ENDO HEALTH SOLUTIONS INC.
Form 10-K
March 03, 2014
Table of Contents

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, 2013
Or
o 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 HEALTH SOLUTIONS 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)
1400 Atwater Drive, Malvern, Pennsylvania	19355
(Address of Principal Executive Offices)	(Zip Code)

(Registrant's Telephone Number, Including Area Code): (484) 216-0000
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock of $0.01 par value	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: N/A

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.	Yes x No o
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.	Yes o 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 o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every interactive data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months.	Yes x No o

x

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.

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	o	Non-accelerated filer (Do not check if a smaller reporting company)	o	Smaller reporting company	o

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

The aggregate market value of the voting common equity held by non-affiliates as of June 30, 2013 was $4,157,589,778 based on a closing sale price of $36.79 per share as reported on the NASDAQ Global Select Market on June 30, 2013. 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, 2014: 115,623,740

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 2014 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, 2013.

Table of Contents

ENDO HEALTH SOLUTIONS INC.
INDEX TO FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2013

Table of Contents

FORWARD-LOOKING STATEMENTS

Statements contained or incorporated by reference in this document contain information that includes or is based on “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements, including estimates of future revenues, future expenses, future net income and future net income per share, contained in the section titled “Management's Discussion and Analysis of Financial Condition and Results of Operations,” which is included in this document, are subject to risks and uncertainties. Forward-looking statements include the information concerning our possible or assumed results of operations. We have tried, whenever possible, to identify such statements by words such as “believes,” “expects,” “anticipates,” “intends,” “estimates,” “plan,” “projected,” “forecast,” “will,” “may” or similar expressions. We have based 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 Part I, Item 1A. of this report "Risk Factors", supplement, and as otherwise enumerated herein, could affect our future financial results and could cause our actual results to differ materially from those expressed in forward-looking statements contained or incorporated by reference in this document.

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

Table of Contents

PART I

Item 1. Business

Overview

Endo Health Solutions Inc., (which we refer to herein as "Endo", the "Company", "we", "our" or "us") is a specialty healthcare company focused on branded and generic pharmaceuticals and devices. We aim to be the premier partner to healthcare professionals and payment providers, delivering an innovative suite of complementary branded and generic drugs and devices to meet the needs of patients in areas such as pain management, urology, oncology and endocrinology.

We regularly evaluate and, where appropriate, execute on opportunities to expand through acquisition of products and companies in areas that will serve patients and customers and that Endo believes will offer above average growth characteristics and attractive margins. In particular, Endo looks to continue to enhance its product lines by acquiring or licensing rights to additional products and regularly evaluating selective acquisition and license opportunities. Such acquisitions or licenses may be effected through the purchase of assets, joint ventures and licenses or by acquiring other companies.

On December 28, 2013, Endo's Board of Directors (the Board) approved a plan to sell its HealthTronics business and on January 8, 2014, the Company entered into a definitive agreement to sell the business. We closed the sale of our HealthTronics business on February 3, 2014. In June 2011, we acquired American Medical Systems Holdings, Inc. (AMS or American Medical Systems), a leading provider of devices and therapies for treating male and female pelvic health conditions. The acquisition of AMS strengthens our leading core urology franchise and expands our presence in the medical devices market. In November 2010, we acquired Generics International (US Parent), Inc. (doing business as Qualitest Pharmaceuticals), a leading U.S. based privately held generics company and currently the sixth largest U.S. generics company, as measured by prescriptions filled. Qualitest Pharmaceuticals is focused on cost competitive, high quality manufactured products with cost advantages or with high barriers to entry such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. We continue to operate across our diversified businesses in three key segments, Endo Pharmaceuticals, Qualitest and AMS, in key therapeutic areas including pain management, urology, oncology and endocrinology. Our segments are further discussed in Note 6. Segment Results in the Consolidated Financial Statements included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules" and in Part II, Item 7. of this report "Management's Discussion and Analysis of Financial Condition and Results of Operations" under the caption "Business Segment Results Review".

We have a portfolio of branded pharmaceuticals that includes established brand names such as Lidoderm®, Opana® ER, Voltaren® Gel, Percocet®, Fortesta® Gel, Frova®, Supprelin® LA, Valstar® and Vantas®. Endo Pharmaceuticals comprised approximately 53% of our total revenues in 2013, with 23% of our revenues coming from Lidoderm®. Our non-branded Qualitest portfolio, which accounted for 28% of total revenues in 2013, currently consists of products primarily focused in pain management through a differentiated portfolio of controlled substances and liquids. Our AMS segment focuses on providing technology solutions to physicians treating men’s and women’s pelvic health conditions and operates in the following business lines: men’s health, women’s health, and benign prostatic hyperplasia (BPH or prostate health) therapy. AMS accounted for 19% of total revenues in 2013. We generated total 2013 revenues of $2.6 billion.

Financial information presented herein reflects the operating results of AMS from June 18, 2011.

We were incorporated under the laws of the State of Delaware on November 18, 1997 and have our principal executive offices at 1400 Atwater Drive, Malvern, Pennsylvania 19355 (telephone number: (484) 216-0000).

Table of Contents

Our Strategy

Our strategy is focused on continuing our progress in becoming a leading global specialty healthcare company. Through a lean and efficient operating model, we are committed to serving patients and customers while continuing to innovate products that make a difference in the lives of its patients. We strive to maximize shareholder value by adapting to market realities and customer needs.

We are committed to driving organic growth at attractive margins by improving execution, optimizing cash flow and leveraging our strong market position, while maintaining a streamlined cost structure throughout each of our businesses. Specific areas of management's focus in each of our segments include:

- Endo Pharmaceuticals: Enhancing performance of organic growth drivers, increasing profitability from the Company’s mature brands and investing in key late-stage pipeline opportunities.
- Qualitest: Capitalizing on encouraging demand trends for a differentiated portfolio of controlled substances and liquids and more effective R&D investment by targeting low-risk, high-return opportunities in generics.
- American Medical Systems: Utilizing its leading position in urology to enhance demand for American Medical Systems’ unique products and services in attractive growth markets.

We remain committed to R&D across each business unit with a particular focus on development capabilities and near-term revenue generating assets. We also seek to identify incremental growth opportunities through product licensing and development.

In addition to a focus on organic growth drivers, we are also actively pursuing accretive acquisitions that offer attractive cost synergies, enhance our strategic position and accelerate future growth.

Since June 2013, we have announced the following acquisitions:

- On August 28, 2013, Endo announced that it had entered into a definitive agreement to acquire Boca Pharmacal LLC (Boca), a specialty generics company that focuses on niche areas, commercializing and developing products in categories that include controlled substances, semisolids and solutions. We believe Boca’s commercial footprint and R&D pipeline are a strong complement to Qualitest.
- On November 5, 2013, Endo announced that it had entered into a definitive agreement to acquire Paladin Labs Inc.(Paladin), which we believe will accelerate Endo’s strategic transformation to a leading global specialty healthcare company and create a platform for future growth in North America and internationally.

See Note 23. Subsequent Events in the Consolidated Financial Statements included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules" and Part II, Item 7. of this report "Management's Discussion and Analysis of Financial Condition and Results of Operations" for further discussion.

Our Competitive Strengths

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

Proactive diversification of our business to become a leading global specialty healthcare company. In light of the evolving healthcare industry, we executed a number of corporate acquisitions during the three years ended December 31, 2013 to diversify our business and become a leading specialty healthcare company that includes both branded and generic prescription drugs, as well as medical devices. Endo regularly evaluates and, where appropriate, executes on opportunities to expand through acquisitions of products and companies in areas that will serve patients and customers and that Endo believes will offer above average growth characteristics and attractive margins. In particular, Endo looks to continue to enhance its product lines by acquiring or licensing rights to additional products and regularly evaluating selective acquisition and license opportunities. Such acquisitions or licenses may be effected through the purchase of assets, joint ventures and licenses or by acquiring other companies.

As a result of recent strategic actions combined with strategic investments in our core business, we have redefined our position in the healthcare marketplace and successfully reduced the revenue concentration of Lidoderm®, which contributed approximately 23% of our business’ revenue in 2013, compared to 33% in 2012. Our acquisitions of AMS and Qualitest Pharmaceuticals have also contributed to our diversification. The acquisition of Qualitest Pharmaceuticals has enabled us to gain critical mass in our generics business. Through AMS, we manufacture medical devices primarily for the urology community.

Established portfolio of branded products. We have assembled a portfolio of branded prescription products to treat and manage pain and conditions in urology, oncology and endocrinology. Our branded products include: Lidoderm®,

Opana® ER, Voltaren® Gel, Percocet®, Frova®, Fortesta® Gel, Supprelin® LA, Vantas® and Valstar®. For a more detailed description of each of our products, see "Products Overview."

Focused branded pipeline. As a result of our focused research and development efforts, we believe we have a promising development pipeline and are well-positioned to capitalize on our core development products. Currently, our core development pipeline consists of one New Drug Application (NDA) filed with the U.S. Food and Drug Administration (FDA) and one product in Phase III trials. We have also initiated development efforts for medical devices and have multiple programs at concept and

Table of Contents

development stages across urology, uro-oncology, endocrinology and urogynocology. For a more detailed description of our development pipeline, see “Select Products in Development.”

Research and development expertise. Our research and development efforts are focused on the development of a balanced, diversified portfolio of innovative and clinically differentiated products. We are continuously seeking opportunities that deepen our presence in the pain management area as well as in the areas of oncology, urology and endocrinology. We will continue to capitalize on our core expertise with analgesics and expand our abilities to pursue other therapeutic areas. Through our acquisition of AMS., we have expanded our expertise in the development of medical devices. Through our acquisition of Qualitest Pharmaceuticals, we have increased our efforts to seek out and develop generic products with complex formulations and high barriers to entry. We remain committed to research and development across each business unit with a particular focus on development capabilities and near-term revenue generating assets. At December 31, 2013, our research and development and regulatory affairs staff consisted of 257 employees, based primarily in Minnetonka, Minnesota, San Jose, California, Huntsville, Alabama and at our corporate headquarters in Malvern, Pennsylvania. Our research and development expenses were $142.5 million, $219.1 million and $179.8 million in 2013, 2012 and 2011, respectively, including upfront and milestone payments of $11.4 million, $57.9 million and $19.1 million, respectively.

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

Targeted sales and marketing infrastructure. We market our branded products directly to physicians through a sales force of over 600 individuals in the pharmaceutical product and device markets. As of December 31, 2013, this sales force consisted of 160 pharmaceutical sales representatives focusing primarily on pain products, 119 sales representatives focusing primarily on bladder and prostate cancer products, 32 medical center representatives focusing on the treatment of central precocious puberty and four account executives focusing on managed markets customers. We also had 306 sales representatives focusing primarily on devices, of which 106 were located outside the United States. We market our products and services to primary care physicians and specialty physicians, including those specializing in pain management, orthopedics, neurology, rheumatology, surgery, anesthesiology, urology and pediatric endocrinology. Our sales force also targets retail pharmacies and other healthcare professionals throughout the U.S. We distribute our products principally through independent wholesale distributors, but we also sell directly to retailers, clinics, government agencies, doctors and retail and specialty pharmacies. Our marketing policy is designed to assure that products and relevant, appropriate medical information are immediately available to physicians, pharmacies, hospitals, public and private payers, and appropriate healthcare professionals throughout the U.S. We work to gain access to healthcare authority, pharmacy benefit managers and managed care organizations’ formularies (lists of recommended or approved medicines and other products), including Medicare Part D plans and reimbursement lists by demonstrating the qualities and treatment benefits of our products within their approved indications.

