



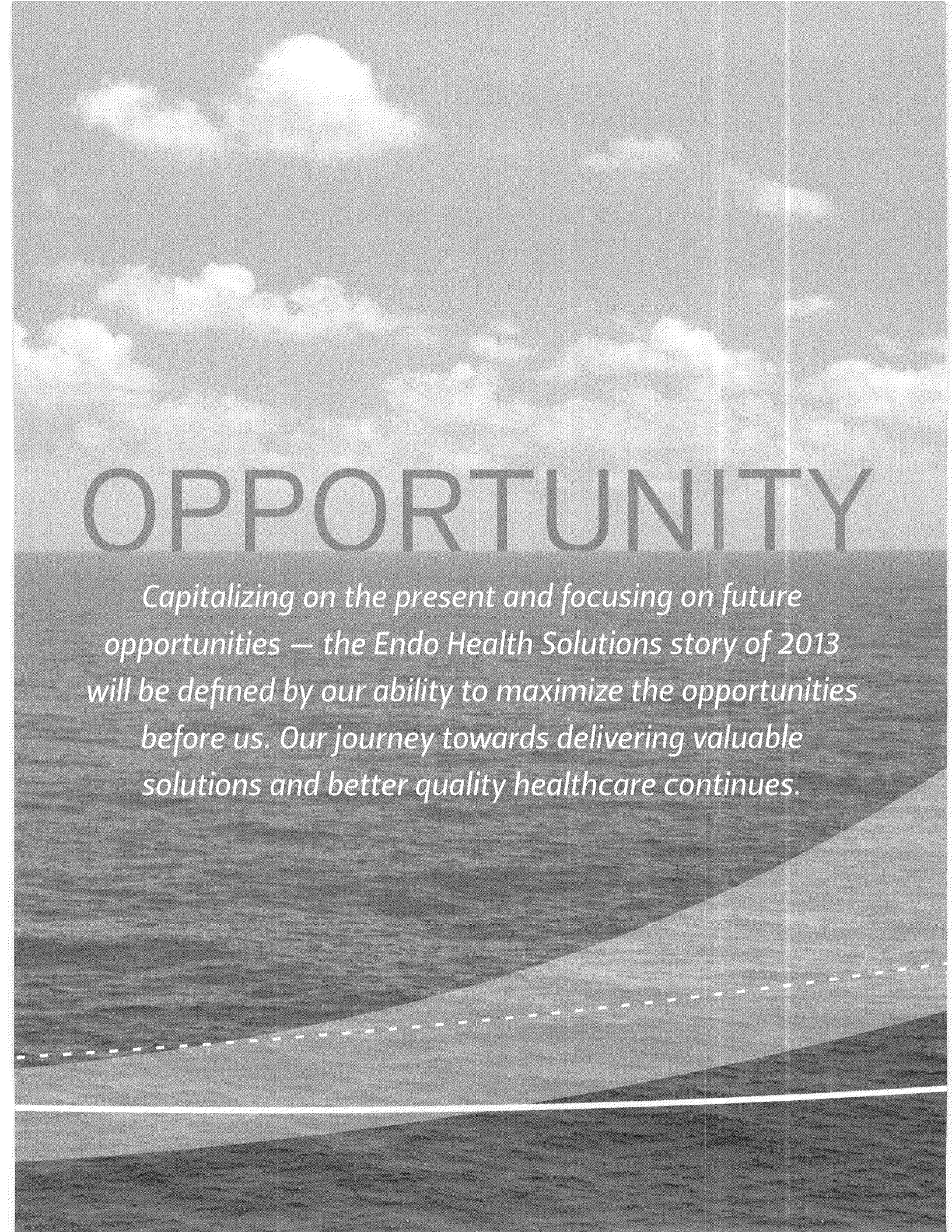
ADAPTIVITY





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# OPPORTUNITY

*Capitalizing on the present and focusing on future opportunities — the Endo Health Solutions story of 2013 will be defined by our ability to maximize the opportunities before us. Our journey towards delivering valuable solutions and better quality healthcare continues.*

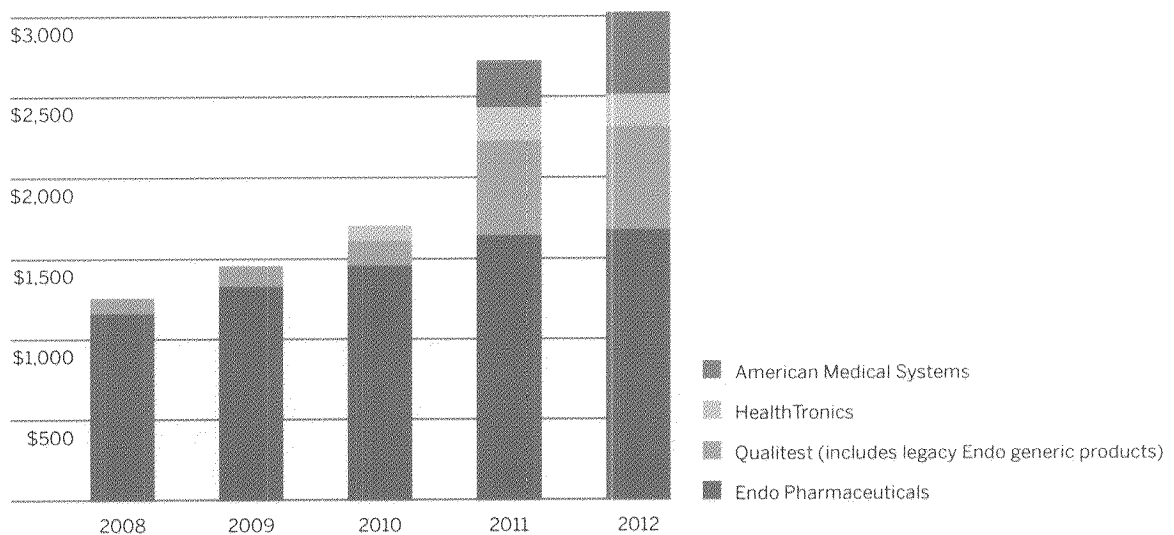


# To Our Shareholders

In 2012, we continued our journey to become a healthcare solutions provider by rebranding the company and changing our name to Endo Health Solutions. While structured as four distinct business segments that are focused on branded and generic pharmaceuticals, devices and services, we operate under a common set of guiding principles that enable us to provide quality products to our customers and improve the lives of patients. We believe growth opportunities exist in each business, though challenges in the changing healthcare landscape have and will continue to test our segments.

We were confronted with numerous challenges over the course of 2012, including declines in procedural volumes in American Medical System's (AMS) women's health business reflecting recent industry shifts following the U.S. Food and Drug Administration's (FDA) September 2011 advisory committee meeting regarding the use of surgical mesh in pelvic organ prolapse, and the disruption of a significant portion of our supply chain as a result of an issue with one of our third party manufacturers, Novartis. Despite these challenges, our revenues exceeded \$3.0 billion, an 11 percent increase from 2011. As we continue our evolution, manage to execute on our four business segments and capitalize on marketplace opportunities, our business remains rooted in the pain management and urology sectors.

*Net Sales* (\$ in millions)







Endo's new company headquarters in Malvern, PA. Building photo courtesy of IMC Construction.

Our Endo Pharmaceuticals revenue was \$1.68 billion and the portfolio revenue rate grew by one percent year-over-year. 2012 was a major transition for several key Endo Pharmaceuticals products. We reached an agreement with Actavis, Inc., resolving an infringement lawsuit over two patents related to LIDODERM® (lidocaine patch 5%), a locally-acting topical medication for the relief of pain associated with post-herpetic neuralgia. The FDA has approved a generic version of LIDODERM, and we expect to see Actavis' generic version of LIDODERM enter the market in mid-September 2013.

In March 2012, we launched a reformulated version of OPANA® ER (oxymorphone HCl) with INTAC® technology designed to be crush resistant. OPANA ER is now available in seven dosage strengths: 5, 7.5, 10, 15, 20, 30 and 40mg. We believe that using innovative crush-resistant technologies is important for patient and societal safety, as these formulations may reduce the rates of some common methods of abuse including pill crushing.

Based on preliminary results from interim analyses of two independently-run, on-going epidemiology studies on the effect of the reformulation on the rates of abuse of OPANA ER, the reported prescription-adjusted rate of abuse of the reformulated OPANA ER dropped more than 39 percent as compared to historical (2011) baseline abuse rates of the original OPANA ER formulation during the period April 1, 2012 through December 31, 2012. Additionally, the reported rate of abuse of the crush-resistant reformulated OPANA ER product was approximately 79 percent lower than the reported rate of abuse of the crushable oxymorphone extended-release generics, during the same period. We believe this data, although preliminary, supports our position that non-crush-resistant formulations of long-acting opioids should not be available on the market if abuse-deterrent formulations are available.

Today, our Qualitest portfolio ranks sixth in U.S. drug prescription volume, based on IMS Health data for the 12 months ending December 31, 2012. Market opportunities continue to exist in generic drug manufacturing, where eight out of every 10 prescriptions filled in the United States are generic drugs. In 2012, our Qualitest segment reached revenues of \$633 million and achieved an 18 percent year-over-year growth in dosages manufactured.

As a leading manufacturer of controlled substances in the United States, Qualitest holds a competitive advantage in the marketplace. Pain products containing controlled substances as well as liquid medications represented nearly 60 percent of Qualitest's net sales in 2012. These products present a higher barrier-to-entry than the broader generics industry and are a strong driver for continued value creation.





# To Our Shareholders

Since Endo acquired Qualitest in 2010, we have expanded manufacturing output significantly. Qualitest manufactured approximately 10 billion doses in 2010 and that has increased to more than 14.1 billion doses in 2012. In order to capture future revenue growth opportunities, we plan to continue expanding production capacity over the next several years through capital investment, more efficiently utilizing our facilities, and selective outsourcing.

In urology, medical devices and procedures are revolutionizing medical practice as the demand for new treatments continues to rise. Endo is well-positioned to answer this call for new and better therapies, and to maximize on expanded opportunities for future growth in this market segment.

AMS is a leader in minimally invasive surgical products and its therapies treat very common urological diseases that are associated with aging. The aging baby boomer population has provided a long runway for growth for the segment and will likely lead to increased demand for such devices. In 2012, more than 315,000 patients were treated with AMS devices. AMS's sales have grown from \$100 million as a standalone company in 2000 to \$504 million in 2012, and we expect to return to low-single digit growth on a pro forma basis in 2013.

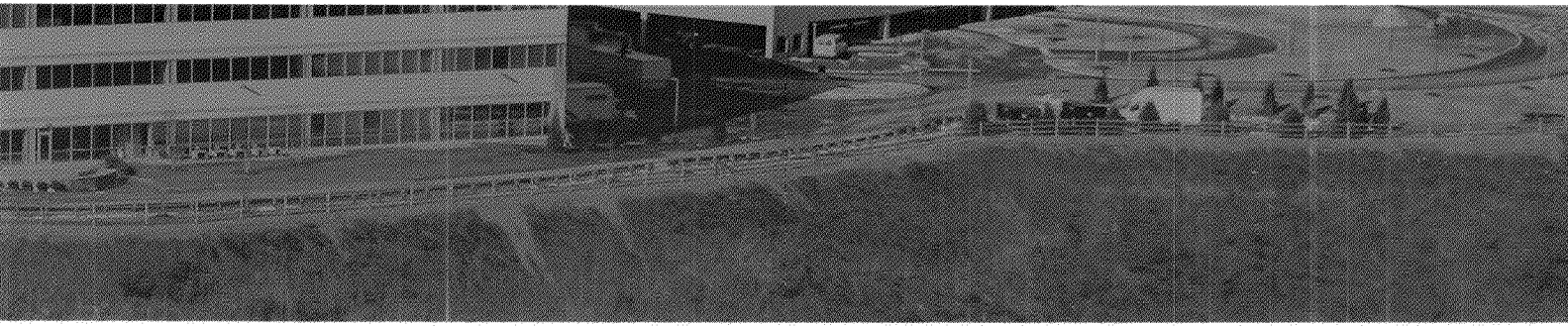
In each of the AMS lines of business — men's health, women's health, and benign prostatic hyperplasia (BPH) — opportunities exist for product development and innovation, international expansion, organic growth and commercial excellence. Device offerings expanded in 2012, including the global launch of three women's health products, and the launch of a new MoXy® 650kJ fiber for the class-leading GreenLight XPS® system.

Net sales declines in women's health were driven by year-over-year declines in procedural volumes reflecting recent industry shifts following the FDA's September 2011 advisory committee meeting regarding the use of surgical mesh in pelvic organ prolapse. AMS remains focused on educational activities as part of an overall effort to continue to encourage patients and physicians to discuss the risks and benefits of AMS's surgical mesh devices as an important treatment option for patients who suffer from stress urinary incontinence and pelvic organ prolapse. In order to return AMS to growth in 2013, it will be essential to stabilize the women's health business in the United States, expand our reach in key men's and prostate health products, and expand operating margins.

AMS also completed enrollment in 2012 for its randomized, prospective, multicenter study (known as the Goliath study) designed to compare GreenLight XPS and transurethral resection of the prostate (TURP). The study — powered for safety and effectiveness, and including healthcare economic data for the treatment for enlarged prostate — enrolled 291 subjects at 30 investigational sites in 11 different European countries. Results of the study will be published in 2013, and, if positive, could help show doctors and patients the benefit of utilizing GreenLight XPS versus TURP.

The interplay between AMS and our HealthTronics segment has allowed for testing and planning for current products and services while evaluating innovation in the marketplace through the eyes of the physician. We believe that this collaboration provides us with a competitive advantage. Together, AMS and HealthTronics have built a strong presence in the urology marketplace where they enjoy broad and comprehensive relationships with providers. These opportunities will allow us to create more organic value from these two segments than either could have achieved on its own.





Within the HealthTronics segment, electronic health records (EHR) represent an important service offering for us in the urology channel. Currently, approximately 2,200 providers are using HealthTronics EHR technologies. We believe that owning these EHR platforms provides HealthTronics with several options for additional revenue opportunities in the future of outcomes-based reimbursement, patient demand for transparent effectiveness measures, and the continued push towards data to enable lower cost, better quality healthcare.

### Maximizing Opportunities

Our evolution into Endo Health Solutions, composed of our four business segments, now encompasses more products, added production capacity, greater research and marketing expertise, a larger and more robust pipeline, new platforms for growth and more treatment options to offer physicians and their patients than it did just three years ago. Where Endo's story in 2012 focused on addressing challenges that faced the business, our story in 2013 will be focused on executing in our four lines of business and continuing integration.

Opportunities exist in our Endo Pharmaceuticals segment by targeting key markets in the healthcare industry, and in AMS to broaden our medical device presence internationally, with new prospects for market expansion and revenue growth. Opportunities also lie in our pipeline to expand our offerings and sustain our record of leadership in the treatment of pain. This includes the development of an investigational chronic pain product, BEMA<sup>®</sup> Buprenorphine. If approved, this drug will enhance our branded pain management portfolio and contribute to growth starting as early as 2015.

In 2013, we will continue to streamline efficiencies in the business to improve overall performance and further focus on maximizing our investments in key growth markets. As part of our streamlining process following an aggressive acquisition period, we've aligned key segments of our company to strengthen our employee collaboration capabilities, and overall enhance our performance. In order to provide a more efficient facility infrastructure for the company, a new Finance Shared Services Center was established in Austin, TX to support business operations across the enterprise, new R&D alignments were implemented, a new AMS-EMEA (Europe, Middle East and Africa) office was established in Amsterdam, and construction of a new company headquarters, located in Malvern, PA was completed.

As I retire from my position as Endo's CEO, I remain enthusiastic about what is to come for the organization. Our progress in the past five years together created fertile ground for Endo to nurture its growth. The vision we embraced is much bigger than one employee or one leader, it was something each colleague developed together and it will continue to inform enterprise decisions for years to come. Endo will continue to be tested in its quest towards fulfilling its vision, but the end reward will provide future generations with a more holistic healthcare experience than ever thought possible. I have full confidence in Endo's future and its employees in creating sustainable growth for the company.

Sincerely,



David P. Holveck  
Retired President and Chief Executive Officer



# To Our Shareholders

## Looking Forward

Over the last several years, Endo has grown from a \$1.3 billion business in 2008 — heavily dependent on its leading product, LIDODERM® — to a diversified \$3.0 billion healthcare solutions company in 2012. Although during this period Endo achieved much success, in 2012 the company's successes were impacted by numerous challenges. However, the diversification strategy we implemented under the leadership of Dave Holveck has left Endo poised for a new chapter in its short history. Our company now has four key business drivers: branded and generic pharmaceuticals, devices and services, where just five years ago we were essentially a specialty branded pharmaceuticals business.

Dave retired in March 2013, and we thank him for his vision and leadership. As we transition to new leadership, the Board is focused on improving operating efficiency and execution as well as continuing integration of our four businesses.

Among the key attributes we were looking for in Endo's CEO was an executive with strong leadership skills, substantial operating and integration experience and knowledge of our markets. We wanted a CEO with the ability to drive outcome-oriented approaches to increase shareholder value using Endo's unique position in the marketplace. We believe Rajiv De Silva possesses these abilities and we are confident that he will apply his substantial operational experience and outstanding leadership skills to build upon the foundation that has been created over the last few years. His track record in generating growth and profitability, managing complex integrations, and delivering for shareholders is sure to serve us well.

The Board and the entire Endo team are excited about what Rajiv can accomplish here — and we look forward to working with him to enhance shareholder value.

Sincerely,



Roger Kimmel  
Chairman, Board of Directors





**Welcome Message from Rajiv De Silva**

It is an honor and privilege to serve as your new CEO and to lead a growing and dynamic organization. From my perspective, Endo occupies a unique position in the healthcare market — able to deliver innovative products and services across multiple platforms with clear strengths in the medically important areas of pain management and urology — and I am excited to work with my Endo colleagues to further strengthen our company in these spaces.

Endo has experienced rapid transformation in the last several years. As with many companies that experience periods of growth and evolution, Endo has seen much success, as well as challenges and obstacles. I am committed to leading the Endo team in delivering meaningful products and services to patients and customers, and enhancing shareholder value. I look forward to working with the Endo team to build on its strengths and deliver growth while also improving cost management, execution and integration to enable Endo to make the most of its many opportunities.

As the healthcare industry continues to evolve, we must work to maximize our opportunities and continuously develop strategies that will enhance our company in the marketplace. Although we still have a lot of work ahead, our foundation is strong, and I am eager to be part of Endo's next chapter.

Sincerely,



Rajiv De Silva  
President and Chief Executive Officer





# Featured Opportunities

## Opportunities in Pain Management

Endo has a long legacy of bringing to market effective and responsible pain management solutions for people in pain. This important therapeutic area offered a springboard that helped launch our company in 1997 and continues to be a significant driver to our success today. Approximately 86 million people in the United States suffer from chronic pain, limiting the daily routines of many Americans. The impact of pain can ripple beyond the individual — a study found that 13 percent of the total workforce experienced a loss in productive time due to common pain conditions, resulting in costs of \$61.2 billion annually.

According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled \$26.8 billion in 2012. Additionally, analgesics were the third most prescribed medication for 2012 in the United States with nearly 313 million prescriptions written for this classification.

As a long-time leader in responsible pain management, Endo strives to offer a range of pain treatment products, while expanding the company's portfolio and offerings. As the pain management market expands and the broader healthcare industry continues to evolve, Endo continually reassesses and realigns its pathway towards success.

### *Opioid Pain Therapies — OPANA® ER adopts new formulation technology*

Patient safety has a tremendous influence on how the Long Acting Opioid category has been shaped in recent years. The chronic pain management market is starting to see the introduction of products that address these concerns. In evaluating our portfolio, Endo took significant steps to utilize crush resistant technologies in an effort to help stem abuse and misuse of one of our pain management products.

In 2012, Endo launched a reformulated, designed to be crush-resistant, OPANA® ER (oxymorphone HCl) with INTAC® technology. Based on preliminary results from interim analyses of two independently-run, on-going epidemiology studies on the effect of the reformulation on the rates of abuse of OPANA ER, the reported prescription-adjusted rate of abuse of the reformulated OPANA ER dropped more than 39 percent as compared to historical (2011) baseline abuse rates of the original OPANA ER formulation during the period April 1, 2012 through December 31, 2012. Additionally, the reported rate of abuse of the crush-resistant reformulated OPANA ER product was approximately 79 percent lower than the reported rate of abuse of the crushable oxymorphone extended-release generics, during the same period.





Although the original formulation of OPANA ER was deemed safe and effective by the FDA when taken according to its prescribing information, the original formulation was subject to both intentional and inadvertent abuse and misuse. We believe that using innovative crush-resistant technologies is imperative for patient and societal safety since these formulations will deter some common methods of abuse involving pill crushing.

As part of our leadership in responsible pain management, Endo requested that the FDA establish a regulatory framework that recognizes and incentivizes abuse-deterrent technologies. Additionally, in the past year, the company developed a long-term growth strategy for OPANA ER that was rooted in strengthening relationships with critical healthcare provider channels, including hospitals, pharmacies and managed care organizations. We re-evaluated our outreach and took a macro approach to supporting the brand by nurturing relationships with specific healthcare professional audiences, creating demand at multiple touch points of care, and working to minimize the impact of impending market factors on the brand.

#### *Deep Brand Connection with VOLTAREN® Gel*

VOLTAREN® Gel (diclofenac sodium topical gel) 1% provides a topical therapy option for sufferers of osteoarthritis joint pain as an important part of Endo's range of pain management solutions. Since its launch in 2008, VOLTAREN Gel gained presence in the osteoarthritis market competing in the analgesic non-narcotic and anti-arthritic classes, which together had more than 200 million prescriptions written in 2012, representing 45 percent of the U.S. pain management market.

The product continues to grow in popularity with its target customers of osteoarthritis joint pain sufferers. Our direct-to-consumer (DTC) campaign following a 2012 supply disruption helped volume rebound by 18 percent in targeted areas. Additionally, total prescription demand grew 2.3 percent in the 4th quarter of 2012 when compared to the same quarter in 2011. The success of the DTC campaign underscored the strength of the relationship between patients and the VOLTAREN Gel brand — a relationship we will continue to nurture in 2013 and beyond.

#### *Building Momentum in the Pain Category*

While we continue to navigate through obstacles in the marketplace, we are taking a broad-based approach in evaluating the long-term strategy of our portfolio of branded and generic products, and continue to evaluate ways to aid patients suffering from pain across the pain-severity spectrum. We support our other pain management products by strengthening our connection with payers and understanding how they define value in pain management treatments. Both LIDODERM® and FROVA® brands introduced promotional strategy enhancements to bolster response rates by non-personal promotion targets in the process. And pending FDA approval, our

# Featured Opportunities

investigational BEMA® Buprenorphine development product could fill an important gap in our pain portfolio as a valuable new chronic pain treatment option.

In 2012, our Endo Pharmaceuticals segment reinforced our commitment to this critical therapeutic area by discovering areas of opportunities that benefit mid- and long-term product growth. This approach helped position our brand portfolio for success in 2013, and the team will continue to leverage an integrated outreach strategy and unlock new opportunities in the years ahead.

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## Opportunities in Urology

Endo's evolution and commitment to the urology market has provided us the opportunity to reach the vast majority of urology practices across the United States — making Endo one of the leading urology specialty companies in the U.S. healthcare industry.

With the current U.S. demographic shift due to the aging baby-boomer population, the long-term growth potential and need for medical interventions in urology will continue to increase. For context:

- The population age 65 and older is expected to more than double between 2012 and 2060, from 43.1 million to 92 million
- It is estimated that in 2013 in the United States, one new case of prostate cancer will be diagnosed every two minutes and that a man will die from prostate cancer every 18 minutes
- At least one-third of all women (approximately 35 million) will be treated for a pelvic health condition by the age of 60

Of our acquisitions over the last several years, three — Indevus, HealthTronics and AMS — have provided Endo with multiple urological growth platforms, featuring strong expertise and a deep portfolio of products and services, establishing and growing Endo's footprint in the urology market.

The Endo urology enterprise consists of branded and generic pharmaceuticals, men's and women's health devices, electronic health records, services and laboratory tests. Our products and solutions support the following therapeutic areas: benign prostate hyperplasia, bladder cancer, erectile dysfunction, kidney cancer, kidney stones, prostate cancer, urethral strictures, urinary and fecal incontinence, and vaginal prolapse.

Utilizing the expertise and offerings of our expanded urology enterprise, Endo is driving advancements in urology by developing technologies and treatment options — spanning the treatment paradigm from diagnosis to treatment to post-treatment and restoration therapies.

In addition to strengthening the enterprise portfolio, our relationships with urologists and the urologic community are critical to our future growth in this important therapeutic area. Across the Endo urology enterprise, we continuously seek ways to engage and partner with urologists and health system executives to strengthen our connection and commitment to our urology customer base.





### *A Partner in Urology*

AMS has created a legacy of clinical support in the operating room and insight into practice management. Helping urologists deliver better patient outcomes, AMS has become the trusted "partner in Urology". Physician training is a cornerstone of the AMS business; nearly 1,200 physicians were trained on AMS products in 2012 with 72 percent of attendees indicating the course exceeded their expectations.

