., or AMBAC, and MBIA Insurance Corp, or MBIA. As of February 25, 2009, MBIA was rated Ba1 by Moody s and BB+ by Standard and Poor s. AMBAC was rated Ba1 by Moody s and BBB by Standard and Poor s. These insurers are reported to be experiencing financial difficulty, which could negatively affect their ratings and thus the ratings of the auction-rate securities that we hold. Any ratings downgrade or potential ratings downgrade could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our auction-rate securities have been in an unrealized loss position since the second quarter of 2008. Prior to November 2008, all unrealized losses on our auction-rate securities were determined to be temporary in nature based on our ability and intent to hold the underlying securities until their anticipated recovery.

On November 10, 2008, the Company accepted an offer (referred to as the UBS Offer) made by UBS AG (UBS) of auction-rate securities rights (the Rights) to the Company and other clients of UBS Securities LLC and UBS Financial Services Inc. (collectively, 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 (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 (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

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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, 2008, we had Eligible Auction-Rate Securities with original par value of $254.1 million, representing 93% of our total auction-rate securities portfolio at par. The remaining seven percent (7%), 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.

Acceptance of the UBS Offer constituted a substantive change in facts and circumstances that altered the Company s view that it intends to hold the Eligible Auction-Rate Securities until their anticipated recovery. As a result, as of November 2008, we recognized an other-than-temporary impairment charge of approximately $26.4 million that is included in interest and other income, net in the Consolidated Statements of Operations included in Part IV Item 15 of this Annual Report on Form 10-K. The charge was measured as the difference between the par value and fair value of the auction-rate securities on November 10, 2008. Previous recognized declines in fair value associated with the Eligible Auction-Rate Securities that were determined to be temporary were transferred out of other comprehensive income and charged to earnings as part of the $26.4 million impairment charge. Concurrent with the acceptance of the UBS offer, the Company made a one-time election to transfer the Eligible Auction-Rate Securities from the available-for-sale category to the trading category pursuant to SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. The Company made the election to transfer the securities into trading after considering the unprecedented failure of the entire market for auction-rate securities and the broad-reaching legal settlements that have been agreed to by certain broker-dealers and securities regulators. Changes in the fair value of the Eligible Auction-Rate Securities are recorded to earnings. Subsequent to the transfer into the trading category, the fair value of these securities decreased by an additional $4.2 million which was recorded as a charge to earnings and included in interest and other income, net in the Consolidated Statements of Operations included in Part IV, Item 15 of this Annual Report on Form 10-K.

At December 31, 2008, the fair value of our auction-rate securities was approximately $240.5 million, representing a 12%, or $32.4 million discount from their original purchase price or par value. Accordingly, the carrying value of our auction-rate securities were reduced by approximately $32.4 million at December 31, 2008, reflecting the change in fair value, which the Company attributes to liquidity issues rather than credit issues. The portion of this decline in fair value related to the Eligible Auction-Rate Securities was recorded in earnings as an other-than-temporary impairment charge or as changes in the fair value of trading securities as described above. The Company has assessed the portion of the decline in fair value not associated with the Eligible Auction-Rate Securities to be temporary due to the financial condition and near-term prospects of the underlying issuers, our intent and ability to retain our investment in the issuers for a period of time sufficient to allow for any anticipated recovery in market value and based on the extent to which fair value is less than par. Accordingly, we recorded a $1.7 million reduction in shareholders equity in accumulated other comprehensive loss.

Our auction-rate securities continue to pay interest according to their stated terms. However, due to the lack of observable market prices, we will continue to evaluate whether our auction-rate securities, not subject to the UBS Offer, that remain classified as available-for-sale securities, have declined in value. If it is concluded that an impairment exists, we must evaluate if the decline in value is considered temporary or other-than-temporary. Although there can be no assurance, we believe that any impairment charge on our available-for-sale auction rate securities would be considered temporary at this time due to the relatively short period of time and the extent to which the fair value has been less than par, the financial condition and near-term prospects of the underlying issuers, and our intent and ability to retain our investment in the issuers for a period of time sufficient to allow for any anticipated recovery in market value. At this point in time, we have the intent and ability to hold the available-for-sale auction-rate securities over their anticipated recovery periods. However, there can be no assurance that our current belief that the available-for-sale auction-rate securities will recover their value will not change, at which time an other-than-temporary impairment could occur. An other-than-temporary impairment would be recorded as a charge to earnings.

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The credit and capital markets have continued to deteriorate in 2009. If uncertainties in these markets continue, these 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 becomes insolvent, UBS may not meet its obligations under the Rights.

Our Rights allow us to require UBS to purchase 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. Our Rights are not secured by any assets of UBS. As a result, if UBS becomes insolvent in the future, UBS may become able 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 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.

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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 recent concerns over corporate governance in the United States, corporate accounting scandals 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 and stockholders equity. As of December 31, 2008, goodwill and other intangibles comprised approximately 20% of our total assets and 34% of our stockholders equity. Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets, prescribes a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our one reporting unit. If the net book value of our reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting unit s fair value to all of its assets and liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit s goodwill is less than its carrying amount. Our other intangible assets, consisting of licenses and patents, are assessed for impairment, in accordance with Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows of the product. In the event the carrying value of the asset exceeds the undiscounted future cash flows of the product and the carrying value is not considered recoverable, impairment exists. An impairment loss is measured as the excess of the asset s carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs. During the year ended December 31, 2008, as a result of our decision to discontinue the development of Rapinyl , we recorded an impairment charge of $8.1 million related to the remaining unamortized portion of our Rapinyl intangible asset. During the year ended December 31, 2007, as a result of the continued lack of commercial success of Synera™, we recorded an impairment charge of $0.9 million related to the remaining unamortized portion of our ZARS intangible asset. During the year ended December 31, 2006, we recorded impairment charges of $31.3 million related to certain intangible assets for Synera™ and DepoDur®.

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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, our 2009 guidance is based upon our assumptions that our sales of Opana® and Opana® ER and Voltaren® Gel 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. Within the last 12 months through December 31, 2008, our stock has traded between $13.87 and $28.48 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 change:

- 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, including 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 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;

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litigation; and

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

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 5,207,735 shares that may be issued upon the exercise of options or vesting of restricted stock units outstanding as of December 31, 2008, 2,579,695 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, should we enter into a new credit facility with a third party lender, it is possible that the lender would limit or restrict the payment of dividends. 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.

We are exposed to risks if we are unable to comply with changes to laws affecting public companies, including the Sarbanes-Oxley Act of 2002, and also to increased costs associated with complying with such laws.

Recently enacted and any future changes to the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 in the United States, will cause us to incur increased costs as we evaluate the implications of new rules and respond to new requirements. Delays or a failure to comply with the new laws, rules and regulations could result in enforcement actions, the assessment of other penalties and civil suits. The new laws and regulations make it more expensive for us under indemnities provided by us to our officers and directors and may make it more difficult for us to obtain certain types of insurance, including liability insurance for directors and officers; as such, we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, or as executive officers. We may be required to hire additional personnel and utilize additional outside legal, accounting and advisory services all of which could cause our general and administrative costs to increase beyond what we currently have planned.