Expanding focus on generic products. Our Qualitest segment has approximately 46 Abbreviated New Drug Applications (ANDAs) under active FDA review in multiple therapeutic areas, including pain management, urology, central nervous system (CNS) disorders, immunosuppression, oncology, women’s health and hypertension, among others. We develop generic products including those that involve significant barriers to entry such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. We believe products with these characteristics will face a lesser degree of competition and therefore provide longer product life cycles and higher profitability than commodity generic products. Our business model continues to focus on being the lowest-cost producer of products in categories with high barriers to entry and lower levels of competition. Our Qualitest segment is focused in categories where there are fewer challenges from low-cost operators in markets such as China and India, with approximately 36% of our product portfolio being comprised of controlled substances, which cannot be manufactured off-shore and imported into the U.S. In addition, approximately 8% of our product portfolio is made up of liquids, which are uneconomical to ship into the U.S. We expect to continue to improve our overall profitability by

optimizing our portfolio for high volume and growth while strengthening our U.S. generics competitive position, product pipeline, portfolio and capabilities.

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

Table of Contents

Significant cash flow. We have historically generated significant cash flow from operating activities due to a unique combination of strong brand equity, attractive margins and low capital expenditures. For the year ended December 31, 2013, we generated $298.5 million of cash from operations. We expect that sales of our currently marketed products and devices and will allow us to continue to generate significant cash flow from operations in the future. We maintain ample liquidity which gives us flexibility to make strategic investments in our business. As of December 31, 2013, we had $529.6 million of cash and marketable securities, up to $500.0 million of availability under the Revolving Credit Facility, and availability of up to $500.0 million of additional revolving or term loan commitments.

Experienced and dedicated management team. Our senior management team has a proven track record of building businesses through licensing and acquisitions. Their expertise has contributed to identifying and consummating such acquisitions. Members of our management team have consummated two acquisitions since June 2013 (Boca and Paladin) and have significantly increased the market value of the Company. As a result of several successful product launches and our strategic acquisitions, we have grown our total revenues from $108.0 million in 1998 to over $2.6 billion in 2013.

Our Areas of Focus

Pharmaceutical Products Markets

Pain Management Market

According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled $28.8 billion in 2013. This represents an approximate 8% compounded annual growth rate since 2009. Our primary area of focus within this market is analgesics and, specifically, opioid analgesics. In 2013, analgesics were the third most prescribed medication in the U.S. with over 304 million prescriptions written for this classification.

Opioid analgesics is a segment that comprised approximately 76% of the total analgesic prescriptions for 2013 and represented almost 53% of the overall U.S. prescription pain management market. Total U.S. sales for the opioid analgesic segment were $8.3 billion in 2013, representing a compounded annual growth rate of 1% since 2009. With the launch of Voltaren® Gel in 2008, Endo gained presence in the osteoarthritis market competing in the analgesic non-narcotic and anti-arthritic classes which together had approximately 206 million prescriptions written in 2013, representing 47% of the U.S. prescription pain management market. The U.S. sales for the analgesic non-narcotic and anti-arthritic markets were $20.4 billion with a compound annual growth rate of 11% since 2009.

Opioid analgesic products are used primarily for the treatment of pain associated with orthopedic fractures and sprains, post herpetic-neuralgia, back injuries, migraines, joint diseases, cancer and various surgical procedures. The growth in this segment has been primarily attributable to:

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

Urology, Endocrinology and Oncology Markets

Through our 2009 acquisition of Indevus Pharmaceuticals, Inc., as well as other business development activities, Endo entered the urology, endocrinology and oncology markets, specifically the prostate cancer therapeutic area with Vantas®, the bladder oncology space with Valstar®, and the central precocious puberty therapeutic area with Supprelin® LA. With our early 2011 launch of Fortesta® Gel, which was approved by the FDA in December 2010 for the treatment of hypogonadism, we entered the testosterone replacement therapy (TRT) market. We anticipate increasing our presence in this market through our development product Aveed™. As a result of our acquisition of AMS, we now offer a broad array of medical devices that deliver innovative medical technology solutions to physicians treating male incontinence, erectile dysfunction, female incontinence, pelvic floor repair and BPH. The markets for our AMS segment's products are discussed below under the caption "Medical Device Markets."

Central Precocious Puberty (CPP)—In a recent study, the incidence of CPP reported from national registries in the European Union subdivided by gender and age at diagnosis was approximately 1 per 10,000 in girls who were younger than 4 years, thereafter gradually rising to 8 per 10,000 for girls aged 5 to 9 years. The incidence in boys

younger than 8 years was approximately 1 per 10,000. Recent market research indicates that girls in the U.S. are physically maturing at an earlier age than they did 30 years ago, and the number of girls diagnosed with precocious puberty is on the rise. In the U.S., 6,000 patients are estimated to have CPP with approximately 2,000 diagnosed annually. CPP is treated by pediatric endocrinologists in the U.S. where there are approximately 790 practicing pediatric endocrinologists.

Table of Contents

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

Bladder cancer—There are more than 500,000 people in the U.S. alive with a history of bladder cancer, which is the third most common cancer among men and the eleventh most common among women in the U.S. The American Cancer Society estimated approximately 74,960 new cases of bladder cancer and 15,580 deaths from this disease in the U.S. in 2013. The 2014 estimate is expected to be similar. Rates of bladder cancer are expected to increase due to the aging population; nearly 90% of cases of bladder cancer are diagnosed in people age 55 or older. The number of patients in the total non-invasive bladder cancer population will thus increase due to the rising incidence as well as high recurrence rates, leading to a substantial prevalent population.

Bacillus Calmette-Guérin (BCG)-refractory carcinoma in situ (CIS) bladder cancer—CIS of the urinary bladder is a rare form of bladder cancer, affecting about 7 of every 100 patients diagnosed with bladder cancer. Standard treatment of CIS of the urinary bladder is transurethral resection of the bladder tumor, followed by one or two courses of immunotherapy with the vaccine BCG. About 50% of patients will become refractory to BCG therapy. Valstar® intravesical therapy is the only FDA-approved treatment of carcinoma in situ of the urinary bladder in patients who are refractory to BCG immunotherapy when cystectomy (bladder removal) is not an option.

Testosterone replacement overview—In the U.S. alone, it is estimated that 13.8 million men have low testosterone levels; however, only about 9% are currently being treated. Hypogonadism, or low testosterone, is under diagnosed and under treated. Factors contributing to this include a lack of screening for low testosterone and the perceived risk of prostate cancer associated with current treatment strategies. In the U.S., TRT sales have dramatically increased from approximately $809.0 million in 2008 to over $2.3 billion in 2013, representing a compounded annual growth rate of 24% since 2008.

Medical Device Markets

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

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

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

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

transvaginal surgeries. We estimate over 400,000 procedures are performed annually around the world to repair some form of pelvic floor prolapse in women. These procedures have historically been performed through the use of suture and graft materials designed for other surgical applications. AMS offers less invasive solutions for pelvic floor repair. Prostate health—AMS's products can be used to relieve restrictions on the normal flow of urine from the bladder caused by bladder obstructions, generally the result of BPH or bulbar urethral strictures. Symptoms of BPH include increased urination frequency, sudden urges to urinate, and weak urine flow. More than 70% of men over age 60 have some symptoms of BPH. Prior to the development of less invasive therapies, the conventional treatment for those experiencing a physical obstruction of the prostatic urethra was a surgical removal of the prostatic tissue performed under general anesthesia, known as a transurethral resection of the

Table of Contents

prostate (TURP). We offer men an alternative to a TURP, using laser therapy designed to reduce the comorbidities associated with TURP. This laser system has paved the way for creating a new standard of care in the treatment of BPH.

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

Products Overview

Endo Pharmaceuticals

The following table summarizes select products in our Endo Pharmaceuticals portfolio:

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

(1) Licensed marketing and development rights from Grünenthal GMBH.

(2) Licensed marketing rights from Novartis Consumer Health, Inc.

(3) Licensed marketing rights from Vernalis Development Limited.

(4) Licensed marketing and development rights from Strakan International Limited.

Lidoderm®. Lidoderm® (lidocaine patch 5%) was launched in September 1999. A topical patch product containing lidocaine, Lidoderm® was the first FDA-approved product for the relief of the pain associated with post-herpetic neuralgia, a condition thought to result after nerve fibers are damaged during a case of Herpes Zoster (commonly known as shingles). Although Lidoderm® continues to receive a certain degree of protection from Orange Book-listed patents for, among other things, a method of treating post-herpetic neuralgia and the composition of the lidocaine-containing patch, in May 2012, we entered into a settlement and license agreement with Watson Pharmaceuticals, Inc. (now doing business as Actavis, Inc. and referred to herein as Watson or Actavis) which allowed Watson to launch its lidocaine patch 5%, a generic version of Lidoderm® on September 15, 2013. This agreement is further discussed in Note 14. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules". Although the Company believes it has successfully contracted with certain Managed Care providers and government agencies, we do expect future net sales of Lidoderm® to continue to be impacted due to generic competition, resulting in additional decreases in Lidoderm® net sales. For the years ended December 31, 2013, 2012 and 2011, Lidoderm® net sales were $603.0 million, $947.7 million and $825.2 million, respectively. Lidoderm® accounted for approximately 23% of our 2013 total revenues.

Opana® ER. Opana® ER was launched during the second half of 2006 and had shown prescription growth since its launch until the 2012 supply disruption, which caused some patients to switch to other pain relief products. Opana® ER is indicated for the relief of moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time. Opana® ER represents the first drug in which oxymorphone is available in an oral, extended-release formulation and is available in 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg and 40 mg tablets. In December 2011, the FDA approved our formulation of Opana® ER designed to be crush-resistant, which is called Opana® ER (oxymorphone hydrochloride) Extended-Release Tablets with INTAC® technology. This formulation of Opana® ER with INTAC® technology has the same dosage strengths, color and packaging and similar tablet size as original Opana® ER. Endo transitioned to the crush-resistant formulation in March 2012 upon

successfully accelerating production of this formulation. While we believe Endo's ongoing commercial efforts, which include direct and indirect sales efforts, coupon programs, education and promotion within targeted customer channels, have contributed positively to the uptake of our crush-resistant formulation, revenues since the transition have not returned to historical pre-transition levels. 2012 revenues included the favorable effects of wholesaler restocking efforts to transition to the crush-resistant formulation of Opana® ER, which did not reoccur during the comparable 2013 periods. In addition, Impax and Actavis launched generic versions of the non-crush-resistant formulation Opana® ER on January 2, 2013 and September 12, 2013, respectively, negatively impacting revenues. Opana® ER net sales were $227.9 million,

Table of Contents

$299.3 million and $384.3 million for the years ended December 31, 2013, 2012 and 2011, respectively. Opana® ER accounted for approximately 9% of our 2013 total revenues.