The AMS portfolio primarily consists of devices that are used to correct physiological problems that otherwise might be extremely compromising to a patient's quality of life. In 2012 alone, more than 315,000 patients were treated with AMS devices. These therapy options build on Endo's opportunity to offer alternative ways to correct underlying physiological problems.

AMS has been a leader in urology for more than 40 years through innovation and dedication to erectile restoration and male continence. We intend to continue to lead in this space by focusing on key programs that will increase patient awareness of erectile dysfunction and male stress urinary incontinence and of our available treatment options.

In 2012, AMS launched the GreenLight™ laser system simulator, the GreenLight SIM®, in residency programs and other customer engagement events worldwide. This simulator, developed in partnership with the University of Minnesota, provides a realistic, simulated hands-on experience with laser therapy for treatment of the enlarged prostate. To date, 30 systems have been deployed, with 17 placed in healthcare systems and residency programs internationally. By the end of 2013, AMS will have 130 simulators available as a supplemental tool used in residency programs and physician training.

HealthTronics, a national provider of urological services, is another valuable avenue for us to reach a significant percentage of U.S. urologists. HealthTronics is a valued partner through its long-seated business partnerships and focus on solutions — including mobile services, lab solutions and electronic health records. It is the largest provider of mobile lithotripsy with technologists assisting urologists with more than 50,000 procedures annually. In addition, HealthTronics now supports more than 12 million electronic records created by over 2,000 urology healthcare providers, which it expects to expand to one-third of all U.S. independent urologists by the end of 2013.

### *Future Opportunities*

Our goal is to be seen as a trusted partner who can help our urology customers identify opportunities to improve patient outcomes, through best-in-class physician training programs. Between AMS and HealthTronics, we have built an unrivaled presence in the urology marketplace where we enjoy broad and comprehensive relationships with providers that cannot be easily duplicated.

# By the Numbers

**\$3.027**  
BILLION

**14.1**  
BILLION

**39**

**\$1.68**  
BILLION

**15**

**315,000**

**1,200**

**291**

**2,200**





**\$3.027 billion** — total revenue

**14.1 billion** — number of Qualitest generic dosages manufactured — an 18% increase from 2011 production

**39** — number of Qualitest ANDAs currently under review with the FDA

**\$1.68 billion** — total 2012 net sales for Endo Pharmaceuticals products

**15** — years in existence for Endo Pharmaceuticals

**315,000** — approximate number of patients treated with AMS products

**1,200** — approximate number of physicians trained in 2012 on AMS devices

**291** — total patients enrolled from 30 sites in 11 countries in the AMS Goliath study\*

**2,200** — approximate providers using HealthTronics electronic health records technology

\* The Goliath study is the first head-to-head, randomized study of its kind between GreenLight XPS® Laser Therapy and transurethral resection of the prostate (TURP) for Benign Prostatic Hyperplasia (BPH)

# Business Segments

## Endo Pharmaceuticals

Endo Pharmaceuticals is focused on creating high-value branded products that meet the needs of patients along care pathways for pain management, urology, oncology and endocrinology.

### 2012 Revenues

- \$1.68 billion

### Year-over-Year Revenue Growth

- 1.2%

### Top Products/Services

- LIDODERM®
- OPANA® ER
- VOLTAREN® Gel

### Milestones

- Reformulated OPANA® ER with INTAC® technology, designed to be crush resistant: launched March 2012 (545,430 new formulation total prescriptions in 2012)
- SUPPRELIN® LA celebrated five-year milestone; more than 9,000 implants prescribed since launch
- VOLTAREN® Gel's direct-to-consumer campaign following the 2012 supply disruption helped volume rebound by 18% in target areas; total prescription demand grew 2.3% Q4 2012 compared to Q4 2011

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## Qualitest

Qualitest, headquartered in Huntsville, Alabama, meets the needs of today's healthcare customers by providing affordable, high-quality generic pharmaceuticals that provide options for patients, providers and payers. Featuring a current portfolio exceeding 600 products, the company has grown significantly since its inception in 1983 and is now ranked in the top ten among all suppliers of generics, based on total prescriptions filled.

### 2012 Revenues

- \$633 million

### Year-over-Year Revenue Growth

- 11.7%

### Top Products/Services

- Hydrocodone and acetaminophen
- ENDOCET®
- Oxycodone

### Milestones

- Launched 10 new products
- 39 Abbreviated New Drug Application currently under FDA review
- Ranked 6th in total U.S. prescriptions





### AMS

AMS, headquartered in Minnetonka, Minnesota, is a diversified supplier of medical devices and procedures to treat incontinence, erectile dysfunction, benign prostatic hyperplasia (BPH), pelvic floor prolapse and other pelvic disorders in men and women. AMS continues to develop new therapies to restore bodily functions and to enable people to improve patients' quality of life.

#### *2012 Revenues*

- \$504 million

#### *Year-over-Year Revenue Decline*

- Pro forma — (6.3)%

#### *Top Products/Services*

- AMS 700® MS Series
- AMS 800® Artificial Urinary Sphincter
- GreenLight™ Laser Therapy Products

#### *Milestones*

- Appointment of President Camille Farhat
- Completed patient enrollment for a randomized, prospective, multicenter study (known as the Goliath study) designed to compare GreenLight XPS and transurethral resection of the prostate (TURP)
- Celebrated 40 years of company's first product: AMS 800® Artificial Urinary Sphincter

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### HealthTronics

For more than 20 years, HealthTronics has been a national provider of urological services and products. Headquartered in Austin, Texas, our HealthTronics segment provides the most advanced technology and premiere support systems to urologists, hospitals, surgery centers and clinics across the United States. HealthTronics' offerings include mobile medical equipment, IT solutions, laboratory solutions, and electronic health records.

#### *2012 Revenues*

- \$212 million

#### *Year-over-Year Revenue Growth*

- 3.1%

#### *Top Products/Services*

- General Urology Solutions
- Oncology Solutions
- Laboratory Solutions
- Information Technology Solutions

#### *Milestones*

- Increased HealthTronics IT Solutions customer base to 25 percent of U.S.-based, independent urologists
- Assumed management of two new lithotripsy entities and acquired a mobile cryotherapy and laser service provider
- Launched new Slimline™ Right Angle Cryoprobes for interventional radiology and PTEN molecular test of prostate cancer aggressiveness

# Company Information

## Directors

**Roger H. Kimmel**<sup>1,3,4</sup>  
*Chairman of the Board  
Vice Chairman, Rothschild, Inc.*

**Rajiv De Silva**\*\*  
*President and Chief Executive Officer*

**John J. Delucca**<sup>1,2</sup>  
*Retired Executive Vice President and  
Chief Financial Officer,  
REL Consultancy Group*

**David P. Holveck**\*  
*President and Chief Executive Officer*

**Nancy J. Hutson, Ph.D.**<sup>2,3,4,5</sup>  
*Retired Senior Vice President, Pfizer Global  
Research and Development*

**Michael Hyatt**<sup>3</sup>  
*Senior Advisor, Irving Place Capital*

**William P. Montague**<sup>1,3,4</sup>  
*Retired Chief Executive Officer and Director,  
Mark IV Industries, Inc.*

**David B. Nash, M.D., M.B.A.**<sup>2,5</sup>  
*Dean, Jefferson School of Population Health*

**Joseph C. Scodari**<sup>2,4,5</sup>  
*Retired Worldwide Chairman,  
Pharmaceutical Group of  
Johnson & Johnson*

**Jill D. Smith**<sup>1,3</sup>  
*Former Chairman, Chief Executive Officer  
and President, DigitalGlobe Inc.*

**William F. Spengler**<sup>1,2,5</sup>  
*Former President and Director,  
ChromaDex Corporation*

<sup>1</sup> Audit Committee Member as of 12/31/2012

<sup>2</sup> Compensation Committee Member as of  
12/31/2012

<sup>3</sup> Nominating & Governance Committee Member  
as of 12/31/2012

<sup>4</sup> Transactions Committee Member as of  
12/31/2012

<sup>5</sup> Research & Development Committee Member  
as of 2/27/13

## Executive Officers

**David P. Holveck**\*  
*President and Chief Executive Officer*

**Rajiv De Silva**\*\*  
*President and Chief Executive Officer*

**Lawrence A. Cunningham**  
*Executive Vice President, Human Resources*

**Camille I. Farhat**  
*President, American Medical Systems, Inc.*

**Ivan P. Gergel, M.D.**  
*Executive Vice President, Research &  
Development and Chief Scientific Officer*

**Kelly Huang, Ph.D.**  
*President, HealthTronics, Inc.*

**Denise L. Hudson**  
*Executive Vice President,  
Enterprise Quality and Supply Chain*

**Alan G. Levin**  
*Executive Vice President and  
Chief Financial Officer*

**Caroline B. Manogue**  
*Executive Vice President, Chief Legal Officer  
and Secretary*

**Julie H. McHugh**  
*Chief Operating Officer*

**Jon A. Smollen**  
*Executive Vice President and  
Chief Compliance Officer*

\* As previously disclosed.  
Mr. Holveck retired in March 2013.

\*\* As previously announced.  
Mr. De Silva was appointed  
President and Chief Executive  
Officer of the company and a  
Director effective March 18, 2013.

## Corporate Information

Endo Health Solutions Inc. (Endo) is a U.S.-based diversified healthcare company that is redefining healthcare value by finding solutions for the unmet needs of patients along care pathways for pain management, pelvic health, urology, endocrinology and oncology. Through our operating segments: AMS, Endo Pharmaceuticals, HealthTronics and Qualitest, Endo is dedicated to improving care through a combination of branded products, generics, devices, technology and services that creates value for patients, providers and payers alike.





Endo was established in 1997 through a management buyout from DuPont Merck. The company is based in Malvern, Pennsylvania, and employed 4,625 employees worldwide as of December 31, 2012.

*Auditors*

Deloitte & Touche LLP  
1700 Market Street,  
25th Floor  
Philadelphia, PA 19103

*Corporate Counsel*

Skadden, Arps, Slate,  
Meagher & Flom LLP  
4 Times Square  
New York, NY 10036

*Transfer Agent*

American Stock Transfer  
& Trust Company  
59 Maiden Lane  
New York, NY 10038

*Investor Relations*

Blaine Davis  
Senior Vice President,  
Corporate Affairs  
(484) 216-7158

Jonathan Neely  
Director, Investor Relations  
(484) 216-6645

*Annual Shareholder Meeting*  
Wednesday, May 22, 2013 at  
10:00 a.m. EST

Endo Health Solutions  
1400 Atwater Drive  
Malvern, PA 19355

*Stock Exchange*

Endo common stock is listed on the  
NASDAQ Global Select Market under  
the ticker symbol ENDP.

*SEC Form 10-K*

A copy of the company's annual report  
on Form 10-K, as filed with the U.S.  
Securities and Exchange Commission  
(SEC), is available on our website  
([www.endo.com](http://www.endo.com)) or may be obtained  
without charge by writing to:

Corporate Affairs  
Endo Health Solutions  
1400 Atwater Drive  
Malvern, PA 19355

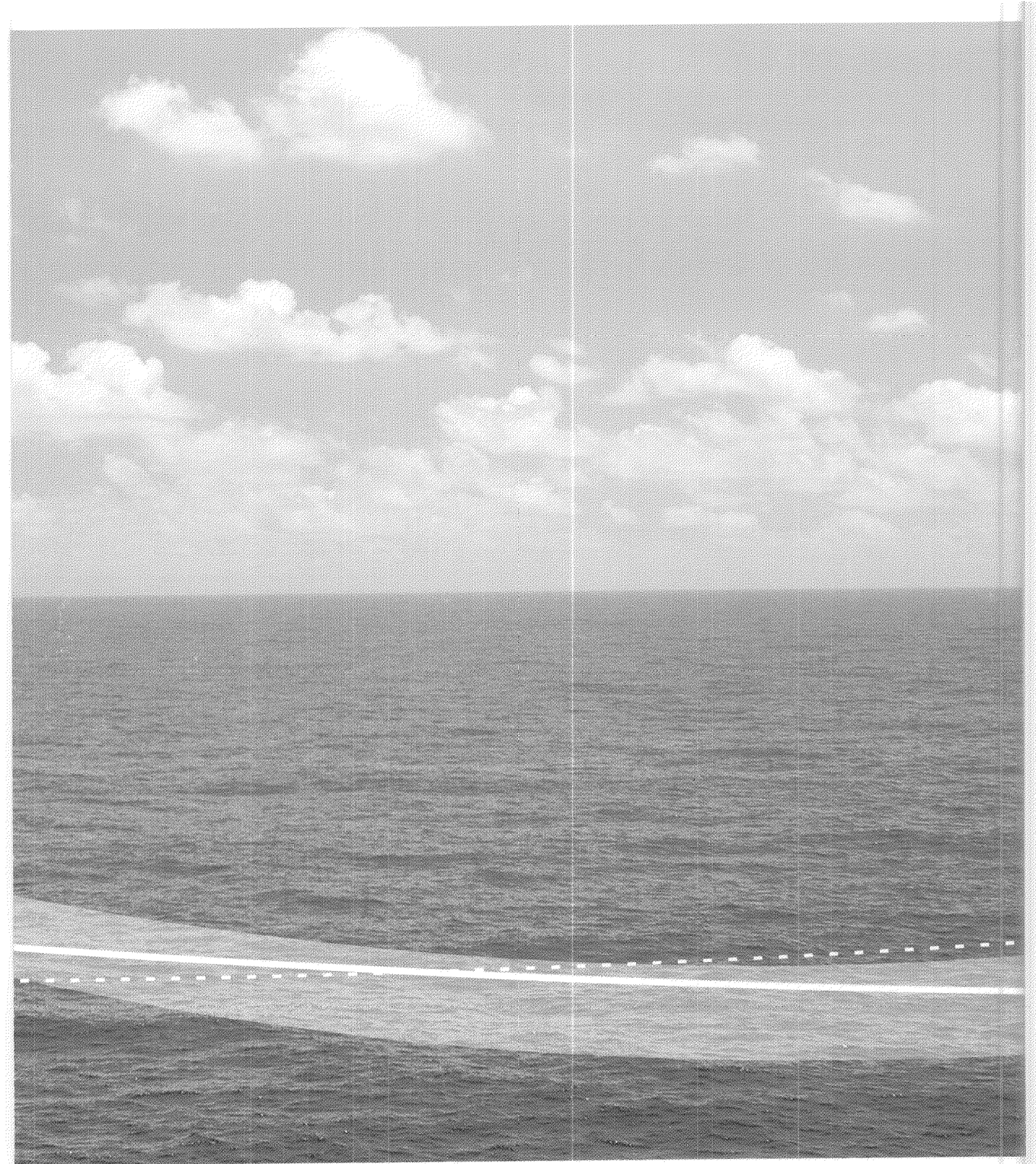
*Caution: Forward-looking Statements*

This document contains certain "forward looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and are subject to uncertainty and changes in circumstances. Actual results may differ materially from these expectations due to changes in economic, business,

competitive, market and regulatory factors. More information about those factors is contained in Endo's filings with the U.S. Securities and Exchange Commission.

Qualitest, HealthTronics, AMS, Endo, FORTESTA, OPANA, OPANA ER, SUPPRELIN, ENDOCET, GREENLIGHT XPS, GREENLIGHT HPS, GREENLIGHT SIM, AMS 700, AMS 800, Slimline and MOXY are trademarks or registered trademarks of Endo Pharmaceuticals Inc. or its affiliates. VOLTAREN is a registered trademark of Novartis Corporation. LIDODERM is a registered trademark of Hind Health Care, Inc. BEMA is a registered trademark of Arius Two, Inc. INTAC is a registered trademark of Grunenthal GmbH LLC.

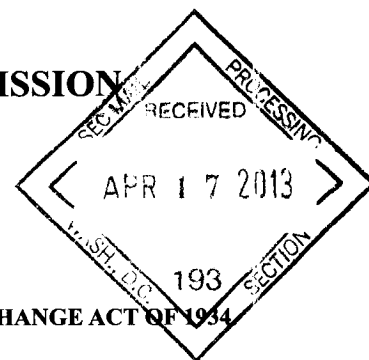
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Endo Health Solutions  
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Malvern, PA 19355  
[www.endo.com](http://www.endo.com)



UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549



FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2012

Or

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

Commission file number: 001-15989

**ENDO HEALTH SOLUTIONS INC.**  
(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or other jurisdiction of incorporation or organization)

13-4022871

(I.R.S. Employer Identification Number)

1400 Atwater Drive, Malvern, Pennsylvania

(Address of Principal Executive Offices)

19355

(Zip Code)

(Registrant's Telephone Number, Including Area Code): (484) 216-0000

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Name of Each Exchange on Which Registered</u>
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  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes  No

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  No

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

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

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  Accelerated Filer  Non-accelerated filer  Smaller reporting company

(Do not check if a smaller reporting company)

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

The aggregate market value of the voting common equity held by non-affiliates as of June 30, 2012 was \$3,600,317,403 based on a closing sale price of \$30.98 per share as reported on the NASDAQ Global Select Market on June 30, 2012. 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, 2013: 110,972,247

**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 2013 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, 2012.

**ENDO HEALTH SOLUTIONS INC.  
INDEX TO FORM 10-K  
FOR THE YEAR ENDED DECEMBER 31, 2012**

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## FORWARD-LOOKING STATEMENTS

Statements contained or incorporated by reference in this document contain information that includes or is based on “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements, including estimates of future revenues, future expenses, future net income and future net income per share, contained in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” which is included in this document, are subject to risks and uncertainties. Forward-looking statements include the information concerning our possible or assumed results of operations. We have tried, whenever possible, to identify such statements by words such as “believes,” “expects,” “anticipates,” “intends,” “estimates,” “plan,” “projected,” “forecast,” “will,” “may” or similar expressions. We have based 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.

## PART I

### Item 1. *Business*

#### Overview

On May 23, 2012, we changed our name from Endo Pharmaceuticals Holdings Inc. to Endo Health Solutions Inc., which we refer to herein as "Endo", "we", "us", or the "Company". Concurrently with this change, the Company also changed the names of its business segments. Effective May 23, 2012, the names of our business segments are Endo Pharmaceuticals (formerly Branded Pharmaceuticals), Qualitest (formerly Generics), AMS (formerly Devices) and HealthTronics (formerly Services). Financial information for our segments is included in Note 6. Segment Results in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

Endo is a U.S. based, specialty healthcare solutions company focused on branded and generic pharmaceuticals, devices and services. We have redefined our position in the healthcare marketplace by anticipating and embracing the evolution of health decisions based on the need for high-quality and cost-effective care. We aim to be the premier partner to healthcare professionals and payment providers, delivering an innovative suite of complementary branded and generic drugs, devices, services and clinical data to meet the needs of patients in areas such as pain management, urology, oncology and endocrinology. We evaluate and, where appropriate, pursue acquisition opportunities. In particular, we look to continue to enhance our product line by acquiring or licensing rights to additional products and compounds and therefore regularly evaluate selective acquisition and license opportunities. Such acquisitions or licenses may be effected through the purchase of assets, joint ventures and licenses or by acquiring other companies.

In June 2011, we acquired American Medical Systems Holdings, Inc. (AMS, Inc.), a leading provider of devices and therapies for treating male and female pelvic health conditions. The acquisition of AMS, Inc. 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. In September 2010, we acquired our partner on Opana<sup>®</sup> ER, Penwest Pharmaceuticals Co. (Penwest), a drug delivery company focused on applying its drug delivery technologies and drug formulation expertise to the formulation of its collaborators' product candidates under licensing collaborations. In July 2010, we acquired HealthTronics, Inc., a provider of healthcare services and manufacturer of certain related medical devices, primarily for the urology community. In February 2009, we completed our acquisition of Indevus Pharmaceuticals, Inc. (now, Endo Pharmaceuticals Solutions Inc., which we refer to herein as Indevus), a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology, endocrinology and oncology. As a combined company, we expect to continue to deliver comprehensive healthcare solutions across our diversified businesses in four key segments, Endo Pharmaceuticals, Qualitest, AMS and HealthTronics, in key therapeutic areas including pain and urology. Our segments are further discussed 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<sup>®</sup>, Opana<sup>®</sup> ER, Voltaren<sup>®</sup> Gel, Percocet<sup>®</sup>, Frova<sup>®</sup>, Supprelin<sup>®</sup> LA, Vantas<sup>®</sup>, Valstar<sup>®</sup> and Fortesta<sup>®</sup> Gel. Endo Pharmaceuticals comprised approximately 55% of our total revenues in 2012, with 31% of our revenues coming from Lidoderm<sup>®</sup>. Our non-branded Qualitest portfolio, which accounted for 21% of total revenues in 2012, currently consists of products primarily focused in pain management. We generally focus on selective generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. Our AMS segment accounted for 17% of total revenues in 2012 and our HealthTronics segment accounted for the remaining 2012 revenue. We generated total revenues of \$3.03 billion for the year ended December 31, 2012.

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

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

We were incorporated 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).



## Our Strategy

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

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

- In July 2010, we acquired HealthTronics, Inc., which gave us an established presence in the healthcare services space and added critical mass in urology;
- In September 2010, we acquired Penwest, which strengthened our pain management franchise by enhancing flexibility around our product Opana<sup>®</sup> ER;
- In November 2010, we acquired Qualitest Pharmaceuticals, which enhanced our solutions platform with the addition of a comprehensive generics business, adding critical mass to our existing generics business while also strengthening our pain management franchise offerings. The combined generics business has approximately 40 abbreviated new drug applications (ANDAs) under active FDA review in multiple therapeutic areas, including pain management, urology, central nervous system (CNS) disorders, immunosuppression, oncology, women's health and hypertension, among others; and
- In June 2011, we acquired AMS, Inc., which furthered Endo's evolution from a pharmaceutical product-driven company to a healthcare solutions provider, strengthened our core urology franchise and expanded our presence in the medical devices market.

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

See 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 anticipation of the evolution of healthcare delivery in the U.S. by diversifying our business away from that of a product-driven pharmaceutical company to that of a healthcare solutions provider.*** In light of the evolving healthcare industry, we executed a number of corporate acquisitions during the three years ended December 31, 2012 to diversify our business and become a healthcare solutions provider with an integrated business model that includes both branded and generic prescription drugs, as well as medical devices and healthcare services. This diversification will enable us to provide customers with quality outcomes and economic value and offer unique solutions along targeted disease care pathways. As a result of recent strategic actions combined with strategic investments in our core business, we have redefined our position in the healthcare marketplace and successfully reduced the revenue concentration of Lidoderm<sup>®</sup>, which contributed approximately 31% of our business' revenue in 2012, compared to 46% in 2010. Our acquisitions of AMS, Inc., Qualitest Pharmaceuticals and HealthTronics, Inc. have also contributed to our diversification. The acquisition of Qualitest Pharmaceuticals has enabled us to gain critical mass in our generics business. Through HealthTronics, Inc. and AMS, Inc., we provide healthcare services and manufacture medical devices, primarily for the urology community.

***Established portfolio of branded products.*** We have assembled a portfolio of branded prescription products to treat and manage pain and conditions in urology, oncology and endocrinology. Our branded products include: Lidoderm<sup>®</sup>, Opana<sup>®</sup> ER, Voltaren<sup>®</sup> Gel, Percocet<sup>®</sup>, Frova<sup>®</sup>, Supprelin<sup>®</sup> LA, Vantas<sup>®</sup>, Valstar<sup>®</sup> and Fortesta<sup>®</sup> Gel. For a more detailed description of each of our products, see "Product Overview."

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

***Research and development expertise.*** Our research and development efforts are focused on the development of a balanced, diversified portfolio of innovative and clinically differentiated products. We are continuously seeking opportunities that deepen our

presence in the pain management area as well as in the areas of oncology, urology and endocrinology. We will continue to capitalize on our core expertise with analgesics and expand our abilities to both capture earlier-stage opportunities and pursue other therapeutic areas. Through our acquisition of AMS, Inc., 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 continue to invest in research and development because we believe it is critical to our long-term competitiveness. At December 31, 2012, our research and development and regulatory affairs staff consisted of 450 employees, based primarily in Minnetonka, Minnesota, San Jose, California, Huntsville, Alabama and at our corporate headquarters in Pennsylvania. Our research and development expenses were \$226.1 million, \$182.3 million and \$144.5 million in 2012, 2011 and 2010, respectively, including upfront and milestone payments of \$57.9 million, \$19.1 million and \$23.9 million, respectively.

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

**Targeted sales and marketing infrastructure.** We market our branded products directly to physicians through a sales force of over 1,000 individuals in the pharmaceutical products, devices and services markets. This sales force consists of 396 Endo pharmaceutical sales representatives and 170 sales contracted representatives focusing primarily on pain products, 54 Endo sales representatives focusing primarily on bladder and prostate cancer products, 35 Endo medical center representatives focusing on the treatment of central precocious puberty and 21 Endo account executives focusing on managed markets customers. We also have 318 sales representatives focusing primarily on devices, of which 155 are located outside the United States, and 59 on services. We market our products and services to primary care physicians and specialty physicians, including those specializing in pain management, orthopedics, neurology, rheumatology, surgery, anesthesiology, urology and pediatric endocrinology. Our sales forces also target retail pharmacies and other healthcare professionals throughout the U.S. We distribute our products principally through independent wholesale distributors, but we also sell directly to retailers, clinics, government agencies, doctors and retail and specialty pharmacies. Our marketing policy is designed to assure that products and relevant, appropriate medical information are immediately available to physicians, pharmacies, hospitals, public and private payers, and appropriate healthcare professionals throughout the U.S. We work to gain access to healthcare authority, pharmacy benefit managers and managed care organizations' formularies (lists of recommended or approved medicines and other products), including Medicare Part D plans and reimbursement lists by demonstrating the qualities and treatment benefits of our products within their approved indications.