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.

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

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

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

Campaigns by significant investors to effect changes at publicly traded companies have increased in recent years. In August 2007, affiliates of D.E. Shaw & Co., L.P., which collectively currently beneficially own approximately 13.2 million shares of our outstanding common stock, sent letters to our Board of Directors suggesting, among other things, that the Company begin a process of evaluating strategic alternatives and explore a recapitalization. In April 2008, we reached an agreement with the D. E. Shaw group, pursuant to which Endo s Board of Directors nominated William F. Spengler at the 2008 Annual Meeting of Stockholders to serve as a member of the Company s Board of Directors. Mr. Spengler is an independent unaffiliated person who was recommended by D.E. Shaw to our Board of Directors. The D. E. Shaw group agreed to vote all of its shares in favor of the election of each of the Board s nominees at our 2008 Annual Meeting of Stockholders. At the 2008 Annual Meeting of Stockholders, the Company stockholders elected Mr. Spengler as a director of the Company. As a condition to the agreement, the D. E. Shaw group has agreed not to solicit proxies from the Company s stockholders in connection with the election of directors or other matters until and, subject to certain other agreements, through the Company s 2009 Annual Meeting of Stockholders.

If a proxy contest were to be pursued by D.E. Shaw or any stockholder 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.

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

Not applicable.

Item 2. ***Properties***

We lease all of our properties pursuant to operating leases. Of these, the most significant are our corporate headquarters in Chadds Ford, Pennsylvania and our research and development facility located in Westbury, New York. A description of the material terms of each of the agreements pertaining to these properties follows:

Chadds Ford, Pennsylvania

Painters Crossing One Associates, L.P. Lease Agreement. On May 5, 2000, we entered into a ten-year lease with Painters Crossing One Associates, L.P. pursuant to which Painters Crossing leases to us an office

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comprised of approximately 47,756 square feet located on the campus of our corporate headquarters in Chadds Ford, Pennsylvania. By amendment dated February 26, 2001, this lease commenced on August 1, 2001 and will end on July 31, 2011. During the term of the lease, the annual rent is a fixed amount paid in equal monthly installments that increase after the first five years of the lease.

Painters Crossing Two Associates, L.P. Lease Agreement. On November 13, 2003, we entered into a ten-year lease with Painters Crossing Two Associates, L.P. pursuant to which Painters Crossing leases to us an office comprised of approximately 64,424 square feet located on the campus of our corporate headquarters in Chadds Ford, Pennsylvania. By amendment dated February 16, 2005, this lease commenced on February 1, 2005 and will end on January 31, 2015. We, at our discretion, have the right to terminate this lease at the end of the sixth year, by providing two years notice and paying a fixed termination fee to Painters Crossing. During the term of the lease, the annual rent is a fixed amount paid in equal monthly installments that increase after the first five years of the lease.

Painters Crossing Three Associates, L.P. Lease Agreement. On January 19, 2007, we entered into a ten-year lease with Painters Crossing Three Associates, L.P. pursuant to which Painters Crossing leases to us an office building of approximately 48,600 square feet located on the campus of our corporate headquarters in Chadds Ford, Pennsylvania. This lease commenced on April 1, 2008 and will end on March 31, 2018. During the term of the lease, the annual rent is a fixed amount paid in equal monthly installments that increase after the first five years of the lease.

Westbury, New York

Dawson Holding Company Lease Agreement. On January 6, 2003, we entered into a ten-year lease with Dawson Holding Company pursuant to which Dawson Holding Company leases to us a facility comprised of approximately 24,190 square feet located in Westbury, New York. The annual rent due for this facility was fixed in the first year of the lease and escalates by a fixed percentage each year thereafter. This ten-year lease is not assignable without the consent of the landlord, Dawson Holding. This lease may be terminated upon 30 day s written notice only upon the occurrence of certain events as defined in the lease agreement.

Indevus Pharmaceuticals, Inc.

Indevus Pharmaceuticals, Inc., our recently acquired majority-owned subsidiary, leases its corporate headquarters comprised of approximately 53,200 square feet located in Lexington, Massachusetts under two leasing agreements with total annual base rent of approximately $1.3 million. The initial terms for these leases expire in 2010 and 2012. Indevus also leases two facilities in Cranbury, New Jersey consisting of a total of approximately 51,000 square feet with total annual base rent of approximately $1.3 million. The initial terms of these leases expire in 2015.

Item 3. ***Legal Proceedings***

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

Item 4. ***Submission of Matters to a Vote of Security Holders***

No matters were submitted to a vote of security holders during the fourth quarter of our fiscal year ended December 31, 2008.

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PART II

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

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

	Endo Common Stock	
	High	**Low**
Year Ending December 31, 2008		
1st Quarter	$ 28.48	$ 22.62
2nd Quarter	$ 26.56	$ 23.60
3rd Quarter	$ 25.47	$ 19.46
4th Quarter	$ 25.99	$ 13.87
Year Ending December 31, 2007		
1st Quarter	$ 32.63	$ 26.91
2nd Quarter	$ 35.85	$ 28.94
3rd Quarter	$ 35.20	$ 28.86
4th Quarter	$ 30.90	$ 26.04

Holders. As of February 20, 2009, we estimate that there were approximately 77 record holders of our common stock.

Dividends. We have never declared or paid any cash dividends on our capital stock. Prior to its expiration on December 21, 2006, our credit facility contained limitations and restrictions on the payment of dividends. Since these restrictions have lapsed, 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. We anticipate that, for the foreseeable future, we will retain our earnings in order to finance strategic investments in our business.

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Performance Graph. The following graph provides a comparison of the cumulative total stockholder return on the Company s common stock with that of the cumulative total stockholder return on the (i) NASDAQ Stock Market Index (U.S.) and (ii) the NASDAQ Pharmaceutical Index, commencing on December 31, 2003 and ending December 31, 2008. The graph assumes $100 invested on December 31, 2003 in the Company s common stock and in each of the comparative indices. Our historic stock price performance is not necessarily indicative of future stock price performance.

	December 31,					
	2003	2004	2005	2006	2007	2008
Endo Pharmaceuticals Holdings Inc.	$ 100.00	$ 108.52	$ 156.30	$ 142.46	$ 137.76	$ 133.68
NASDAQ Composite Index	$ 100.00	$ 110.08	$ 112.88	$ 126.51	$ 138.13	$ 80.47
NASDAQ Pharmaceutical Index	$ 100.00	$ 110.22	$ 111.87	$ 114.89	$ 106.37	$ 97.32

Recent sales of unregistered securities; Use of proceeds from registered securities. During the fourth quarter of 2008, the Company did not sell any unregistered securities.