Voltaren® Gel. We launched Voltaren® Gel (diclofenac sodium topical gel 1%) in March 2008 upon closing of the license and supply agreement with Novartis AG and Novartis Consumer Health, Inc. Voltaren® Gel received regulatory approval in October 2007 from the FDA, becoming the first topical prescription treatment for use in treating pain associated with osteoarthritis and the first new product approved in the U.S. for osteoarthritis since 2001. Voltaren® Gel was granted marketing exclusivity in the U.S. as a prescription medicine until October 2010. It is the first prescription topical osteoarthritis treatment to have proven its effectiveness in both the knees and joints of the hands through clinical trials. Voltaren® Gel delivers effective pain relief with a favorable safety profile as its systemic absorption is 94% less than the comparable oral diclofenac treatment. For the years ended December 31, 2013, 2012 and 2011, net sales of Voltaren® Gel were $170.8 million, $117.6 million and $142.7 million, respectively. Voltaren® Gel accounted for approximately 7% of our 2013 total revenues.

Percocet®. Launched in 1976, Percocet® (oxycodone hydrochloride and acetaminophen USP) Tablets CII is approved for the treatment of moderate-to-moderately severe pain. The Percocet® family of products had net sales of $105.8 million, $103.4 million and $104.6 million for the years ended December 31, 2013, 2012 and 2011, respectively. The Percocet® franchise accounted for approximately 4% of our 2013 total revenues.

Frova®. We began shipping Frova® (frovatriptan succinate) tablets upon closing of the license agreement with Vernalis in mid-August 2004. Frova® is indicated for the acute treatment of migraine headaches in adults. We believe that Frova® has differentiating features from other migraine products, including the longest half-life in the triptan class and a very low reported migraine recurrence rate in its clinical program. For the years ended December 31, 2013, 2012 and 2011, Frova® net sales were $60.9 million, $61.3 million and $58.2 million, respectively.

Fortesta® Gel. Fortesta® Gel is a patented two percent (2%) testosterone transdermal gel and is a treatment for men suffering from hypogonadism, also known as low testosterone (Low T). The precision-metered dose delivery system can be accurately customized and adjusted to meet individual patient needs with the appropriate dose. In August 2009, we entered into a License and Supply Agreement (the ProStrakan Agreement) with Strakan International Limited, a subsidiary of ProStrakan Group plc (ProStrakan), for the exclusive right to commercialize Fortesta® Gel in the U.S. Fortesta® Gel was approved by the FDA in December 2010. We launched Fortesta® Gel in the first quarter of 2011. Net sales of Fortesta® Gel were $65.9 million, $30.6 million and $14.9 million for the years ended December 31, 2013, 2012 and 2011, respectively.

Supprelin® LA. Supprelin® LA (histrelin acetate) was launched in the U.S. in June 2007. Supprelin® LA is a soft, flexible 12-month hydrogel implant based on our hydrogel polymer technology that delivers histrelin acetate, a gonadotropin releasing hormone (GnRH) agonist and is indicated for the treatment of CPP in children. CPP is the early onset of puberty in young children resulting in the development of secondary sex characteristics and, if left untreated, can result in diminished adult height attainment. The development of these secondary sex characteristics is due to an increase in the secretion of sex hormones, the cause of which is unknown. We market Supprelin® LA in the U.S. through a specialty sales force primarily to pediatric endocrinologists. For the years ended December 31, 2013, 2012 and 2011, Supprelin® LA net sales were $58.3 million, $57.4 million and $50.1 million, respectively.

Valstar®. We launched Valstar® (valrubicin) in September 2009. Valstar® is a sterile solution for intravesical instillation of valrubicin, a chemotherapeutic anthracycline derivative. Valstar® is indicated for intravesical therapy of bacillus Calmette-Guerin (BCG)-refractory carcinoma in situ (CIS) of the urinary bladder in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality. Net sales of Valstar® were $23.7 million, $27.1 million and $21.5 million for the years ended December 31, 2013, 2012 and 2011, respectively.

Vantas®. Vantas® (histrelin acetate) was launched in the U.S. in November 2004. Vantas® is a soft, flexible 12-month hydrogel implant based on our hydrogel polymer technology that delivers histrelin acetate, a GnRH agonist and is indicated for the palliative treatment of advanced prostate cancer. Net sales of Vantas® were $13.2 million, $17.5 million and $19.0 million for the years ended December 31, 2013, 2012 and 2011, respectively, primarily in the U.S.

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

products: Vantas® and Supprelin® LA.

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

Other. The balance of our other branded portfolio consists of a number of products, each of which accounted for 1% or less of our total revenues in 2013.

Table of Contents

Qualitest

The following table summarizes select products currently in our Qualitest portfolio:

Generic Pharmaceutical Products	Active Ingredient(s)	Status
Hydrocodone and Acetaminophen	Hydrocodone and Acetaminophen	Marketed
Endocet®	Oxycodone Hydrochloride and Acetaminophen	Marketed
Phenobarbital	Phenobarbital	Marketed
Methylprednisolone	Methylprednisolone	Marketed
Modafinil	Modafinil	Marketed
Oxycodone and Acetaminophen	Oxycodone and Acetaminophen	Marketed
Promethazine	Promethazine	Marketed
Prednisone	Prednisone	Marketed
Lisinopril	Lisinopril	Marketed
Montelukast	Montelukast	Marketed
Oxybutynin	Oxybutynin	Marketed
Butalb/APAP/Caff	Butalbital and Acetaminophen	Marketed
Gildess FE 1/20	Norethindrone Acetate, Ethinyl Estradiol and Ferrous Fumarate	Marketed
Hydrocortisone	Hydrocortisone	Marketed
Nystatin	Nystatin	Marketed

When a branded pharmaceutical product is no longer protected by any relevant patents, normally as a result of a patent's expiration, or by other, non-patent market exclusivity, third parties have an opportunity to introduce generic counterparts to such branded product. Generic pharmaceutical products are therapeutically equivalent to their brand-name counterparts and are generally sold at prices significantly less than the branded product. Accordingly, generic pharmaceuticals may provide a safe, effective and cost-effective alternative to users of branded products. Our generic products are sold across multiple therapeutic categories, with pain management being the largest, and in various dosage forms including solids, semi-solids and liquids. Qualitest's top 15 products provided revenues of $415.9 million, $376.1 million and $294.9 million in 2013, 2012 and 2011, respectively.

AMS

The following table summarizes select products in our AMS portfolio:

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

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

AMS 700 MS™ Series. The AMS 700 MS™ Series are market leading penile implants to treat erectile dysfunction, which is the inability to achieve or maintain an erection sufficient for sexual intercourse. This service contains a complete range of more naturally functioning inflatable prostheses than earlier generations of the product and is distinguished from other penile implants with the use of the InhibiZone® antibiotic coating. InhibiZone® is intended to reduce the rate of revision surgery due to surgical infections and this claim was approved by the FDA in July 2009. AMS 700 MS™ revenue accounted for approximately 5% of our total revenues in 2013 compared to 4% in 2012.

AMS 800® Artificial Urinary Sphincter. The AMS 800® artificial urinary sphincter is designed for the treatment of moderate to severe male urinary incontinence, the involuntary release of urine from the body. It includes an inflatable urethral cuff to restrict flow through the urethra and a control pump that allows the patient to discreetly open the cuff

when he wishes to urinate. AMS 800® revenue accounted for approximately 4% of our total revenues in both 2013 and 2012.

Table of Contents

GreenLight™ XPS Laser System. The GreenLight™ XPS laser system is used to relieve restrictions on the normal flow of urine from the bladder caused by bladder obstructions, generally the result of BPH or bulbar urethral strictures. This therapy offers men experiencing a physical obstruction of the prostatic urethra an alternative to TURP. The GreenLight™ photovaporization of the prostate is designed to reduce the comorbidities associated with TURP. The GreenLight™ XPS and MoXy™ Liquid Cooled Fiber system provide shorter treatment times with similar long-term results compared to other laser systems. The GreenLight™ laser system offers an optimal laser beam that balances vaporization of tissue with coagulation to prevent blood loss and provides enhanced surgical control compared to other laser systems. The GreenLight™ laser and fiber system revenue accounted for approximately 3% of our total revenues in both 2013 and 2012.

Elevate™ Anterior and Posterior Pelvic Floor Repair System. Our AMS segment offers the Elevate® transvaginal pelvic floor repair system, for the treatment of pelvic organ prolapse, which may be caused by pregnancy, labor, and childbirth. Using an anatomically designed needle and self-fixating tips, Elevate® allows for safe, simple and precise mesh placement through a single vaginal incision, avoiding an external incision. Elevate® revenue accounted for approximately 1% of our total revenues in both 2013 and 2012.

Monarc® Subfascial Hammock. The Monarc® subfascial hammock is our leading device to treat female stress urinary incontinence, which generally results from a weakening of the tissue surrounding the bladder and urethra which can be a result of pregnancy, childbirth and aging. It incorporates unique helical needles to place a self-fixating, sub-fascial hammock through the obturator foramin. Monarc® revenue accounted for approximately 1% of our total revenues in both 2013 and 2012.

Select Products in Development

Endo Pharmaceuticals

Our branded pharmaceuticals pipeline portfolio contains products and product candidates that have differentiating features for multiple therapeutic areas, including pain, urology and endocrinology. A selection of Endo Pharmaceutical's pipeline products follows. We cannot predict when or if any of these pipeline products will be approved by the FDA.

Aveed™. Aveed™ is a novel, long-acting injectable testosterone preparation for the treatment of male hypogonadism. Male hypogonadism is an increasingly recognized medical condition characterized by a reduced or absent secretion of testosterone from the testes. Reduced testosterone levels can lead to health problems and significantly impair quality of life. Common effects of hypogonadism include decreased sexual desire, erectile dysfunction, muscle loss and weakness, depression, and an increased risk of osteoporosis. If approved, Aveed™ would be the first long-acting injectable testosterone preparation available in the U.S. in the growing market for testosterone replacement therapies. The U.S. rights to Aveed™ were acquired from Schering AG, Germany, in July 2005. Although not yet approved in the U.S., Aveed™ is approved in and currently marketed in Europe and a number of other countries. In May 2010, a new patent covering Aveed™ was issued by the U.S. Patent and Trademark Office. The patent’s expiration date is March 14, 2027.

On December 2, 2009, we received a Complete Response letter from the FDA regarding Aveed™. In 2010 and 2011, the Company met with the FDA to discuss the existing clinical data provided to the FDA as well as the potential path-forward. In November 2012, as a follow up to our 2011 meeting with the FDA, Endo Pharmaceuticals submitted a complete response to the FDA after conducting an extensive review of all clinical study and post-marketing data. The FDA held an advisory committee meeting in April 2013, and Endo submitted new data to FDA in August 2013. A new PDUFA date was set for February 28, 2014.

BEMA® Buprenorphine. In January 2012, Endo Pharmaceuticals signed a worldwide license and development agreement with BioDelivery Sciences International, Inc. (BioDelivery) for the exclusive rights to develop and commercialize BEMA® Buprenorphine. BEMA® Buprenorphine is a transmucosal form of buprenorphine, a partial mu-opiate receptor agonist, which incorporates a bioerodible mucoadhesive (BEMA®) technology. In January 2014, the Company achieved positive top-line results from its pivotal Phase III efficacy study of BEMA buprenorphine in opioid- "naive" subjects for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. The second Phase III clinical study of BEMA Buprenorphine in an opioid "experienced" patient group is ongoing with results anticipated in mid-2014.

Qualitest

Our generics pharmaceuticals pipeline portfolio contains products and product candidates for multiple therapeutic areas, including pain, urology, oncology, and endocrinology. Our Qualitest business has a number of products at various stages of development, including approximately 46 ANDAs under active FDA review as of December 31, 2013. The timing of final FDA approval of ANDA applications depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and whether the manufacturer of the reference listed drug is entitled to one or more statutory exclusivity periods, during which the FDA is prohibited from approving generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date.