**Expanding focus on generic products.** Our Qualitest segment has approximately 40 ANDAs under active FDA review in multiple therapeutic areas, including pain management, urology, CNS disorders, immunosuppression, oncology, women's health and hypertension, among others. We develop generic products including those that involve significant barriers to entry such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. We believe products with these characteristics will face a lesser degree of competition and therefore provide longer product life cycles and higher profitability than commodity generic products. Our business model continues to focus on being the lowest-cost producer of products in categories with high barriers to entry and lower levels of competition. Our Qualitest segment is focused in categories where there are fewer challenges from low-cost operators in markets such as China and India, with approximately 45% of our product portfolio being comprised of controlled substances, which cannot be manufactured off-shore and imported into the U.S. In addition, approximately 12% 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 (BPH), women's incontinence and pelvic floor repair. These devices strengthen our leading core urology franchise, where we remain focused on expanding the markets for our products because the portion of afflicted patients seeking treatment remains relatively low. When patients seek treatment, they generally begin with options that will be as minimally invasive as possible, such as pharmaceutical therapies. Also, when patients initially seek treatment, their first physician contact is usually with a general practitioner and not with a surgical specialist. If less invasive options have proven unsuccessful, patients and their physicians may consider surgery as a solution. Sales of these products benefit from an aging population with a desire to maintain a high quality of life, the expanding availability of safe and effective treatments, minimally invasive solutions and increasing patient and physician awareness of these treatments.

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



**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, 2012, we generated \$733.9 million of cash from operations. We expect that sales of our currently marketed products, devices and services will allow us to continue to generate significant cash flow from operations in the future. We maintain ample liquidity which gives us flexibility to make strategic investments in our business. As of December 31, 2012, we had \$549.7 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 internal growth as well as through licensing and acquisitions. Their expertise has contributed to identifying and consummating such acquisitions. Members of our management team have consummated four significant acquisitions since 2010 (AMS, Inc., Qualitest Pharmaceuticals, Penwest and HealthTronics, Inc.) and have received FDA approval on more than twenty new products and product line extensions since 1997. As a result of several successful product launches and our strategic acquisitions, we have grown our total revenues from \$108 million in 1998 to over \$3.03 billion in 2012.

## **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 \$26.8 billion in 2012. This represents an approximate 7% compounded annual growth rate since 2008. Our primary area of focus within this market is analgesics and, specifically, opioid analgesics. In 2012, analgesics were the third most prescribed medication in the U.S. with nearly 313 million prescriptions written for this classification.

Opioid analgesics is a segment that comprised approximately 77% of the analgesic prescriptions for 2012 and represented almost 55% of the overall U.S. prescription pain management market. Total U.S. sales for the opioid analgesic segment were \$8.3 billion in 2012, representing a compounded annual growth rate of 3% since 2008. With the launch of Voltaren<sup>®</sup> Gel in 2008, Endo gained presence in the osteoarthritis market competing in the analgesic non-narcotic and anti-arthritic classes which together had approximately 200 million prescriptions written in 2012, representing 45% of the U.S. prescription pain management market. The U.S. sales for the analgesic non-narcotic and anti-arthritic markets were \$18.5 billion with a compound annual growth rate of 10% since 2008.

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 as well as other business development activities, Endo entered the urology, endocrinology and oncology markets, specifically the prostate cancer therapeutic area with Vantas<sup>®</sup>, the bladder oncology space with Valstar<sup>®</sup>, and the central precocious puberty therapeutic area with Supprelin<sup>®</sup> LA. With our early 2011 launch of Fortesta<sup>®</sup> 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<sup>™</sup>. As a result of our acquisition of AMS, Inc., we now offer a broad array of medical devices which deliver innovative medical technology solutions to physicians treating male incontinence, erectile dysfunction, female incontinence, pelvic floor repair and BPH. The markets for our AMS segment's products are discussed below under the caption "Medical Device Markets." As a result of our acquisition of HealthTronics, Inc., we now offer a full suite of urology products and services with the addition of lithotripsy, BPH and prostate cancer therapies, as well as anatomical pathology services for the detection and diagnosis of cancer and other conditions from our HealthTronics, Inc. subsidiary. These markets are discussed below under the caption "Medical Services 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.

**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 72,570 new cases of bladder cancer and 15,210 deaths from this disease in the U.S. in 2012. The 2013 estimate is expected to be similar. Rates of bladder cancer are expected to increase due to the aging population; nearly 90% of cases of bladder cancer are diagnosed in people age 55 or older. The number of patients in the total non-invasive bladder cancer population will thus increase due to the rising incidence as well as high recurrence rates, leading to a substantial prevalent population.

**BCG-refractory CIS bladder cancer**—CIS of the urinary bladder is a rare form of bladder cancer, affecting about 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 percent of patients will become refractory to BCG therapy. Valstar® intravesical therapy is the only FDA-approved treatment of carcinoma in situ of the urinary bladder in patients who are refractory to BCG immunotherapy when cystectomy – or bladder removal – is not an option.

**Testosterone replacement overview**—In the U.S. alone, it is estimated that 13.8 million men have low testosterone levels; however, only about 9% are currently being treated. Hypogonadism, or low testosterone, is under diagnosed and under treated. Factors contributing to this include a lack of screening for low testosterone and the perceived risk of prostate cancer associated with current treatment strategies. In the U.S., TRT sales have dramatically increased, from approximately \$809 million in 2008 to nearly \$2.2 billion in 2012, representing a compounded annual growth rate of 28% 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 percent of patients using these drugs do not have a positive response. If such drugs are not effective, the patient may elect to have an implant of one of our penile prosthesis products, which provide consistent, reliable solutions.

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

**Pelvic floor repair**—Pregnancy, labor, and childbirth are some of the primary causes of pelvic floor prolapse and other pelvic floor disorders. Prolapse and other pelvic floor defects may be treated with a variety of open, laparoscopic, and transvaginal surgeries. We estimate over 400,000 procedures are performed annually around the world to repair some form of pelvic floor prolapse in women. These procedures have historically been performed through the use of suture and graft materials designed for other surgical applications. We offer less invasive solutions for pelvic floor repair.

**BPH therapy**—Our products can be used to relieve restrictions on the normal flow of urine from the bladder caused by bladder obstructions, generally the result of BPH or bulbar urethral strictures. Symptoms of BPH include increased urination frequency, sudden urges to urinate, and weak urine flow. More than 70 percent of men over age 60 have some symptoms of BPH. Prior to the development of less invasive therapies, the conventional treatment for those experiencing a physical obstruction of the prostatic

urethra was a surgical removal of the prostatic tissue performed under general anesthesia, known as a transurethral resection of the prostate (TURP). We offer men an alternative to a TURP, using laser therapy designed to reduce the comorbidities associated with TURP. This laser system has paved the way for creating a new standard of care in the treatment of BPH.

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

### ***Medical Services Markets***

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

*Lithotripsy services*—We provide lithotripsy services, which is a medical procedure where a device called a lithotripter transmits high energy shockwaves through the body to break up kidney stones. Our lithotripsy services are provided principally through limited partnerships and other entities that we manage, which use lithotripters. In 2012, physicians who are affiliated with us used our lithotripters to perform more than 50,000 procedures in the U.S. As the general partner of limited partnerships or the manager of other types of entities, we also provide services relating to operating our lithotripters, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting with payors, hospitals, and surgery centers.

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

*Anatomical pathology services*—We provide anatomical pathology services primarily to the urology community. We have one pathology lab located in Georgia, HealthTronics Laboratory Solutions, that provides laboratory detection and diagnosis services to urologists throughout the U.S. In addition we manage pathology laboratories for physician practice groups located in Texas, Florida and Pennsylvania. Through HealthTronics Laboratory Solutions, we also provide administrative services to in-office pathology labs for practice groups and provide pathology services to physicians and practice groups with our lab equipment and personnel at our HealthTronics Laboratory Solutions laboratory sites.

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

*Information Technology Solutions*—In the second half of 2011, as part of our effort to increase and broaden the relationships within the urology community, we acquired two electronic medical records software companies, Intuitive Medical Software, LLC and meridianEMR, Inc., which provide electronic medical records for urologists. Together, these acquisitions provide access to more than 2,000 urology health care providers using data platforms that will enhance service offerings in urology practice management.



## Products Overview

### Endo Pharmaceuticals

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

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

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

**Lidoderm<sup>®</sup>.** Lidoderm<sup>®</sup> (lidocaine patch 5%) was launched in September 1999. A topical patch product containing lidocaine, Lidoderm<sup>®</sup> 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<sup>®</sup> 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) allowing Watson to launch its lidocaine patch 5%, a generic version of Lidoderm<sup>®</sup> on September 15, 2013. This agreement is further discussed in Note 15. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules". In 2012, 2011 and 2010, Lidoderm<sup>®</sup> net sales were \$947.7 million, \$825.2 million and \$782.6 million, respectively. Lidoderm<sup>®</sup> accounted for approximately 31% of our 2012 total revenues.

**Opana<sup>®</sup> ER.** Opana<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> ER designed to be crush-resistant, which is called Opana<sup>®</sup> ER (oxymorphone hydrochloride) Extended-Release Tablets with INTAC<sup>®</sup> technology. This formulation of Opana<sup>®</sup> ER with INTAC<sup>®</sup> technology has the same dosage strengths, color and packaging and similar tablet size as original Opana<sup>®</sup> ER. Endo transitioned to the crush-resistant formulation in March 2012 upon successfully accelerating production of this formulation. Opana<sup>®</sup> ER net sales were \$299.3 million, \$384.3 million and \$239.9 million in 2012, 2011 and 2010, respectively. Opana<sup>®</sup> ER accounted for approximately 10% of our 2012 total revenues.

**Voltaren<sup>®</sup> Gel.** We launched Voltaren<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Gel delivers effective pain relief with a favorable safety profile as its systemic absorption is 94% less than the comparable oral diclofenac treatment. In 2012, 2011 and 2010, net sales of Voltaren<sup>®</sup> Gel were \$117.6 million, \$142.7 million and \$104.9 million, respectively. Voltaren<sup>®</sup> Gel accounted for approximately 4% of our 2012 total revenues.

**Percocet<sup>®</sup>.** Launched in 1976, Percocet<sup>®</sup> (oxycodone hydrochloride and acetaminophen USP) Tablets CII is approved for the treatment of moderate-to-moderately severe pain. The Percocet<sup>®</sup> family of products had net sales of \$103.4 million, \$104.6 million and \$121.3 million in 2012, 2011 and 2010, respectively. The Percocet<sup>®</sup> franchise accounted for approximately 3% of our 2012 total revenues.

**Frova®.** We began shipping Frova® (frovatriptan succinate) Tablets upon closing of the license agreement with Vernalis in mid-August 2004. Frova® is indicated for the acute treatment of migraine headaches in adults. We believe that Frova® has differentiating features from other migraine products, including the longest half-life in the triptan class and a very low reported migraine recurrence rate in its clinical program. In 2012, 2011 and 2010, Frova® net sales were \$61.3 million, \$58.2 million and \$59.3 million, respectively.

**Supprelin® LA.** Supprelin® LA (histrelin acetate) was launched in the U.S. in June 2007. Supprelin® LA is a soft, flexible 12-month hydrogel implant based on our hydrogel polymer technology that delivers histrelin acetate, a gonadotropin releasing hormone (GnRH) agonist and is indicated for the treatment of central precocious puberty (CPP) in children. CPP is the early onset of puberty in young children resulting in the development of secondary sex characteristics and, if left untreated, can result in diminished adult height attainment. The development of these secondary sex characteristics is due to an increase in the secretion of sex hormones, the cause of which is unknown. We market Supprelin® LA in the U.S. through a specialty sales force primarily to pediatric endocrinologists. In 2012, 2011 and 2010, Supprelin® LA net sales were \$57.4 million, \$50.1 million and \$46.9 million, respectively.

**Vantas®.** Vantas® (histrelin acetate) was launched in the U.S. in November 2004. Vantas® is a soft, flexible 12-month hydrogel implant based on our hydrogel polymer technology that delivers histrelin acetate, a GnRH agonist and is indicated for the palliative treatment of advanced prostate cancer. We are party to a License, Supply and Distribution Agreement with Orion Corporation (Orion) granting Orion the rights to market Vantas® throughout Europe as well as certain other countries. Vantas® is also approved in Thailand, Singapore, Malaysia, and Argentina. Net sales of Vantas® were \$17.5 million, \$19.0 million and \$17.0 million in 2012, 2011 and 2010, respectively, primarily in the U.S.

**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 \$27.1 million, \$21.5 million and \$14.1 million in 2012, 2011 and 2010, 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 \$30.6 million and \$14.9 million in 2012 and 2011, respectively.

**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 2012.

## Qualitest

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

Generic Pharmaceutical Products	Active Ingredient(s)	Status
Endocet®	oxycodone hydrochloride and acetaminophen	Marketed
Morphine Sulfate ER	morphine sulfate	Marketed
Hydrocodone and acetaminophen	hydrocodone and acetaminophen	Marketed
Oxycodone and acetaminophen	oxycodone and acetaminophen	Marketed
Carisoprodol	carisoprodol	Marketed
Hydrocortisone	hydrocortisone	Marketed
Promethazine	promethazine	Marketed
Multi Vitamins	multi vitamins	Marketed
Acetaminophen and codeine	acetaminophen and codeine	Marketed
Spiroinolactone	spiroinolactone	Marketed
Isosorbide Mononitrate ER	isosorbide	Marketed
Triamcinolone	triamcinolone	Marketed
Phenobarbital	phenobarbital	Marketed
Methylprednisolone	methylprednisolone	Marketed
Lisinopril	lisinopril	Marketed

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

Our generic products are sold across multiple therapeutic categories, with pain management being the largest, and in various dosage forms including solids, semi-solids and liquids. Qualitest's top 15 products provided revenues of \$373.1 million, \$335.6 million and \$122.7 million in 2012, 2011 and 2010, 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 XPST™	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 since our June 2011 acquisition of AMS accounted for approximately 4% of our total revenues in 2012 compared to 2% in 2011.

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



revenue since our June 2011 acquisition of AMS accounted for approximately 3% of our total revenues in 2012 compared to 2% in 2011.

**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 since our June 2011 acquisition of AMS accounted for approximately 3% of our total revenues in 2012 compared to 2% in 2011.

**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 since our June 2011 acquisition of AMS accounted for approximately 1% of our total revenues in both 2012 and 2011.

**Monarc® Subfascial Hammock.** The Monarc® subfascial hammock is our leading device to treat female stress urinary incontinence, which generally results from a weakening of the tissue surrounding the bladder and urethra which can be a result of pregnancy, childbirth and aging. It incorporates unique helical needles to place a self-fixating, sub-fascial hammock through the obturator foramin. Monarc® revenue since our June 2011 acquisition of AMS accounted for approximately 1% of our total revenues in both 2012 and 2011.

## 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, oncology, and endocrinology. A selection of the Company's pipeline products are as follows:

**Aveed™.** Aveed™ is a novel, long-acting injectable testosterone preparation for the treatment of male hypogonadism. Male hypogonadism is an increasingly recognized medical condition characterized by a reduced or absent secretion of testosterone from the testes. Reduced testosterone levels can lead to health problems and significantly impair quality of life. Common effects of hypogonadism include decreased sexual desire, erectile dysfunction, muscle loss and weakness, depression, and an increased risk of osteoporosis. If approved, Aveed™ would be the first long-acting injectable testosterone preparation available in the U.S. in the growing market for testosterone replacement therapies. The U.S. rights to Aveed™ were acquired from Schering AG, Germany, in 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, the Company submitted a complete response to the FDA after conducting an extensive review of all clinical study and post-marketing data. The FDA has set a tentative PDUFA date for May 2013, the outcome of which could have a material impact on (1) management's assessment of the overall probability of approval, (2) the timing of such approval, (3) the targeted indication or patient population and (4) the likelihood of additional clinical trials.

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

**ODM-201.** In January 2011 the Company signed a discovery, development and commercialization agreement with Orion Corporation. ODM-201, the most advanced compound in the alliance, is an androgen receptor antagonist being developed for the treatment of castrate resistant prostate cancer. It is currently in Phase II clinical testing.

**EN3342.** EN3342 is a soft, flexible six-month polyurethane implant designed to deliver risperidone for the maintenance treatment of schizophrenia in adults. It is currently in Phase I/II clinical testing.

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

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

### **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 40 abbreviated new drug applications (ANDAs) under active FDA review.

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

### **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 enhancements to our minimally invasive sling for mild to moderate incontinence in men, a urology drug delivery device, an adjustable tensioning sling for female incontinence 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 Watson Pharmaceuticals, Inc., vary depending on product category, dosage strength and drug-delivery systems.

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

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

The Company is aware of certain competitive activities involving Lidoderm<sup>®</sup>, Opana<sup>®</sup> ER and Frova<sup>®</sup>. For a full description of these competitive activities, including the litigation related to Paragraph IV Certification Notices, see Note 15. 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 Watson, 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 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.

### **HealthTronics**

The lithotripsy services market is highly fragmented and competitive. We compete with other companies, private facilities and medical centers that offer lithotripsy machines and services, including smaller regional and local lithotripsy service providers. Additionally, while we believe that lithotripsy has emerged as the superior treatment for kidney stone disease, we also compete with hospitals, clinics and individual medical practitioners that offer alternative treatments for kidney stones.

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

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

### **Seasonality**

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

### **Major Customers**

We primarily sell our branded pharmaceuticals and generics 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:

	2012	2011	2010
Cardinal Health, Inc. ....	23%	25%	33%
McKesson Corporation .....	25%	24%	28%
AmerisourceBergen Corporation .....	11%	13%	15%

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 what are referred to as distribution service agreements pursuant to which the wholesale distributors provide the pharmaceutical manufacturers with specific services, including the provision of periodic retail demand information and current inventory levels and other information. To date we have entered into six such agreements.

None of our AMS or HealthTronics customers or distributors accounted for 10% or more of our total revenues during 2012, 2011 and 2010.

### Patents, Trademarks, Licenses and Proprietary Property

As of February 20, 2013, we held approximately: 435 U.S. issued patents, 384 U.S. patent applications pending, 814 foreign issued patents, and 599 foreign patent applications pending. In addition, as of February 20, 2013, 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, 2013 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 <sup>®</sup>	Exclusive License	USA
5,616,603	April 1, 2014	Frova <sup>®</sup>	Exclusive License	USA
5,637,611	June 10, 2014	Frova <sup>®</sup>	Exclusive License	USA
5,827,871	October 27, 2015	Frova <sup>®</sup>	Exclusive License	USA
5,962,501	December 16, 2013	Frova <sup>®</sup>	Exclusive License	USA
5,827,529	October 27, 2015	Lidoderm <sup>®</sup>	Exclusive License	USA
5,741,510	March 30, 2014	Lidoderm <sup>®</sup>	Exclusive License	USA
5,662,933	September 9, 2013	Opana <sup>®</sup> ER	Owned	USA
5,958,456	September 9, 2013	Opana <sup>®</sup> ER	Owned	USA
7,276,250	February 4, 2023	Opana <sup>®</sup> ER	Owned	USA
7,851,482	July 10, 2029	Opana <sup>®</sup> ER	Exclusive License	USA
8,075,872	November 20, 2023	Opana <sup>®</sup> ER	Exclusive License	USA
8,114,383	August 5, 2024	Opana <sup>®</sup> ER	Exclusive License	USA
8,309,060	November 20, 2023	Opana <sup>®</sup> ER	Exclusive License	USA
8,309,122	February 4, 2023	Opana <sup>®</sup> ER	Owned	USA
8,329,216	February 4, 2023	Opana <sup>®</sup> ER	Owned	USA
2131647	September 8, 2014	Opana <sup>®</sup> ER	Owned	Canada
2208230	November 4, 2016	Opana <sup>®</sup> ER	Owned	Canada
2251816	April 18, 2017	Opana <sup>®</sup> ER	Owned	Canada
8,062,652	June 16, 2026	Supprelin <sup>®</sup> LA	Owned	USA
8,062,209	December 2, 2023	AMS 700 <sup>®</sup>	Owned	USA
7,946,975	February 21, 2030	AMS 700 <sup>®</sup>	Owned	USA
6,554,824	July 24, 2021	GreenLight <sup>™</sup> Laser	Owned	USA
6,986,764	July 24, 2021	GreenLight <sup>™</sup> Laser	Owned	USA
7,070,556	November 9, 2023	Monarc <sup>®</sup>	Owned	USA
7,347,812	March 17, 2026	Monarc <sup>®</sup>	Owned	USA
7,988,615	November 9, 2023	Monarc <sup>®</sup>	Owned	USA
7,357,773	January 5, 2026	Monarc <sup>®</sup>	Owned	USA
6,911,003	January 23, 2023	Monarc <sup>®</sup>	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 products and certain generic products, such as Endocet<sup>®</sup> and Endodan<sup>®</sup>, are sold under trademarks. To achieve a competitive position, we rely on trade secrets, non-patented proprietary know-how and continuing technological innovation, where patent protection is not believed to be appropriate or attainable. In addition, as outlined above, we have a number of patent licenses from third parties, some of which may be important to our business. See Note 7. License and Collaboration Agreements in the Consolidated Financial Statements, included in Part IV, Item 15. of this 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 15. 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, 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 December 2003, Congress passed measures intended to speed the process by which generic versions of brand name drugs are introduced to the market. Among other things, these measures are intended to limit regulatory delays of generic drug applications and penalize companies that reach certain agreements with makers of brand name drugs that delay the introduction of generic versions. The Federal Trade Commission (FTC) has expressed its concern with agreements between brand and generic drug companies that may delay the introduction of a

generic drug to the market, and the U.S. Supreme Court will review a case involving such agreements during the 2013 Supreme Court term. These changes and the results of the Supreme Court review could result in increased generic competition for our branded and generic products and could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, on September 27, 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007 (FDAAA) that re-authorized requirements for testing drug products in children, where appropriate, which were made permanent by the Food and Drug Administration Safety and Innovation Act, which was signed into law in July 2012 and is further described below. The FDAAA also included new requirements for post-approval studies or clinical trials of drugs that are known to or that signal the potential to pose serious safety risks, and authority to require risk evaluation and mitigation strategies, or REMS to confirm that the benefits of a drug outweigh the risks of the drug, all of which may increase the time and cost necessary for new drug development as well as the cost of maintaining regulatory compliance for a marketed product.

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 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. 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 ongoing policy debate on the use of opioid medications, at the hearing, 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. While it is not presently known what, if any actions the FDA may take, as a result of the Citizen Petition or the public hearing, if the FDA requires changes to the indications for use or duration of use in the labeling of opioid drug products, it could have a material adverse effect 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. A New Drug Application (NDA) or Biologics License Application (BLA) is a filing submitted to the FDA to obtain approval of new chemical entities and other innovations for which thorough applied research is required to demonstrate safety and effectiveness in use. The process generally involves:

- Completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's Good Laboratory Practice, or GLP, regulations;
- Submission to the FDA of an Investigational New Drug (IND) application for human clinical testing, which must become effective before human clinical trials may begin in the U.S.;
- Approval by an independent institutional review board, or IRB, before each trial may be initiated, and continuing review during the trial;
- Performance of human clinical trials, including adequate and well-controlled clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each intended use;
- Submission of an NDA or BLA to the FDA;
- Satisfactory completion of an FDA pre-approval inspection of the product's manufacturing processes and facility or facilities to assess compliance with the FDA's current Good Manufacturing Practice (cGMP) regulations, and/or review of the Chemistry, Manufacturing, and Controls 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, metabolism, excretion and other elements of clinical pharmacology.
- Phase II typically involves studies in a small sample of the intended patient population to assess the efficacy of the compound for a specific indication, to determine dose tolerance and the optimal dose range as well as to gather additional information relating to safety and potential adverse effects.
- Phase III trials are undertaken to further evaluate clinical safety and efficacy in an expanded patient population at typically dispersed study sites, in order to determine the overall risk-benefit ratio of the compound and to provide an adequate basis for product labeling.

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

On January 4, 2011, the FDA published a final rule to amend its regulations that govern the informed consent process for clinical trials of products regulated by the FDA. The final rule requires that all informed consent documents for applicable drug and medical device clinical trials initiated on or after March 7, 2012, inform individual clinical trial subjects that a description of the clinical trial in which they are participating will be published in the National Institutes of Health/National Library of Medicine [clinicaltrials.gov](http://clinicaltrials.gov) website. The rule became effective March 7, 2011.

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 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 FDA's Web site to healthcare professionals and patients.