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Purchase of equity securities by the issuer and affiliated purchasers. The following table reflects purchases of Endo Pharmaceuticals Holdings Inc. common stock by the Company during the three months ended December 31, 2008:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plan(1)	Approximate Dollar Value of Shares that May Yet be Purchased Under the Plan
October 1, 2008 to October 31, 2008	548,500	$ 20.25	548,500	$ 325,184,018
November 1, 2008 to November 30, 2008				$ 325,184,018
December 1, 2008 to December 31, 2008				$ 325,184,018
Total	548,500	$ 20.25	548,500	$ 325,184,018

(1) In April 2008, our Board of Directors approved a share repurchase program, authorizing the Company to repurchase in the aggregate up to $750 million of shares of its outstanding common stock. Purchases under this program may be made from time to time in open market purchases, privately-negotiated transactions, accelerated stock repurchase transactions or otherwise, as determined by Endo. In April 2008 we entered into a privately-negotiated $325.0 million accelerated repurchase agreement as part of the broader share repurchase program described above. Pursuant to the accelerated share repurchase agreement, we purchased approximately 11.9 million shares of our common stock on April 15, 2008. On August 14, 2008, Endo received approximately 1.4 million additional shares of our common stock based on the volume-weighted average price of our common stock during a specified averaging period set forth by the accelerated share repurchase agreement. In addition to the accelerated share repurchase, beginning in April 2008 we made open market purchases of our common stock as part of our broader share repurchase program. During the three months ended December 31, 2008, we purchased approximately 0.5 million shares of our common stock on the open market for a total purchase price of approximately $11.1 million. During the year ended December 31, 2008, we purchased approximately 4.5 million shares of our common stock on the open market for a total purchase price of approximately $99.8 million. This column discloses the number of shares purchased pursuant to the Board s authorization.

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

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

	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Net sales	$ 1,260,536	$ 1,085,608	$ 909,659	$ 820,164	$ 615,100
Cost and Expenses:					
Cost of sales	267,235	217,369	208,889	192,296	143,964
Selling, general and administrative	488,063	411,869	346,303	217,267	183,692
Research and development	110,211	138,255	86,629	91,837	54,709
Loss on disposal of other intangible					3,800
Impairment of other intangible assets	8,083	889	31,263	5,515	
Purchased in-process research and development	(530)		26,046		
Operating income	387,474	317,226	210,529	313,249	228,935
Interest expense	8,354	117	1,384	1,744	1,255
Interest and other income, net	(23,080)	(36,141)	(24,589)	(12,739)	(3,416)
Income before income tax	402,200	353,250	233,734	324,244	231,096
Income tax	140,459	125,810	95,895	121,949	87,787
Net income	$ 261,741	$ 227,440	$ 137,839	$ 202,295	$ 143,309
Basic and Diluted Net Income Per Share:					
Basic	$ 2.12	$ 1.70	$ 1.03	$ 1.53	$ 1.09
Diluted	$ 2.12	$ 1.69	$ 1.03	$ 1.52	$ 1.08
Shares Used to Compute Basic Net Income Per Share	123,248	133,903	133,178	132,242	131,805
Shares Used to Compute Diluted Net Income Per Share	123,720	134,525	133,911	133,289	132,718
Cash dividends declared per share					

	As of and for the Year Ended December 31,				
	2008	2007	2006	2005	2004
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 775,693	$ 350,325	$ 628,085	$ 500,956	$ 278,034
Working capital	797,221	668,489	697,915	483,872	294,329
Total assets	1,956,631	1,702,638	1,396,689	1,371,678	947,491
Long-term debt	371,695				
Other long-term obligations, including capitalized leases	70,729	13,390	17,602	18,795	18,293
Stockholders equity	$ 1,127,734	$ 1,292,290	$ 1,040,988	$ 843,370	$ 655,950
Other Financial Data:					
Net cash provided by operating activities	$ 356,602	$ 365,742	$ 345,334	$ 284,644	$ 170,545
Net cash provided by (used in) investing activities	178,832	(614,528)	(66,449)	(26,684)	(107,824)
Net cash used in financing activities	$ (110,066)	$ (28,974)	$ (151,756)	$ (35,038)	$ (14,260)

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

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

EXECUTIVE SUMMARY

About the Company

Endo Pharmaceuticals, which we refer to as Endo , we , us or the Company , is a specialty pharmaceutical company with market leadership in pai management. We are engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used primarily to treat and manage pain. Through a dedicated sales force of approximately 725 sales representatives in the United States and through a contracted field force of approximately 275 sales representatives and other sales management positions, we market our branded pharmaceutical products to high-prescribing physicians in pain management, neurology, surgery, anesthesiology, oncology and primary care. Our sales force also targets retail pharmacies and other healthcare professionals throughout the United States.

We have a portfolio of branded products that includes brand names such as Lidoderm®, Opana® ER and Opana®, Percocet®, Frova®, and Voltaren® Gel. Branded products comprised approximately 93% of our net sales in 2008, with 61% of our net sales coming from Lidoderm®. Our non-branded generic portfolio, which accounted for 7% of net sales in 2008, currently consists of products primarily focused in pain management. We focus on selective generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing.

We have recently acquired Indevus Pharmaceuticals, a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. Indevus s approved products include Sanctura® and Sanctura XR™ for overactive bladder (OAB), which is co-promoted with Allergan, Inc. (Allergan), Vantas® for advanced prostate cancer, Supprelin® LA for central precocious puberty (CPP), Delatestryl® for the treatment of hypogonadism and Valstar for bladder cancer. Indevus also has a core urology and endocrinology portfolio containing multiple compounds in development including Nebido® for hypogonadism, PRO 2000 for the prevention of infection by HIV and other sexually-transmitted pathogens, and the octreotide implant for acromegaly and carcinoid syndrome.

2008 A Year in Review

We believe that the Company s 2008 results reflect the Company s ability to operate in a competitive environment through execution of its business strategy. Significant items affecting the results of our 2008 operations include:

- The continued growth in net sales of our branded product portfolio;
- An in-depth review of research and development (R&D) activities, including an analysis of R&D priorities, focus and available resources for current and future projects as well as the commercial potential for each product;
- A focus on operations to assess our core competencies and cost infrastructure, resulting in improved effectiveness of our business operations and a reduction in certain operating expenses; and
- The balanced deployment of cash for investment in business development initiatives, strengthening of our capital structure and stock repurchases.

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Net sales for the year ended December 31, 2008 were $1.26 billion, a 16% increase over 2007, with net income in 2008 of $261.7 million, or $2.12 per diluted share, as compared to 2007 net income of $227.4 million or $1.69 per diluted share. The increase in sales was primarily due to the continued growth of Lidoderm®, Opana® ER and Opana®, and the launch of Voltaren® Gel in March of 2008. The increase in net income is primarily attributable to increased sales growth and favorability in research and development expense as upfront and milestone payment to partners decreased year-over-year.

Working capital as of December 31, 2008 improved to $797.2 million due to cash generated from operating activities of $356.6 million, offset by certain cash outlays for licensing and other investments totaling $105.0 million, treasury share repurchases totaling approximately $111.0 million and capital expenditures of $17.4 million. See Working Capital below.