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

Table of Contents

AMS

Our AMS segment maintains a portfolio of products and product candidates in development with differentiating features for our areas of focus in pelvic health. Current development products showing significant promise include a urology drug delivery device and a fecal incontinence device. We also have other products, including certain undisclosed products in our therapeutic areas of interest in early stages of development.

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

Competition

Endo Pharmaceuticals

The branded pharmaceutical industry is highly competitive. Our products compete with products manufactured by many other companies in highly competitive markets throughout the U.S. Our competitors vary depending upon therapeutic and product categories. Competitors include many of the major brand name and generic manufacturers of pharmaceuticals, especially those doing business in the U.S. In the market for branded pharmaceuticals, our competitors, including Abbott Laboratories, Johnson & Johnson, Pfizer, Inc., Purdue Pharma, L.P., Allergan, Inc. and Actavis Pharmaceuticals, Inc., vary depending on product category, dosage strength and drug-delivery systems.

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

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

The Company is aware of certain competitive activities involving Lidoderm®, Opana® ER and Frova®. For a full description of these competitive activities, including the litigation related to Paragraph IV Certification Notices, see Note 14. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

Qualitest

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

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

As a result of consolidation among wholesale distributors as well as rapid growth of large retail drug store chains, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. This has resulted in customers gaining more purchasing power.

Consequently, there is heightened competition among generic drug producers for the business of this smaller and more selective customer base.

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

Table of Contents

developments in improved and/or advanced drug delivery technologies or other therapeutic techniques may provide therapeutic or cost advantages to competing products.

AMS

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

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

Seasonality

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

Major Customers

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

	2013		2012		2011	
Cardinal Health, Inc.	21	%	25	%	27	%
McKesson Corporation	26	%	26	%	26	%
AmerisourceBergen Corporation	15	%	12	%	14	%

Revenues from these customers are included within our Endo Pharmaceuticals and Qualitest segments.

As a result of consolidation among wholesale distributors as well as rapid growth of large retail drug store chains, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. Some wholesale distributors have demanded that pharmaceutical manufacturers, including us, enter into distribution service agreements (DSAs) 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. Currently, we have entered into four such agreements.

None of our AMS customers or distributors accounted for 10% or more of our total revenues during 2013, 2012 and 2011.

Table of Contents

Patents, Trademarks, Licenses and Proprietary Property

As of February 20, 2014, we held approximately: 305 U.S. issued patents, 235 U.S. patent applications pending, 257 foreign issued patents, and 351 foreign patent applications pending. In addition, as of February 20, 2014, we have licenses for approximately 52 U.S. issued patents, 16 U.S. patent applications pending, 179 foreign issued patents and 115 foreign patent applications pending. The following table sets forth information as of February 20, 2014 regarding each of our currently held material patents:

Patent No.	Patent Expiration*	Relevant Product	Ownership	Jurisdiction Where Granted
5,464,864	November 7, 2015	Frova®	Exclusive License	USA
5,616,603	April 1, 2014	Frova®	Exclusive License	USA
5,637,611	June 10, 2014	Frova®	Exclusive License	USA
5,827,871	October 27, 2015	Frova®	Exclusive License	USA
5,827,529	October 27, 2015	Lidoderm®	Exclusive License	USA
5,741,510	March 30, 2014	Lidoderm®	Exclusive License	USA
7,276,250	February 4, 2023	Opana® ER	Owned	USA
7,851,482	July 10, 2029	Opana® ER	Owned	USA
8,075,872	November 20, 2023	Opana® ER	Exclusive License	USA
8,114,383	August 5, 2024	Opana® ER	Exclusive License	USA
8,309,060	November 20, 2023	Opana® ER	Exclusive License	USA
8,309,122	February 4, 2023	Opana® ER	Owned	USA
8,329,216	February 4, 2023	Opana® ER	Owned	USA
2131647	September 8, 2014	Opana® ER	Owned	Canada
2208230	November 4, 2016	Opana® ER	Owned	Canada
2251816	April 18, 2017	Opana® ER	Owned	Canada
8,062,652	June 16, 2026	Supprelin® LA	Owned	USA
8,062,209	December 2, 2023	AMS 700®	Owned	USA
7,946,975	February 21, 2030	AMS 700®	Owned	USA
6,554,824	July 24, 2021	GreenLight™ Laser	Owned	USA
6,986,764	July 24, 2021	GreenLight™ Laser	Owned	USA
7,070,556	November 9, 2023	Monarc®	Owned	USA
7,347,812	March 17, 2026	Monarc®	Owned	USA
7,988,615	November 9, 2023	Monarc®	Owned	USA
7,357,773	January 5, 2026	Monarc®	Owned	USA
6,911,003	January 23, 2023	Monarc®	Owned	USA

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

The effect of these issued patents is that they provide us with patent protection for the claims covered by the patents. The coverage claimed in a patent application can be significantly reduced before the patent is issued. Accordingly, we do not know whether any of the applications we acquire or license will result in the issuance of patents, or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because unissued U.S. patent applications are maintained in secrecy for a period of eighteen months and U.S. patent applications filed prior to November 29, 2000 are not disclosed until such patents are issued, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the U.S. 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

Table of Contents

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 11. License and Collaboration Agreements in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules". There can be no assurance that any of our patents, licenses or other intellectual property rights will afford us any protection from competition.

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

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

Governmental Regulation

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

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

Based on scientific developments, post-market experience, or other legislative or regulatory changes, the current FDA standards of review for approving new pharmaceutical products are sometimes more stringent than those that were applied in the past. Some new or evolving review standards or conditions for approval were not applied to many established products currently on the market, including certain opioid products. As a result, the FDA does not have as extensive safety databases on these products as on some products developed more recently. Accordingly, we believe the FDA has expressed an intention to develop such databases for certain of these products, including many opioids. We cannot determine what effect changes in the FDA’s laws or regulations, when and if promulgated, or changes in the FDA’s legal or regulatory interpretations or requirements, 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 2013, the Supreme Court, in The Federal Trade Commission v. Actavis, determined that reverse payment patent settlements between generic and brand companies should be evaluated under the rule of reason, and provided limited guidance beyond the selection of this standard. The impact of this decision is not certain, and could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

EPI and Qualitest Pharmaceuticals sell products that are controlled substances as defined in the Controlled Substances Act of 1970 (CSA), which establishes certain security and record keeping requirements administered by the Drug Enforcement Agency (DEA). The DEA is concerned with the control of registered handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances, with Schedule I and II substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Our Qualitest segment sells a significant amount of hydrocodone-containing products. Hydrocodone combination products are currently regulated as Schedule III substances. Pursuant to the Food and Drug Administration Safety and Innovation Act, which is further described below, Congress has required the FDA to convene a meeting to solicit advice and recommendations to assist in conducting a scientific and medical evaluation on whether to

Table of Contents

reschedule combination products containing hydrocodone. Congress is acting in response to continued reports of misuse, abuse and addiction of products containing hydrocodone. An advisory committee to take public comments on the proposed rescheduling took place on January 24-25, 2013. At this advisory committee, the FDA's Drug Safety and Risk Management Advisory Committee recommended that hydrocodone be rescheduled to Schedule II. The FDA is responsible for preparing the documentation to reschedule a drug. Upon completion, the medical and scientific evaluation and scheduling recommendation of the FDA are forwarded to the Assistant Secretary for Health (ASH) who makes the final determination on behalf of the Secretary of the Department of Health and Human Services (HHS). The medical and scientific evaluation and the recommendation as to the appropriate schedule for the drug are then forwarded to the DEA. Should the DEA reschedule hydrocodone-containing products, it will be done through the rule-making process. A change from a Schedule III substance to a Schedule II substance could restrict patient access to needed medication. It would also require significant changes to the entire industry's supply chain from manufacturers, to wholesalers and retailers. We believe the increased burden and cost to the healthcare system would be substantial. While the briefing document published by the FDA on October 25, 2012, in advance of the advisory committee meeting suggests the FDA may not be prepared to recommend to the DEA that hydrocodone products be rescheduled to Schedule II, the FDA did, however, acknowledge that the question remains on how to reduce levels of abuse of hydrocodone combination products. In October 2013 the FDA issued a statement confirming that they plan to submit by December 2013 their formal recommendation package to HHS to reclassify hydrocodone combination products into Schedule II. The FDA anticipates the National Institute on Drug Abuse (NIDA)/HHS will concur with the recommendation. This will begin a process that will lead to a final decision by the DEA on the appropriate scheduling of these products. As part of our expansion of our Huntsville site, we have factored in the potential for hydrocodone being rescheduled.

On February 7-8, 2013, the FDA held a public hearing to obtain information, particularly scientific evidence, such as study data or peer-reviewed analyses, on issues pertaining to the use of opioid drugs in the treatment of chronic pain. The FDA is considering a Citizen Petition filed in July 2012 by a group of physicians seeking changes to the labeling of opioid drug products relating to indications and duration of use. In considering the petition and the ongoing policy debate on the use of opioid medications, the FDA heard presentations from individuals and groups on diagnosing and understanding patient pain, and what it would mean to change or limit patient access to opioids. On September 10, 2013 FDA announced class-wide safety labeling changes and new postmarket study requirements for all extended-release and long-acting (ER/LA) opioid. The updated indication states that ER/LA opioids are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The updated indication further clarifies that, because of the risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death, these drugs should be reserved for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain; ER/LA opioid analgesics are not indicated for as-needed pain relief. Recognizing that more information is needed to assess the serious risks associated with long-term use of ER/LA opioids, the FDA is also requiring drug companies that make these products to conduct further studies and clinical trials. The goals of these postmarket requirements are to further assess the known serious risks of misuse, abuse, increased sensitivity to pain (hyperalgesia), addiction, overdose, and death. It is not presently known what impact, if any, these changes to the indications for use or results from the post marketing studies may have on our business, financial position, results of operations and cash flows.

The FFDCA allows the FDA to impose mandatory and permissive debarment and other penalties on individuals and companies that are convicted of certain offenses relating to the drug approval process. In some situations, the FFDCA authorizes the FDA to not accept or review applications for a period of time from a company or an individual that has committed certain violations. It also authorizes the temporary denial of approval of applications during the investigation of certain violations that could lead to debarment and also, in more limited circumstances, authorizes the suspension of the distribution of approved drugs by the affected company. Lastly, the FFDCA allows for civil penalties and withdrawal of previously approved applications. In addition, the Social Security Act authorizes the Department of HHS's Office of Inspector General (OIG) to impose mandatory and permissive exclusion of individuals

and entities from participation in federal healthcare programs, such as Medicare and Medicaid, if convicted of certain offenses relating to health care fraud. We believe neither we nor any of our employees have ever been subject to debarment or exclusion.

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

NDA / BLA Process

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

- Completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's Good Laboratory Practice (GLP) regulations;
- Submission to the FDA of an Investigational New Drug (IND) application for human clinical testing, which must become effective before human clinical trials may begin in the U.S.;

Table of Contents

- Approval by an independent institutional review board (IRB) before each trial may be initiated, and continuing review during the trial;
- Performance of human clinical trials, including adequate and well-controlled clinical trials in accordance with good clinical practices (GCP) to establish the safety and efficacy of the proposed drug product for each intended use;
- Submission of an NDA or BLA to the FDA;
- Satisfactory completion of an FDA pre-approval inspection of the product's manufacturing processes and facility or facilities to assess compliance with the FDA's current Good Manufacturing Practice (cGMP) regulations, and/or review of the Chemistry, Manufacturing, and Controls (CMC) section of the NDA or BLA to require that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality, purity and potency;
- Satisfactory completion of an FDA advisory committee review, if applicable; and
- Approval by the FDA of the NDA or BLA.