On February 6, 2009, the FDA sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a REMS to address whether the benefits of these products continue to outweigh the risks. The FDA has authority to require a REMS under the FDAAA when necessary to prove that the benefits of a drug outweigh the risks. The affected opioid drugs include brand name and generic products. Three products sold by Endo were included in the list of affected opioid drugs: Opana<sup>®</sup> ER, morphine sulfate ER and oxycodone ER. On December 9, 2011, the FDA approved our interim REMS for Opana<sup>®</sup> ER, which was subsequently superseded by 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 mg over a three-year phase-out period. At the end of that period, the FDA could seek to withdraw those prescription combination drug products that contain more than 325 mg of acetaminophen from the market, citing its authority to initiate withdrawal proceedings under the FFDCA. Among the products impacted by the FDA's action are three Endo combination drug pain relief products: Percocet<sup>®</sup>, Endocet<sup>®</sup> and Zydone<sup>®</sup>; and the Qualitest Pharmaceuticals combination drug pain relief products: butalbital/acetaminophen/caffeine, hydrocodone/acetaminophen and oxycodone/acetaminophen. In addition, under additional authority granted to the FDA by the FDAAA, the FDA notified holders of approved NDAs and ANDAs that they would be required to modify the labeling of prescription acetaminophen drug products to include a Boxed Warning to include new safety information about acetaminophen and liver toxicity, and a Warning on the potential for allergic reactions. The Company has implemented several measures to comply with the FDA action. 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 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 Federal Food Drug and Cosmetic Act provides a procedure for an applicant to seek approval of a drug product for which safety and/or efficacy has been established through preclinical and clinical data that the applicant does not have proprietary rights to use. Under that section, despite not having a right of reference, an applicant can cite to studies containing such clinical data to prove safety or efficacy, along with any additional clinical data necessary to support the application. Section 505(b)(2) NDAs are subject to patent certification and notification requirements that are similar to those that are required for ANDAs (refer to next section). Approval of Section 505(b)(2) NDAs, like ANDAs, also may be delayed by market exclusivity that covers the reference product. However, despite the similarities, Section 505(b)(2) applications are not permitted when an applicant could submit and obtain approval of an ANDA.

### ***ANDA Process***

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

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

The timing of final FDA approval of ANDA applications depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and whether the manufacturer of the reference listed drug is entitled to one or more statutory exclusivity periods, during which the FDA is prohibited from approving generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date. For example, under the Best Pharmaceuticals for Children Act, if a manufacturer receives and accepts a written request from the FDA to conduct studies on the safety and efficacy of its product in children, the exclusivity of a product is extended by six months past the patent or regulatory expiration date if the manufacturer completes and submits the results of the studies, a so-called pediatric 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 bases upon which the patents are challenged, and (2) the holder of the listed drug does not sue the later applicant for patent infringement within 45 days of receipt of notice. Under the current law, if an infringement suit is filed, the FDA may not approve the later application until the earliest of: 30 months after submission; entry of an appellate court judgment holding the patent invalid, unenforceable or not infringed; such time as the court may order; or the patent expires.

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



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

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

### **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, Inc. and HealthTronics, Inc. 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.

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

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

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

On January 19, 2011, the FDA's Center for Devices and Radiological Health (CDRH) unveiled a plan of 25 action items it 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 through 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 Institute of Medicine (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, whether to develop guidance on a new class of devices, called "class IIb," for which additional data would be necessary to support a 510(k) determination.

On July 29, 2011, the IOM released its report, which recommended that the FDA move towards replacing the current 510(k) review process, which is based on "substantial equivalence" determinations, with a new "integrated premarket and post-market regulatory framework" that provides a reasonable assurance of safety and 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, 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 pre-submission meetings for investigation device applications (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. In addition, the FDA issued a proposed rule that would require a unique identifier on distributed devices for tracking purposes, and a final rule that revises and expands medical device registration and listing requirements. 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. These 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, and for the marketing of medical 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 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 FDCA. To assure compliance requires a continuous commitment of time, money and effort in all operational areas.

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

The FDA also conducts periodic inspections of drug and device facilities to assess 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.

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 manufacturing facility in Huntsville, Alabama, our subsidiary, Qualitest Pharmaceuticals, received a Form 483 Notice of Inspectional Observations dated December 7, 2011, listing six observations of the inspectors. The observations focused on product and process control procedures, product release specifications and building maintenance. A comprehensive response was provided to the FDA on December 28, 2011, addressing the issues in each of the observations, corrective actions, and remediation plans. On March 13, 2012, Qualitest Pharmaceuticals received a response from the FDA acknowledging receipt of our December 28, 2011 response and, except in connection with two minor observations where the FDA indicated that the changes seem adequate but would be confirmed at a subsequent inspection, confirming our proposed corrective actions and remediation plans.

In February 2013, the FDA conducted an inspection of AMS, Inc.'s Minnetonka, Minnesota facility, and, following such inspection, issued two observations on a Form 483. Both observations relate to timeliness of complaint handling procedures. AMS, Inc. will provide a written response to the FDA no later than March 1, 2013 (within fifteen working days of the issuance of the Form 483, as recommended by the FDA) detailing proposed corrective actions, and has initiated efforts and redirected resources to address the FDA's observations. It is important to note that neither of the observations identified a specific issue regarding the clinical or field performance of any particular device. The Minnetonka, Minnesota facility will continue to manufacture products while AMS, Inc. 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 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. The FDA has also stated that it will issue guidance on the use of social media in advertising or promoting a product. 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, and failure to abide by these regulations can result in compliance or enforcement action, including the issuance of warning letters directing entities to correct deviations from FDA regulations and civil and criminal investigations and prosecutions. These activities could have a material adverse effect on our business, results of operations, financial condition and cash flows.

#### ***Drug Enforcement Administration***

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

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

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

launches, or could cause trade inventory disruptions for those products that have already been launched, which could have a material adverse effect on our business, financial position, results of operations and cash flows.

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

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

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

### ***Clinical Laboratory Improvement Amendments of 1988 and State Regulation***

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

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

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

### ***Government Benefit Programs***

Statutory and regulatory requirements for Medicaid, Medicare, TRICARE and other government healthcare programs govern provider reimbursement levels, including requiring that all pharmaceutical companies pay rebates to individual states based on a percentage of their net sales arising from Medicaid program-reimbursed products. In addition, under a final rule promulgated by the 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 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 as a whole and consequently, also for the Company.

From time to time, legislative changes are made to government healthcare programs that impact our business. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003 created 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 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 percent 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 percent by 2020. The law provided that if a state did not expand its Medicaid program eligibility to 133 percent, 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 will 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 are expected to improve patients' ability to obtain and maintain health insurance. Such measures include: the elimination of lifetime caps; no rescission of policies; and no denial of coverage due to preexisting conditions. The expansion of healthcare insurance and these additional market reforms should result in greater access to the Company's products.

Our estimate of the overall impact of healthcare reform reflects a number of uncertainties. However, we believe that the impact to our business will be largely attributable to changes in the Medicare Part D Coverage Gap, the imposition of an annual fee on branded prescription pharmaceutical manufacturers, and increased rebates in the Medicaid Fee-For-Service Program and Medicaid Managed Care plans. There are a number of other provisions in the legislation that collectively are expected to have a small impact, including originator average manufacturers' price (AMP) for new formulations, an excise tax on manufactured or imported medical devices offered for sale in the U.S., and the expansion of 340B pricing to new entities. Certain elements of healthcare reform reduced total revenues by approximately \$40 million in 2011 and have had and will continue to have a similar impact in future years.

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. However, Congress was able to avert sequestration when it passed the American Taxpayer Relief Act of 2012 (H.R. 8). This law delays the sequestration from January 2, 2013 until March 1, 2013. The automatic spending cuts that would occur as a result of the sequestration process are unpalatable for many lawmakers and Congress may use the 2013 session to consider repealing the cuts by finding savings in other programs, such as Medicaid.

### ***Healthcare Fraud and Abuse Laws***

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

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

value. In addition, the recently enacted 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.

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 of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claim laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program.

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

Also, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several new federal crimes, including health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully

executing a scheme to defraud any health care benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

In addition, some states have enacted compliance and reporting requirements aimed at drug and device manufacturers. For example, under California law, pharmaceutical companies must adopt a comprehensive compliance program that is in accordance with both the April 2003 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 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 Sunshine Law, which is part of the healthcare reform law, imposes federal “sunshine” provisions, with annual reporting anticipated 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.

Finally, our HealthTronics, Inc. subsidiary is subject to the federal self-referral prohibition commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain “designated health services” (DHS) reimbursed by Medicare if the physician (or a member of the physician’s immediate family) has a financial relationship with the entity, unless the relationship meets an exception to the prohibition, and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral. These restrictions generally prohibit us from billing for any DHS furnished by HealthTronics, Inc. to a Medicare beneficiary, when the physician ordering the DHS, or any member of the physician’s immediate family, has an investment interest in, or compensation arrangement with, HealthTronics, Inc., unless the arrangement meets an exception to the prohibition. Any person who presents or causes to be presented a claim to the Medicare program in violation of the Stark Law is subject to civil monetary penalties of up to \$15,000 per bill submission, an assessment of up to three times the amount of claims, and possible exclusion from participation in federal governmental payor programs. Many states also have self-referral prohibitions which, unlike the Stark Law, are not limited to Medicare patient referrals. While we have attempted to comply with the Stark Law and similar state laws, it is possible that some of our financial arrangements with physicians could be subject to regulatory scrutiny at some point in the future, and we cannot provide an assurance that we will be found to be in compliance with these laws following any such regulatory review.

#### ***Healthcare Privacy and Security Laws***

Our HealthTronics, Inc. subsidiary is a “covered entity” subject to the administrative simplification section of HIPAA, the Health Information Technology for Economic and Clinical Health Act (HITECH Act) and their implementing regulations (collectively, HIPAA), which establish, among other things, standards for the privacy, security and notification of the security breach of certain individually identifiable health information (protected health information). To the extent that one of our other business units is a “business associate” because it receives protected health information from a health care provider, health plan or other covered entity to provide a service on behalf of the covered entity, the business unit is also directly subject to the privacy, security and breach notification standards and the HIPAA civil and criminal enforcement scheme. As a business associate of a covered entity, we also have potential contractual liability for privacy, security or breach notification standard violations to the covered entity under a business associate agreement. HIPAA also limits our ability to use protected health information for certain marketing initiatives and receive

payments from third parties for marketing initiatives involving protected health information. The HITECH Act, adopted in 2009 as part of the American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce 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 15. 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 7. 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, 2013, we have 4,629 employees, of which 423 are engaged in research and development and regulatory work, 1,251 in sales and marketing, 1,247 in manufacturing, 396 in quality assurance and 1,312 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, 2013 regarding each of our current executive officers:

Name	Age	Position and Offices
David P. Holveck.....	67	President and Chief Executive Officer and Director
Julie H. McHugh.....	48	Chief Operating Officer
Alan G. Levin.....	50	Executive Vice President, Chief Financial Officer
Ivan P. Gergel, M.D.....	52	Executive Vice President, Research and Development and Chief Scientific Officer
Caroline B. Manogue.....	44	Executive Vice President, Chief Legal Officer and Secretary
Camille Farhat.....	43	President of American Medical Systems



## **Biographies**

Our executive officers are briefly described below:

DAVID P. HOLVECK, 67, is President, Chief Executive Officer and a Director of Endo. Prior to joining Endo in April 2008, Mr. Holveck was President of Johnson & Johnson Development Corporation and Vice President, Corporate Development of Johnson & Johnson, a diversified healthcare company, since 2004. Mr. Holveck joined Johnson & Johnson as a Company Group Chairman in 1999, following the acquisition of Centocor, Inc., a biotechnology company, by Johnson & Johnson. Mr. Holveck was Chief Executive Officer of Centocor, Inc. at the time of the acquisition. Mr. Holveck joined Centocor in 1983 and progressed through various executive positions. In 1992, he assumed the role of President and Chief Operating Officer and later that year was named President and Chief Executive Officer. Prior to joining Centocor, he had held positions at General Electric Company, Corning Glass Works and Abbott Laboratories. Mr. Holveck is a member of the Board of Trustees for The Fund for West Chester University, as well as the Board of Directors of the Pharmaceutical Research & Manufacturers of America (PhRMA), the University City Science Center and the Kimmel Center.

On December 12, 2012, the Company announced that Mr. Holveck will retire in 2013 as President and Chief Executive Officer. On February 25, 2013, the Company announced the appointment of Mr. Rajiv De Silva to the position of President and Chief Executive Officer of the Registrant, effective March 18, 2013, which will be the effective date of Mr. Holveck's retirement. Mr. De Silva will also be appointed to the Board effective March 18, 2013, which is the effective date of Mr. Holveck's resignation from the Board.

JULIE H. MCHUGH, 48, is Chief Operating Officer of Endo Pharmaceuticals. Prior to joining Endo, Ms. McHugh was the CEO of Nora Therapeutics, Inc., a venture capital-backed biotech company focused on the treatment of infertility disorders. Prior to joining Nora Therapeutics, she was Company Group Chairman for Johnson & Johnson's Worldwide Virology Business Unit, which included oversight of a R&D portfolio including compounds for HIV, Hepatitis C, and Tuberculosis. Prior to her role as Company Group Chairman, Ms. McHugh was President of Centocor, Inc. a J&J subsidiary. Ms. McHugh received a Bachelor of Science degree from Pennsylvania State University and her masters of business administration degree from St. Joseph's University. She currently serves on the Board of Directors of ViroPharma Inc., the Board of Directors of the Biotechnology Organization (BIO), the Board of Directors of the New England Healthcare Institute (NEHI), the Board of Visitors for the Smeal College of Business of the Pennsylvania State University, and the Board of Directors for the Nathaniel Adamczyk Foundation. She is a past Chairman of the Board of Directors of the Pennsylvania Biotechnology Industry Organization.

ALAN G. LEVIN, 50, was appointed Executive Vice President and Chief Financial Officer in June 2009. Prior to joining Endo, Mr. Levin worked with Texas Pacific Group, a leading private equity firm, and one of their start-up investments in Emerging Markets. Before that, he was Senior Vice President & Chief Financial Officer of Pfizer, Inc. where he worked for 20 years in a variety of executive positions of increasing responsibility, including Treasurer and Senior Vice President of Finance & Strategic Management for the company's research and development organization. He received a bachelor's degree from Princeton University and a master's degree from New York University's Stern School of Business. Mr. Levin is a certified public accountant. He is a member of the Advisory Board of Celtic Therapeutics, a private equity fund.

IVAN P. GERGEL, M.D., 52, was appointed Executive Vice President, Research & Development and Chief Scientific Officer in April 2008. Prior to joining Endo, Dr. Gergel was Senior Vice President of Scientific Affairs and President of the Forest Research Institute of Forest Laboratories Inc. Prior to that, Dr. Gergel served as Vice President and Chief Medical Officer at Forest and Executive Vice President of the Forest Research Institute. He joined Forest in 1998 as Executive Director of Clinical Research following nine years at SmithKline Beecham, and was named Vice President of Clinical Development and Clinical Affairs in 1999. Dr. Gergel received his M.D. from the Royal Free Medical School of the University of London and an MBA from the Wharton School. Dr. Gergel is a member of the Board of Directors of Pennsylvania BIO, a member of PhRMA's Scientific and Regulatory Executive Committee, as well as a member of the Board of Directors of the PhRMA Foundation.

CAROLINE B. MANOGUE, 44, has served as Endo's Executive Vice President, Chief Legal Officer and Secretary since 2004. Prior to joining Endo in 2000 as Endo's Senior Vice President, General Counsel and Secretary, she practiced law in the New York office of the law firm Skadden, Arps, Slate, Meagher & Flom LLP, where she specialized in mergers & acquisitions, securities and corporate law. At Endo, she is responsible for all aspects of the company's legal function, including securities law, litigation, government affairs, intellectual property and commercial law, as well as overseeing compliance with current laws and existing pharmaceutical company guidelines relating to, among other things, clinical, sales and marketing practices. In her capacity as Secretary, she is responsible for corporate governance matters and reports directly to the Board of Directors. Ms. Manogue received her J.D. from Fordham Law School and her B.A. cum laude from Middlebury College. She is the 2011-2012 Chairperson of the PhRMA Law Section, a member of the Board of Trustees of the Healthcare Institute of New Jersey (HINJ) and a member of HINJ's Finance and Audit Committee.

CAMILLE FARHAT, 43, joined Endo in September 2012 as President of AMS, Inc., a world leader in developing and delivering medical devices and procedures to treat patients with pelvic health conditions. 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](http://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 Watson Pharmaceuticals, Inc., vary depending on product category, product dosage strength and drug-delivery systems. It is possible that developments by our competitors will make our products or technologies uncompetitive or obsolete. Because we are smaller than some of our national competitors in the branded pharmaceuticals sector, we may lack the financial and other resources needed to maintain our profit margins and market share in this sector.

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

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

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

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

Under the Hatch-Waxman Act, the FDA can approve an ANDA for a generic 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<sup>®</sup> and both the original and crush-resistant formulations of Opana<sup>®</sup> 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<sup>®</sup>, Opana<sup>®</sup> ER and Voltaren<sup>®</sup> Gel (for which our marketing exclusivity rights expired in October 2010), as well as the fact that multiple ANDAs have been filed for Lidoderm<sup>®</sup> and both the original and crush-resistant formulations of Opana<sup>®</sup> 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<sup>®</sup> 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 15. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

Lidoderm<sup>®</sup> accounted for 31% of our total revenues in 2012, 30% in 2011 and 46% in 2010. Opana<sup>®</sup> ER accounted for 10% of our total revenues in 2012, 14% in 2011 and 14% in 2010. Voltaren<sup>®</sup> Gel accounted for 4% of our total revenues in 2012, 5% in 2011 and 6% in 2010. 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. Upon a launch of a generic version of Lidoderm<sup>®</sup>, which we now expect will occur in September 2013 pursuant to our settlement agreement with Watson, our revenues from Lidoderm<sup>®</sup> would decrease significantly, and these revenues could decrease further should one or more additional generic versions launch. Impax's recently launched generic version of the non-crush resistant formulation Opana<sup>®</sup> ER adversely affected our results of operations since its launch on 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<sup>®</sup> ER, our revenues from Opana<sup>®</sup> ER could decrease further. Similarly, the launch of a generic version of Voltaren<sup>®</sup> 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 products 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 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, 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.

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, Inc. 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 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 issued an order to consolidate and transfer certain of these claims filed against AMS, Inc. 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 pelvic organ prolapse and stress urinary incontinence. We have not yet received a subpoena relating to this investigation, and 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 three to four reportable segments.

	2012		2011		2010	
	\$	%	\$	%	\$	%
Lidoderm®.....	\$ 947,680	31	\$ 825,181	30	\$ 782,609	46
Opana® ER.....	299,287	10	384,339	14	239,864	14
Voltaren® Gel.....	117,563	4	142,701	5	104,941	6
Percocet®.....	103,406	3	104,600	4	121,347	7
Frova®.....	61,341	2	58,180	2	59,299	3
Supprelin® LA.....	57,416	2	50,115	2	46,910	3
Other brands.....	91,291	3	92,651	3	112,602	7
Total Endo Pharmaceuticals*.....	\$ 1,677,984	55	\$ 1,657,767	61	\$ 1,467,572	86
Qualitest.....	633,265	21	566,854	21	146,513	9
AMS.....	504,487	17	300,299	11	—	—
HealthTronics.....	211,627	7	205,201	8	102,144	6
Total revenues*.....	\$ 3,027,363	100	\$ 2,730,121	100	\$ 1,716,229	100

\* Percentages may not add due to rounding.

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

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

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

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

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

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

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

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

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

Companies may not promote drugs or medical devices for “off-label” uses – that is, uses that are not described in the product’s labeling and that differ from those that were approved or cleared by the FDA. Under what is known as the “practice of medicine,” physicians and other healthcare practitioners may prescribe drug products and use medical devices for off-label or unapproved uses, and such uses are common across some medical specialties. Although the FDA does not regulate a physician’s choice of medications, treatments or product uses, the FDCA, and FDA regulations significantly restrict permissible communications on the subject of off-label uses of drug products and medical devices by pharmaceutical and medical device companies. The FDA, FTC, OIG of the Department of HHS, the Department of Justice (DOJ) and various state Attorneys General actively enforce laws and regulations that prohibit the promotion of off-label uses. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil fines, criminal fines and penalties, civil damages and exclusion from federal funded healthcare programs such as Medicare and Medicaid as well as potential liability under the federal False Claims Act and state false claims acts. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payors or other persons allegedly harmed by such conduct.

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

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

Goodwill and other intangibles represent a significant portion of our assets. As of December 31, 2012 and 2011, goodwill and other intangibles comprised approximately 63% and 69%, respectively, of our total assets. Goodwill and other intangible assets are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually. The procedures and assumptions used in our goodwill and indefinite-lived intangible assets impairment testing, and the results of our testing, are discussed in Part II, Item 7. of this report "Management's Discussion and Analysis of Financial Condition and Results of Operations" under the captions "CRITICAL ACCOUNTING ESTIMATES" and "RESULTS OF OPERATIONS".

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

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

Product promotion educational activities, support of continuing medical education programs, and other interactions with health care professionals must be conducted in a manner consistent with the FDA regulations and the Anti-Kickback Statute (described below). The FDA has stated that it will provide further guidance to industry on advertising and promotion regulation. In this regard, 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. These and other statements of the FDA interpreting the FFDCRA and the FDA's regulatory authority may place further limits and restrictions on the advertising of our products. Although we endeavor to follow the applicable requirements, should it be determined that we have not appropriately followed the requirements, the government may initiate an action against us which may result in significant liability, including administrative, civil and criminal sanctions. Such penalties could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, management's attention could be diverted and our reputation could be damaged.

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

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

Also, our HealthTronics subsidiary is subject to the federal self-referral prohibition commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain "designated health services" (DHS), reimbursed by Medicare if the physician (or a member of the physician's immediate family) has a financial relationship with the entity, unless the relationship meets an exception to the prohibition, and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral. These restrictions generally prohibit us from billing for any DHS furnished by HealthTronics, Inc. to a Medicare beneficiary, when the physician ordering the DHS, or any member of the physician's immediate family, has an investment interest in, or compensation arrangement with HealthTronics, Inc., unless the arrangement meets an exception to the prohibition. Any person who presents or causes to be presented a claim to the Medicare program in violation of the Stark Law is subject to civil monetary penalties of up to \$15,000 per bill submission, an assessment of up to three times the amount claimed, and possible exclusion from participation in federal governmental payor programs. Many states also have self-referral prohibitions which, unlike the Stark Law, are not limited to Medicare patient referrals. While we have attempted to comply with the Stark Law and similar state laws, it is possible that some of our financial arrangements with physicians could be subject to regulatory scrutiny at some point in the future, and we cannot assure you that we will be found to be in compliance with these laws following any such regulatory review.

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

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

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

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

Many of our core products contain narcotic ingredients. Misuse or abuse of such drugs can lead to physical or other harm. For example, in the past, reportedly widespread misuse or abuse of OxyContin<sup>®</sup>, a product of Purdue Pharma L.P., or Purdue, containing the narcotic oxycodone, resulted in the strengthening of warnings on its labeling. In addition, we believe that Purdue, the manufacturer of OxyContin<sup>®</sup>, faces or did face numerous lawsuits, including class action lawsuits, related to OxyContin<sup>®</sup> misuse or abuse. We may be subject to litigation similar to the OxyContin<sup>®</sup> suits related to any narcotic-containing product that we market.

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



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

Federal and state governmental authorities in the U.S., principally the FDA, impose substantial requirements on the development, manufacture, holding, labeling, marketing, advertising, promotion, distribution and sale of therapeutic pharmaceutical and medical device products through lengthy and detailed laboratory and clinical testing and other costly and time-consuming procedures. With respect to pharmaceutical products, the submission of an NDA or ANDA to the FDA with supporting clinical safety and efficacy data, for example, does not guarantee that the FDA will grant approval to market the product. Meeting the FDA's regulatory requirements to obtain approval to market a drug product typically takes many years, varies substantially based upon the type, complexity and novelty of the pharmaceutical product, and the application process is subject to uncertainty. The NDA approval process for a new product varies in time, generally requiring a minimum of 10 months, but could also take several years from the date of application. The timing for the ANDA approval process for generic products is difficult to estimate and can vary significantly. NDA approvals, if granted, may not include all uses (known as indications) for which a company may seek to market a product. The FDA may also require companies to conduct post-approval studies. The FDA also requires companies to undertake post-approval surveillance regarding their drug products and to report adverse events.

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

HealthTronics, Inc.'s currently commercialized products have received premarket clearance under Section 510(k) of the FDCA. AMS, Inc.'s currently commercialized products have received premarket clearance or PMA from the FDA under Section 510(k) or 515 of the FDCA.

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

In July 2011, FDA issued an update to the October 2008 Public Health Notification regarding mesh to further advise the public and the medical community of the potential complications associated with transvaginal placement of surgical mesh to treat POP and SUI. In this July 2011 update, the FDA maintained that adverse events are not rare, as previously reported, and questioned the relative effectiveness of transvaginal mesh as a treatment for POP as compared to non-mesh surgical repair. The July 2011 notification continued to encourage physicians to seek specialized training in mesh procedures, to consider and to advise their patients about the risks associated with these procedures and to be diligent in diagnosing and reporting complications. FDA also convened an advisory panel which met on September 8-9, 2011 to further address the safety and effectiveness of transvaginal surgical mesh used to treat POP and SUI. At the conclusion of the meetings, the advisory panel recommended reclassifying transvaginal mesh products used to treat POP to Class III devices (premarket approval) and recommended that manufacturers of these products be required to conduct additional post-market surveillance studies. The advisory panel recommended that transvaginal surgical mesh products used to treat SUI remain as Class II devices. Regarding retropubic and transobturator (TOT) slings, the advisory panel recommended that no additional post-market surveillance studies are necessary. Regarding mini-slings, the advisory panel recommended premarket study for new devices and additional post-market surveillance studies.