Strategic Focus

Our business strategy is to maximize the future growth of the Company and to strengthen our position as a leading specialty pharmaceutical company by delivering innovative, commercially viable products and technologies to meet unmet medical needs in our existing therapeutic and complementary areas. Execution of our strategy will incorporate the following key elements:

- Developing new products through both an internal and a virtual research and development organization with greater scientific and clinical capabilities;
- Expanding the Company s product line by acquiring new products and technologies in existing therapeutic and complementary areas;
- Increasing revenues and earnings through sales and marketing programs for our innovative product offerings and effectively using the Company s resources; and
- Providing additional resources to support our generics business.

We believe that successful execution of our business strategy will enhance shareholder value.

During 2008, we completed a review of operations to assess our core competencies, cost infrastructure and growth opportunities. As a result of this review, we are pursuing several initiatives to improve the effectiveness of our business operations, reduce expenses and create additional long-term value for our customers and stockholders. In addition to implementing selective personnel reductions, we have decided to change our business structure and reduce our utilization of outside consultants to create a more effective operating model relative to our historical operating model.

The Company is working to implement this new strategy through the following initiatives:

Refocused sales and marketing programs:

We recently reorganized our commercial group and sales territories to increase the operating efficiency and effectiveness of the Company s sales teams. This reorganization is intended to make the Company s sales representatives more responsive to our customers and better able to allocate time to physicians who may require additional information about the Company s products, particularly Lidoderm®, Opana® ER and Opana® , Voltaren® Gel and Frova®.

New research and development priorities:

Subsequent to the appointment of Dr. Ivan Gergel as executive vice president of research and development in 2008, the Company conducted an in-depth review of its research and development activities. The review included an analysis of the Company s R&D priorities, focus and available resources for current and future

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projects as well as the commercial potential for each product. As a result of this review, the Company decided to discontinue development of EN3267, Rapinyl , the sub-lingual, fast-dissolving tablet of fentanyl intended for treatment of breakthrough cancer pain, and EN3269, topical ketoprofen patch, being studied for the treatment of acute pain associated with soft-tissue injuries. In January 2009, the Company announced that by mutual agreement it concluded its research collaboration with Alexza Pharmaceuticals, Inc. to develop an inhaled fentanyl product for the treatment of breakthrough pain using Alexza s Staccato® inhalation technology. Further, in February 2009, the Company decided to discontinue all development activities related to EN3285, an oral rinse being studied for the prevention or delay of oral mucositis (OM) and EN3270 transdermal sufentanil patch for the treatment of moderate-to-severe chronic pain.

The Company also decided to expand its medicinal chemistry, project management and biostatistics competencies to help it conduct preclinical research and more efficiently manage the clinical development of new product candidates by contract research organizations.

Investment in new therapeutic areas:

We believe Endo s pain management products, strong revenue base and sales teams represent strategic assets that can be leveraged to expand the Company s pharmaceutical business beyond the treatment of pain. We are identifying complementary medical specialties where demographic, healthcare and reimbursement trends favor the consideration of new products to address unmet medical needs, such as certain pelvic diseases that are treated by urologists, endocrinologists and oncologists.

This strategy underlies our recent acquisition of Indevus Pharmaceuticals. Indevus currently markets products to treat overactive bladder, prostate cancer, hypogonadism and central precocious puberty and is pursuing regulatory approval of drugs to treat hypogonadism and acromegaly. The combined company will market products through three sales forces and have the capability to develop innovative new therapies using a novel drug delivery technology. We believe this acquisition will make Endo a stronger competitor, a more valuable healthcare supplier and a more successful company.

Endo intends to pursue other strategic acquisitions that support the growth of the Company s pain management business and its expansion into other therapeutic specialties, while continuing to make strategic decisions to support and grow our generics business.

Indevus Acquisition

On February 23, 2009, BTB Purchaser Inc. (Purchaser), a Delaware corporation and a wholly-owned subsidiary of Endo Pharmaceuticals Holdings Inc., a Delaware corporation (Parent), completed its initial tender offer (the Offer) for all outstanding shares of common stock, par value $0.001 per share (the Shares), of Indevus Pharmaceuticals, Inc., a Delaware corporation (Indevus), at a price of $4.50 per Share, net to the seller in cash (less any required withholding taxes and without interest), plus contractual rights to receive up to an additional $3.00 per Share in contingent cash consideration payments (the Offer Price), pursuant to the terms of the Agreement and Plan of Merger, dated as of January 5, 2009, by and among Parent, Purchaser and Indevus (as amended, the Merger Agreement). Indevus was advised by the depositary for the Offer that, as of the expiration of the Offer, a total of approximately 61.4 million Shares were validly tendered and not withdrawn (including Shares delivered through notices of guaranteed delivery), representing approximately 77.972% of the Shares outstanding. On February 23, 2009, Parent announced that Purchaser had accepted for payment in accordance with the terms of the Offer all Shares that were validly tendered and not withdrawn prior to the expiration of the Offer. On that same day, Purchaser paid $276.1 million in aggregate initial cash consideration for the Shares tendered to the depositary and Parent entered into the Nebido Contingent Cash Consideration Agreement and the Octreotide Contingent Consideration Agreement (each as defined in the Merger Agreement), providing for the payment of up to an additional $3.00 per Share in contingent cash consideration payments, in accordance with the terms of the Offer. Additionally, the Purchaser placed $175 million in escrow until December 2009 to fund the potential Nebido Contingent Cash Agreement.

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On February 23, 2009, Parent also announced that Purchaser had commenced a subsequent offering period for all remaining untendered Shares. Indevus was advised by the depositary for the Offer that, as of the expiration of the subsequent offering period, an additional 2,238,757 Shares were validly tendered and not withdrawn, which together with the 61,358,944 Shares previously tendered represents approximately 80% of the Shares outstanding.

The offering period has been extended until March 13, 2009 in accordance with the terms of the Merger Agreement and the applicable rules and regulations of the Securities and Exchange Commission. The same Offer Price per Share offered in the initial offering period of the Offer will be paid during the subsequent offering period. Purchaser will immediately accept for payment all Shares validly tendered during this subsequent offering period, and payment will be made promptly after acceptance, in accordance with the terms of the Offer. Procedures for tendering Shares during the subsequent offering period are the same as during the initial offering period with two exceptions: (1) Shares cannot be delivered by the guaranteed delivery procedure, and (2) pursuant to Rule 14d-7(a)(2) promulgated under the Securities Exchange Act of 1934, as amended, Shares tendered during the subsequent offering period may not be withdrawn. Indevus supports the Purchaser s decision to pursue the subsequent offering period.

The $286.2 million in initial cash consideration paid and payable to holders of Shares tendered during the initial and subsequent offer period has been, and any cash payable to holders of Shares tendered during the additional subsequent offering period and for Shares to be converted into the right to receive the Offer Price upon the merger of Purchaser with and into Indevus pursuant to the Merger Agreement, whereby Indevus will become a wholly owned subsidiary of Parent (the Merger), has been and will be provided by cash on hand at Parent and its subsidiaries.

