ENDO PHARMACEUTICALS HOLDINGS INC
Form 10-K
March 01, 2007
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**
For the fiscal year ended December 31, 2006

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	**NASDAQ**

Annual Report for the Year Ended December 31, 2006

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes þ 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 þ

Indicate by check 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 þ No ¨

Indicate by check 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. þ

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer þ Accelerated filer ¨ Non-accelerated filer ¨

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant s most recently completed second fiscal quarter (June 30, 2006): $4,294,385,560 based on the last reported sale price on the NASDAQ on June 30, 2006.

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of February 22, 2007: 133,607,185.

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 2007 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, 2006.

Table of Contents

ENDO PHARMACEUTICALS HOLDINGS INC.

INDEX TO FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2006

Table of Contents

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;

significant cash payments we may be required to make to Endo Pharma LLC pursuant to a tax sharing agreement;

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 most of our core products;

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

Table of Contents

our ability to protect our proprietary technology;

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

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

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

the availability of third-party reimbursement for our products;

the outcome of any pending or future litigation or claims by the government;

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;

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; and

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

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.

Table of Contents

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. According to Wolters Kluwer Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled $19.7 billion in 2006. This represents an approximately 8% compounded annual growth rate since 2002. Our primary area of focus within this market is analgesics and, specifically, opioid analgesics. In 2006, analgesics were the fourth most prescribed medication in the United States with over 260 million prescriptions written for this classification. Opioid analgesics is a segment that comprised approximately 80% of the analgesics prescriptions for 2006. Total U.S. sales for the opioid analgesic segment were $7.3 billion in 2006, representing a compounded annual growth rate of 8% since 2002.

We have a portfolio of branded products that includes established brand names such as Lidoderm®, Percocet®, Frova® and Percodan®, as well as three newly launched products in 2006 Opana® ER, Opana® and Synera™. Branded products comprised approximately 80% of our net sales in 2006, with 62% of our net sales coming from Lidoderm®. Our non-branded generic portfolio, which accounted for 20% of net sales in 2006, currently consists of products primarily focused in pain management, with our generic oxycodone extended-release tablets accounting for 6% of our net sales in 2006. 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 established research and development expertise in analgesics and devote significant resources to this effort so that we can maintain and develop our product pipeline. Our late-stage branded product pipeline includes one filed supplemental New Drug Application (sNDA), two products in Phase III clinical trials and three products in Phase II clinical trials.

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 590 sales representatives in the United States, 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 on terms we consider favorable. 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. Currently, however, we have no binding commitment related to any acquisitions.

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

Table of Contents

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 continue to strengthen our position as a market leader in pain management while also pursuing other markets, especially those in complementary therapeutic areas such as neurology and supportive care oncology. To supplement our internal efforts in support of our business strategies, we continually evaluate business development opportunities that we believe will strengthen our product portfolio. We regularly evaluate opportunities, particularly in the areas of strategic product acquisitions and/or corporate mergers and acquisitions. We also evaluate partnership arrangements that may involve new technology platforms on which to expand our high-barrier to market entry generic strategy, and products or companies for new proprietary therapeutic categories. As we continue to grow, we expect that our business development activities, including product and company acquisitions will continue to play an important part in our strategy. The elements of our strategy include:

Leveraging our pain management expertise by developing proprietary products and generic products with significant barriers to market entry. To capitalize on our expertise in pain management, we are developing new products to address acute, chronic and neuropathic pain conditions. Specifically, we are developing new patent-protected products that may substantially improve the treatment of pain. We have co-developed an oral extended-release (ER) version of oxymorphone with Penwest Pharmaceuticals Co. and internally developed an oral immediate-release (IR) version of oxymorphone. On December 22, 2005, we filed complete responses to the U.S. Food and Drug Administration s FDA approvable letters on the Company s New Drug Applications (NDAs) for each of its investigational products containing oxymorphone. As previously disclosed on October 20, 2003, the FDA issued approvable letters for oxymorphone ER and IR tablets but had requested that we address certain questions and provide more clarification and information, including data from additional clinical trials to further confirm the safety and efficacy of these products. In order to meet the FDA s request for more clinical information for oxymorphone ER, we conducted two separate multi-center, randomized, double-blind, placebo-controlled, 12-week, parallel group trials evaluating this product in two distinct groups of patients with chronic low back pain: opioid-naive and opioid-experienced. These trials demonstrated statistically ($p<0.0001$) and clinically significant efficacy in these patient populations. The trial involving opioid-naive patients was conducted under the FDA s Special Protocol Assessment (SPA) process. We also reported that the complete response to the oxymorphone IR approvable letter included previously disclosed positive results for a placebo-controlled, multi-center Phase III trial for oxymorphone IR in the treatment of acute post-operative pain. Endo also conducted this study under the FDA s SPA process. The data from the two new oxymorphone ER Phase III studies and from the one oxymorphone IR Phase III study supplemented the previously submitted Phase III trials for both products that the Company believed the FDA already had accepted as demonstrating efficacy in the intended patient populations. On June 22, 2006, the NDA s for each of these products were approved by the FDA, and during the second half of 2006, we launched oxymorphone ER and IR under the brand names Opana® and Opana ER®. Opana® ER competes in the market for long-acting, strong opioids.

Table of Contents

On June 7, 2005, we announced that the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., had affirmed the Opinion and Order issued in Endo s favor by the U.S. District Court for the Southern District of New York on January 5, 2004, which found Purdue had committed inequitable conduct in the U.S. Patent and Trademark Office. This affirmance by the Federal Circuit Court dismissed the claims that Endo s oxycodone extended-release tablets, 10mg, 20mg, 40mg, and 80mg, a bioequivalent version of Purdue Frederick s OxyContin®, infringe Purdue s U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, and permanently enjoined Purdue from enforcing these patents. The U.S. Food and Drug Administration had previously granted final approval of Endo s Abbreviated New Drug Application (ANDA) for all four strengths of the product in 2004. Endo s oxycodone extended-release tablets are AB-rated bioequivalent versions of OxyContin®, indicated for the management of moderate-to-severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. On February 1, 2006, we announced that the Federal Circuit Court of Appeals had vacated its unanimous June 7, 2005 affirmance of the Opinion and Order in our favor and affirmed the District Court s finding that, if Purdue s patents are enforceable, Endo s oxycodone extended-release tablets infringe these patents. Further, the Federal Circuit issued a new opinion on February 1, 2006 remanding the case to the same District Court for its further consideration as to whether the Purdue patents are unenforceable. On August 28, 2006, we announced that we reached an agreement with The Purdue Frederick Company, The P.F. Laboratories, Inc., and Euro-Celtique, S.A. to settle this long-running litigation. Pursuant to this settlement, Endo continued selling to its customers its oxycodone extended-release products until December 31, 2006. Endo, as well as its manufacturers, distributors, purchasers, and patients, were released from all liability for infringement of Purdue s patents in connection with Endo s prior and future sales of these products. Though the settlement agreement was submitted to the U.S. Federal Trade Commission and the Antitrust Division of the Department of Justice as required by statute, the release will survive unless overturned by a court order. On October 6, 2006, the district court entered a Consent Judgment the effect of which is to conclude the litigation in accordance with the terms of the settlement agreement. See Item 3. Legal Proceedings .

Acquiring and in-licensing complementary products, compounds and technologies. We look to continue to enhance our product line through selective product acquisitions and in-licensing, or acquiring licenses to products, compounds and technologies from third parties. In August 2004, we entered into a license agreement with Vernalis Development Limited (Vernalis), under which Vernalis agreed to exclusively license to us rights to market Frova® (frovatriptan) in North America. Launched in the U.S. in June 2002, Frova® is indicated for the acute treatment of migraine headaches in adults. During the third quarter of 2006, the FDA accepted for substantive review the sNDA relating to Frova® for the short-term (six days per menstrual cycle) prevention of menstrual migraine (MM) and confirmed May 19, 2007 as the review completion date for this application. Subject to FDA approval, we intend to launch Frova® during the second half of 2007 for the anticipated expanded indication for prevention of menstrual migraine.