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, Inc., to conduct post-market safety studies and to monitor adverse event rates relating to the use of these products. AMS, Inc. received nineteen study orders, of which sixteen have been put on hold for various commercial reasons and three remain active. AMS, Inc. is continuing to work with the FDA to comply with these outstanding orders. In its order, the FDA also noted that it is still considering the recommendation of an advisory committee, made on September 9, 2011, that urogynecological surgical mesh for transvaginal repair of pelvic organ prolapse be reclassified from Class II to Class III.

Failure to comply with applicable regulatory requirements can result in, among other things, suspensions or withdrawals of approvals or clearances, seizures or recalls of products, injunctions against the manufacture, holding, distribution, marketing and sale of a product, and civil and criminal sanctions. Furthermore, changes in existing regulations or the adoption of new regulations could

prevent us from obtaining, or affect the timing of, future regulatory approvals or clearances. Meeting regulatory requirements and evolving government standards may delay marketing of our new products for a considerable period of time, impose costly procedures upon our activities and result in a competitive advantage to larger companies that compete against us.

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

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

Based on scientific developments, post-market experience, or other legislative or regulatory changes, the current FDA standards of review for approving new pharmaceutical and medical device products, or new indications or uses for approved or cleared products, are sometimes more stringent than those that were applied in the past. For example, in 2011, the FDA's Center for Devices and Radiological Health, or 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 through 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 Institute of Medicine, or 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, whether to develop guidance on a new class of devices, called "class IIb," for which additional data would be necessary to support a 510(k) determination.

On July 29, 2011, the IOM released its report, which recommended that the FDA move towards replacing the current 510(k) review process, which is based on "substantial equivalence" determinations, with a new "integrated premarket and post-market regulatory framework" that provides a reasonable assurance of safety and 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, 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 CDRH's evaluation of substantial equivalence in premarket notification 510(k) submissions, on pre-submission meetings for investigation device applications (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. In addition, the FDA issued a proposed rule that would require a unique identifier on distributed devices for tracking purposes, and a final rule that revises and expands medical device registration and listing requirements. 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. These 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, and for the marketing of medical devices. Further, some new or evolving review standards or conditions for approval or clearance were not applied to many established products currently on the market, including certain opioid products. As a result, the FDA does not have as extensive safety databases on these products as on some products developed more recently. Accordingly, we believe the FDA has expressed an intention to develop such databases for certain of these products, including many opioids.

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

More stringent controls of the levels of these impurities have been required and may continue to be required for FDA approval of drug products containing these impurities. Also, labeling revisions, formulation or manufacturing changes and/or product modifications may be necessary for new or existing products containing such impurities. The FDA's more stringent requirements together with any additional testing or remedial measures that may be necessary could result in increased costs for, or delays in,

obtaining approval for certain of our products in development. Although we do not believe that the FDA would seek to remove a currently marketed product from the market unless such mutagenic effects are believed to indicate a significant risk to patient health, we cannot make any such assurance.

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

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

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

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

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

Following a FDA inspection of the manufacturing facility in Huntsville, Alabama, our subsidiary, Qualitest Pharmaceuticals, received a Form 483 Notice of Inspectional Observations dated December 7, 2011, listing six observations of the inspectors. The observations focused on product and process control procedures, product release specifications and building maintenance. A comprehensive response was provided to the FDA on December 28, 2011, addressing the issues in each of the observations, corrective actions, and remediation plans. On March 13, 2012, Qualitest Pharmaceuticals received a response from the FDA acknowledging receipt of our December 28, 2011 response and, except in connection with two minor observations where the FDA indicated that the changes seem adequate but would be confirmed at a subsequent inspection, confirming our proposed corrective actions and remediation plans.

In February 2013, the FDA conducted an inspection of AMS, Inc.'s Minnetonka, Minnesota facility, and, following such inspection, issued two observations on a Form 483. Both observations relate to timeliness of complaint handling procedures. AMS, Inc. will provide a written response to the FDA no later than March 1, 2013 (within fifteen working days of the issuance of the Form 483, as recommended by the FDA) detailing proposed corrective actions, and has initiated efforts and redirected resources to address the FDA's observations. It is important to note that neither of the observations identified a specific issue regarding the clinical or field

performance of any particular device. The Minnetonka, Minnesota facility will continue to manufacture products while AMS, Inc. works with the FDA to address these observations.

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

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

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

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

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

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

Before obtaining regulatory approvals for the sale of any of our new product candidates, we must demonstrate through preclinical studies and clinical trials that the product is safe and effective for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product. Likewise, we may not be able to demonstrate through clinical trials that a product candidate's therapeutic benefits outweigh its risks. Even promising results from preclinical and early clinical studies do not



always accurately predict results in later, large scale trials. A failure to demonstrate safety and efficacy could or would result in our failure to obtain regulatory approvals.

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

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

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

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

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

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

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

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

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

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

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

Our future revenues and profitability will depend, to a significant extent, upon our ability to successfully commercialize new branded and generic pharmaceutical products and medical devices in a timely manner. As a result, we must continually develop, test and manufacture new products, and these new products must meet regulatory standards and receive requisite regulatory approvals. Products we are currently developing may or may not receive the regulatory approvals or clearances necessary for us to market them. Furthermore, the development and commercialization process is time-consuming and costly, and we cannot assure you that any of our products, if and when developed and approved, can be successfully commercialized. Some of our collaboration partners may decide to

make substantial changes to a product's formulation or design, may experience financial difficulties or have limited financial resources, any of which may delay the development, commercialization and/or marketing of new products. In addition, if a co-developer on a new product terminates our collaboration agreement or does not perform under the agreement, we may experience delays and, possibly, additional costs in developing and marketing that product.

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

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

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

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

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

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

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

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

The products for which we are developing generic versions may be claimed by their manufacturer to be protected by one or more patents. If we file an ANDA to seek FDA approval of our generic version of such a drug, we are required to certify that any

patent or patents listed as covering the approved listed drug are invalid, unenforceable or will not be infringed by our generic version. Similar certification requirements apply to new drug applications filed under Section 505(b)(2) of the FDCA, where we rely on information to which we do not have a right of reference. Once the FDA accepts our ANDA or Section 505(b)(2) NDA, we are required to notify the brand manufacturer of this fact. The brand manufacturer then has 45 days from the receipt of the notice in which to file a suit for patent infringement. If it does so, the FDA is generally prevented from granting approval of the ANDA or Section 505(b)(2) NDA until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in the generic's favor or expiration of the patent(s).

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

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

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

From time to time, state Medicaid programs review our products to assess whether such products should be subject to a prior authorization process, which processes vary state-by-state but generally require physicians prescribing the products to answer several questions prior to the product being dispensed. The institution of a prior authorization process may adversely impact the sales of the related product in the state and depending on the state, may adversely affect our business and results of operations. On February 20, 2008, in connection with its Clinical Drug Review Program, the Pharmacy and Therapeutics Committee of the New York State Department of Health reviewed our product Lidoderm<sup>®</sup> and recommended that it be subject to a prior authorization process. As a result, on July 31, 2008, the New York State Department of Health placed Lidoderm<sup>®</sup> in its Clinical Drug Review Program, which is a specific program within its prior authorization program. There can be no assurance that such a process, or the implementation thereof, in New York State or elsewhere would not have a material adverse effect on our business, financial condition, results of operations and cash flows.

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 2, 2013 which would result in across-the-board spending cuts to certain government programs, including Medicare, in order to meet the deficit reduction goal. Congress was able to avert sequestration when it passed the American Taxpayer Relief Act of 2012 (H.R. 8), which delays the sequestration from January 2, 2013 until March 1, 2013. The automatic spending cuts that would occur as a result of the sequestration process are unpalatable for many lawmakers and Congress may use the 2013 session to consider repealing the cuts by finding savings in other programs, such as Medicaid.

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

- the trend toward managed healthcare in the U.S.;
- the growth of organizations such as HMOs and managed care organizations;

- legislative proposals to reform healthcare and government insurance programs; and
- price controls and non-reimbursement of new and highly priced medicines for which the economic therapeutic rationales are not established.

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

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

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

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

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

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

We are subject to provisions that require us to enter into a Medicaid Drug Rebate Agreement and a 340B Pharmaceutical Pricing Agreement as a condition for having our products eligible for payment under Medicare Part B and Medicaid. We have entered into such agreements. In addition, we are required to report certain pricing information to the Centers for Medicare and Medicaid Services on a periodic basis to allow for accurate determination of rebates owed under the Medicaid Drug Rebate Agreement, ceiling prices under the 340B program and certain other government pricing arrangements, and reimbursement rates for certain drugs paid under Medicare Part B. On January 27, 2012, the Centers for Medicare and Medicaid Services issued a Proposed Rule to implement the Medicaid Drug Rebate provisions incorporated into the March 2010 healthcare reform law. The Proposed Rule has not been finalized yet, but we anticipate that if the Proposed Rule becomes final, it will require operational adjustments by the Company in order to maintain its compliance with applicable law. Changes included in the Proposed Rule that would revise how manufacturers are required



to calculate Average Manufacturer Price (AMP) and Best Price, if they are included in the Final Rule may affect the quarterly amounts that the Company owes to state Medicaid programs through the Medicaid Drug Rebate program.

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

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

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

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

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

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

	2012	2011	2010
Cardinal Health, Inc. ....	23%	25%	33%
McKesson Corporation .....	25%	24%	28%
AmerisourceBergen Corporation .....	11%	13%	15%

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

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

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

Because most of our products are manufactured by third parties, we have a limited ability to control the manufacturing process or costs related to this process. Increases in the prices we pay our manufacturers, interruptions in our supply of products or lapses in quality could adversely impact our margins, profitability and cash flows. We are reliant on our third party manufacturers to maintain the facilities at which they manufacture our products in compliance with FDA, DEA, state and local regulations. If they fail to maintain compliance with FDA, DEA or other critical regulations, they could be ordered to cease manufacturing, or product may be recalled, which would have a material adverse impact on our business, results of operations, financial condition and cash flows. For example, in December 2011, Novartis Consumer Health, Inc.'s Lincoln, Nebraska manufacturing facility was temporarily shut down to facilitate its implementation of certain manufacturing process improvements, resulting in short-term supply constraints for certain Endo analgesic products which had been manufactured at this facility prior to the shutdown. Additionally, if any facility that manufactures our products experiences a natural disaster, we could experience a material adverse impact on our business, results of operations, financial condition and cash flows. In addition to FDA and DEA regulation, violation of standards enforced by the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA) and their counterpart agencies at the state level, could slow down or curtail operations of third party manufacturers.

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

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

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

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

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

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

In November 2010, we acquired Qualitest Pharmaceuticals' pharmaceutical manufacturing facilities located in Huntsville, Alabama and Charlotte, North Carolina. The Qualitest Pharmaceuticals facilities currently manufacture many of the Qualitest Pharmaceuticals products that we acquired. In connection with the AMS, Inc. acquisition, we acquired AMS, Inc.'s manufacturing facilities in Minnesota and California, where many of AMS, Inc.'s products are made. In 2012, we began manufacturing in our facility in Ireland.

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

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

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

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

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

Property, product liability, directors' and officers' and general liability insurance represent significant costs to us. Since the events of September 11, 2001, and due to an increased focus on corporate governance in the U.S., and product liability lawsuits related to pharmaceuticals and medical devices, liability and other types of insurance have, in some instances, become more difficult and costly to obtain. As we continue to expand our portfolio of available products, we may experience an increase in the number of product liability claims against us. Moreover, we may be subject to claims that are not covered by insurance. In addition, products for which we currently have coverage may be excluded from coverage in the future. Certain claims may be subject to our self-insured retention, exceed our policy limits or relate to damages that are not covered by our policy. In addition, product liability coverage for certain pharmaceutical entities is becoming more expensive and increasingly difficult to obtain and, as a result, we may not be able to obtain the type and amount of coverage we desire or to maintain our current coverage. Unanticipated additional insurance costs could have a material adverse effect on our results of operations and cash flows. There can be no assurance that we will be able to maintain our existing insurance policies or obtain new policies in meaningful amounts or at a reasonable cost. Any failure to obtain or maintain

any necessary insurance coverage could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

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

**Our revenues and operating results may fluctuate in future periods and we may fail to meet expectations, which may cause the market value of the debt and equity securities issued by us to decline.**

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

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

The market prices for securities of healthcare companies in general have been highly volatile and may continue to be highly volatile in the future. For example, in 2012, our stock traded between \$25.49 and \$39.29 per share. The following factors, in addition to other risk factors described in this section, may cause the market value of our securities to fluctuate:

- FDA approval or disapproval of any of the drug or medical device applications we have submitted;
- the success or failure of our clinical trials;
- new data or new analyses of older data that raises potential safety or effectiveness issues concerning our approved products;
- product recalls;
- competitors announcing technological innovations or new commercial products;
- introduction of generic substitutes for our products, including the filing of ANDAs with respect to generic versions of our branded products;
- developments concerning our or others' proprietary rights, including patents;
- competitors' publicity regarding actual or potential products under development;
- regulatory developments in the U.S. and foreign countries, or announcements relating to these matters;
- period-to-period fluctuations in our financial results;
- new legislation in the U.S. relating to the development, sale or pricing of pharmaceuticals or medical devices;
- a determination by a regulatory agency that we are engaging or have engaged in inappropriate sales or marketing activities, including promoting the "off-label" use of our products;
- litigation; and
- economic and other external factors, including market speculation or disasters and other crises.

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

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

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

From time to time, studies or clinical trials on various aspects of pharmaceutical products are conducted by academics or others, including government agencies. The results of these studies or trials, when published, may have a dramatic effect on the market for the pharmaceutical product that is the subject of the study. The publication of negative results of studies – or clinical trials related to our products or the therapeutic areas in which our products compete – could adversely affect our sales, the prescription trends for our products and the reputation of our products. In the event of the publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our products compete, our business, financial condition, results of operations and cash flows



could be materially adversely affected. In addition, on September 27, 2007, Congress enacted requirements for the reporting of clinical trial information by expanding the type of clinical trials for which a sponsor or investigator of a drug, medical device or biological product clinical trial must register and provide results to the National Institutes of Health (NIH) for inclusion in the publicly-available Clinical Trial Registry database of clinical trials. It remains unclear what impact the publication of clinical research data will have for our products.

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

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

**If we are required to pay on unindemnified claims or if the indemnitors default on their obligations, the outcome of the Redux litigation could materially harm us.**

On September 15, 1997, Indevus (then known as Interneuron Pharmaceuticals, Inc.) announced a market withdrawal of its first commercial prescription product, the anti-obesity medication Redux (dexfenfluramine hydrochloride capsules C-IV), which had been launched in June 1996 by its licensee, American Home Products Corporation, which became Wyeth and was later acquired by Pfizer. The withdrawal of Redux was based on a preliminary analysis by the FDA of potential abnormal echocardiogram findings associated with certain patients taking Redux or the combination of fenfluramine with phentermine. Following the withdrawal, Indevus was named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions in federal and state courts relating to the use of Redux and other weight loss drugs. Fewer than 36 cases are still pending against Indevus. The existence of such litigation may materially adversely affect our business. In addition, although we are unable to predict the outcome of any such litigation, if successful uninsured or insufficiently insured claims, or if a successful indemnification claim, were made against us, our business, financial condition and results of operations could be materially adversely affected. In addition, the uncertainties associated with these legal actions may have an adverse effect on the market price of our common stock and on our ability to obtain product liability insurance for other products at costs acceptable to us, or at all, which may materially adversely affect our business, financial condition and results of operations.

On May 30, 2001, Indevus (then known as Interneuron Pharmaceuticals, Inc.) entered into an Indemnity and Release Agreement with Wyeth (then known as American Home Products Corporation and referred to herein as Wyeth), which provided for indemnification of Redux-related claims brought by plaintiffs who initially opted out of Wyeth's national class action settlement of diet drug litigation and by those claimants who allege primary pulmonary hypertension. This agreement also provided for funding of all defense costs related to all Redux-related claims and provided for Wyeth to fund through May 31, 2012 certain additional insurance coverage to supplement the Company's existing product liability insurance. However, there can be no assurance that uninsured or insufficiently insured Redux-related claims or Redux-related claims for which we are not otherwise indemnified or covered under the indemnity and release agreement will not have a material adverse effect on our future business, results of operations or financial condition or that the potential of any such claims would not adversely affect our ability to obtain sufficient financing to fund operations. Additionally, there is no assurance that as indemnitor, Wyeth will remain solvent and able to respond to all claims covered by the indemnity and release agreement. We are unable to predict whether the existence of such litigation may adversely affect our business.

Pursuant to agreements we have with Les Laboratoires Servier, from whom Indevus in-licensed rights to Redux, Boehringer Ingelheim Pharmaceuticals, Inc., which assembled Redux, and other parties, we may be required to indemnify such parties for Redux-related liabilities. We are unable to predict whether such indemnification obligations, if they arise, may adversely affect our business.

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

We are involved in numerous patent litigations in which generic companies challenge the validity or enforceability of our products' listed patents and/or the applicability of these patents to the generic applicant's products. Likewise, our Qualitest segment is also involved in patent litigations in which we challenge the validity or enforceability of innovator companies' listed patents and/or their applicability to our generic products. Therefore, settling patent litigations has been and is likely to continue to be part of our business. Parties to such settlement agreements in the U.S., including us, are required by law to file them with the FTC and the

Antitrust Division of the DOJ for review. The FTC has publicly stated that, in its view, some of these settlement agreements violate the antitrust laws and has brought actions against some brand and generic companies that have entered into such agreements. Accordingly, we may receive formal or informal requests from the FTC for information about a particular settlement agreement, and there is a risk that the FTC may commence an action against us alleging violation of the antitrust laws. Any adverse outcome of these actions or investigations could have a significant adverse effect on our business, financial condition and results of operations. In addition, some members of Congress have proposed legislation that would limit the types of settlement agreements generic manufacturers can enter into with brand companies. In addition, the U.S. Supreme Court will review a case involving such settlements during its 2013 term. The impact of such pending litigation, legislative proposals and Supreme Court review is uncertain and could adversely affect our business, financial condition and results of operations.

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

In March 2010, President Obama signed into law healthcare reform legislation. This legislation has both current and longer-term impacts on us, as discussed below.

The provisions of this healthcare reform legislation have already become or will become effective on various dates over the next several years. The principal provisions affecting us provide for the following:

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively (effective January 1, 2010);
- extension of Medicaid prescription drug rebates to drugs dispensed to enrollees in certain Medicaid managed care organizations (effective March 23, 2010);
- an increase in the additional Medicaid rebates for “new formulations” of oral solid dosage forms of innovator drugs;
- the revision of the average manufacturers’ price, or AMP, definition to remove the “retail pharmacy class of trade” (effective October 1, 2010);
- expansion of the types of institutions eligible for the “Section 340B discounts” for outpatient drugs provided to hospitals meeting the qualification criteria under Section 340B of the Public Health Service Act of 1944 (effective January 1, 2010) (340B Pricing);
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition of the manufacturer’s outpatient drugs to be covered under Medicare Part D (effective January 1, 2011);
- an annual fee payable to the federal government (which is not deductible for U.S. income tax purposes) based on our prior-calendar-year share relative to other companies of branded prescription drug sales to specified government programs (effective January 1, 2011, with the total fee to be paid each year by the pharmaceutical industry increasing annually through 2019);
- a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the U.S., with limited exceptions (effective January 1, 2013);
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting any “transfer of value” made or distributed to physicians and teaching hospitals and reporting any investment interests held by physicians and their immediate family members during each calendar year (with the effective date to be clarified in the final regulations);
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians (effective April 1, 2012);
- creation of the Independent Payment Advisory Board which will have authority to recommend certain changes to the Medicare program that could result in reduced payments for items and services (recommendations could have the effect of law even if Congress does not act on the recommendations, and the implementation of changes based upon Independent Payment Advisory Board recommendations may affect payments beginning in 2015); and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending, (beginning January 1, 2011).
- creation of the Patient-Centered Outcomes Research Institute, an independent, non-partisan organization established by Congress to fund research into evidence-based information about treatment options (established in 2010; first grants approved in December 2012).

A number of the provisions of this healthcare reform legislation may adversely affect reimbursement for our products. Additionally, the best price requirements with respect to Medicaid rebates have traditionally been a significant consideration with respect to the level of rebates in our Medicare and commercial contracting. Healthcare reform legislation’s effects on rebate amounts could adversely impact our future results of operations.

Over the next few years, regulations and guidance implementing this healthcare reform legislation as well as additional healthcare reform proposals may have a financial impact on the Company. In addition, healthcare reform legislation requires that,

except in certain circumstances, individuals must obtain health insurance beginning in 2014, and it also provides for an expansion of Medicaid coverage in 2014. It is expected that, as a result of these provisions, there will be a substantial increase in the number of Americans with health insurance beginning in 2014, a significant portion of whom will be eligible for Medicaid. We anticipate that this will increase demand for pharmaceutical products and medical devices overall. However, in view of the many uncertainties, including but not limited to pending litigation challenging the new law and changes in the partisan composition of Congress, we are unable at this time to determine whether and to what extent sales of our prescription pharmaceutical products or medical devices in the U.S. will be impacted.

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

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

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

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

**Our sales may be adversely affected if physicians do not recommend or use AMS, Inc.'s products.**

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

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

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

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

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

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

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

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

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

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

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

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

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

We are subject to various federal and state laws and regulations. Among the applicable federal laws and regulations are the Stark Law, Anti-Kickback Statute, False Claims Act, and Clinical Laboratory Improvement Amendments, or CLIA, and similar state licensure laws as well as associated regulations and anti-markup regulations, reassignment regulations, and Medicare usual charge regulations. The applicable state laws and regulations include account billing statutes and regulations of various forms (including direct billing, anti-markup, and disclosure statutes and regulations), fee-splitting statutes and regulations, anti-kickback statutes and regulations, self-referral statutes and regulations, lab licensure and certification statutes and regulations, and insurance fraud statutes and regulations. If it is determined that any aspect of our pathology laboratory services business model or any specific pathology laboratory services facility or partnership is not in compliance with any of these laws or regulations, this could threaten our ability to



carry on aspects of the business model, the business model in its entirety, or activities relating to one or more facilities or partnerships. Noncompliance could also expose the Company to federal or state enforcement actions or other proceedings or private lawsuits or other proceedings against the Company. Our obligation to operate the pathology laboratory services unit within the strictures of various applicable federal and state laws and regulations constrains our ability to implement new strategies for generating business opportunities. In the future, additional laws and regulations may arise at the federal or state level in the pathology laboratory services field that may create additional uncertainty, negatively impact results for this unit, or jeopardize the functioning of aspects of the business model, the business model in its entirety, or specific facilities or partnerships.

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

Our AMS segment derives a significant portion of its net sales from operations in international markets. In 2012 and 2011, 34.6% and 32.6%, respectively, of our AMS segment's total revenues were to customers outside the U.S. Some of these sales were to governmental entities and other organizations with extended payment terms. A number of factors, including differing economic conditions, changes in political climate, differing tax structures, changes in diplomatic and trade relationships, and political or economic instability in the countries where AMS, Inc. does business, could affect payment terms and AMS, Inc.'s ability to collect foreign receivables. We have little influence over these factors and changes could have a material adverse impact on our business. In addition, foreign sales are influenced by fluctuations in currency exchange rates, primarily the euro, British pound, Canadian dollar, Australian dollar, and Swedish krona. Increases in the value of the foreign currencies relative to the U.S. dollar would positively impact our earnings and decreases in the value of the foreign currencies relative to the U.S. dollar would negatively impact our earnings.

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

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

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

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

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

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

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

Economic conditions could also affect the financial strength of AMS, Inc.'s vendors and their ability to fulfill their commitments to AMS, Inc., and the financial strength of AMS, Inc.'s customers and its ability to collect accounts receivable. While AMS, Inc. believes that worldwide economic conditions may have contributed to a softening in AMS, Inc.'s recent revenue growth rates, the specific impact is difficult to measure. We cannot predict how these economic conditions will impact future sales, cost of goods sold, or bad debt expense.

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

We currently have a substantial amount of indebtedness. As of December 31, 2012, we have total debt of approximately \$3.2 billion in aggregate principal amount. This debt primarily consists of \$1.3 billion of senior notes, \$1.5 billion secured term loan indebtedness and \$0.4 billion of convertible senior subordinated notes. As of December 31, 2012, we have availability of \$0.5 billion under our revolving credit facility, not including an up to \$0.5 billion uncommitted expansion option available under our 2011 Credit Facility, subject to satisfaction of certain conditions. We may also incur significant additional indebtedness in the future. Our substantial indebtedness may:

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

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

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

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

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

- incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;
- issue redeemable stock and preferred stock;
- pay dividends or distributions or redeem or repurchase capital stock;
- prepay, redeem or repurchase debt;
- make loans, investments and capital expenditures;
- enter into agreements that restrict distributions from our subsidiaries;
- sell assets and capital stock of our subsidiaries;
- enter into certain transactions with affiliates; and
- consolidate or merge with or into, or sell substantially all of our assets to, another person.