Indevus currently markets products to treat overactive bladder, prostate cancer, hypogonadism and central precocious puberty and is pursuing regulatory approval of additional drugs to treat hypogonadism and acromegaly. Indevus s approved products include Sanctura® and Sanctura XR™ for overactive bladder, Vantas® for advanced prostate cancer, Supprelin® LA for central precocious puberty, Delatestryl® for the treatment of hypogonadism and Valstar for bladder cancer. The core urology and endocrinology portfolio of Indevus also contains multiple compounds in development in addition to its approved products. Indevus s most advanced compounds are Nebido® for hypogonadism, Pro 2000 for the prevention of infection by HIV and other sexually-transmitted diseases, the octreotide implant for acromegaly and cardinoid syndrome, and pagoclone for the treatment of stuttering.

Business Environment

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

In the pharmaceutical industry, the majority of an innovative product s commercial value is usually realized during the period that the product has market exclusivity. When a product loses exclusivity, it is no longer protected by a patent and is subject to new competing products in the form of generic brands. Upon exclusivity loss, the Company can lose a major portion of that product s sales in a short period of time. Intellectual property rights have increasingly come under attack in the current healthcare environment. Generic drug firms have filed

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Abbreviated New Drug Applications (ANDAs) seeking to market generic forms of certain of the Company s key pharmaceutical products, prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in ANDA filings, the generic firms will then introduce generic versions of the product at issue, resulting in the potential for substantial market share and revenue losses for that product. For a complete description of legal proceedings, see Note 15 of the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

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

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

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

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

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

Pipeline Developments

Significant activities related to our product pipeline are as follows:

As part of our continuing strategic review of projects and programs, in February 2009, we decided to discontinue development activities related to EN3285, our oral rinse for the treatment of oral mucositis obtained through our acquisition of RxKinetix in October 2006 and EN3270 transdermal sufentanil patch for the treatment

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of moderate-to-severe chronic pain. EN3270 was licensed from Durect Corporation in March 2005. We will return to Durect all development rights to its transdermal sufentanil patch.

In February 2009, we entered into a discovery collaboration agreement with Aurigene Discovery Technologies Limited (referred to as the Aurigene Agreement). The Aurigene Agreement is a three-year collaboration to discover novel drug candidates to treat cancer. Endo has agreed to provide discovery research funding of approximately $3.0 million over the first three years of the Aurigene Agreement. Endo will be responsible for all clinical development and commercialization of drug candidates that advance into human testing. We also may be required to make additional clinical, regulatory and approval milestones of up to $29.8 million and commercial milestone payments of up to an additional $32.5 million based on cumulative net sales of products commercialized under the Aurigene Agreement. The Aurigene Agreement includes an initial three-year discovery research program, which may be terminated by Endo at our sole discretion upon 60 days prior written notice without penalty. The Aurigene Agreement will expire in its entirety if Endo does not select any development product candidates by the end of the discovery research program or upon satisfaction and/or expiration of Endo s obligations to make the milestone payments. Subsequent to the initial discovery research program, Endo may terminate the Aurigene Agreement at our sole discretion upon 30 days prior written notice without penalty.

In February 2009, we entered into a development, license and supply agreement with Grünenthal GMBH, referred to as Grünenthal, granting us the exclusive right in North America to develop and market Grünethal s investigational drug, axomadol (referred to as the Grünenthal Agreement). Currently in Phase II trials, axomadol is a patented new chemical entity being developed for the treatment of moderate to moderately-severe chronic pain and diabetic peripheral neuropthic pain. Under the terms of the Grünenthal Agreement, Endo will pay Grünenthal approximately 22.4 million euros up-front, and possibly additional clinical, regulatory and approval milestones of up to an additional 21.7 million euros and possibly development and commercial milestone payments of up to an additional $68 million. In addition, Grünenthal will receive payments from Endo based on a percentage of Endo s annual net sales of the product in the United States and Canada. The Grünenthal Agreement will expire in its entirety on the date of (i) the 15th anniversary of the first commercial sale of the product; or (ii) the expiration of the last issued patent claiming or covering the product, or (iii) the expiration of exclusivity granted by the FDA for the product, whichever occurs later. Among other standard and customary termination rights granted under the Grünenthal Agreement, we may terminate the Grünenthal Agreement at our sole discretion at any time upon 90 days written prior notice to Grünenthal and payment of certain penalties.

On January 29, 2009, the Company announced that by mutual agreement it concluded its research collaboration with Alexza Pharmaceuticals, Inc. to develop an inhaled fentanyl product for the treatment of breakthrough pain using Alexza s Staccato® inhalation technology. The product, Staccato®fentanyl (AZ-003/EN-3284), has completed Phase I clinical testing and will be returned to Alexza. In 2007, Endo licensed exclusive rights to develop and commercialize AZ-003 in North America.

In December 2008, we entered into a license agreement and a sponsored research agreement with Harvard University (referred to as the Harvard Agreement). Under the terms of the Harvard Agreement, we obtained the exclusive worldwide rights to a new combination pain-drug-delivery technique that targets pain-sensing neurons without affecting motor neurons. Endo will be responsible for development and commercialization of any drug candidates discovered under the Harvard Agreement. Under the terms of the Harvard Agreement, we made an upfront payment of $2.0 million and may pay up to an additional $16.5 million in clinical, regulatory and approval milestones. In addition, we agreed to provide research funding with respect to these products of approximately $2.0 million over the three-year life of the sponsored research agreement. Harvard will also receive payments from Endo based on a percentage of Endo s annual net sales of licensed products commercialized under the Harvard Agreement. Endo may terminate the Harvard Agreement upon 60 days prior written notice without penalty.

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During the second quarter of 2008, the Company completed an in-depth review of its research and development (R&D) activities. The review included an analysis of the Company s R&D priorities, focus and available resources for current and future projects as well as the commercial potential for each product. As a result of this review, the Company decided to discontinue development of Rapinyl , the sub-lingual, fast-dissolving tablet of fentanyl intended for treatment of breakthrough cancer pain, and topical ketoprofen patch being studied for the treatment of acute pain associated with soft-tissue injuries.

In April 2008, we notified the U.S. Food and Drug Administration (FDA) of the withdrawal of the supplemental new drug application (sNDA) without prejudice to refiling as afforded under 21 CFR 314.65 for Frova® (frovatriptan succinate) 2.5 mg tablets. This sNDA was for the additional indication of Frova® for the short-term (six days per month) prevention of menstrual migraine. Frova® is already approved and marketed for the acute treatment of migraine with or without aura in adults where a clear diagnosis of migraine has been established.

In April 2008, upon written notice to DURECT, we terminated the DURECT CHRONOGESIC™ License Agreement. Under the current terms of this license agreement, we were not responsible for any development costs for CHRONOGESIC prior to May 1, 2008 so long as written notification of termination of the agreement is provided to DURECT by April 30, 2008. This return of CHRONOGESIC rights has no effect on DURECT and Endo s collaboration with respect to the sufentanil transdermal patch (TRANSDUR -Sufentanil) licensed by Endo from DURECT for the U.S. and Canada. There was no fee due to DURECT as a result of terminating the DURECT CHRONOGESIC™ License Agreement.