In August 2004, we entered into an agreement granting us the exclusive rights to develop and market Orexo AB s (a Swedish company) patented sublingual muco-adhesive fentanyl product (Rapinyl) in North America. Rapinyl is a sub-lingual, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. The benefits of Rapinyl are believed to include both a fast onset of action and patient convenience. In 2005, Rapinyl advanced into Phase III clinical trials. The projected NDA (New Drug Application) filing date for Rapinyl has been changed from the second half of 2007 to the first half of 2008 due to slower than expected enrollment of patients in its two ongoing Phase III trials.

Table of Contents

This reflects the inherent challenges in recruiting cancer patients for placebo-controlled trials, as well as competition in 2006 with other pharmaceutical companies seeking to enroll patients in trials for the same indication. With the completion of many of these competing trials, the Company expects the pace of patient recruitment to accelerate in 2007.

In March 2005, we entered into an agreement with ProEthic Pharmaceuticals, Inc. for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form. Also, in March 2005, we entered into an agreement that will give us the exclusive license to develop and commercialize DURECT s sufentanil-containing transdermal patch in the U.S. and Canada. The sufentanil patch, which is in early-stage clinical development, is intended to provide relief of moderate-to-severe chronic pain for up to seven (7) days. In January 2006, we licensed in Synera , an FDA-approved topical local anesthetic patch for which we acquired the exclusive North American marketing rights. We launched Synera during the second half of 2006.

During the fourth quarter of 2006, the Company purchased RxKinetix, Inc., a privately held company headquartered in Boulder, Colorado, that develops new formulations of approved products for oral mucositis and other supportive care oncology conditions. RxKinetix s lead product, now named EN 3285, is a topical oral rinse with the active ingredient formulated in its proprietary ProGelz® drug delivery platform. EN 3285 is in clinical Phase II for the prevention of oral mucositis (OM), painful mouth sores that often occur in cancer patients undergoing radiation and chemotherapeutic treatment. We believe a product such as EN 3285, if approved, would be a natural extension of our cancer-related portfolio consisting of the recently launched Opana® ER and Opana® tablets, and Rapinyl , our quick-dissolving fentanyl tablet in development for breakthrough cancer pain, currently in Phase III trials. See the disclosures under Note 3. Acquisitions, included in the consolidated financial statements in Part IV, Item 15 of this Report for further information.

Capitalizing on our established brand names and brand awareness through focused marketing and promotional efforts. We believe that our strong corporate and product reputation combined with focused marketing and promotional efforts leads to more rapid adoption of our new products by physicians and institutions.

Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, continues to increase market penetration due to our ongoing promotional and educational efforts. Continued growth will be supported by the product s proven clinical effectiveness combined with incremental promotional support generated by the expansion of Endo s sales force in 2006.

We consider two of our brands, Percocet® and Percodan®, to be gold standards of pain management. Percocet® has been prescribed by physicians since 1976, while Percodan® has been prescribed since 1950. We believe that we have established credibility with physicians as a result of these products history of demonstrated effectiveness and safety. We plan to continue to capitalize on this brand awareness to market new products and explore new indications for existing products.

Table of Contents

During 2004, we launched Frova® for the treatment of migraine headaches in adults. We believe Frova® has differentiating features from other migraine products, including the longest half-life in the triptan class and a very low reported recurrence rate in its clinical program. We believe these distinct characteristics have yet to be fully exploited in the North American market and that we will be able to capitalize on Frova® s clinical benefits and commercial potential by targeting the specialty physician audience and effectively leveraging the relationships and reputation that we have built with the neurology and pain specialist community over the years.

During 2006, we launched Synera™, the first self-contained topical patch for prevention of pain associated with superficial venous access and superficial dermatological procedures in patients three years of age and older. The Synera™ patch addresses an important issue in the area of topical pain management, particularly in the pediatric population. The Synera™ patch is marketed in the institutional setting and while we are redeploying our existing 70-person hospital sales force to a Specialty II sales force, we will continue to promote Synera primarily in key pediatric institutions to drive awareness and increase usage of this topical local anesthetic patch.