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

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

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

- their earnings;
- covenants contained in our debt agreements and the debt agreements of our subsidiaries;
- covenants contained in other agreements to which we or our subsidiaries are or may be subject;
- business and tax considerations; and
- applicable law, including state laws regulating the payment of dividends and distributions.

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

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

A substantial portion of our borrowings under the 2011 Credit Facility are at variable rates of interest, exposing us to interest rate risks. We are exposed to the risk of rising interest rates to the extent that we fund our operations with short-term or variable-rate borrowings. As of December 31, 2012, our total aggregate principal of debt consists of approximately \$1.5 billion of floating-rate debt. Based on this amount, a 1% rise in interest rates would result in approximately \$15 million in incremental annual interest expense. If London Inter-Bank Offer rates (LIBOR) increase in the future, then our floating-rate debt could have a material effect on our interest expense.

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

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

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

We expect to obtain the funds to pay our expenses and the amounts due under our indebtedness primarily from operations. Our ability to meet our expenses and make these payments thus depends on our future performance, which will be affected by financial, business, economic, competitive, legislative, regulatory and other factors, many of which are beyond our control. Our business may not generate sufficient cash flow from operations in the future and our currently anticipated growth in revenue and cash flow may not be realized, either or both of which could result in our being unable to pay amounts due under our outstanding indebtedness, or to fund other liquidity needs, such as future capital expenditures. If we do not have sufficient cash flow from operations, we may be required to refinance all or part of our then existing indebtedness, sell assets, reduce or delay capital expenditures or seek to raise additional capital, any of which could have a material adverse effect on our operations. There can be no assurance that we will be able to accomplish any of these alternatives on terms acceptable to us, or at all. Our ability to restructure or refinance our indebtedness, including the notes, will depend on the condition of the capital markets and our financial condition at such time. Any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. In addition, the terms of existing or future debt agreements, including the indentures governing the notes, may restrict us from adopting any of these alternatives. Any failure to make scheduled payments of interest or principal on our outstanding indebtedness would likely result in a reduction of our credit rating, which could negatively impact our ability to incur additional indebtedness on commercially reasonable terms or at all. The failure to generate sufficient cash flow or to achieve any of these alternatives could materially adversely affect the value of our notes, our business, financial condition and other results of operations, and our ability to pay the amounts due under the notes and our other indebtedness.

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

If there were an event of default under any of the agreements relating to our outstanding indebtedness, the holders of the defaulted debt could cause all amounts outstanding with respect to that debt to be due and payable immediately and our lenders could terminate all commitments to extend further credit. The instruments governing our debt contain cross-default or cross-acceleration provisions that may cause all of the debt issued under such instruments to become immediately due and payable as a result of a default

under an unrelated debt instrument. An event of default or an acceleration under one debt agreement could cause a cross-default or cross-acceleration of other debt agreements. Upon acceleration of certain of our other indebtedness, holders of the notes could declare all amounts outstanding under the notes immediately due and payable. We cannot assure you that our assets or cash flow would be sufficient to fully repay borrowings under our outstanding debt instruments if the obligations thereunder were accelerated upon an event of default. Further, if we are unable to repay, refinance or restructure our secured debt, the holders of such debt could proceed against the collateral securing that indebtedness. We have pledged substantially all of our assets as collateral under the 2011 Credit Facility. If the lenders under the 2011 Credit Facility accelerate the repayment of borrowings, we may not have sufficient assets to repay the obligations outstanding under the 2011 Credit Facility and our other indebtedness, including the notes. Furthermore, our borrowings under the 2011 Credit Facility are expected to be at variable rates of interest and expose us to interest rate risk. If interest rates increase, our debt service obligations on the variable rate indebtedness would increase even though the amount borrowed remains the same, and our net income would decrease. For a description of our indebtedness, see Note 19. Debt in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

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

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

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

Our significant properties at December 31, 2012 are as follows:

<u>Location</u>	<u>Purpose</u>	<u>Approximate Square Footage</u>	<u>Ownership</u>
<b><u>Corporate Properties:</u></b>			
Malvern, Pennsylvania	Corporate Headquarters	299,000	Leased(1)
Austin, Texas	Shared Services Center	15,730	Leased(2)
Chadds Ford, Pennsylvania	Former Corporate Headquarters*	47,756	Leased(3)
Chadds Ford, Pennsylvania	Former Corporate Headquarters*	64,424	Leased(4)
Chadds Ford, Pennsylvania	Former Corporate Headquarters*	48,600	Leased(5)
Chadds Ford, Pennsylvania	Former Corporate Headquarters*	23,949	Leased(6)
<b><u>Endo Pharmaceuticals Segment Properties:</u></b>			
Cranbury, New Jersey	Distribution/Manufacturing	51,000	Leased(7)
<b><u>Qualitest Segment Properties:</u></b>			
Westbury, New York	Research & Development	24,190	Leased(8)
Huntsville, Alabama	Qualitest Pharmaceuticals Headquarters/Distribution	280,000	Owned
Huntsville, Alabama	Distribution/Manufacturing/Laboratories	180,000	Owned
Huntsville, Alabama	Distribution/Manufacturing/Laboratories	309,000	Owned
Charlotte, North Carolina	Distribution/Manufacturing/Laboratories	60,000	Owned
Charlotte, North Carolina	Distribution	58,000	Leased(9)
<b><u>AMS Segment Properties:</u></b>			
Minnnetonka, Minnesota	AMS, Inc. Headquarters/Warehouse/Research & Development/Manufacturing	230,000	Owned
Westmeath, Ireland	AMS, Inc. Manufacturing	33,700	Leased(10)
San Jose, California	AMS, Inc. Office/Manufacturing/Research & Development/Warehouse	68,644	Leased(11)
<b><u>HealthTronics Segment Properties:</u></b>			
Austin, Texas	HealthTronics, Inc. Headquarters and Manufacturing/Service Center	80,236	Leased(12)

(1) Lease term ends December, 2024  
(2) Lease term ends December, 2017  
(3) Lease term ends August, 2013  
(4) Lease term ends January, 2015  
(5) Lease term ends March, 2018  
(6) Lease term ends January, 2015

- (7) Lease term ends March, 2015
- (8) Lease term ends May, 2015. In connection with the consolidation of our generics research and development operations to Huntsville, Alabama, we exited this facility in February 2013.
- (9) Lease term ends May, 2021
- (10) Initial lease term ends January, 2021
- (11) Lease term ends October, 2016
- (12) Lease term ends December, 2017
- \* In connection with the relocation of our headquarters to Malvern, Pennsylvania, we exited these properties in early 2013.

**Item 3.            *Legal Proceedings***

The disclosures under Note 15. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules" are incorporated in this Part I, Item 3. by reference.

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

None.



**PART II**

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

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

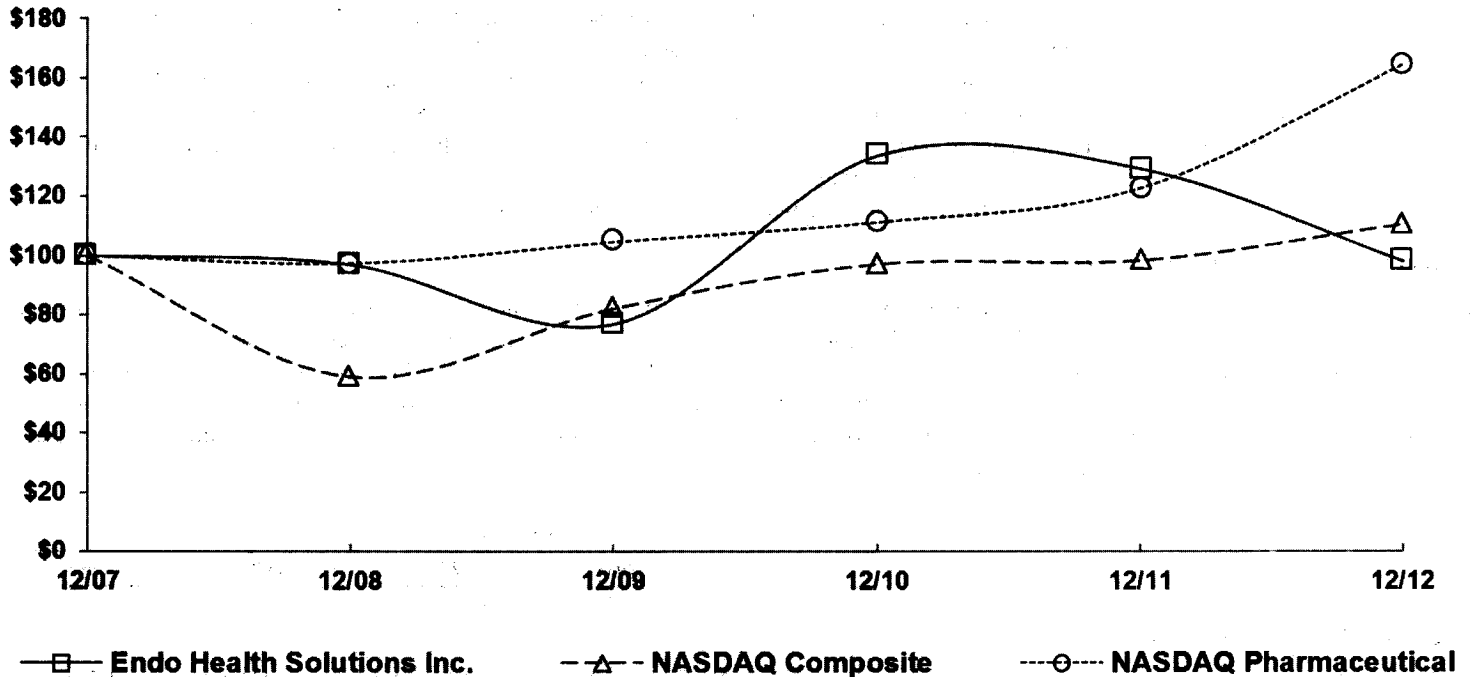
	Endo Common Stock	
	High	Low
<b>Year Ended December 31, 2012</b>		
1st Quarter.....	\$ 39.29	\$ 32.82
2nd Quarter .....	\$ 38.96	\$ 28.83
3rd Quarter .....	\$ 33.86	\$ 28.89
4th Quarter .....	\$ 33.03	\$ 25.49
<b>Year Ended December 31, 2011</b>		
1st Quarter.....	\$ 38.51	\$ 32.14
2nd Quarter .....	\$ 44.53	\$ 36.65
3rd Quarter .....	\$ 42.09	\$ 26.76
4th Quarter .....	\$ 36.41	\$ 26.02

*Holdings.* As of February 20, 2013, we estimate that there were approximately 55 record holders of our common stock.

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

*Performance Graph.* The following graph provides a comparison of the cumulative total stockholder return on the Company's common stock with that of the cumulative total stockholder return on the (i) NASDAQ Stock Market Index (U.S.) and (ii) the NASDAQ Pharmaceutical Index, commencing on December 31, 2007 and ending December 31, 2012. The graph assumes \$100 invested on December 31, 2007 in the Company's common stock and in each of the comparative indices. Our historic stock price performance is not necessarily indicative of future stock price performance.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***  
 Among Endo Health Solutions Inc., the NASDAQ Composite Index,  
 and the NASDAQ Pharmaceutical Index



\*\$100 invested on 12/31/07 in stock or index, including reinvestment of dividends.  
 Fiscal year ending December 31.

	December 31,					
	2007	2008	2009	2010	2011	2012
Endo Health Solutions Inc. ....	\$ 100.00	\$ 97.04	\$ 76.94	\$ 133.90	\$ 129.47	\$ 98.35
NASDAQ Composite Index.....	\$ 100.00	\$ 59.03	\$ 82.25	\$ 97.32	\$ 98.63	\$ 110.78
NASDAQ Pharmaceutical Index .....	\$ 100.00	\$ 97.45	\$ 104.75	\$ 111.47	\$ 123.06	\$ 164.89

*Recent sales of unregistered securities; Use of proceeds from registered securities.* During the fourth quarter of 2012, the Company did not sell any unregistered securities.

Purchase of equity securities by the issuer and affiliated purchasers. The following table reflects purchases of Endo Health Solutions Inc. common stock by the Company during the three-months ended December 31, 2012:

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share (2)	Total Number of Shares Purchased as Part of Publicly Announced Plan	Approximate Dollar Value of Shares that May Yet be Purchased Under the Plan (1)
October 1, 2012 to October 31, 2012 .....	—	\$ —	—	\$ 350,000,023
November 1, 2012 to November 30, 2012 .....	2,153,500	27.02	2,153,500	291,809,408
December 1, 2012 to December 31, 2012 .....	1,476,906	28.31	1,476,906	250,000,024
Total.....	<u>3,630,406</u>	\$ 27.55	<u>3,630,406</u>	

- (1) All shares were repurchased under the Company's announced repurchase programs. In August 2012, our Board of Directors approved a share repurchase program (the 2012 Share Repurchase Program). The 2012 Share Repurchase Program authorizes the Company to repurchase in the aggregate of up to \$450 million of shares of its outstanding common stock and is set to expire on March 31, 2015. The amounts above reflect shares remaining under the 2012 Share Repurchase Plan at December 31, 2012. All shares are to be purchased in the open market or in privately negotiated transactions, as in the opinion of management, market conditions warrant.
- (2) Average price paid per share is calculated on a settlement basis and excludes commission.

#### Item 6. Selected Financial Data

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

	Year Ended December 31,				
	2012	2011	2010	2009	2008
	(dollars in thousands, except per share data)				
<b>Consolidated Statement of Operations Data:</b>					
Total revenues .....	\$ 3,027,363	\$ 2,730,121	\$ 1,716,229	\$ 1,460,841	\$ 1,260,536
Operating (loss) income .....	(551,727)	508,366	465,366	390,024	387,474
(Loss) income before income tax .....	(741,583)	351,691	420,698	359,660	391,828
Consolidated net (loss) income .....	(688,021)	242,065	287,020	266,336	255,336
Less: Net income attributable to noncontrolling interests .....	52,316	54,452	28,014	—	—
Net (loss) income attributable to Endo Health Solutions Inc. ....	<u>\$ (740,337)</u>	<u>\$ 187,613</u>	<u>\$ 259,006</u>	<u>\$ 266,336</u>	<u>\$ 255,336</u>
<b>Basic and Diluted Net (Loss) Income Per Share Attributable to Endo Health Solutions Inc.:</b>					
Basic .....	\$ (6.40)	\$ 1.61	\$ 2.23	\$ 2.27	\$ 2.07
Diluted .....	\$ (6.40)	\$ 1.55	\$ 2.20	\$ 2.27	\$ 2.06
Shares used to compute basic net income per share attributable to Endo Health Solutions Inc. ....	115,719	116,706	116,164	117,112	123,248
Shares used to compute diluted net income per share attributable to Endo Health Solutions Inc. ....	115,719	121,178	117,951	117,515	123,720
Cash dividends declared per share .....	\$ —	\$ —	\$ —	\$ —	\$ —

As of and for the Year Ended December 31,

	2012	2011	2010	2009	2008
	(dollars in thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents.....	\$ 547,916	\$ 547,620	\$ 466,214	\$ 708,462	\$ 775,693
Total assets.....	6,568,559	7,292,583	3,912,389	2,488,803	1,908,733
Long-term debt, less current portion, net.....	3,037,947	3,424,329	1,045,801	322,534	243,150
Other long-term obligations, including capitalized leases.....	669,386	706,885	327,431	196,678	71,999
Total Endo Health Solutions Inc. stockholders' equity.....	1,072,856	1,977,690	1,741,591	1,497,411	1,207,111
Noncontrolling interests.....	60,350	61,901	61,738	—	—
Total stockholders' equity.....	<u>\$ 1,133,206</u>	<u>\$ 2,039,591</u>	<u>\$ 1,803,329</u>	<u>\$ 1,497,411</u>	<u>\$ 1,207,111</u>
<b>Other Financial Data:</b>					
Net cash provided by operating activities.....	\$ 733,879	\$ 702,115	\$ 453,646	\$ 295,406	\$ 355,627
Net cash (used in) provided by investing activities ..	\$ (88,467)	\$ (2,374,092)	\$ (896,323)	\$ (245,509)	\$ 179,807
Net cash (used in) provided by financing activities..	\$ (645,547)	\$ 1,752,681	\$ 200,429	\$ (117,128)	\$ (110,066)

The comparability of the forgoing information is impacted by certain charges for asset impairments and certain litigation-related and other matters during 2012, and a number of significant acquisitions that have occurred since 2009, along with the debt incurred to finance these acquisitions. These business combinations have had a significant impact on the Company's financial statements in their respective years of acquisition and in subsequent years. This impact results from the consideration transferred by the Company for the acquisition, the initial and subsequent purchase accounting for the underlying acquisition and the post-acquisition consolidation of the acquired entity's assets, liabilities and results of operations. For further information regarding the comparability of the financial data presented in the tables above and factors that may impact comparability of future results, refer to Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations as well as the Consolidated Financial Statements and related notes included in this report and previously filed Annual Reports on Form 10-K.

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

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

## EXECUTIVE SUMMARY

### *About the Company*

At our Annual Meeting of Stockholders on May 23, 2012, our stockholders approved the proposal to amend and restate our Amended and Restated Certificate of Incorporation to change our name from Endo Pharmaceuticals Holdings Inc. to Endo Health Solutions Inc., which we refer to herein as "Endo", "we", "us", or the "Company". This change became effective on May 23, 2012. Concurrently with this change, the Company also changed the names of its business segments. Effective May 23, 2012, the names of our business segments are Endo Pharmaceuticals (formerly Branded Pharmaceuticals), Qualitest (formerly Generics), AMS (formerly Devices) and HealthTronics (formerly Services).

Endo Health Solutions Inc. is a U.S. based, specialty healthcare solutions company with a diversified business model, operating in four key business segments—Endo Pharmaceuticals, Qualitest, AMS and HealthTronics. Our Endo Pharmaceuticals and Qualitest segments offer a variety of branded and generic pharmaceutical products in multiple therapeutic areas. AMS provides technology solutions to physicians treating men's and women's pelvic health conditions. Finally, HealthTronics provides urological services, products and support systems to urologists, hospitals, surgery centers and clinics. As a combined entity, we deliver comprehensive healthcare solutions across our diversified businesses in key therapeutic areas, including pain and urology, and believe we are positioned to address the changing economics that are driving the continued transformation of the U.S. healthcare environment.

We believe our diversified business model enables us to strengthen our partnerships with providers, payers and patients by offering multiple products and platforms to deliver healthcare solutions. We have a portfolio of branded pharmaceuticals that includes established brand names such as Lidoderm<sup>®</sup>, Opana<sup>®</sup> ER, Voltaren<sup>®</sup> Gel, Percocet<sup>®</sup>, Frova<sup>®</sup>, Supprelin<sup>®</sup> LA, Vantas<sup>®</sup>, Valstar<sup>®</sup> and Fortesta<sup>®</sup> Gel. Endo Pharmaceuticals comprised approximately 55% of our total revenues in 2012, with 31% of our revenues coming

from Lidoderm®. Our non-branded Qualitest portfolio, which accounted for 21% of total revenues in 2012, currently consists of products primarily focused in pain management. We generally focus on selective generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. Our AMS segment accounted for 17% of total revenues in 2012 and our HealthTronics segment accounted for the remaining 2012 revenue.

### ***Business Environment***

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

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

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

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

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

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

### ***Healthcare Reform***

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, comprehensive healthcare reform legislation. On March 30, 2010, the President signed H.R. 4872, the Health Care and Education Reconciliation Act of 2010



(Reconciliation Act), which included a package of changes to the PPACA, as well as additional elements to reform health care in the U.S.

While some provisions of the new healthcare reform law have already taken effect, most of the provisions to expand access to health care coverage will not be implemented until 2014 and beyond. Since implementation is incremental to the enactment date of the law, there are still many challenges and uncertainties ahead. Such a comprehensive reform measure will require expanded implementation efforts on the part of federal and state agencies embarking on rule-making to develop the specific components of their new authority.

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 percent 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 percent by 2020. The law provided that if a state did not expand its Medicaid program eligibility to 133 percent, 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 will 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 are expected to improve patients' ability to obtain and maintain health insurance. Such measures include: the elimination of lifetime caps; no rescission of policies; and no denial of coverage due to preexisting conditions. The expansion of healthcare insurance and these additional market reforms should result in greater access to the Company's products.

Our estimate of the overall impact of healthcare reform reflects a number of uncertainties. However, we believe that the impact to our business will be largely attributable to changes in the Medicare Part D Coverage Gap, the imposition of an annual fee on branded prescription pharmaceutical manufacturers, and increased rebates in the Medicaid Fee-For-Service Program and Medicaid Managed Care plans. There are a number of other provisions in the legislation that collectively are expected to have a small impact, including originator average manufacturers' price (AMP) for new formulations, an excise tax on manufactured or imported medical devices offered for sale in the U.S., and the expansion of 340B pricing to new entities. Certain elements of healthcare reform reduced total revenues by approximately \$40 million in 2011 and have had and will continue to have a similar impact in future years.

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

In response to the U.S. debt-ceiling crisis, Congress passed the Budget Control Act of 2011 on August 2, 2011. Within the Act, Congress created the Joint Select Committee on Deficit Reduction (JSC), which was charged with issuing a formal recommendation on how to reduce the federal deficit by \$1.2 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. However, Congress was able to avert sequestration when it passed the American Taxpayer Relief Act of 2012 (H.R. 8). This law delays the sequestration from January 2, 2013 until March 1, 2013. The automatic spending cuts that would occur as a result of the sequestration process are unpalatable for many lawmakers and Congress may use the 2013 session to consider repealing the cuts by finding savings in other programs, such as Medicaid.

#### *Governmental Regulation*

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

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

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

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

We cannot determine what effect changes in the FDA's laws or regulations, when and if promulgated, or changes in the FDA's legal or regulatory interpretations 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 December 2003, Congress passed measures intended to speed the process by which generic versions of brand name drugs are introduced to the market. Among other things, these measures are intended to limit regulatory delays of generic drug applications and penalize companies that reach certain agreements with makers of brand name drugs that delay the introduction of generic versions. The FTC has expressed its concern with agreements between brand and generic drug companies that may delay the introduction of a generic drug to the market, and the U.S. Supreme Court will review a case involving such agreements during the 2013 Supreme Court term. These changes and the results of the Supreme Court review could result in increased generic competition for our branded and generic products and could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, on September 27, 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007 (FDAAA) that re-authorized requirements for testing drug products in children, where appropriate, which were made permanent by the Food and Drug Administration Safety and Innovation Act, which was signed into law in July 2012 and is further described below. The FDAAA also included new requirements for post-approval studies or clinical trials of drugs that are known to or that signal the potential to pose serious safety risks, and authority to require risk evaluation and mitigation strategies, or REMS to confirm that the benefits of a drug outweigh the risks of the drug, all of which may increase the time and cost necessary for new drug development as well as the cost of maintaining regulatory compliance for a marketed product.

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 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 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 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. 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 ongoing policy debate on the use of opioid medications, at the hearing, 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. While it is not presently known what, if any actions the FDA may take, as a result of the Citizen Petition or the public hearing, if the FDA requires changes to the indications for use or duration of use in the labeling of opioid drug products, it could have a material adverse effect on our business, financial position, results of operations and cash flows.

**Medical devices.** 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 FDCA, medical devices, such as those manufactured by AMS, Inc. and HealthTronics, Inc. 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.

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

Class III devices are approved through a Premarket Approval Application, or PMA, under which the applicant must submit data from adequate and well-controlled clinical trials to the FDA that demonstrate the safety and effectiveness of the device for its intended use(s). All of our marketed devices have been approved or cleared for marketing pursuant to a PMA or the 510(k) process. The FDA also has authority under the FDCA 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, Inc. to conduct post-market 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, Inc. for pelvic floor repair and mini-sling products, three remain active. AMS, Inc. is in the process of complying with these orders. In its orders, the FDA also noted that it is still considering the recommendation of an advisory committee on September 9, 2011, that urogynecological surgical mesh for transvaginal repair of pelvic organ prolapse be reclassified from Class II to Class III.

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

On January 19, 2011, the FDA's Center for Devices and Radiological Health (CDRH) unveiled a plan of 25 action items it 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 through 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 Institute of Medicine (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, whether to develop guidance on a new class of devices, called “class IIb,” for which additional data would be necessary to support a 510(k) determination.

On July 29, 2011, the IOM released its report, which recommended that the FDA move towards replacing the current 510(k) review process, which is based on “substantial equivalence” determinations, with a new “integrated premarket and post-market regulatory framework” that provides a reasonable assurance of safety and 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, 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 investigation device applications (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. In addition, the FDA issued a proposed rule that would require a unique identifier on distributed devices for tracking purposes, and a final rule that revises and expands medical device registration and listing requirements. 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. These 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, and for the marketing of medical devices.

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.