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

- Phase I, which frequently begins with the initial introduction of the compound into healthy human subjects prior to introduction into patients, involves testing the product for safety, adverse effects, dosage, tolerance, absorption, distribution, metabolism, excretion and other elements of clinical pharmacology.
- Phase II typically involves studies in a small sample of the intended patient population to assess the efficacy of the compound for a specific indication, to determine dose tolerance and the optimal dose range as well as to gather additional information relating to safety and potential adverse effects.
- Phase III trials are undertaken to further evaluate clinical safety and efficacy in an expanded patient population at typically dispersed study sites, in order to determine the overall risk-benefit ratio of the compound and to provide an adequate basis for product labeling.

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

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

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

On January 30, 2007, the FDA announced a drug safety initiative to implement a number of proposals made by the Institute of Medicine (IOM) in a September 2006 report. As part of this program, the FDA began publishing a newsletter that contains non-confidential, non-proprietary information regarding post-marketing review of new drug products. Additionally, in 2005, the FDA created a Drug Safety Oversight Board to provide oversight and advice to

the Center for Drug Evaluation and Research Director on the management of important drug safety issues and to manage the dissemination of certain safety information through the FDA's Web site to healthcare professionals and patients.

On February 6, 2009, the FDA sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a Risk Evaluation and Mitigation Strategy (REMS) to verify that 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 (FDAAA) when necessary to substantiate that the benefits of a drug outweigh the risks. The affected opioid drugs include branded and generic products. Three products sold by Endo were included in the list of affected opioid drugs: Opana® ER, morphine sulfate ER and oxycodone ER. On December 9, 2011, the FDA approved our interim REMS for Opana® ER, which was subsequently superseded by

Table of Contents

the class-wide extended-release/long-acting REMS approved on July 9, 2012. The goal of this REMS is to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse and abuse of extended-release or long-acting opioid analgesics while maintaining patient access to pain medications. The REMS includes a Medication Guide, Elements to Assure Safe Use and annual REMS Assessment Reports. These changes, or others required by the FDA, could have an adverse effect on the sales, gross margins and marketing costs of these products.

On January 14, 2011, the FDA announced in the Federal Register that it was taking steps to reduce the maximum strength of acetaminophen in prescription combination drug products to help reduce or prevent the risk of liver injury from an unintentional overdose of acetaminophen. A variety of prescription combination drug products include acetaminophen, such as those that contain the opioids oxycodone hydrochloride or hydrocodone bitartrate and acetaminophen, among others. Specifically, the FDA announced that it was asking product sponsors to limit the maximum strength of acetaminophen per dosage unit of the prescription combination drug products to 325 milligrams (mg) over a three-year phase-out period. The FDA also notified holders of approved NDAs and ANDAs that they would be required to modify the labeling of prescription acetaminophen drug products to include a Boxed Warning to include new safety information about acetaminophen and liver toxicity, and a Warning on the potential for allergic reactions. Additionally, in August 2013, the FDA announced that it will require a warning added to labels of prescription drugs containing acetaminophen to address the risk of serious skin reactions. On January 14, 2014, the FDA issued a recommendation that healthcare professionals discontinue prescribing and dispensing prescription combination products containing more than 325 mg of acetaminophen per dosage unit. The FDA also stated that it intends to initiate proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit pursuant to its authority under FFDCA. Among the products impacted by the FDA's actions are three Endo combination drug pain relief products: Percocet®, Endocet® and Zydone®; and the Qualitest Pharmaceuticals combination drug pain relief products: butalbital/acetaminophen/caffeine, hydrocodone/acetaminophen and oxycodone/acetaminophen. The Company has implemented several measures to comply with these FDA actions. Specifically, any high dose prescription product containing more than 325 mg of acetaminophen will have an expiration date that will prevent saleable product remaining in the marketplace after January 2014. In addition, steps are being taken to increase production of similar low dose products to provide uninterrupted supply to all customers as demand transitions to the alternate products. Nonetheless, these regulatory changes, or others required by the FDA, could have an adverse effect on our business, financial condition, results of operations and cash flows.

Finally, the FDA is developing guidance for the industry on how to test, detect and prevent safety problems during drug development, including tests that would identify preclinical biomarkers of toxicity. Because these initiatives and other similar initiatives are still being developed, it is unclear what impact, if any, they may have on our ability to obtain approval of new drugs or on our sales of existing products.

In addition to these initiatives, the Prescription Drug User Fee Act (PDUFA) was reauthorized on September 27, 2007 through passage of the FDAAA. In connection with that reauthorization legislation, Congress enacted new measures authorizing FDA to require companies to undertake post-approval testing of products to assess known or signaled potential serious safety risks and to make labeling changes to address safety risks. The legislation also re-authorized the FDA to require testing of drug products in children where appropriate and provided additional incentives to companies that agree to undertake such testing in connection with a new NDA as part of the Best Pharmaceuticals for Children Act (BPCA). The legislation also contained provisions to expedite new drug development and collect data and results from clinical trials of drug products more readily available via a registry managed by the National Institutes of Health. These provisions, depending on how they are and continue to be implemented by the FDA, could impact our ability to market existing and new products. The PDUFA and the Medical Device User Fee and Modernization Act (MDUFMA) were reauthorized and amended in 2012 by the Food and Drug Administration Safety and Innovation Act (FDASIA), which is further described below.

On July 9, 2012, the FDASIA, which primarily amends existing legislation, was signed into law. In addition to reauthorizing and amending several drug and medical device provisions that were scheduled to sunset, including PDUFA and MDUFMA, the new law establishes new user fee statutes for generic drugs and biosimilars. FDASIA also, among other provisions, provides the FDA with tools intended to expedite the development and review of

innovative new medicines that address certain unmet medical needs, affords the FDA new authority concerning drug shortages, makes significant changes to enhance the FDA's inspection authority and drug supply chain and includes several miscellaneous provisions such as provisions on prescription drug abuse, 180-day generic drug marketing exclusivity, citizen petitions and controlled substances. The law significantly changes existing legislation in several respects that will have considerable short- and long-term effects on the regulated industries and could impact our ability to market existing and new products.

Section 505(b)(2) of the FFDCA provides a procedure for an applicant to seek approval of a drug product for which safety and/or efficacy has been established through preclinical and clinical data that the applicant does not have proprietary rights to use. Under that section, despite not having a right of reference, an applicant can cite studies containing such clinical data to prove safety or efficacy, along with any additional clinical data necessary to support the application. Section 505(b)(2) NDAs are subject to patent certification and notification requirements that are similar to those that are required for ANDAs (refer to next section). Approval of

Table of Contents

Section 505(b)(2) NDAs, like ANDAs, also may be delayed by market exclusivity that covers the reference product. However, despite the similarities, Section 505(b)(2) applications are not permitted when an applicant could submit and obtain approval of an ANDA.

ANDA Process

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

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

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

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 basis 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 (2003 Medicare Act), with accompanying amendments to the Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act), this marketing exclusivity would begin to run upon the earlier of the commercial launch of the generic product or upon an appellate court decision in the generic company's favor.

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

Table of Contents

Medical Device Regulation

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

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

Class III devices are approved through a Premarket Approval Application (PMA), under which the applicant must submit data from adequate and well-controlled clinical trials to the FDA that demonstrate the safety and effectiveness of the device for its intended use(s). All of our marketed devices have been approved or cleared for marketing pursuant to a PMA or the 510(k) process. The FDA also has authority under the FFDCA to require a manufacturer to conduct post-market surveillance of a Class II or Class III device. On January 3, 2012, the FDA ordered manufacturers of transvaginal surgical mesh used for pelvic organ prolapse and of single incision mini-slings for urinary incontinence, such as AMS to conduct post-market surveillance safety studies and to monitor adverse event rates relating to the use of these products. Of the nineteen class-wide post market study orders received by AMS for pelvic floor repair and mini-sling products, three remain active. AMS is in the process of complying with these orders. In its orders, the FDA also noted that it is still considering the recommendation of an advisory committee on September 9, 2011, that urogynecological surgical mesh for transvaginal repair of pelvic organ prolapse be reclassified from Class II to Class III. On March 27, 2013, the FDA updated its Urogynecologic Surgical Mesh Implant website to include additional information intended for patients about the use of mesh for repair of stress urinary incontinence. The update was based on an analysis of adverse events reported to FDA, findings reported in the scientific literature, and input received from the advisory committee meeting. FDA highlighted complications associated with placement of mesh through vaginal wall incision, but did not link them to any single brand or model of mesh. Vaginal erosion, infection, pain, urinary problems and recurrence of incontinence were listed as the most frequent complications, and additional complications were listed, including erosion of the mesh and painful vaginal scarring. The need for explantation was noted, as well as other complications which included injuries to nearby organs such as bowel, bladder, or blood vessels. Specific queries for the physician were recommended, and reporting of complications was encouraged.

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

grant future premarket clearances or approvals, withdrawals or suspensions of current product applications, and criminal prosecution.

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

Table of Contents

On July 29, 2011, the IOM released its report, which recommended that the FDA move towards replacing the current 510(k) review process, which is based on substantial equivalence determinations, with a new integrated premarket and post-market regulatory framework that provides a reasonable assurance of safety and efficacy. The IOM also recommended that the FDA prioritize enhancement of its post-market surveillance program. The IOM also stated that it was unable to study fully the seven specific actions referred to it by the FDA because the requests came at the end of its review. The FDA decided not to act on the IOM recommendation to replace the 510(k) substantial equivalence framework, but since January 2011, the CDRH has issued numerous guidance documents and proposed and final regulations impacting all medical devices (PMA and 510(k)), that have the potential to significantly impact how the FDA regulates medical devices. These include issuing guidance on data requirements for pivotal clinical investigations for medical devices, on CDHR's evaluation of substantial equivalence in premarket notification 510(k) submissions, on presubmission meetings for investigational device exemption (IDEs), including with regard to multiple predicate devices, and on its decisions on whether and how to approve a device clinical study, among other draft guidance. While the FDA issued and withdrew (pursuant to a requirement of the MDUFMA legislation), a draft guidance on when device modifications require a new 510(k), it plans to issue another draft guidance on device modification requirements subsequent to issuance of a required congressional report. In addition, in September 2013, the FDA issued a final rule that requires a unique identifier on distributed devices for tracking purposes. This requirement becomes effective in September 2014, initially for Class III, implantable, life supporting and life sustaining devices.

Further, pursuant to the March 2010 healthcare reform law, a medical device tax went into effect January 1, 2013, for devices listed with the FDA.

The extent and how the FDA will implement some or all of its planned action items, draft guidance and proposed and final rules is unknown at this time. Congress expressed concern regarding a number of FDA’s medical device initiatives, and altered the pace and scope of some of these changes. For example, FDA may not disapprove an IDE study solely because it is insufficient to support approval, clearance or de novo classification. Also, FDASIA pushes FDA toward broader and more rapid usage of the de novo classification process by allowing a sponsor to bypass an initial 510(k) submission for low-moderate risk devices. Additionally, FDA had issued a 2011 guidance to clarify when manufacturers must submit a new 510(k) for a modification of a Class II device, imposing stringent criteria. Congress disagreed with FDA’s approach, requiring withdrawal of the guidance and a reinstatement and rereview of the 1997 guidance governing when a modification requires a new 510(k) submission. Nonetheless, FDA actions could have a significant effect on the cost of applying for and maintaining applications under the 510(k) clearance mechanism, on the criteria required for achieving clearance for additional uses of existing devices or new 510(k) devices, for the marketing of medical devices and for the post-market support of marketed devices.