We believe this interaction with the thought leaders and our track record of developing and launching new products has enabled us to pursue, through in-licensing and acquisitions, novel products for the treatment of pain and complementary therapeutic areas.

During the second half of 2006, we launched Opana® and Opana ER® and during the fourth quarter of 2006, we implemented a full range of promotional activities to generate broader physician awareness and continued steady adoption of these products. Endo is committed to providing healthcare professionals and patients with safe and effective opioid analgesic medications and support programs that will facilitate the appropriate and responsible use of opioid analgesics. Through extensive experience with opioid analgesics and communicating with the FDA and industry experts, Endo has developed a comprehensive risk minimization action plan for Opana® ER and Opana®. Evolving from this risk minimization action plan is a new initiative to further help reduce the inherent risk of misuse, abuse and diversion of opioid analgesics: The Partnership for Responsible Opioid Management through Information, Support, and Education (PROMISE). The PROMISE initiative contains essential information and guidance to healthcare professionals so that they can prescribe opioids to patients responsibly and appropriately. PROMISE includes educational support and practical patient management tools. For patients, the program raises the level of knowledge of those suffering from moderate-to-severe pain and empowers them to manage their condition with the help of their healthcare professional.

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. These products include:

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. There are approximately 200,000 patients per year who suffer from this condition in the United States. The FDA had granted Lidoderm® orphan drug status, generally meaning that no other lidocaine-containing topical patch product can be approved for this indication until the

Table of Contents

orphan drug status expiration date, which occurred on March 19, 2006. On October 17, 2006, Endo 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 the Company submitted a Citizen Petition with the FDA requesting that the FDA apply existing bioequivalence regulations to any ANDA seeking regulatory approval of a generic drug product that references Endo s Lidoderm®. The petition emphasizes that this 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®, Endo 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®. To our knowledge, there is no competitive product that has been, or is being developed. 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 will expire in 2015. In 2006, 2005 and 2004, Lidoderm® net sales were $566.8 million, $419.4 million and $309.2 million, respectively. Lidoderm® accounted for approximately 62% of our 2006 net sales. In addition, we are currently exploring the safety and efficacy of Lidoderm® in other indications and have initiated both Phase II and Phase IV clinical trials. On January 17, 2007, we received a subpoena from the U.S. Department of Health and Human Services, Office of Inspector General, requesting documents from 1999 to the present regarding the Company s sales and promotional practices relating to Lidoderm®. We are cooperating with this request. The subpoena requests documents generally related to the Company s knowledge of the use of Lidoderm® for non-indicated uses by physicians. See Item 3. Legal Proceedings for further details.

Percocet®, our oxycodone/acetaminophen combination product, and Percodan®, our oxycodone/aspirin combination product, which have been marketed since 1976 and 1950, respectively, are our gold standards of pain management based on their long history of demonstrated product safety and effectiveness. Net sales of Percocet® were $102.7 million for the year ended December 31, 2006 compared with $110.7 million in the same period in 2005. We believe our close relationships with physicians who are considered to be pain management thought leaders in pain centers, hospitals, and other pain management institutions enable us to maintain our market penetration.

Frova®, for the treatment of migraine headaches in adults, was added to our portfolio of branded products during 2004. We believe Frova® has differentiating features from other migraine products, including the longest half-life in the triptan class and a very low reported recurrence rate in its clinical program. We believe these distinct characteristics have yet to be fully exploited in the North American market and that we will be able to capitalize on Frova® s clinical benefits and commercial potential by targeting the specialty physician audience and effectively leveraging the relationships and reputation that we have built with the neurology and pain specialist community over the years. Net sales of Frova® were $40.6 million for the year ended December 31, 2006 compared with $38.1 million in 2005.

Table of Contents

Opana® ER and Opana® were launched during the second half of 2006. A new oral extended-release opioid analgesic treatment option for patients, 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, 10mg, 20mg 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 2006 of Opana® ER and Opana®, representing end-user demand, were recorded as $6.8 million. Although commercial shipments totaling $20.6 million of Opana® ER and Opana® to customers began during the third quarter of 2006, the Company determined that it was not appropriate to recognize revenue for these shipments at that time under accounting principles generally accepted in the United States. The approximately $13.8 million balance of deferred revenue may be recorded as net sales in future periods. 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 590-person sales force beginning in the third quarter 2006.