### ***2012—A Year in Review***

Despite first quarter supply disruptions for several of our key pharmaceutical products resulting from the shutdown of a third party supplier's manufacturing facility, in 2012 we grew revenue for the fourteenth consecutive year. The Company also renamed itself Endo Health Solutions in the early part of the year to reflect the integration of our diversified operating companies and our significant transformation into a broader healthcare solutions company as a result of a series of recent strategic acquisitions and business development decisions. In March, we launched our new formulation of Opana<sup>®</sup> ER designed to be crush-resistant, which by the end of the year accounted for more than 90% of total dispensed prescriptions of Opana<sup>®</sup> ER. In May, we entered into an agreement with Watson Laboratories, Inc. settling patent litigation over Lidoderm<sup>®</sup> and thereby substantially reducing the uncertainty around the future of this product. During the year we also initiated the Phase III program for BEMA Buprenorphine for the treatment of moderate to severe chronic pain, which we expect to complete by late 2013 or early 2014.

Total revenues for the year ended December 31, 2012 increased 11% over 2011 to \$3.03 billion, with a Net loss attributable to Endo Health Solutions Inc. of \$740.3 million, or \$6.40 per diluted share, as compared to Net income attributable to Endo Health Solutions Inc. of \$187.6 million or \$1.55 per diluted share in 2011. The increase in revenues was driven by revenue growth from our Endo Pharmaceuticals, Qualitest and HealthTronics segments as well as the timing of our acquisition of AMS, Inc. during the second quarter of 2011, from which we derived a full year's revenue in 2012 compared to less than seven months in 2011. The 2012 Net loss attributable to Endo Health Solutions Inc. was primarily attributable to certain charges for asset impairments totaling \$768.5 million and certain litigation-related and other matters, including patent litigation settlement costs and the accrual for payment to Impax related to sales of Opana<sup>®</sup> ER, totaling \$503.5 million during 2012.

### ***Watson Litigation Settlement***

On May 28, 2012, Endo Pharmaceuticals Inc. (EPI) entered into a Settlement and License Agreement (the Watson Settlement Agreement) among EPI and Teikoku, on the one hand, and Watson, on the other hand. The Watson Settlement Agreement settled all ongoing patent litigation among the parties relating to Watson's generic version of Lidoderm<sup>®</sup>.

On August 23, 2012, Watson announced it received FDA approval on its Abbreviated New Drug Application (ANDA) for its lidocaine patch 5%, a generic version of Lidoderm®. The Company anticipates Watson will launch its generic version of Lidoderm® on September 15, 2013 pursuant to the terms of the Watson Settlement Agreement.

For further details, see Note 15. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

### ***Litigation-Related and Other Contingencies***

During 2012, we recorded total accruals in the amount of \$316.4 million for certain of our legal and other related proceedings, with respect to certain pricing litigation matters, product liability litigation, and the investigation by the HHS-OIG and the DOJ relating to the sale, marketing and promotion of Lidoderm®. These matters are described in more detail in Note 15. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

### ***Impax***

Pursuant to the June 2010 Settlement and License Agreement (the Impax Settlement Agreement) with Impax Laboratories Inc. (Impax) the Company agreed to provide a payment to Impax should prescription sales of the non-crush resistant formulation of Opana® ER, as defined in the Impax Settlement Agreement, fall below a predetermined contractual threshold in the quarter immediately prior to the date on which Impax was authorized to launch its generic version of the non-crush resistant formulation of Opana® ER, which occurred on January 2, 2013. During the first quarter of 2012, the Novartis shut-down of its Lincoln, Nebraska manufacturing facility and resulting lack of 2012 oxymorphone active pharmaceutical ingredient (API) quota granted by the DEA to Novartis caused EPI to attempt an accelerated launch of the crush-resistant formulation of Opana® ER. While significant uncertainties existed throughout the first quarter of 2012 about our ability to rapidly ramp up production of the formulation designed to be crush-resistant and produce finished goods at a new, untested manufacturing facility in a very short period of time, we were able to do so in March 2012. Accordingly, the Company recognized a liability under the Impax Settlement Agreement upon the Company's sale of the formulation designed to be crush-resistant, which occurred in March 2012. The total charge of \$102.0 million was recorded in Cost of revenues in our 2012 Consolidated Financial Statements.

### ***Pipeline Developments***

#### ***BEMA® Buprenorphine***

In January 2012, the Company signed a worldwide license and development agreement with BioDelivery Sciences International, Inc. (BioDelivery) for the exclusive rights to develop and commercialize BEMA® Buprenorphine, a transmucosal form of buprenorphine which incorporates a bioerodible mucoadhesive (BEMA®) technology and is currently in Phase III trials for the treatment of moderate to severe chronic pain. At this time, the Company made an upfront payment to BioDelivery for \$30.0 million, which was expensed as Research and development in the first quarter of 2012. An additional \$15.0 million payment related to the achievement of certain regulatory milestones was triggered and recorded as Research and development expense during the first quarter of 2012. We paid this amount in the second quarter of 2012. In August 2012, the Company and BioDelivery announced the initiation of the Phase III clinical program for BEMA® Buprenorphine for the treatment of moderate to severe chronic pain. Both studies are anticipated to be completed by late 2013 or early 2014.

#### ***JetTouch™ / Botox® Co-Development Program***

In June 2012, AMS, Inc. announced a co-development agreement with Allergan, Inc. to jointly develop and seek regulatory approval for the delivery of Botox® (onabotulinumtoxinA) using the JetTouch™ system for treatment of overactive bladder.

### ***Recent Business Activity***

#### ***Lidoderm®***

In August 2012, the Company received a letter from the FDA, noting that it had denied our Citizen Petition (CP) related to the approval requirements for generic versions of Lidoderm®. Also on August 23, 2012, Watson announced it received FDA approval on its ANDA for its lidocaine patch 5%, a generic version of Lidoderm®. We anticipate Watson will launch its generic version of Lidoderm® in September of 2013 pursuant to the terms of the Company's settlement agreement with Watson.

#### ***Opana® ER***

In December 2011, the FDA approved a formulation of Opana® ER designed to be crush-resistant, which is called Opana® ER with the same dosage strengths, color and packaging and similar tablet size. Endo transitioned to the crush-resistant formulation in March 2012 upon successfully accelerating production of this formulation. In June 2012, we announced the FDA had moved the old formulation of Opana® ER to the Orange Book Discontinued List in connection with our transition to the crush-resistant formulation and in September 2012, we announced that, according to IMS Health data estimates, the crush-resistant formulation of Opana® ER now accounts for more than 90 percent of the Opana® ER total prescription volume.



On August 13, 2012, EPI submitted a Citizen Petition with the FDA requesting that it (1) determine that the discontinued, non-crush-resistant version of Opana<sup>®</sup> ER approved under NDA No. 021610 was discontinued for safety and can no longer serve as a Reference List Drug (RLD) for an ANDA or generic applicant; (2) refuse to approve any pending ANDA for a generic version of the non-crush resistant version of Opana<sup>®</sup> ER approved under NDA No. 021610; and (3) suspend and withdraw the approval of any ANDA referencing Opana<sup>®</sup> ER approved under NDA No. 021610 as the RLD.

On August 31, 2012, EPI submitted an additional Citizen Petition requesting that the FDA (1) require that any ANDA referencing the crush-resistant formulation of Opana<sup>®</sup> ER contain data and information demonstrating that the proposed ANDA product is similarly crush-resistant; (2) classify extended-release opioid formulations incorporating crush-resistant technologies, such as the new Opana<sup>®</sup> ER, as new dosage forms in Appendix C of FDA's Orange Book; and (3) confirm that any ANDA referencing Opana<sup>®</sup> ER approved under NDA No. 021610 will not be identified in the Orange Book as therapeutically equivalent to the crush-resistant formulation of Opana<sup>®</sup> ER.

In November 2012, EPI supplemented its Citizen Petition to include emerging safety data that demonstrate that the crush-resistant formulation of Opana<sup>®</sup> ER is reducing rates of abuse. In January 2013, EPI received a letter from the FDA noting it had denied its August 31, 2012 Citizen Petition without comment on the merits. The FDA stated that it intends to make its determination regarding whether the original formulation of Opana<sup>®</sup> ER was withdrawn for safety reasons by May 2013.

From September 21, 2012 through February 6, 2013, EPI and its partner Grünenthal received Paragraph IV Notices from each of Teva Pharmaceuticals USA, Inc. (Teva), Amneal Pharmaceuticals, LLC (Amneal), Sandoz Inc. (Sandoz), ThoRx Laboratories, Inc. (ThoRx), Par Pharmaceuticals (Par), Actavis South Atlantic LLC (Actavis) and Impax Pharmaceuticals (Impax), advising of the filing by each such company of an ANDA for a generic version of the formulation of Opana<sup>®</sup> ER designed to be crush-resistant.

In December 2012, Endo launched 7.5 mg and 15 mg strengths of its crush-resistant formulation of Opana<sup>®</sup> ER, which is now commercially available in 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg and 40 mg dosage strengths.

#### *MoXy<sup>®</sup> Fiber*

In August 2012, the Company introduced the new 650kJ MoXy<sup>®</sup> fiber for our GreenLight XPS<sup>®</sup> system for photoselective vaporization of the prostate, which provides more than 50 percent more energy than the previous fiber for the same price. The new MoXy<sup>®</sup> fiber will enable physicians to treat larger glands with a single fiber, offering improved overall value and greater cost efficiency.

#### *Montelukast Sodium Tablets*

In August 2012, the Company announced it had launched its montelukast sodium tablets and chewable tablets, generic versions of Singulair<sup>®</sup>, following the expiration of the last patent that provides Merck U.S. market exclusivity. The Company began shipping the product immediately. Montelukast sodium tablets are labeled for use in treating symptoms of asthma and allergic rhinitis. The total combined branded and generic sales for montelukast sodium tablets and chewable tablets in the U.S. for the twelve months ending June 30, 2012 were approximately \$4.9 billion, according to IMS Health.

#### *Levetiracetam*

In April 2012, Qualitest Pharmaceuticals announced it had received FDA approval on its ANDA for levetiracetam oral solution 100 mg/mL, a generic version of Keppra<sup>®</sup> to begin distribution in late 2012. The total sales for levetiracetam oral solution 100 mg/mL in the U.S. for the twelve months ending December 31, 2011 were approximately \$62 million, according to IMS Health. Subsequently, in July 2012, Qualitest Pharmaceuticals announced it had received FDA approval on its ANDA for levetiracetam extended-release 500 and 750 mg tablets, a generic version of Keppra XR<sup>®</sup>. The total sales for levetiracetam extended-release 500 and 750 mg tablets in the U.S. for the 12 months ending May 31, 2012 were approximately \$125 million, according to IMS Health.

#### *Other*

In October, Qualitest Pharmaceuticals received, through its partner Alembic Pharmaceuticals Limited, FDA approval for irbesartan tablets, a generic version of Avapro<sup>®</sup>, irbesartan/HCTZ tablets, a generic version of Avalide<sup>®</sup> and modafinil tablets, a generic version of Provigil<sup>®</sup>. Total combined branded and generic sales for irbesartan tablets, irbesartan/HCTZ tablets and modafinil tablets in the U.S. for the 12 months ended September 30, 2012 were approximately \$1.7 billion, according to IMS Health.

In November 2012, Qualitest Pharmaceuticals received FDA approval for Gildagia<sup>™</sup> (ethinyl estradiol and norethindrone) tablets, 0.035 mg / 0.4 mg. Total combined branded and generic sales of these products in the U.S. for the 12 months ended December 31, 2012 were approximately \$23 million, according to IMS Health.

In December 2012, Qualitest Pharmaceuticals received FDA approval for disulfiram tablets, a generic version of Antabuse<sup>®</sup>. Total combined branded and generic sales of disulfiram tablets in the U.S. for the 12 months ended December 31, 2012 were approximately \$18 million, according to IMS Health.

### ***Goodwill and Indefinite-Lived Intangible Assets Impairment Testing***

During the three months ended September 30, 2012, we changed our annual goodwill and indefinite-lived intangible assets impairment test date from January 1 to October 1. The selection of October 1 as the annual testing date for the impairment of goodwill aligns the timing of the annual impairment test with the completion of our planning and budgeting process, which allows us to utilize the updated business plans that result from the budget process to estimate the fair value of our reporting units. This change necessitated completing a test as of October 1, 2012 so that no more than 12 months elapsed between annual tests. A description of the procedures and assumptions used in our goodwill and indefinite-lived intangible assets impairment testing, as well as the results of our testing, is included below under the caption "CRITICAL ACCOUNTING ESTIMATES". The impairment charges recorded as a result of our goodwill and indefinite-lived intangible assets impairment testing are described in detail below under the caption "RESULTS OF OPERATIONS".

### ***Changes in Directors & Officers and Other Related Matters***

On July 18, 2012, Endo announced the appointment of Camille Farhat as President of AMS, Inc., a wholly owned subsidiary of Endo Health Solutions Inc. Prior to joining AMS, Inc., Mr. Farhat served in a variety of senior leadership positions within the healthcare industry; most recently as General Manager of Baxter Pharmaceuticals and Technologies. As General Manager, Mr. Farhat significantly enhanced the performance and improved the operating efficiency of the business while focusing on the needs of patients. During his time at Baxter, he also held the role of General Manager for Baxter Global Infusion Systems. Before that, Mr. Farhat provided executive leadership at Medtronic, including roles in Business Development, as well as Global General Manager, Gastroenterology and Urology. In addition, he held a variety of positions at GE Healthcare, including roles as a Global General Manager of the Computed Tomography Business. He also held leadership positions in strategic planning and global sourcing at General Electric.

On September 27, 2012, the Company increased the size of its Board of Directors from nine to ten and appointed Jill D. Smith to fill this new vacancy. Ms. Smith currently serves on the board of SoundBite Communications and is a member of the executive committee for the Women's Cancer Program at Dana Farber Hospital, and a member of the board of trustees for The Rashi School. Previously, Ms. Smith served as the chairman of the board of directors and chief executive officer of DigitalGlobe, Inc., and prior to DigitalGlobe, Ms. Smith was president and chief executive officer of eDial, chief executive officer of SRDS, L.P., as well as chief operating officer of Micron Electronics, Inc. Ms. Smith also has served on the corporate boards of Elster Group and Smith & Hawken. Ms. Smith's earlier professional experience includes co-founding Treacy & Company, LLC, a consulting and boutique investment business and holding executive positions at Sara Lee Corporation and Bain & Company.

On December 12, 2012, the Company announced that David P. Holveck will retire in 2013 as President and Chief Executive Officer. On February 25, 2013, the Company announced the appointment of Mr. Rajiv De Silva to the position of President and Chief Executive Officer of the Registrant, effective March 18, 2013, which will be the effective date of Mr. Holveck's retirement. Mr. De Silva will also be appointed to the Board effective March 18, 2013, which is the effective date of Mr. Holveck's resignation from the Board. In connection with Mr. De Silva's appointment as President and Chief Executive Officer of the Company, he entered into an executive employment agreement, effective as of March 18, 2013.

### **RESULTS OF OPERATIONS**

The Company reported a Net loss attributable to Endo Health Solutions Inc. for the year ended December 31, 2012 of \$740.3 million or \$6.40 per diluted share on total revenues of \$3.03 billion compared with Net income attributable to Endo Health Solutions Inc. of \$187.6 million or \$1.55 per diluted share on total revenues of \$2.73 billion for the year ended December 31, 2011.

### **Consolidated Results Review**

#### ***Year Ended December 31, 2012 Compared to the Year Ended December 31, 2011***

**Revenues.** Revenues in 2012 increased 11% to \$3.03 billion from \$2.73 billion in 2011. This increase in revenues was driven by revenue growth from our Endo Pharmaceuticals, Qualitest and HealthTronics segments, as well as the timing of our acquisition of AMS, Inc. during the second quarter of 2011, from which we derived a full year's revenue during 2012, compared to less than seven months during 2011.

The following table displays our revenues by category and as a percentage of total revenues for the years ended December 31 (dollars in thousands):

	2012		2011	
	\$	%	\$	%
Lidoderm® .....	\$ 947,680	31	\$ 825,181	30
Opana® ER.....	299,287	10	384,339	14
Voltaren® Gel.....	117,563	4	142,701	5
Percocet® .....	103,406	3	104,600	4
Frova® .....	61,341	2	58,180	2
Supprelin® LA.....	57,416	2	50,115	2
Other brands.....	91,291	3	92,651	3
Total Endo Pharmaceuticals* .....	\$ 1,677,984	55	\$ 1,657,767	61
Qualitest.....	633,265	21	566,854	21
AMS .....	504,487	17	300,299	11
HealthTronics .....	211,627	7	205,201	8
Total revenues*.....	\$ 3,027,363	100	\$ 2,730,121	100

\* Percentages may not add due to rounding.

**Lidoderm®.** Net sales of Lidoderm® in 2012 increased 15% to \$947.7 million from \$825.2 million in 2011. We were required to pay Hind royalties based on net sales of Lidoderm® until this obligation expired on November 23, 2011. Hind royalties were recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm®. Due to the expiration of the Hind royalty, net sales were \$77.9 million higher during 2012, respectively, compared to 2011. Beyond this change for the Hind royalty, Lidoderm® had solid performance this year on increased scripts from 2011, and continues to generate strong cash flow that we can use to invest in our business to continue to further diversify our revenue base. Pursuant to the Watson Settlement Agreement, we expect Watson to launch its lidocaine patch 5%, a generic version of Lidoderm®, on September 15, 2013, negatively impacting future net sales of Lidoderm®.

**Opana® ER.** Net Sales of Opana® ER in 2012 decreased 22% to \$299.3 million from \$384.3 million in 2011. In the first half of 2012, after our first quarter supply disruption associated with the shutdown of Novartis's Lincoln, Nebraska manufacturing facility, we transitioned to our formulation of Opana® ER, designed to be crush-resistant. While we believe our 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. The decrease during 2012 compared to 2011, was driven by a combination of the reduced volumes associated with our previously discussed transition efforts as well as the direct impact of the first quarter 2012 supply disruption, which caused some patients to switch to other pain relief products. As a result of the above-referenced market disruption and increased competition within the extended release opioid category beginning in January 2013, we expect Opana® ER sales to decline in 2013. However, the extent to which our revenues will be affected is subject to a number of uncertainties including the FDA's determination regarding whether the original formulation of Opana® ER was withdrawn for safety reasons, which we expect will be decided in May 2013, as well as certain other FDA actions that could impact the ability of both branded and generic competition for Opana® ER to enter the market.

**Voltaren® Gel.** Net Sales of Voltaren® Gel in 2012 decreased 18% to \$117.6 million from \$142.7 million in 2011. Due to short-term Voltaren® Gel supply constraints resulting from the shutdown of Novartis's Lincoln, Nebraska manufacturing facility, there were no sales of Voltaren® Gel during the three months ended March 31, 2012, which negatively impacted sales on a full-year basis, resulting in a sales decrease from 2012 to 2011. This decline was partially offset by the effect of the market's efforts to return stock of Voltaren® Gel to normal levels during the second quarter of 2012. Subject to FDA approval, we believe one or more competing products could potentially enter the market during the second quarter of 2014, negatively impacting future sales of Voltaren® Gel.

**Percocet®.** Net sales of Percocet® in 2012 decreased 1% to \$103.4 million from \$104.6 million in 2011. This decrease was primarily attributable to reduced volumes, partially offset by price increases.

**Frova®.** Net sales of Frova® in 2012 increased 5% to \$61.3 million from \$58.2 million in 2011. The increase was primarily attributable to price increases, partially offset by reduced volumes.

**Supprelin® LA.** Net sales of Supprelin® LA in 2012 increased 15% to \$57.4 million from \$50.1 million in 2011. This increase was driven by increases to both price and volume, resulting primarily from an increase in new patient starts and a growing base of

continued care patients. We believe this growth is largely due to a strong base of national opinion leader support and ongoing efforts to streamline the treatment initiation process.

**Other brands.** Net sales of our other branded products in 2012 decreased 1% to \$91.3 million from \$92.7 million in 2011. This decrease was primarily driven by sales growth of Valstar® and Fortesta® Gel, partially offset by decreased sales of Opana® as demand continues to shift to Opana® ER.

**Qualitest.** Net sales of our generic products in 2012 increased 12% to \$633.3 million from \$566.9 million in 2011. This increase was primarily driven by strong demand for Qualitest's diversified product portfolio and favorable pricing as a result of market opportunities, which drove gross profit of over 35%. During the year ended December 31, 2012, revenues from Qualitest's top 15 products increased 11% to \$373.1 million in 2012 from \$335.6 million in 2011. This increase, which was largely driven by increased volumes and pricing upside, was partially offset by reduced revenues from products impacted by the supply disruption associated with the previously disclosed shutdown of Novartis Consumer Health's Lincoln, Nebraska manufacturing facility.

**AMS.** Revenues from our AMS segment in 2012 increased 68% to \$504.5 million from \$300.3 million in 2011. This increase is attributable to the timing of our acquisition of AMS, Inc., which contributed revenue during the full twelve months ended December 31, 2012 compared to less than seven months of revenue during 2011. However, this increase was partially offset by lower than usual sales in AMS's women's health line, which relates primarily to a reduction in mesh procedural volumes, particularly as to pelvic organ prolapse (POP) repair procedures. This reduction in mesh procedural volumes may be in response to a July 2011 update to the October 2008 Public Health Notification issued by the FDA to further advise the public and medical community regarding potential complications associated with transvaginal placement of surgical mesh to treat POP and SUI, as well as to the attorney advertising associated with transvaginal mesh litigation.

**HealthTronics.** Revenues from our HealthTronics segment in 2012 increased 3% to \$211.6 million from \$205.2 million in 2011. This increase was primarily attributable to the revenues from the electronic medical records software companies, Intuitive Medical Software, LLC and meridianEMR, Inc. which we acquired in the second half of 2011, partially offset by the loss of sales from our IGRT business, which was sold in August 2011.

**Gross Margin, Costs and Expenses.** The following table sets forth costs and expenses for the years ended December 31 (dollars in thousands):

	2012		2011	
	\$	% of Revenues	\$	% of Revenues
Cost of revenues .....	\$ 1,261,093	42	\$ 1,065,208	39
Selling, general and administrative* .....	898,847	30	813,271	30
Research and development .....	226,120	7	182,286	7
Patent litigation settlement, net .....	85,123	3	—	—
Litigation-related and other contingencies* .....	316,425	10	11,263	—
Asset impairment charges .....	768,467	25	116,089	4
Acquisition-related and integration items, net .....	23,015	1	33,638	1
Total costs and expenses** .....	\$ 3,579,090	118	\$ 2,221,755	81

\* \$11.3 million of costs incurred in 2011, associated primarily with an unfavorable court decision in the matter of Allmed Systems Inc. d/b/a Lisa Laser USA, Inc. and Lisa Laser Products OHG. vs. HealthTronics, Inc., which had previously been reported as a component of Selling, general and administrative expenses, have been reclassified as Litigation-related and other contingencies to conform to current year presentation.

\*\* Percentages may not add due to rounding.

**Cost of Revenues and Gross Margin.** Cost of revenues in 2012 increased 18% to \$1,261.1 million from \$1,065.2 million in 2011. This increase was primarily driven by increased revenues and our June 2011 acquisition of AMS, Inc., which contributed approximately \$162.9 million to our Cost of revenues in 2012, compared to \$124.2 million in 2011. Cost of revenues was also impacted by the 2012 charge of \$102.0 million related to the 2010 Impax Settlement Agreement. In addition, gross profit margins decreased to 58% in 2012 from 61% in 2011. This decrease in gross profit was primarily due to changes in the mix of revenues and the corresponding margins.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses in 2012 increased 11% to \$898.8 million from \$813.3 million in 2011. This increase was primarily attributable to the timing of our acquisition of AMS, Inc. and the inclusion, during 2012, of \$272.6 million of a full twelve months of AMS expense, compared to \$153.1 million in 2011, representing less than seven months of AMS Selling, general and administrative expense. Also contributing to this increase was an increase in expenses of \$9.0 million related to separation benefits incurred in connection with continued efforts to enhance the Company's

operations. These increases were partially offset by a decrease in Endo Pharmaceuticals sales, advertising and promotional expenses of approximately \$22 million, incentive compensation of approximately \$10 million and other expenses of approximately \$5 million.

**Research and Development Expenses.** Research and development expenses in 2012 increased 24% to \$226.1 million from \$182.3 million in 2011. This increase is primarily due to \$57.9 million in expense related to upfront and milestones payments in 2012, which included the initiation of the BEMA<sup>®</sup> Buprenorphine development program, compared to \$19.1 million in 2011. In addition, expenses increased \$29.4 million as a result of the addition of AMS's research and development portfolio upon our June 2011 acquisition of AMS, Inc. Due to the timing of our AMS, Inc. acquisition, our AMS segment incurred Research and development expenses during the entire twelve month period ended December 31, 2012, as compared to a partial period's expense in 2011. These increases were partially offset by a decrease in expenses of approximately \$21 million related to our branded R&D programs as we focused our efforts on key products in development.

We invest in research and development because we believe it is important to our long-term competitiveness. As a percent of revenues, R&D expense was approximately 7% in 2012 and 2011, and 8% in 2010. The variation in R&D expense as a percent of revenues is primarily due to upfront and milestone payments to third party collaborative partners included in R&D expense totaling \$57.9 million or 2% of revenue, \$19.1 million or 1% of revenue and \$23.9 million or 1% of revenue in 2012, 2011 and 2010, respectively. In addition to upfront and milestone payments, total research and development expenses include the costs of discovery research, preclinical development, early- and late-clinical development and drug formulation, as well as clinical trials, medical support of marketed products, other payments under third-party collaborations and contracts and other costs. Research and development spending also includes enterprise-wide costs which support our overall research and development infrastructure. These enterprise-wide costs, which primarily relate to our Endo Pharmaceuticals segment, are not allocated by product or to specific R&D projects. Unallocated enterprise-wide R&D costs were \$52.5 million, \$63.5 million and \$57.3 million in 2012, 2011 and 2010, respectively.