Branded Business Activity

In May 2008, we entered into a services agreement with Ventiv Commercial Services, LLC (Ventiv), (referred to as the Ventiv Agreement) pursuant to which Ventiv will provide certain sales and marketing services, namely the promotion of Voltaren® Gel and other Endo products. The Ventiv Agreement will expire on June 30, 2010 unless earlier terminated in accordance with its terms. In January 2009, we agreed to certain changes to the Ventiv Agreement allowing for modifications to certain provisions, including the modification to the termination rights such that Endo is now permitted to terminate the Ventiv Agreement at our sole discretion at any time upon 60 days written prior notice.

In March 2008, we entered into a licensing agreement with Novartis to obtain the exclusive U.S. marketing rights for the prescription medicine Voltaren® Gel (diclofenac sodium topical gel) 1%. Voltaren® Gel received regulatory approval in October 2007 from the U.S. Food and Drug Administration, 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. Voltaren® Gel, which is a nonsteroidal anti-inflammatory (NSAID) medication, is indicated for use in treating pain associated with osteoarthritis in joints amenable to topical treatment, such as the knees and those of the hands. Clinical trials have demonstrated Voltaren® Gel to be highly effective in treating osteoarthritis pain in the hands and knees, which are the body s most commonly affected joints. Voltaren® Gel delivers effective pain relief with a favorable safety profile as its systemic absorption is on average 6% of the systemic exposure from a comparable dose of an oral form of diclofenac sodium. Voltaren® Gel will compete in the emerging topical NSAID market, which is expected to grow given the aging U.S. population. Of the estimated 84 million NSAID and Cox-II prescriptions written annually in the U.S., about 40% are osteoarthritis-related. The dollar value of this market is approximately $3.3 billion, with roughly half of the value coming from NSAIDs and the remainder from Cox-IIs.

In March 2008, the Company commercialized Voltaren® Gel, initially using one of its two specialty sales forces, consisting of 160 representatives, prior to executing a full physician launch in late May with an additional 275 contract sales representatives targeting primary care physicians who treat patients with osteoarthritis.

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In March 2008, the U.S. Food and Drug Administration approved three new dosage strengths of Opana® ER (oxymorphone HCl) extended-release tablets CII. The new strengths, 7.5 mg, 15 mg, and 30 mg, became available on April 1, 2008 and joined previously approved Opana® ER dosage strengths of 5 mg, 10 mg, 20 mg, and 40 mg.

In February 2008, we amended our license agreement with Vernalis dated July 14, 2004. In addition to amending certain specific terms and conditions of the license agreement, this amendment sets forth an annual minimum net sales threshold that must be achieved prior to any royalties becoming due. Once the annual minimum net sales threshold is reached, royalty payments will be due on the portion of annual net sales that exceed the threshold. In addition, both parties agreed to terminate the co-promotion agreement effective in February 2008. Also in February 2008, we entered into a termination agreement with Vernalis to terminate the existing loan agreement between the parties. Pursuant to the termination agreement, payment of our outstanding note receivable was satisfied by a cash payment from Vernalis of $7 million and by way of a reduction in royalties payable to Vernalis pursuant to the amended license agreement as described above.

Change in Executives and Directors

On February 26, 2009, the Company announced the appointment of William P. Montague to the Company s board of directors. Mr. Montague, 62, who was chief executive officer and a director of Mark IV Industries, retired in July 2008 . Mark IV is a diversified, global manufacturer of highly-engineered systems and components for the transportation, industrial and automotive markets. He joined Mark IV Industries in April 1972 as treasurer and controller, became chief financial officer in 1986 and was named president in 1996. Mr. Montague is also a director of Gibraltar Industries, Inc., a NASDAQ-listed company that is a leading manufacturer, processor and distributor of products for the building, industrial, and vehicular markets. His appointment brings the number of Endo board members to eight. Mr. Montague will serve as a member of the audit committee of Endo s board.

On November 28, 2008, George F. Horner, III notified the Company of his intention to resign as a director of the Company so he may more actively pursue other business opportunities. Mr. Horner s resignation was effective on January 1, 2009.

On September 2, 2008, the Company announced the resignation of Executive Vice President and Chief Financial Officer, Charles A. Rowland, Jr. The Company has engaged an executive search firm to assist in the search for a new chief financial officer.

In July 2008, Joyce N. LaViscount elected to pursue an operational role as the Company s Vice President, Sales Operations and resigned her position as the Company s Chief Accounting Officer, effective August 1, 2008. Ms. LaViscount s employment contract has been amended accordingly. In connection with this change, the Company decided to eliminate the Chief Accounting Officer position and Edward J. Sweeney assumed the responsibilities as the Principal Accounting Officer of the Company. Mr. Sweeney is Vice President, Controller and joined the Company in March 2004 as Director, Financial Reporting and was named Vice President, Controller in June 2007.

In April 2008, David A. Lee, M.D., Ph.D. resigned his position as Chief Scientific Officer to devote more time to pursue his philanthropic activities. Dr. Lee, who had been working part-time for the Company for over a year, has agreed at the Company s request to remain with the Company as a senior strategic adviser primarily to continue to support the Company s activities in the area of public affairs.

In April 2008, Company director Michel de Rosen informed the Board of Directors that he did not intend to stand for re-election upon the expiration of his term at the 2008 Annual Meeting of Stockholders so that he may devote more time to his new position as Chief Executive Officer of Saint-Gobain Desjonqueres in France, a position he has held since March 31, 2008. Mr. de Rosen served as a director of the Company until the expiration

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of his term at the 2008 Annual Meeting of Stockholders held on June 26, 2008. The Board nominated Joseph C. Scodari at the 2008 Annual Meeting of Stockholders to fill the vacancy left by Mr. de Rosen s departure. At the 2008 Annual Meeting of Stockholders on June 26, 2008, the Company stockholders elected Mr. Scodari a director of the Company.

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. Show to our Board of Directors. The D. E. Shaw group, which owns approximately 13.2 million shares of the Company s common stock, 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. The Board of Directors increased to eight members, effective June 26, 2008. As a condition to the agreement, the D. E. Shaw group has agreed not to solicit proxies from the Company s stockholders in connection with the election of directors or other matters until and, subject to certain other agreements, through the Company s 2009 Annual Meeting of Stockholders. At the 2008 Annual Meeting of Stockholders, the Company stockholders elected Mr. Spengler a director of the Company. Mr. Spengler also serves on the Audit Committee and Compensation Committee of the Board of Directors of the Company.

In April 2008, Ivan Gergel, M.D. was hired as Executive Vice President, Research & Development. Dr. Gergel has responsibility for all of the Company s research and development 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. In connection with Dr. Gergel s appointment as Executive Vice President, Research & Development of the Company, he entered into an executive employment agreement, effective as of April 29, 2008.

In March 2008, we announced the appointment of David P. Holveck to the position of President and Chief Executive Officer of the Registrant and its wholly owned subsidiary, Endo Pharmaceuticals Inc., effective April 1, 2008. Mr. Holveck was appointed to the Board of Directors effective March 25, 2008. In connection with Mr. Holveck s appointment as President and Chief Executive Officer of the Company, he entered into an executive employment agreement, effective as of April 1, 2008.