Quality Assurance Requirements

The FDA enforces regulations to require that the methods used in, and the facilities and controls used for, the manufacture, processing, packing and holding of drugs and medical devices conform to current good manufacturing practices, or cGMP. The cGMP regulations the FDA enforces are comprehensive and cover all aspects of manufacturing operations, from receipt of raw materials to finished product distribution, insofar as they bear upon whether drugs meet all the identity, strength, quality and purity characteristics required of them. The cGMP regulations for devices, called the Quality System Regulation, are also comprehensive and cover all aspects of device manufacture, from pre-production design requirements and validation to installation and servicing, insofar as they bear upon the safe and effective use of the device and whether the device otherwise meets the requirements of the FFDCA. To assure compliance requires a continuous commitment of time, money and effort in all operational areas. The FDA conducts pre-approval inspections of facilities engaged in the development, manufacture, processing, packing, testing and holding of the drugs subject to NDAs and ANDAs. If the FDA concludes that the facilities to be used do not or did not meet cGMP, good laboratory practices or GLP or good clinical practices or GCP requirements, it will not approve the application. Corrective actions to remedy the deficiencies must be performed and are usually verified in a subsequent inspection. In addition, manufacturers of both pharmaceutical products and active pharmaceutical ingredients (APIs) used to formulate the drug also ordinarily undergo a pre-approval inspection, although the inspection can be waived when the manufacturer has had a passing cGMP inspection in the immediate

past. Failure of any facility to pass a pre-approval inspection will result in delayed approval and would have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

Table of Contents

On January 9, 2012, we announced that, as a result of a shutdown by Novartis Consumer Health Division of its manufacturing facility in Lincoln, Nebraska to facilitate certain manufacturing process improvements, there would be a short-term supply constraint for our Opana® ER product, which was manufactured by Novartis. To the best of our knowledge, these manufacturing improvements were intended to address the possibility of packaging errors that could potentially result in product mix-ups. We have transitioned the production of the formulation of Opana® ER designed to be crush-resistant to a third-party manufacturing facility managed by our development partner, Grünenthal, began production of our Voltaren® Gel product at an alternative Novartis manufacturing source, and made alternative arrangements for supply of certain other of our analgesic products which had been manufactured at the Nebraska facility prior to the shutdown. On December 31, 2012, Endo and Novartis Consumer Health entered into a settlement agreement whereby the parties agreed to terminate the manufacturing agreement between the parties. Also, Novartis Consumer Health has agreed to reimburse Endo for certain out-of-pocket costs, including costs related to recalls of certain of our products manufactured at the Lincoln facility and incremental freight charges associated with the transfer of Voltaren® Gel to an alternate Novartis manufacturing site.

Following an FDA inspection of the solid dose manufacturing facility in Charlotte, North Carolina, that took place from January 14, 2014 through February 14, 2014, our subsidiary, Qualitest Pharmaceuticals, received a Form 483 Notice of Inspectional Observations dated February 14, 2014, listing observations of the inspector focused on improper adherence to established processes and procedures. Qualitest Pharmaceuticals is currently drafting a comprehensive response to the observations.

Following an FDA inspection of the tablet manufacturing facility in Huntsville, Alabama in May 2013, our subsidiary, Qualitest Pharmaceuticals, received a Form 483 Notice of Inspectional Observations dated May 30, 2013. The observations focused on investigations and the proper follow-up and tablet counters. A comprehensive response was provided to the FDA on June 12, 2013 addressing each observation and providing corrective actions and appropriate remediation plans. The final corrective action report was sent to the FDA in September 2013. No further feedback from the FDA has been received.

The FDA also inspected the liquids facility of our Qualitest Pharmaceuticals subsidiary in Huntsville, Alabama in March 2013, with no 483s issued.

In February 2013, the FDA conducted an inspection of AMS's Minnetonka, Minnesota facility. Following such inspection, the FDA issued two observations on a Form 483 Notice of Inspectional Observations. Both observations related to timeliness of complaint handling procedures. AMS provided a written response to the FDA on February 28, 2013 detailing proposed corrective actions. AMS has provided the FDA updates on the progress on these corrective actions, which are substantially complete. In February 2014, the FDA conducted another inspection of AMS's Minnetonka, Minnesota facility. Following such inspection, the FDA issued three observations on a Form 483. These observations relate to process validation, risk analysis and corrective and preventive action procedures. AMS is currently drafting a comprehensive response to the observations and is cooperating with the FDA to address this Form 483. The Minnetonka, Minnesota facility will continue to manufacture products while AMS works with the FDA to address these observations.

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 the FDA, and in many cases, approval for such changes must be submitted to the FDA. Additionally, the FDA regulates post-approval promotional labeling and advertising activities to assure that such activities are being conducted in conformity with statutory and regulatory requirements. These regulations include standards or restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities and off-label promotion. While physicians may prescribe for off-label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. In December 2011, the FDA issued a draft guidance document on responding to unsolicited requests for off-label information about a drug or device, which suggests limits on a company's ability to respond, and in March 2012 issued a draft guidance on pre-dissemination review of direct-to-consumer TV advertising. In January 2014, the FDA issued a draft guidance on postmarketing submission of interactive promotional media, and it is likely to issue further guidance on the use of social media in advertising or

promoting a product (mandated by FDASIA to occur by July 2014). These and other statements of the FDA interpreting the FFDCA and the FDA's regulatory authority may place further limits and restrictions on the advertising of our products. The FDA has very broad enforcement authority under the FFDCA. Failure to abide by these regulations can result in compliance or enforcement action, including the issuance of warning letters directing entities to correct deviations from FDA regulations and civil and criminal investigations and prosecutions. These activities could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Drug Enforcement Administration

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

Table of Contents

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

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

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

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

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

Government Benefit Programs

Statutory and regulatory requirements for Medicaid, Medicare, TRICARE and other government healthcare programs govern provider reimbursement levels, including requiring that all pharmaceutical companies pay rebates to individual states based on a percentage of their net sales arising from Medicaid program-reimbursed products. In addition, under a final rule promulgated by the U.S. Department of Defense (DOD) on March 17, 2009 and reissued on October 15, 2010 with an effective date of December 27, 2010, payments made to retail pharmacies under the TRICARE Retail Pharmacy Program for prescriptions filled on or after January 28, 2008 are subject to certain price ceilings. Under the final rule and as a condition for placement on the Uniform Formulary, manufacturers are required, among other things, to make refunds for prescriptions filled beginning on January 28, 2008 and extending to future periods based on the newly applicable price limits. On April 17, 2012, the TRICARE Management Authority issued guidance regarding the obligation to pay refunds for prescription drug utilization for the period first quarter 2008 to second quarter 2009. On January 4, 2013, the D.C. Circuit Court of Appeals upheld the DOD's interpretation of the final rule that refunds are due on any prescription filed after January 28, 2008. We had requested a waiver to be exempt from such refunds for the period January 28, 2008 through May 25, 2009, based upon our belief that the DOD was not likely to prevail in court with its interpretation that such refunds were owed. In September 2012, DOD denied our waiver. As a result, we paid TRICARE approximately $16.0 million in full satisfaction of our obligations. 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 and the Company.

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

In addition, in March 2010, President Obama signed into law healthcare reform legislation that will make major changes to the healthcare system.

While some provisions of the new healthcare reform law have already taken effect, most of the provisions to expand access to health care coverage will not be implemented until 2014 and beyond. Since implementation is incremental to the enactment date of the law, there are still many challenges and uncertainties ahead. Such a comprehensive reform measure will require expanded

Table of Contents

implementation efforts on the part of federal and state agencies embarking on rule-making to develop the specific components of their new authority.

In March 2012, the U.S. Supreme Court addressed challenges to the constitutionality of the health care reform law. The Court considered the constitutionality of the individual mandate, as well as whether the overall health care law could still stand even if the individual mandate was ruled unconstitutional. On June 28, 2012, the Supreme Court upheld the individual mandate. In its ruling, the Court did address the expansion of Medicaid required under the law, a provision that requires states to expand Medicaid to approximately 17 million additional low-income individuals up to 133% of the federal poverty level. Under the law, the federal government would pay the additional costs for the expansion of Medicaid for the years 2014 to 2016 and then the federal share would phase down to 90% by 2020. The law provided that if a state did not expand its Medicaid program eligibility to 133%, it would risk losing the federal share for all its Medicaid funding and not just the funding for the expansion. On this matter, the Supreme Court upheld the constitutionality of the Medicaid expansion but ruled that the punitive aspects of the provision are unconstitutional meaning that the federal government does not have the authority to terminate existing federal funding for Medicaid if the states do not expand Medicaid. This aspect of the ruling may cause some states to refuse to expand Medicaid eligibility thereby limiting the number of individuals with access to health insurance.

The implementation of the healthcare reform law has and will continue to result in a transformation of the delivery and payment for health care services in the U.S., including the expansion of health insurance coverage to an estimated 32 million Americans. In addition, there are significant health insurance reforms that have improved patients' ability to obtain and maintain health insurance. Such measures include: the elimination of lifetime caps; no rescission of policies; and no denial of coverage due to preexisting conditions. The expansion of healthcare insurance and these additional market reforms should result in greater access to the Company's products.

In response to the U.S. debt-ceiling crisis, Congress passed the Budget Control Act of 2011 on August 2, 2011. Within the Act, Congress created the Joint Select Committee on Deficit Reduction (JSC), which was charged with issuing a formal recommendation on how to reduce the federal deficit by $1.2 trillion to $1.5 trillion over the next ten years. The Budget Control Act provided that if Congress failed to pass a deficit reduction plan by December 23, 2011, a process of sequestration would occur on January 1, 2013 which would result in across-the-board spending cuts to certain government programs, including Medicare, in order to meet the deficit reduction goal. Since the JSC failed to put forth a proposal and Congress ultimately failed to pass a deficit reduction plan, the sequestration process was scheduled to be triggered on January 2, 2013. Congress initially was able to delay sequestration when it passed the American Taxpayer Relief Act of 2012 (H.R. 8) until March 1, 2013. On April 1, 2013, however, Medicare provider payments were cut by two percent under the Budget Control Act of 2011. Although the Bipartisan Budget Act of 2013, signed into law on December 26, 2013, did not provide relief to the two percent sequestration reduction, it did implement 0.5% increase for physician services provided through March 31, 2014.

Healthcare Fraud and Abuse Laws

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

In particular, the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Remuneration is not defined in the federal Anti- Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. In addition, the recently enacted healthcare reform legislation, among other things, amends the intent requirement of the federal Anti-Kickback Statute

and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the U.S. Health Reform Law provides that the government may assert that a claim including items or services resulting from a violation of 42 U.S.C. § 1320a-7b constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Moreover, the lack of uniform court interpretation of the Anti-Kickback Statute makes compliance with the law difficult, as virtually any relationship with entities that purchase or refer for our services could implicate the Anti-Kickback Statute.