Substantial pipeline focused on pain management with a balanced focus on complementary therapeutic areas. As a result of our focused research and development efforts, we have a robust development pipeline and are well-positioned to capitalize on our core expertise with analgesics.

In July 2006, we submitted to the FDA a sNDA for Frova® 2.5 mg tablets for the short-term (six days per menstrual cycle) prevention of menstrual migraine (MM). This sNDA for Frova® is supported by data from four studies, including two Phase III studies examining the efficacy and safety of once- and twice-daily dose regimens of Frova® in the short-term prevention of MM, a pharmacokinetics and tolerability study of once and twice-daily dosing of Frova®, and a 12-month open-label safety study evaluating a six-day dosing regimen of Frova® in 525 women. During the third quarter of 2006, the FDA accepted for substantive review the sNDA relating to Frova® for the short-term (six days per menstrual cycle) prevention of menstrual migraine (MM) and confirmed May 19, 2007 as the review completion date for this application. Subject to FDA approval, we intend to launch Frova® during the second-half of 2007 for the anticipated expanded indication for prevention of menstrual migraine.

In August 2004, we entered into an agreement granting us the exclusive rights to develop and market Orexo AB s (a Swedish company) patented sublingual muco-adhesive fentanyl product (Rapinyl) in North America. Rapinyl is a sub-lingual, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. The benefits of Rapinyl are believed to include both a fast onset of action and patient convenience. In 2005, Rapinyl advanced into Phase III clinical trials and currently has two ongoing Phase III trials. The NDA (New Drug Application) filing date for Rapinyl is expected to be submitted to the FDA in the first half of 2008.

In March 2005, we entered into an agreement with ProEthic Pharmaceuticals, Inc. for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form. Currently in Phase III clinical trials in the U.S., the ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains.

Table of Contents

In addition, we currently have three products in Phase II clinical trials and one product in Phase I clinical trials.

Research and development expertise. Our research and development effort is focused on expanding our product portfolio by capitalizing on our core expertise with analgesics. We have assembled an experienced and multi-disciplined research and development team of scientists and technicians with a proven expertise working with analgesics and complex formulations. We believe this expertise allows for timely FDA approval of our products. We have demonstrated our ability to commercialize our research and development efforts during the last nine years through the launch of 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 590 specialty and office-based representatives. Through our sales force, we market our branded pharmaceutical products to just over 70,000 physicians, which include both specialists and primary care physicians.

Selective focus on generic products. Our generic product portfolio includes products focused on pain management. Development of these products involves 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 and oxycodone extended-release tablets, which we introduced in June 2005 as a bioequivalent version of Purdue s OxyContin. See Item 3. Legal Proceedings .

Table of Contents

Experienced and dedicated management team. Our senior management team has a proven track record of building our business through internal growth as well as through licensing and acquisitions, including the recent acquisition of RxKinetix, Inc. Members of our senior management were responsible for the licensing of Lidoderm®, CHRONOGESIC , Frova®, Rapinyl and Synera , as well as two other products, a topical ketoprofen patch being studied for soft tissue injuries, and a 7-day transdermal sufentanil patch being studied for moderate to severe chronic pain. Management has received FDA approval on more than seventeen new products and product line extensions since 1997, and as a result of several successful product launches, has grown our net sales from $108.4 million in 1998 to $909.7 million in 2006.

Our Industry

According to Wolters Kluwer Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled $19.7 billion in 2006. This represents an approximately 8% compounded annual growth rate since 2002. Our primary area of focus within this market is analgesics. In 2006, analgesics were the fourth most prescribed medication in the United States with over 260 million prescriptions written for this classification. These products are used primarily for the treatment of pain associated with orthopedic fractures and sprains, back injuries, migraines, joint diseases, cancer and various surgical procedures.