In January 2008, Peter A. Lankau resigned as President and Chief Executive Officer of the Company effective March 1, 2008. Mr. Lankau also resigned from the Company s board of directors effective January 28, 2008.

RESULTS OF OPERATIONS

The Company reported net income for 2008 of $261.7 million or $2.12 per diluted share on total net sales of $1.26 billion compared with net income of $227.4 million or $1.69 per diluted share on total net sales of $1.09 billion for 2007.

Year Ended December 31, 2008 Compared to the Year Ended December 31, 2007

Net Sales

Net sales for the year ended December 31, 2008 increased 16% to $1.26 billion from $1.09 billion in the comparable 2007 period. This increase in net sales is primarily driven by increased sales of Lidoderm® as well as increased net sales of Opana® ER and Opana®, and Voltaren® Gel which launched in March of 2008. For the year-ended December 31, 2008, increased sales volume contributed 15% of the total net sales growth of 16%, while price increases contributed the remaining 1% of the total net sales growth.

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The following table displays our net sales by product category and as a percentage of total net sales for the year ended December 31, 2008 and 2007 (dollars in thousands):

	Year Ended December 31			
	2008		2007	
	$	%	$	%
Lidoderm®	765,097	61	705,587	65
Opana® ER and Opana®	180,429	14	107,143	10
Percocet®	129,966	10	121,742	11
Frova®	58,017	5	52,437	5
Voltaren® Gel	23,791	2		
Other brands	10,904	1	11,065	1
Total brands	1,168,204	93	997,974	92
Total generics	92,332	7	87,634	8
Total net sales	1,260,536	100	1,085,608	100

Lidoderm®. Net sales of Lidoderm® for the year ended December 31, 2008 increased by $59.5 million or 8%, to $765.1 million from $705.6 million in the comparable 2007 period. The increase is primarily attributable to continued prescription growth of the product. We believe the continued growth of Lidoderm® is driven by the product s proven clinical effectiveness combined with our continued promotional activities positioning Lidoderm® as the *only* prescription analgesic patch specifically designed to effectively relieve the localized pain of post-herpetic neuralgia (PHN) with low risk of systemic side effects and drug to drug interactions. We believe we also are benefiting from our educational programs designed to improve our target audience s understanding regarding the localized pain of PHN. In addition, our managed care efforts are focused on Medicare Part D, which consists predominately of elderly patients who are at greater risk for PHN. Medicare Part D has also served to raise overall awareness among formulary decision-maker resulting in an ongoing assessment of how best to secure access for patients. As expected, we recognize that the growth of this product is beginning to slow as it matures and competition in the topical pain market increases.

Opana® ER and Opana®. Net sales of Opana® ER and Opana® for the year ended December 31, 2008 increased by 68% or $73.3 million to $180.4 million from $107.1 million in the comparable 2007 period. The growth in net sales is primarily attributable to continued prescription growth of the product, as we continue to drive our promotional efforts through our expanded sales force and our contracting strategy. In addition, net sales of Opana® ER and Opana® for the year ended December 31, 2007 includes $13.8 million of deferred revenue recognized during the first quarter of 2007 for commercial shipments made to customers during 2006.

Percocet®. Net sales of *Percocet®* for the year ended December 31, 2008 increased by $8.3 million or 7%, to $130.0 million from $121.7 million in the comparable 2007 period. This increase is primarily attributable to improved pricing during the year ended December 31, 2008.

Frova®. Net sales of Frova® for the year ended December 31, 2008 increased by $5.6 million or 11%, to $58.0 million from $52.4 million in the comparable 2007 period. The growth in net sales is primarily attributable to continued prescription growth of the product, as we continue to drive our promotional efforts through our sales force.

Voltaren® Gel. Net sales of Voltaren® Gel for the year ended December 31, 2008 were $23.8 million. The Company launched Voltaren® Gel in March 2008.

Generics. Net sales of our generic products for the year ended December 31, 2008 increased by $4.7 million or 5%, to $92.3 million from $87.6 million in the comparable 2007 period. Generic competition with all of our products may have a material impact on our results of operations and cash flows in the future.

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Gross Margin, Costs and Expenses

The following table sets forth costs and expenses for the years ended December 31, 2008 and 2007:

	December 31,			
	2008	% of net sales	2007	% of net sales
	(in thousands)			
Cost of sales	$ 267,235	21%	$ 217,369	20%
Selling, general and administrative	488,063	38%	411,869	38%
Research and development	110,211	9%	138,255	13%
Impairment of other intangible assets	8,083	1%	889	%
Purchased in-process research and development	(530)	%		%
Total costs and expenses	$ 873,062	69%	$ 768,382	71%

Costs of Sales and Gross Margin. Costs of sales for the year ended December 31, 2008 increased by $49.8 million or 23%, to $267.2 million from $217.4 million in the comparable 2007 period. Cost of sales as a percent of net sales was 21% for the year ended December 31, 2008 compared with 20% during the year ended December 31, 2007. The increase in costs of sales is primarily due to a $25.9 million increase in intangible asset amortization expense related to commercial products and the increase in net sales volume. In 2008, the Company s intangible assets included additions totaling $175.7 million, $46.7 million of which resulted from the settlement of our note receivable with Vernalis, and the remaining $129.0 million resulting from our licensing arrangement with Novartis AG for Voltaren® Gel. The increase in cost of sales as a percent of net sales is primarily due to the increased amortization as mentioned above.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the year ended December 31, 2008 increased by 18% to $488.1 million from $411.9 million in the comparable 2007 period. This increase is primarily due to an increase in sales and promotional efforts in 2008 over the comparable 2007 periods due to our continued investment in our commercial business and our infrastructure to support our key on-market products and pipeline. Selling, general and administrative expenses in 2008 include the impact of the continuing investments in infrastructure to support Endo s long-term growth, including the addition of approximately 100 sales representatives during the second half of 2007, as well as the addition during 2008 of 275 contract sales representatives for the launch of Voltaren® Gel. In addition, during the year ended December 31, 2008, we recognized $10.5 million in separation benefits provided to former employees. These increases have been partially offset by cost reduction initiatives and headcount reduction completed in July 2008. Selling, general and administrative expenses in 2007 include the full year impact of the expansion of the sales force that occurred in the second half of 2006, combined with continuing investments in infrastructure to support Endo s long-term growth and the continued launch expenses of Opana® ER and Opana®.

Research and Development Expenses. Research and development expenses for the year ended December 31, 2008 decreased by 20% to $110.2 million from $138.3 million in the comparable 2007 period. Research and development expense reflects the Company s ongoing commitment to clinical research as well as the impact of the Company s external collaborations. The reduction in expense for the year ended December 31, 2008 when compared to the same period in 2007 is primarily attributable to a reduction in upfront and milestone payments from $34.9 million in 2007 to $8.9 million in 2008.