Table of Contents

Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, the HHS-OIG issued regulations in July 1991, and additional safe harbor regulation periodically since that time, which the HHS-OIG refers to as safe harbors. These safe harbor regulations set forth certain provisions which, if met in form and substance, will assure pharmaceutical and medical device companies, healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Although full compliance with these provisions safeguards against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. However, conduct and business arrangements that do not fully satisfy each element of an applicable safe harbor may result in increased scrutiny by government enforcement authorities, such as the HHS-OIG or federal prosecutors. Additionally, there are certain statutory exceptions to the federal Anti-Kickback Statute, one or more of which could be used to protect a business arrangement, although we understand that the HHS-OIG is of the view that an arrangement that does not meet the requirements of a safe harbor cannot satisfy the corresponding statutory exception, if any, under the federal Anti-Kickback Statute.

Additionally, many states have adopted laws similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any third-party payer, not only the Medicare and Medicaid programs, and do not contain identical safe harbors.

Government officials have focused their Anti-Kickback Statute enforcement efforts relating to drug and device manufacturers, including False Claims Act (described below) actions on marketing of healthcare services and products, among other activities, and have brought cases against numerous pharmaceutical and medical device companies, and certain sales and marketing personnel for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business or reward past purchases or recommendations.

Another development affecting the healthcare industry is the increased use of the federal civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act's whistleblower or qui tam provisions. The civil False Claims Act imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted or caused the submission of a false claim to the federal government, and to share in any monetary recovery. In recent years, the number or suits brought by private individuals has increased dramatically. In addition, various states have enacted false claim laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program.

When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of $5,500 to $11,000 for each separate false claim. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act also has been used to assert liability of the basis of inadequate care, kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or AMP, improper use of Medicare reimbursement information when detailing the provider of services, improper promotion of off-label uses (i.e., uses not expressly approved by FDA in a drug's or device's label), misrepresentations with respect to the services rendered and causing improper claims to be submitted for allegedly unapproved drugs or other products. Our activities relating to the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products, the sale and marketing of our products and our service arrangements or data purchases, among other activities, may be subject to scrutiny under these laws. For example, a number of cases brought by local and state government entities are pending that allege generally that our wholly owned subsidiary, EPI, and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid. The cost of defending these cases and any other actions that may be brought under the False Claims Act or a similar state law, as well as any sanctions imposed, could adversely affect our financial performance.

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

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

Table of Contents

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

The Federal Physician Payments Sunshine Act, which is part of the healthcare reform law, imposes federal sunshine provisions, with annual reporting to begin in 2014 for various types of payments to physicians and teaching hospitals, beginning with payments made in 2013. On February 8, 2013, the Centers for Medicare and Medicaid Services (CMS) published a long-awaited final rule implementing the sunshine law. Under the final regulations, applicable drug, biological, device, and medical supply manufacturers are required to report to CMS payments or other transfers of value made to physicians and teaching hospitals, and the regulations also require the manufacturers and applicable group purchasing organizations (GPOs) to report ownership and investment interests held by physicians or their immediate family members. The final rule sets forth a reporting process that permits physicians, teaching hospitals, and physician owners and investors to dispute information reported by applicable manufacturers and GPOs. Under the regulations, information that is the subject of a dispute not resolved within the initial allotted 60-day review and dispute resolution period will be posted on CMS's public website in the manner in which it was submitted by the manufacturer or GPO, rather than in a manner that includes the version provided by the disputing physician, teaching hospital, or physician owner or investor. Under the rule, applicable manufacturers and GPOs must begin collecting the required data on August 1, 2013, and must submit their first reports to CMS by March 31, 2014. When fully implemented, failure to comply with required reporting requirements could subject manufacturers and others to substantial civil money penalties.

Healthcare Privacy and Security Laws

HIPAA, the Health Information Technology for Economic and Clinical Health Act (HITECH Act) and their implementing regulations (collectively, HIPAA), establish, among other things, standards for the privacy, security and notification of the security breach of certain individually identifiable health information (protected health information). To the extent that one of our business units is a business associate under HIPAA because it receives protected health information from a health care provider, health plan or other covered entity to provide a service on behalf of the covered entity, the business unit is directly subject to the privacy, security and breach notification standards and the HIPAA civil and criminal enforcement scheme. The HITECH Act, adopted in 2009 as part of the American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney’s fees and costs associated with pursuing federal civil actions. The states also have health information privacy and security laws which may be more restrictive of our uses and disclosures of patient information than HIPAA. While we have attempted to comply with HIPAA and similar state laws, it is possible that some of our health information management activities could be subject to regulatory scrutiny at some point in the future, and we cannot provide an assurance that we will be found to be in compliance with all of these laws following any such regulatory review.

Service Agreements

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

For a complete description of our manufacturing, supply and other service agreements, see Note 14. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

Acquisitions, License and Collaboration Agreements

We continue to seek to enhance our product line and develop a balanced portfolio of differentiated products through selective product acquisitions and in-licensing, or acquiring licenses to products, compounds and technologies from third parties or through company acquisitions. The Company enters into strategic alliances and collaborative arrangements with third parties, which give the Company rights to develop, manufacture, market and/or sell pharmaceutical products, the rights to which are primarily owned by these third parties. These alliances and arrangements can take many forms, including licensing arrangements, co-development and co-marketing agreements, co-promotion arrangements, research collaborations and joint ventures. Such alliances and arrangements enable us to share the risk of incurring all research and development expenses that do not lead to revenue-generating products; however, because profits from alliance products are shared with the counter-parties to the collaborative arrangement, the gross margins on alliance products are generally lower, sometimes substantially so, than the gross margins that could be achieved had the Company not opted for a development partner. For a full discussion, including agreement terms and status, see our disclosures under Note 11.

Table of Contents

License and Collaboration Agreements in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

Environmental Matters

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

Employees

As of February 20, 2014, we have 3,371 employees, of which 238 are engaged in research and development and regulatory work, 641 in sales and marketing, 1,148 in manufacturing, 385 in quality assurance and 959 in general and administrative capacities. Our employees are not represented by unions and we believe that our relations with our employees are good.

Executive Officers of the Registrant

The following table sets forth information as of February 20, 2014 regarding each of our current executive officers:

Name	Age	Position and Offices
Rajiv De Silva	47	President and Chief Executive Officer and Director
Suketu P. Upadhyay	44	Executive Vice President, Chief Financial Officer
Donald W. DeGolyer	52	Chief Operating Officer of Endo Pharmaceuticals Inc.
Ivan P. Gergel, M.D.	53	Executive Vice President, Research and Development and Chief Scientific Officer
Caroline B. Manogue	45	Executive Vice President, Chief Legal Officer and Secretary
Camille Farhat	44	President of American Medical Systems

Biographies

Our executive officers are briefly described below:

RAJIV DE SILVA, 47, is President, Chief Executive Officer and a Director of Endo. Prior to joining Endo in March 2013, Mr. De Silva served as the President of Valeant Pharmaceuticals International, Inc. from October 2010 to January 2013 and served as its Chief Operating Officer, Specialty Pharmaceuticals from January 2009 until January 2013. He was responsible for all specialty pharmaceutical operations, including sales and marketing, research and development, manufacturing and business development. He has broad international experience, having managed businesses in the United States, Europe, Canada, Latin America, Asia, South Africa and Australia/New Zealand. Prior to joining Valeant, Mr. De Silva held various leadership positions with Novartis. He served as President of Novartis Vaccines USA and Head, Vaccines of the Americas at Novartis. During this time, he played a key leadership role at Novartis' Vaccines & Diagnostics Division. Mr. De Silva also served as President of Novartis Pharmaceuticals Canada. He originally joined Novartis as Global Head of Strategic Planning for Novartis Pharma AG in Basel, Switzerland. Prior to his time at Novartis, Mr. De Silva was a Principal at McKinsey & Company and served as a member of the leadership group of its Pharmaceuticals and Medical Products Practice. Mr. De Silva was a Director of AMAG Pharmaceuticals, Inc. and is currently a Member of the Board of Trustees at Kent Place School in Summit, NJ. He holds a Bachelor of Science in Engineering, Honors from Princeton University, a Master of Science from Stanford University and a Master of Business Administration with Distinction from the Wharton School at the University of Pennsylvania.

SUKETU UPADHYAY, 44, is Executive Vice President and Chief Financial Officer, joined Endo in September 2013. Prior to joining Endo, since 2010, Mr. Upadhyay served as Interim Chief Financial Officer as well as Senior Vice President of Finance and Corporate Controller of Becton, Dickinson & Co (BD). In addition to other executive finance roles at BD, from 2007 to 2010, he served in various finance leadership roles at AstraZeneca and Johnson & Johnson. Mr. Upadhyay spent the early part of his career in public accounting with KPMG and received his CPA in May 1996. He received a Bachelor of Science in Finance from Albright College and received a Master of Business Administration from The Fuqua School of Business at Duke University.

DONALD DeGOLYER, 52, Chief Operating Officer, Pharmaceuticals, joined Endo in August 2013. In this role he leads both the Qualitest and Endo Pharmaceuticals businesses as fully integrated business units. Prior to joining Endo, Mr. DeGolyer served as President of Sandoz Inc. (a Novartis company) the second largest generics company in the world. While at Novartis, Mr. DeGolyer held various senior leadership positions including, US Managed Markets, Established Medicines for Novartis Pharmaceuticals and was a member of the Executive Committee. Prior to Novartis, Mr. DeGolyer held positions of increasing responsibilities with Johnson and Johnson for 11 years in pharmaceutical commercial roles including senior leadership positions in marketing and sales.

Table of Contents

Additionally, Mr. DeGolyer has international pharmaceutical experience and health information technology expertise, having held senior leadership roles at Oxford GlycoSciences Plc and ParkStone Medical, respectively. He began his career at Pfizer in sales and sales management. Mr. DeGolyer served as Vice Chairman on the Executive Committee and Board of Directors for the Generic Pharmaceutical Association (GPhA). He holds a Masters of Business Administration from Fairleigh Dickinson University and is a graduate of University of Rochester.

IVAN P. GERGEL, M.D., 53, was appointed Executive Vice President, Research & Development and Chief Scientific Officer in April 2008. Prior to joining Endo, Dr. Gergel was Senior Vice President of Scientific Affairs and President of the Forest Research Institute of Forest Laboratories Inc. Prior to that, Dr. Gergel served as Vice President and Chief Medical Officer at Forest and Executive Vice President of the Forest Research Institute. He joined Forest in 1998 as Executive Director of Clinical Research following nine years at SmithKline Beecham, and was named Vice President of Clinical Development and Clinical Affairs in 1999. Dr. Gergel received his M.D. from the Royal Free Medical School of the University of London and an MBA from the Wharton School. Dr. Gergel is a member of the Board of Directors of Pennsylvania BIO, as well as a member of the Board of Directors of the PhRMA Foundation and has served as a Member of PhRMA's Scientific and Regulatory Executive Committee.

CAROLINE B. MANOGUE, 45, has served as Executive Vice President, Chief Legal Officer and Secretary since 2004. Prior to joining Endo in 2000 as Endo's Senior Vice President, General Counsel and Secretary, she practiced law in the New York office of the law firm Skadden, Arps, Slate, Meagher & Flom LLP, where she specialized in mergers & acquisitions, securities and corporate law. At Endo, she is responsible for all aspects of the company's legal function, including securities law, litigation, intellectual property and commercial law, as well as overseeing compliance with current laws and existing pharmaceutical company guidelines relating to, among other things, clinical, sales and marketing practices. In her capacity as Secretary, she is responsible for corporate governance matters and reports directly to the Board of Directors. Ms. Manogue received her J.D. from Fordham Law School and her B.A. cum laude from Middlebury College. She was the 2011-2012 Chairperson of the PhRMA Law Section, and is a member of the Board of Trustees of the Healthcare Institute of New Jersey (HINJ) and a member of HINJ's Finance and Audit Committee.