Opioid analgesics comprised approximately 80% of the U.S. analgesics prescriptions in 2006. This market segment has grown to $7.3 billion in 2006, representing a compounded annual growth rate of 8% since 2002. If branded products were substituted for generic products, we believe the dollar value of this market segment would be substantially larger. 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.

Table of Contents

Product Overview

The following table summarizes select products in our marketed portfolio as well as selected products in development as of December 31, 2006:

Product	Active ingredient(s)	Branding	Status
Lidoderm®	lidocaine 5%	Branded	Marketed
Percocet®	oxycodone and acetaminophen	Branded	Marketed
Percodan®	oxycodone and aspirin	Branded	Marketed
Frova®(1)	frovatriptan	Branded	Marketed
DepoDur®(2)	morphine sulfate	Branded	Marketed
Synera™ (3)	lidocaine and tetracaine	Branded	Marketed
Opana® ER(4)	oxymorphone hydrochloride	Branded	Marketed
Opana®	oxymorphone hydrochloride	Branded	Marketed
Endocet®	oxycodone and acetaminophen	Generic	Marketed
Morphine Sulfate ER	morphine sulfate	Generic	Marketed
Oxycodone ER(5)	oxycodone hydrochloride	Generic	Marketed
Frova® (menstrual migraine)(1)	frovatriptan	Branded	PDUFA date May 19, 2007
Rapinyl (6)	fentanyl	Branded	Phase III
Topical Ketoprofen Patch(7)	ketoprofen	Branded	Phase III
Lidoderm® (new indications)	lidocaine 5%	Branded	Phase II
LidoPAIN® BP(8)	lidocaine	Branded	Phase II
EN 3285 oral rinse	N-acetylcysteine	Branded	Phase II
Transdermal Sufentanil Patch(9)	sufentanil	Branded	Phase I
CHRONOGESIC (10)	sufentanil	Branded	Early Stage

(1) Licensed marketing rights from Vernalis Development Limited.

(2) Licensed marketing rights from SkyePharma, Inc. The licensing agreement has been terminated by Endo with an effective date of March 31, 2007.

(3) Licensed marketing rights from ZARS Pharma.

(4) Marketed pursuant to an alliance agreement with Penwest Pharmaceuticals Co.

(5) Pursuant to a settlement agreement with The Purdue Frederick Company and related companies, Endo ceased all commercial activity on December 31, 2006. See Item 3. Legal Proceedings for further details.

(6) Licensed marketing and development rights from Orexo AB.

(7) Licensed marketing and development rights from ProEthic Pharmaceuticals, Inc.

(8) Licensed marketing rights from EpiCept Corporation.

(9) Licensed marketing and development rights from DURECT Corporation.

(10) Licensed marketing rights from DURECT Corporation.

Table of Contents

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. There are approximately 200,000 patients per year who suffer from this condition in the United States. The FDA had granted Lidoderm® orphan drug status, generally meaning that no other lidocaine-containing topical patch product can be approved for this indication until the orphan drug status expiration date, which occurred on March 19, 2006. On October 17, 2006, Endo 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 the Company submitted a Citizen Petition with the U.S. Food and Drug Administration requesting that the FDA apply existing bioequivalence regulations to any ANDA seeking regulatory approval of a generic drug product that references Endo s Lidoderm®. The petition emphasizes that this 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®, Endo 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®. To our knowledge, there is no competitive product to Lidoderm® that has been, or is being developed. Lidoderm® is also currently protected by Orange Book-listed patents for, among other things, a method of treating post-herpetic neuralgia and the composition of the lidocaine-containing patch. The last of these patents is set to expire in 2015. In 2006, 2005 and 2004, Lidoderm® net sales were $566.8 million, $419.4 million and $309.2 million, respectively. Lidoderm® accounted for approximately 62% of our 2006 net sales.

In addition, we are currently exploring the safety and efficacy of Lidoderm® in other indications and have initiated both Phase II and Phase IV clinical trials.

On January 17, 2007, we received a subpoena from the U.S. Department of Health and Human Services, Office of Inspector General, requesting documents from 1999 to the present regarding the Company s sales and promotional practices relating to Lidoderm