Impairment of Other Intangible Assets. During the year ended December 31, 2008, as a result of our decision to discontinue the development of Rapinyl™ we recorded an impairment charge in the amount of $8.1 million to write-off the remaining balance of our Rapinyl™ intangible asset. During the year ended December 31, 2007, as a result of the continued lack of commercial success of Synera , we recorded an impairment charge of $0.9 million related to the remaining unamortized portion of our ZARS intangible asset.

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

Interest Expense

Interest expense for the year ended December 31, 2008 was $8.4 million compared with $0.1 million for the comparable period in 2007. This increase is primarily attributable to the interest expense on our 1.75% Convertible Senior Subordinated Notes issued in April 2008 and the recognition of interest expense during 2008 representing accretion of our minimum royalty guarantee payable to Novartis AG, related to Voltaren® Gel .

Interest and Other Income, net

The components of interest and other income, net at December 31, 2008 and 2007 are as follows (in thousands):

	2008	2007
Interest income	$ (24,833)	$ (35,543)
Other-than-temporary impairment of auction-rate securities	26,417	
Unrealized losses on trading securities	4,225	
Gain on Auction-Rate Securities Rights	(27,321)	
Other	(1,568)	(598)
Interest and other income, net	$ (23,080)	$ (36,141)

Interest and other income, net for the year ended December 31, 2008, decreased by 36% to $23.1 million from $36.1 million in the comparable 2007 period. During the fourth quarter of 2008, upon accepting the auction-rate securities rights from UBS, the Company determined that the decline in fair value on certain of our auction-rate securities was other-than temporary and we recorded in interest and other income, net a $26.4 million other-than-temporary impairment charge to earnings. In addition, the Company made a one-time election to transfer these securities out of the available-for-sale category and into the trading category. As such, the decline in the fair value of these securities subsequent to the transfer, which amounted to $4.2 million, has been charged to earnings and included in interest and other income, net. The impairment charge and additional declines in fair value were partially offset by a $27.3 million gain recorded in the fourth quarter of 2008 resulting from the recognition of a freestanding financial instrument which arose from our auction-rate securities rights from UBS. The remaining decrease in interest and other income, net is a result of the fluctuations in the amount of cash invested in interest-bearing accounts, including our money market funds and auction-rate securities and the yields on those investments. During 2008, as a result of uncertainties in the global credit markets, the auction-rate securities market became illiquid and yields on these securities have decreased significantly from the yields experienced in 2007. In March 2008, the Board of Directors approved an amended investment policy which seeks to preserve the value of capital, consistent with maximizing return on the Company s investment, while maintaining adequate liquidity. As a result, yields on our interest-bearing accounts have generally been lower than yields earned on the same or similar investments during the comparable periods of 2007.

Income Tax

Income tax expense for the year ended December 31, 2008 increased by 12% to $140.5 million from $125.8 million in the comparable 2007 period. The increase in income tax expense is primarily a result of the increase in income before income tax for the year ended December 31, 2008 compared to the comparable period in 2007. The impact of the increase in income before income tax is partially offset by a reduction in our effective tax rate. Our effective tax rate for the year ended December 31, 2008 decreased to 34.9% from 35.6% in the comparable period of 2007. The decrease in the effective income tax rate is primarily the result of a reversal of certain of the

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Company s unrecognized tax benefits, net of deferred federal and state benefits, for the settlement of various tax issues and adjustments for prior year tax provision and return differences, which are partially offset by an increase in the effective tax rate due to lower tax-exempt interest.

2009 Outlook

We estimate that our 2009 net sales will be between $1.390 billion and $1.440 billion. Our estimate is based on the continued growth of our branded product portfolio, primarily driven by prescription demand for Opana® ER and Opana® and Voltaren® Gel and our recent acquisition of Indevus Pharmaceuticals Inc. Cost of sales as a percent of net sales are expected to increase when compared to 2008. Although higher-margin branded products should continue to represent a higher proportion of total revenue, this increase is expected due to continued expansion of our contracting with managed care organizations, a full year of amortization expense on the Voltaren® Gel intangible asset, additional amortization expense related to the acquisition of Indevus and the impact of a full year of royalties on the 2009 net sales of Opana® ER. Selling, general and administrative expenses are expected to increase as we continue to provide promotional support behind our key on-market products, including those being acquired as part of our acquisition of Indevus. R&D expenses are expected to increase as we invest in clinical development programs in support of our recently announced third party collaboration agreements as well as the further advancement of the development products being acquired from Indevus. The increase in operating expenses is expected to be partially offset by the continued rationalization of our cost infrastructure. Of course, there can be no assurance that the Company will achieve these results.

Year Ended December 31, 2007 Compared to the Year Ended December 31, 2006

Net Sales

Net sales for the year ended December 31, 2007 increased 20% to $1.09 billion from $909.7 million in the comparable 2006 period. This increase in net sales is primarily driven by increased sales of Lidoderm® as well as increased net sales of Opana® ER and Opana®, which were launched in the second half of 2006. These increases are partially offset by the reduction in sales of our generic oxycodone extended-release tablets, resulting from the Company s settlement with Purdue (as described in more detail below). For the year ended December 31, 2007, increased sales volume contributed 15% of the total sales growth of 20%, while selling price increases contributed the remaining 5% of the total sales growth. The volume growth achieved in 2007 includes the unfavorable impact of reduced inventories at our major wholesaler customers. We believe this decline in inventory levels at these wholesalers is due to improved distribution efficiencies, resulting in their ability to maintain lower levels of inventory on-hand.

The following table displays our net sales by product category and as a percentage of total net sales for the year ended December 31, 2007 and 2006 (dollars in thousands):

	Year Ended December 31			
	2007		2006	
	$	%	$	%
Lidoderm®	705,587	65	566,785	62
Percocet®	121,742	11	102,707	11
Opana® ER and Opana®	107,143	10	6,845	1
Frova®	52,437	5	40,564	5
Other brands	11,065	1	14,027	1
Total brands	997,974	92	730,928	80
Generic oxycodone extended-release tablets			57,075	6
Other generics	87,634	8	121,656	14
Total generics	87,634	8	178,731	20
Total net sales	1,085,608	100	909,659	100

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Lidoderm®. Net sales of Lidoderm® for the year ended December 31, 2007 increased by $138.8 million or 24%, to $705.6 million from $566.8 million in the comparable 2006 period. The increase is primarily attributable to continued prescription growth of the product.

Percocet®. Net sales of *Percocet*® for the year ended December 31, 2007 increased by $19.0 million or 19%, to $121.7 million from $102.7 million in the comparable 2006 period. The increase is primarily attributable to improved pricing during the year ended December 31, 2007.

Opana® *ER and Opana*®. Net sales of Opana® ER and Opana® for the twelve moths ended December 31, 2007 increased by $100.3 million to $107.1 million from $6.8 million in the comparable 2006 period. Opana® ER and Opana® were not launched until the second half of 2006. In addition, net sales of Opana® ER and Opana® for the year ended December 31, 2007 includes $13.8 million of deferred revenue recognized during the first quarter of 2007 for commercial shipments made to customers during 2006.