CAMILLE FARHAT, 44, joined Endo in September 2012 as President of AMS. Mr. Farhat brings broad global experience from assignments in 10 countries and nine industries over 22 years. He is a business executive with a track record of revitalizing, turning around, and profitably growing businesses. Before joining Endo, Mr. Farhat held the position of General Manager of Baxter Pharmaceuticals & Technologies (BPT). Camille joined Baxter in February 2006 as General Manager of Global Infusion Systems. Prior to Baxter, Mr. Farhat was with Medtronic where he held the position of Vice President of Business Development after he was Global General Manager of Medtronic's Gastroenterology and Urology division. He spent 13 years with General Electric (GE) where he gained broad executive experience with assignments in many businesses, geographies, and functional areas, leading up to his final role with the company as General Manager for the Computed Tomography (CT) business. He holds a Master of Business Administration from Harvard University, a degree in European Union Studies from Institut National d'Etudes Politiques de Paris, and a Bachelor of Sciences (summa cum laude) in International Finance and Accounting from Northeastern University.

We have employment agreements with each of our executive officers.

Available Information

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

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

Item 1A. Risk Factors

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

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

Table of Contents

systems. It is possible that developments by our competitors will make our products or technologies uncompetitive or obsolete. Because we are smaller than some of our national competitors in the branded pharmaceuticals sector, we may lack the financial and other resources needed to maintain our profit margins and market share in this sector.

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

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

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

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

Under the Hatch-Waxman Act, the FDA can approve an ANDA for a generic bioequivalent version of a previously approved drug, without undertaking the full clinical testing necessary to obtain approval to market a new drug. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its generic product is bioequivalent to the branded product.

The Hatch-Waxman Act requires us to submit patient information for all our branded drugs. Where an applicant for a drug relies, at least in part, on the data we submit for one of our drugs, the Hatch-Waxman act requires the applicant to notify us of their application and potential infringement of our patent rights. Upon receipt of this notice we have 45 days to bring a patent infringement suit in federal district court against the applicant seeking approval of a generic equivalent of a product covered by one of our patents. If such a suit is commenced, the FDA is generally prohibited from granting approval of the ANDA until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in the generic applicant’s favor, or the expiration or invalidity of the patent(s). Frequently, the unpredictable nature and significant costs of patent litigation leads the parties to settle to remove this uncertainty. Settlement agreements between branded companies and generic applicants may allow, among other things, a generic product to enter the market prior to the expiration of any or all of the applicable patents covering the branded product, either through the introduction of an authorized generic or by providing a license to the applicant for the patents in suit.

In recent years, various generic manufacturers have filed ANDAs seeking FDA approval for generic versions of certain of the Company's key pharmaceutical products, including but not limited to Lidoderm® and both the original and crush-resistant formulations of Opana® ER. In connection with such filings, these manufacturers have challenged the validity and/or enforceability of one or more of the underlying patents protecting our products. It has been and continues to be our practice to vigorously defend and pursue all available legal and regulatory avenues in defense of the intellectual property rights protecting our key products. As a result, there are currently ongoing legal proceedings brought by the Company and/or its subsidiaries, and in certain cases its third party partners, against manufacturers seeking FDA approval for generic versions of the Company's products.

Despite our efforts to defend our products, litigation is inherently uncertain, and we cannot predict the timing or outcome of our efforts. If we are not successful in defending our intellectual property rights or opt to settle, or if a

product's marketing exclusivity rights expire or become otherwise unenforceable, our competitors could ultimately launch generic versions of our products, which could significantly decrease our revenues and could have a material adverse effect on our business, results of operations, financial condition and cash flows as well as our stock price. Due in large part to the materiality of our revenues from Lidoderm®, Opana® ER and Voltaren® Gel (for which our marketing exclusivity rights expired in October 2010), as well as the fact that multiple ANDAs have been filed for Lidoderm® and both the original and crush-resistant formulations of Opana® ER, we believe our most significant risks from generic competition relate to these products. Additionally, although we no longer market the non-crush resistant formulation of Opana® ER, generic versions of this formulation are commercially available, which have resulted and may continue to result in reduced sales of our crush-resistant formulation. For a complete description of the related legal proceedings, see Note 14. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

Table of Contents

Lidoderm® accounted for 23% of our total revenues for the year ended December 31, 2013, 34% in 2012 and 33% in 2011. Opana® ER accounted for 9% of our total revenues for the year ended December 31, 2013, 11% in 2012 and 15% in 2011. Voltaren® Gel accounted for 7% of our total revenues for the year ended December 31, 2013, 4% in 2012 and 6% in 2011. Although these percentages have generally decreased in recent years as a result of strategic acquisitions and organic growth of our Endo Pharmaceuticals product portfolio, these products continue to represent significant percentages of our total revenues. Our revenues from Lidoderm® have been negatively affected by the September 16, 2013 launch of Actavis's lidocaine patch 5%, a generic version of Lidoderm®, and these revenues could decrease further should one or more additional generic versions launch. Impax's and Actavis's launch of generic versions of the non-crush-resistant formulation Opana® ER on January 2, 2013 and September 12, 2013, respectively, adversely affected our results of operations since January 2, 2013 and will likely continue to do so in the future. Should additional generic competition enter the market for either formulation of Opana® ER, our revenues from Opana® ER could decrease further. Similarly, the launch of a generic version of Voltaren® Gel or any of our other products could negatively affect that product's revenues. Decreases in revenue related to generic competition could have a material adverse effect on our business, results of operations, financial condition and cash flows as well as our stock price.

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

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

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 and/or medical device companies based upon claims for injuries allegedly caused by the use of their products. In addition, in the age of social media, plaintiffs' counsel now have a wide variety of tools to advertise their services and solicit new clients for litigation. Thus, we could expect that any significant product liability litigation or mass tort in which we are a defendant will have a larger number of plaintiffs than such actions have seen historically because of the increasing use of wide-spread and media-varied advertising. In addition, it may be necessary for us to voluntarily or mandatorily recall or withdraw products that do not meet approved specifications or which subsequent data demonstrate may be unsafe or ineffective, which would also result in adverse publicity as well as in costs connected to the recall and loss of revenue.

Qualitest Pharmaceuticals and, in certain cases, the Company and certain of our other subsidiaries, along with several other pharmaceutical manufacturers, have been named as defendants in a number of cases filed in various state and federal courts that allege plaintiffs experienced injuries as a result of using the prescription medicine metoclopramide. Qualitest Pharmaceuticals and, in certain cases, the Company and certain of our other subsidiaries are also named as defendants in cases that have been filed in various state and federal courts that allege plaintiffs experienced injuries as a result of using prescription medications containing propoxyphene, which has been manufactured and marketed by Qualitest Pharmaceuticals as well as other manufacturers. We may be subject to liabilities arising out of these cases, and are responsible for the cost of managing these cases. We intend to contest all of these cases vigorously. Additional litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions with respect to metoclopramide, propoxyphene-containing prescription medications or other products in the future. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us and/or Qualitest Pharmaceuticals. Subject to certain terms and conditions, we will be indemnified by the former

owners of Qualitest Pharmaceuticals with respect to, among other things, metoclopramide and propoxyphene litigation arising out of the sales of the product by Qualitest Pharmaceuticals between January 1, 2006 and November 30, 2010, the date on which the acquisition was completed, subject to an overall liability cap.

Also, Qualitest Pharmaceuticals and, in certain cases, the Company and certain of our other subsidiaries, have been named as defendants in lawsuits that were filed after the September 2011 recall of several lots of Qualitest Pharmaceuticals' oral contraceptive products in which the plaintiffs seek out-of-pocket losses, medical expenses, and other damages associated with the alleged failure of these products. Three of these lawsuits sought certification of a nationwide class of all patients who used the recalled products. We have successfully defeated certification of such a class in two of these cases. The issue of whether a class will be certified in the third matter has not yet been resolved. We may be subject to liabilities arising out of these cases, and may be responsible for certain costs of managing these cases. We intend to contest all of these cases vigorously. Additional litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions, though given the date of the recall and the fact that these products are taken on a monthly basis, we believe the likelihood that additional cases will be filed in the future is remote.

Table of Contents

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

Mesh litigation and FDA actions in connection with transvaginal mesh may continue to adversely affect sales of our female incontinence and pelvic floor repair products and the expense or potential liabilities of that litigation may exceed our current insurance coverage.

As previously discussed, there have been FDA actions to continue to advise the public and medical community regarding potential complications associated with transvaginal placement of surgical mesh to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). Additionally, AMS and, in certain cases, the Company or certain of its other subsidiaries, have been named as defendants in multiple lawsuits in various federal and state courts, as well as in Canada, alleging personal injury resulting from use of transvaginal surgical mesh products designed to treat POP and SUI. Plaintiffs in these suits allege various personal injuries including chronic pain, incontinence and inability to control bowel function, and permanent deformities. On February 7, 2012, the U.S. Judicial Panel on Multidistrict Litigation (MDL) issued an order to consolidate and transfer certain of these claims filed against AMS in various federal courts to the Southern District of West Virginia as MDL 2325. We may be subject to liabilities arising out of these cases, and are responsible for the cost of managing these cases. We intend to contest all of these cases vigorously but will also explore all options as appropriate in the best interests of the Company. However, there can be no assurance that our defense will be successful, and any defense may result in significant expense and divert management's attention from our business. We believe it is reasonably possible that the outcomes of such cases could result in losses in excess of insurance reimbursement levels that could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We believe that the significant increase in the number of lawsuits filed against AMS and/or the Company concerning transvaginal mesh devices may have contributed to recent declines in our AMS segment's women's health revenue. This litigation and any additional action on the part of the FDA may negatively affect revenue in our AMS segment's women's health line in the future. We cannot predict the extent to which these developments could result in future decreases in the number of surgical procedures using surgical mesh. Future decreases in the number of surgical procedures using surgical mesh may adversely affect sales of our female incontinence and pelvic floor repair products.

In addition, we have been contacted regarding a civil investigation that has been initiated by a number of state attorneys general into mesh products, including transvaginal surgical mesh products designed to treat POP and SUI. In November 2013, we received a subpoena relating to this investigation from the State of California, and have subsequently received additional subpoenas from other states. We are cooperating fully with this investigation. At this time, we cannot predict or determine the outcome of this investigation 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 from this investigation.

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

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

	2013		2012		2011	
	$	%	$	%	$	%
Lidoderm®	$602,998	23	$947,680	34	$825,181	33
Opana® ER	227,878	9	299,287	11	384,339	15
Voltaren® Gel	170,841	7	117,563	4	142,701	6
Percocet®	105,814	4	103,406	4	104,600	4
Frova®	60,927	2	61,341	2	58,180	2
Fortesta® Gel	65,860	3	30,589	1	14,869	1
Supprelin® LA	58,334	2	57,416	2	50,115	2

Other brands	101,363	4	60,702	2	77,782	3
Total Endo Pharmaceuticals*	$1,394,015	53	$1,677,984			