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

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

We consider our branded R&D programs in Phase III, or late-stage development, to be our significant R&D programs as they could potentially have an impact on our near-term revenue and earnings. As of December 31, 2012, our late-stage branded pharmaceutical programs, excluding on-market assets, include Aved<sup>™</sup> and BEMA<sup>®</sup> Buprenorphine.

The Company's pharmaceutical research and development efforts are also focused on the goal of developing a balanced, diversified portfolio of innovative and clinically differentiated generic products across a wide range of therapeutic areas. We generally focus on selective generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. We believe products with these characteristics will face a lesser degree of competition and therefore provide longer product life cycles and higher profitability than commodity generic products. For the years ended December 31, 2012, 2011 and 2010, the Company's direct R&D expense related to generics was \$29.1 million, \$29.1 million and \$17.5 million, respectively.

FDA approval of an abbreviated new drug application (ANDA) is required before a generic equivalent of an existing or reference-listed drug can be marketed. As of December 31, 2012, we have approximately 40 ANDAs under active FDA review in multiple therapeutic areas. The timing of final FDA approval of ANDA applications depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and whether the manufacturer of the reference listed drug is entitled to one or more statutory exclusivity periods, during which the FDA is prohibited from approving generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date.

We are also committed to developing new products and improving our current products in our medical device business to provide physicians and patients with better clinical outcomes through less invasive and more efficiently delivered therapies. Most of these R&D activities are conducted in our Minnesota and California facilities, although we also work with physicians, research hospitals, and universities around the world. Many of the ideas for new and improved products come from a global network of leading physicians who also work with us in evaluating new concepts and in conducting clinical trials to gain regulatory approvals. We conduct applied research in areas that we think will likely lead to product commercialization activities. This research is often done at a



technology platform level such that the science can be utilized to develop a number of different products. The development process for any new product can range from months to several years, primarily depending on the regulatory pathway required for approval.

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

The following table presents the composition of our total R&D expense as of December 31, 2012 and, for our branded pharmaceuticals R&D portfolio, the number of projects by stage of development:

	Research and Development Expense (in thousands)			Number of Projects at December 31, 2012			
	2012	2011	2010	Preclinical and Phase I	Phase II	Phase III(1)	Phase IV
Early-stage .....	\$ 18,903	\$ 26,638	\$ 22,872	13			
Middle-stage .....	5,595	11,697	13,373		2		
Late-stage .....	53,510	21,447	33,485			2	2
Sub-Total(2) .....	\$ 78,008	\$ 59,782	\$ 69,730				
Qualitest portfolio(2) .....	29,057	29,121	17,452				
AMS portfolio(2) .....	59,207	29,850	—				
HealthTronics portfolio(2) .....	7,368	—	—				
Enterprise-wide unallocated R&D costs	52,480	63,533	57,343				
Total R&D expense .....	<u>\$ 226,120</u>	<u>\$ 182,286</u>	<u>\$ 144,525</u>				

- (1) Includes projects for which an NDA has been filed with the FDA.  
(2) Excludes all costs not allocated to specific products and R&D projects.

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

R&D expenses, excluding upfront and milestone payments, are expected to decrease as we continue to streamline and integrate the R&D functions of our subsidiaries and focus our efforts on key products in development. As we continue to execute on our strategy of being a healthcare solutions provider with an integrated business model that includes branded and generic prescription drugs, medical devices and healthcare services, the composition of research and development expense may change reflecting our focus on these multiple products and platforms.

**Patent Litigation Settlement, net.** On May 28, 2012, Endo Pharmaceuticals Inc. (EPI) entered into a Settlement and License Agreement (the Watson Settlement Agreement) among EPI and Teikoku, on the one hand, and Watson, on the other hand. The Watson Settlement Agreement settled all ongoing patent litigation among the parties relating to Watson's generic version of Lidoderm®. Under the terms of the Watson Settlement Agreement, the parties dismissed their respective claims and counterclaims without prejudice. As part of the settlement, Watson agreed not to challenge the validity or enforceability of Endo's and Teikoku's patents relating to Lidoderm® with respect to Watson's generic version of Lidoderm®. Watson also agreed not to sell its generic version of Lidoderm® until it received FDA approval and, in any event, no sooner than September 15, 2013, except in limited specific circumstances (such date being the Start Date). Endo and Teikoku agreed to grant Watson a license permitting the sale of generic Lidoderm® upon the Start Date in the U.S. The license to Watson is exclusive as to Endo's launch of an authorized generic version of Lidoderm® until the earlier of 1) the introduction of a generic version of Lidoderm® by a company other than Watson, or 2) seven and a half months after Watson launches its generic version of Lidoderm®. Endo will receive an at market royalty equal to 25% of the gross profit generated on Watson's sales of its generic version of Lidoderm® during Watson's period of exclusivity.

Additionally, the Watson Settlement Agreement provides that Endo and Teikoku will provide, at no cost, to Watson's wholesaler affiliate branded Lidoderm® product for Watson's wholesaler affiliate's distribution, subject to certain terms and conditions. Given that Watson received FDA approval of its generic version of Lidoderm® in August 2012, Endo and Teikoku will provide branded Lidoderm® of value totaling \$12.0 million each month (\$96.0 million in total for 2013) (valued at the then-prevailing wholesale acquisition cost) beginning on January 1, 2013 through August 1, 2013. The obligation of Endo and Teikoku to provide this branded product at no cost terminates immediately upon the launch of a third party's generic version of Lidoderm® in the U.S., including its territories, possessions and the Commonwealth of Puerto Rico (the Territory).

Endo will be responsible for the payment of all gross to net adjustments arising from Watson's sale of the branded Lidoderm® product.

In contemplation of the Watson Settlement Agreement, Teikoku has agreed to provide a rebate to Endo equal to 50% of the cost of branded Lidoderm® product that is required to be provided to Watson's wholesaler affiliate pursuant to Section 3(b), 3(c) and 3(d) of the Watson Settlement Agreement.

The Company has concluded that the Watson Settlement Agreement is a multiple-element arrangement and during the second quarter of 2012 recognized a liability and corresponding charge of \$131.4 million in Patent litigation settlement, net in the Consolidated Statements of Operations representing the initial estimated fair value of the settlement component. Fair value of the settlement component was estimated using the probability adjusted expected value of branded Lidoderm® product to be provided to Watson at the anticipated wholesaler acquisition cost (WAC) expected to be in place at the time of shipment, less a reasonable estimate of Watson's selling costs. The resultant probability-weighted values were then discounted using a discount rate of 5.1%.

The Company believes that the level and timing of branded Lidoderm® product to be shipped, discount rate, and probabilities used in the model appropriately reflect market participant assumptions. Because the liability is recorded at fair value using WAC, the net charge recognized in 2012 is comprised of several elements, including our cost of product to be shipped, estimated gross-to-net deductions to be paid by the Company and the estimated product profit margin. We believe this is the most appropriate measure of fair value as these components combined represent the value accruing to Watson. As a result of using a fair value measurement, the charge will be greater than the actual cost to the Company. As such, relief of the liability in subsequent periods through shipments of branded Lidoderm® product will result in income, which we expect to record as a component of Other income, net in the Company's Consolidated Statements of Operations. We intend to reclassify the portion of the settlement liability related to the gross-to-net component into our gross-to-net reserves as product is shipped to Watson, the effect of which will be to offset a portion of the income that will be recognized into Other income, net in the Company's Consolidated Statements of Operations, as the settlement liability is relieved. The rebate arrangement with Teikoku will also be accounted for prospectively as product purchased from Teikoku will be recorded into inventory at the discounted purchase price and relieved as shipments are made to Watson. The benefit associated with this rebate will be recorded as a component of Other income, net in the Company's Consolidated Statements of Operations.

On August 23, 2012, Watson announced it received FDA approval on its ANDA for its lidocaine patch 5%, a generic version of Lidoderm®. The Company anticipates Watson will launch its generic version of Lidoderm® on September 15, 2013 pursuant to the terms of the Watson Settlement Agreement. In light of Watson's anticipated September 2013 launch, the Company reassessed its obligation to Watson and believes it will not be obligated to provide to Watson's wholesaler affiliate branded Lidoderm® product beyond September 2013. Accordingly, in the third quarter of 2012, the Company recognized a change in estimate with respect to its obligation and reduced its liability associated with the Watson Settlement Agreement by \$46.2 million to \$85.1 million. The corresponding gain of \$46.2 million was recorded in Patent litigation settlement, net in the Consolidated Statements of Operations. Future changes, if any, resulting from revisions to the timing or the amount of the original estimate will be recognized as an increase or a decrease in the carrying amount of the litigation settlement liability and the related Patent litigation settlement, net during the period of change. Future changes in estimates to the settlement liability could have a material impact on our results of operations.

**Litigation-Related and Other Contingencies.** Charges for Litigation-related and other contingencies in 2012 totaled \$316.4 million compared to \$11.3 million in 2011. The 2012 amount relates to charges associated with certain of our legal proceedings and other contingent matters as described in more detail in Note 15. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules". The 2011 charge relates primarily to an unfavorable court decision in the matter of Allmed Systems Inc. d/b/a Lisa Laser USA, Inc. and Lisa Laser Products OHG. vs. HealthTronics, Inc.

**Asset Impairment Charges.** Asset impairment charges in 2012 totaled \$768.5 million compared to \$116.1 million in 2011. The impairment charges were related to goodwill, other intangibles and other miscellaneous assets and are further discussed below by segment. Our impairment review processes are described in further detail under the caption "CRITICAL ACCOUNTING ESTIMATES".

### **Endo Pharmaceuticals Segment**

As part of our year-end financial close and reporting process, the Company concluded that impairment assessments were required to evaluate the recoverability of certain definite-lived intangible assets associated with our Supprelin® and Vantas® franchises

in certain non-U.S. markets. After performing these assessments, we recorded pre-tax non-cash impairment charges of \$2.0 million and \$3.7 million, respectively, representing the remaining carrying amounts of these assets.

The Company also reviewed its in-process research and development indefinite-lived intangible assets in connection with its annual impairment testing. As a result of market and potential regulatory changes in certain non-U.S. markets, we determined that our European Valstar<sup>®</sup> asset and our Asian Sanctura<sup>®</sup> asset were not recoverable. In the fourth quarter of 2012, we recorded pre-tax non-cash impairment charges of \$2.0 million, and \$8.0 million, respectively, representing the carrying amounts of these assets.

Pursuant to the Sanctura XR<sup>®</sup> Amended and Restated License, Commercialization and Supply Agreement with Allergan USA, Inc. (Allergan), the Company receives royalties based on net sales of Sanctura XR<sup>®</sup> made by Allergan. In March 2009, Watson Pharmaceuticals, Inc. (now doing business as Actavis, Inc. and referred to herein as Watson or Actavis) filed an Abbreviated New Drug Application (ANDA) seeking FDA approval to market generic versions of Sanctura XR<sup>®</sup> before the expiration of Allergan's patents listed in the Orange Book. Subsequent to Watson's ANDA filing, Sandoz Inc. and Paddock Laboratories, Inc. (acquired by Perrigo Company in August 2011) also filed ANDAs for a generic version of Sanctura XR<sup>®</sup>. In April 2012, the U.S. District Court for the District of Delaware ruled that five patents covering Allergan's Sanctura XR<sup>®</sup> (trospium chloride) extended-release capsules were invalid. The Company appealed this ruling, and subsequently in June 2012, our appeal was dismissed.

As part of our first quarter 2012 financial close and reporting process, the Company concluded that an impairment assessment was required to evaluate the recoverability of the indefinite-lived intangible asset. The Company assessed the recoverability of this asset and determined the fair value of the Sanctura XR<sup>®</sup> intangible asset to be \$21.6 million at March 31, 2012. Accordingly, the Company recorded a pre-tax non-cash impairment charge of \$40.0 million in March 2012, representing the difference between the carrying amount of the intangible asset and its estimated fair value. In October 2012, Watson announced that it had received FDA approval for its generic version of Sanctura XR<sup>®</sup> and that it intended to begin shipping its product immediately. As a result, the Company reevaluated the recoverability of the asset and determined that an impairment existed. The fair value of the Sanctura XR<sup>®</sup> intangible asset was determined to be \$5.0 million at September 30, 2012. Accordingly, the Company recorded an additional pre-tax non-cash impairment charge of \$11.2 million in September 2012. The remaining net book value was amortized in its entirety by December 31, 2012, commensurate with the expected rate of erosion due to generic competition.

In early 2012, the Company terminated Penwest's A0001 development program after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, during the fourth quarter of 2011 we recorded a pre-tax, non-cash impairment charge of \$1.6 million to write off this intangible asset in its entirety.

On December 27, 2011, the Company terminated its pagoclone development program after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, we recorded a pre-tax, non-cash impairment charge of \$8.0 million in 2011 to write off the remaining intangible asset in its entirety.

On November 11, 2011, the Company terminated development of the octreotide implant for the treatment of acromegaly after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, we recorded a pre-tax non-cash impairment charge of \$9.0 million in 2011 to completely write-off the octreotide – acromegaly intangible asset.

From September 21, 2012 through November 1, 2012, EPI and its partner Grünenthal received Paragraph IV Notices from each of Teva, Amneal, Sandoz and ThoRx advising of the filing by each such company of an ANDA for a generic version of the formulation of Opana<sup>®</sup> ER designed to be crush-resistant. EPI intends, and has been advised by Grünenthal that they too intend, to vigorously defend the intellectual property rights covering Opana<sup>®</sup> ER and to pursue all available legal and regulatory avenues in defense of Opana<sup>®</sup> ER, including enforcement of the product's intellectual property rights and approved labeling. However, there can be no assurance that we will be successful. If we are unsuccessful and Teva, Amneal, Sandoz or ThoRx is able to obtain FDA approval of its product, it may be able to launch a generic version of Opana<sup>®</sup> ER prior to the applicable patents' expirations in 2023, 2024, 2025 and 2029 respectively.

While the original formulation of Opana<sup>®</sup> ER is safe and effective when taken as prescribed, it was nevertheless subject to abuse, misuse and diversion. Consequently, our subsidiary, EPI discontinued from sale for safety reasons all strengths of Opana<sup>®</sup> ER approved under New Drug Application (NDA) No. 021610 and notified the FDA of this discontinuation. As a result, the FDA moved Opana<sup>®</sup> ER to the Discontinued List section of the Agency's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). On August 13, 2012, EPI submitted a Citizen Petition with the FDA requesting that it (1) determine that the discontinued, non-crush-resistant version of Opana<sup>®</sup> ER approved under NDA No. 021610 was discontinued for safety and can no longer serve as a Reference List Drug (RLD) for an ANDA or generic applicant; (2) refuse to approve any pending ANDA for a generic version of the non-crush resistant version of Opana<sup>®</sup> ER approved under NDA No. 021610; and (3) suspend and withdraw the approval of any ANDA referencing Opana<sup>®</sup> ER approved under NDA No. 021610 as the RLD. The petition emphasizes the potential

widespread availability of non-crush resistant generics of all strengths of Opana<sup>®</sup> ER in early 2013 and calls into question whether generics can properly be marketed in view of the discontinuation of Opana<sup>®</sup> ER for safety reasons.

On August 31, 2012, EPI submitted an additional Citizen Petition requesting that the FDA (1) require that any ANDA referencing the crush-resistant formulation of Opana<sup>®</sup> ER contain data and information demonstrating that the proposed ANDA product is similarly crush resistant; (2) classify extended-release opioid formulations incorporating crush-resistant technologies, such as the new Opana<sup>®</sup> ER, as new dosage forms in Appendix C of the FDA's Orange Book; and (3) confirm that any ANDA referencing Opana<sup>®</sup> ER approved under NDA No. 021610 will not be identified in the Orange Book as therapeutically equivalent to the crush-resistant formulation of Opana<sup>®</sup> ER. The petition emphasized that the abuse of prescription opioid analgesics is at the center of a major public health crisis of addiction, misuse, abuse, overdose and death and that objective criteria are required to evaluate whether a formulation is truly crush-resistant. In January 2013, we received notice from the FDA that it had denied our August 31, 2012 Citizen Petition. Other than an acknowledgment of receipt, we have received no response from the FDA with respect to our August 13, 2012 Citizen Petition.

In light of recent legal, regulatory and competitive activity related to the crush-resistant formulation of Opana<sup>®</sup> ER, we concluded that an impairment assessment was required to evaluate the recoverability of the Opana<sup>®</sup> ER indefinite-lived intangible assets and performed this analysis in conjunction with our third quarter 2012 10-Q filing. In performing this assessment, we calculated the anticipated undiscounted cash flows related to Opana<sup>®</sup> ER on a probability-weighted basis, considering the potential outcomes that could result from the recent regulatory developments discussed in the above paragraphs, and concluded that no impairment charge was required at September 30, 2012. Changes in any of the assumptions used in determining the fair value of this asset may result in the need for future impairment testing, which could result in future impairment charges.

### ***Qualitest Segment***

During the fourth quarter of 2011, the Company received a deficiency from the FDA on an ANDA submission for one of its lead assets in its Qualitest Pharmaceuticals IPR&D portfolio. Subsequently, in early 2012, the Company terminated its development program for this asset as a result of the regulatory challenges and changes in the development timeline resulting from the FDA's request. In addition, as a result of changes in market conditions since the acquisition date, there has been a significant deterioration in the commercial potential for this product. Accordingly, we recorded a pre-tax non-cash impairment charge of \$71.0 million in 2011 to write off the intangible asset in its entirety.

### ***AMS Segment***

Based on the results of the Company's Step II analysis for the AMS reporting unit, we recorded a pre-tax, non-cash goodwill impairment charge in the Consolidated Statement of Operations for \$507.5 million, representing the difference between the implied fair value of the reporting unit's goodwill and its carrying amount as of October 1, 2012. The decline in the fair value for the AMS reporting unit is the result of lower projected revenue growth and profitability levels. The lower projected operating results reflect changes in the assumptions related to organic revenue growth, market trends, business mix, cost structure and other expectations about the anticipated short-term and long-term operating results of the AMS reporting unit identified as part of our fourth quarter 2012 strategic planning and budgeting processes. Future changes, if any, to our assumptions may result in additional and potentially full future impairment charges to our AMS goodwill of up to \$1.3 billion.

As a result of the Step II analysis, we also determined that the carrying amounts of the women's health developed technology intangible asset and one of the AMS, Inc. IPR&D intangible assets were impaired. This determination was based primarily on lower than initially expected revenue and profitability levels over a sustained period of time and downward revisions to management's short-term and long-term forecasts for the AMS women's health product line. Accordingly, we recorded a pre-tax non-cash impairment charge of \$128.5 million to impair the women's health developed technology intangible asset in its entirety. We also recorded a pre-tax non-cash impairment charge of \$4.0 million to impair the IPR&D asset, representing the difference between the fair value and the carrying amount. Future changes, if any, to our assumptions may result in additional and potentially full future impairment charges related to this IPR&D asset of up to \$8.0 million.

During the second quarter of 2012, as a result of market and potential regulatory changes affecting the commercial potential in the U.S. for one of the AMS, Inc. IPR&D assets, the Company determined that the asset's carrying amount was no longer fully recoverable. Accordingly, in the second quarter of 2012, we recorded a pre-tax non-cash impairment charge of \$3.0 million, representing the difference between the fair value and the carrying amount.

### ***HealthTronics Segment***

Based on the results of the Company's Step II analysis for the Anatomical Pathology Services and HITS reporting units, we recorded pre-tax, non-cash goodwill impairment charges in the Consolidated Statement of Operations for \$24.8 million and \$25.1 million, respectively, representing the difference between the implied fair value of each reporting unit's goodwill and the respective carrying amounts as of October 1, 2012. The declines in the fair values for these reporting units resulted from lower projected revenue

growth and profitability levels for each respective business. The lower projected operating results reflect changes in the assumptions related to organic revenue growth, new product development, strategic business changes, cost structure, market trends, business mix and other expectations about the anticipated short-term and long-term operating results of these reporting units identified as part of our fourth quarter 2012 strategic planning and budgeting processes. Future changes, if any, to our assumptions related to the HITS reporting unit may result in additional and potentially full future impairment charges of \$19.8 million.

As a result of the HITS Step II analysis, we also determined that the carrying amounts of certain HITS intangible assets were impaired. This determination was based primarily on lower than initially expected revenue and profitability levels over an expected sustained period of time and downward revisions to management's short-term and long-term forecasts for the HITS reporting unit. Accordingly, we recorded pre-tax non-cash impairment charges of \$3.0 million on these intangible assets, representing the difference between the fair values and the carrying amounts.

**Other**

In July 2008, the Company made a \$20 million investment in a privately-held company focused on the development of an innovative treatment for certain types of cancer. In September 2011, we impaired our investment in this privately-held company due to the negative clinical trial results related to its lead asset. Accordingly, we wrote off our investment in its entirety and recorded an impairment charge of \$22.7 million.

Remaining Asset impairment charges were not material to the Consolidated Financial Statements in either 2012 or 2011.

**Acquisition-Related and Integration Items, net.** Acquisition-related and integration items, net totaled \$23.0 million in expense in 2012 compared to \$33.6 million in expense in 2011. The decrease is primarily a result of the nonrecurring transaction costs in 2011 directly associated with the closing of the AMS acquisition of \$25.8 million, partially offset by an unfavorable change in the fair value of contingent consideration in 2012, which resulted in a loss of \$0.2 million compared to a favorable change resulting in a gain of \$7.4 million in 2011. The remaining change is a result of integration costs related to our recent acquisitions.

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

	2012	2011
Interest expense.....	\$ 183,240	\$ 148,623
Interest income.....	(406)	(599)
Interest expense, net.....	<u>\$ 182,834</u>	<u>\$ 148,024</u>

Interest expense during 2012 totaled \$183.2 million compared to \$148.6 million in 2011. The increase from 2011 to 2012 was primarily attributable to increases in our average total indebtedness resulting from our June 2011 borrowings of \$900.0 million of senior notes and \$2.2 billion of term loan indebtedness in connection with our June 2011 acquisition of AMS, Inc.

**Net Loss on Extinguishment of Debt.** In February 2012, we made a prepayment of \$205.0 million on our Term Loan B Facility. We made additional prepayments of \$33.0 million and \$39.7 million in July 2012 and September 2012, respectively. In accordance with the applicable accounting guidance for debt modifications and extinguishments, approximately \$7.2 million of the remaining unamortized financing costs were written off in connection with our 2012 prepayments. This amount was included in the Consolidated Statements of Operations as a Net loss on extinguishment of debt.

Upon the establishment of our 2011 Credit Facility, financing costs of \$56.2 million paid to establish the 2011 Credit Facility as well as financing costs of \$6.2 million associated with prior credit facilities, were deferred and are being amortized to interest expense over the life of the 2011 Credit Facility. Approximately \$8.5 million of the deferred financing costs associated with prior credit facilities was also written off at this time in accordance with the applicable accounting guidance for debt modifications and extinguishments and was included in the Consolidated Statements of Operations as a Net loss on extinguishment of debt. Additionally, in September 2011 and December 2011, we made prepayments of \$135.0 million and \$125.0 million, respectively, on our Term Loan B Facility. In accordance with the applicable accounting guidance for debt modifications and extinguishments, approximately \$3.4 million of the remaining unamortized financing costs was written off in connection with our 2011 prepayments and included in the Consolidated Statements of Operations as a Net loss on extinguishment of debt.

**Other Income, Net.** Other income, net was \$0.2 million of income in 2012 compared to \$3.3 million of income in 2011.

**Income Tax.** In 2012, we recognized \$53.6 million of income tax benefit compared to expense of \$109.6 million in 2011. The effective income tax rate was 7.2% in 2012 compared to 31.2% in 2011. The change in the effective tax rate is largely driven by charges not deductible for tax purposes including our goodwill impairment charge and certain non-deductible litigation-related and other contingent matters.



Additionally, in 2012 we recorded a \$6.3 million benefit for a prior period adjustment related to the reversal of a 2010 capital loss valuation allowance recorded in connection with our acquisition of HealthTronics, Inc. The valuation allowance was reversed because of a 2011 transaction that resulted in a realized ordinary loss for income tax purposes.

**Net Income Attributable to Noncontrolling Interests.** As a result of our July 2010 acquisition of HealthTronics, Inc., we own interests in various partnerships and limited liability corporations (LLCs) where we, as the general partner or managing member, exercise effective control. Accordingly, we consolidate various entities where we do not own 100% of the entity in accordance with the accounting consolidation principles. Net income attributable to noncontrolling interests relates to the portion of the net income of these partnerships and LLCs not attributable, directly or indirectly, to our ownership interests. Net income attributable to noncontrolling interest totaled \$52.3 million in 2012 and \$54.5 million in 2011.

**2013 Outlook.** We estimate that our 2013 total revenues will be between \$2.80 billion and \$2.95 billion. This estimate is based on our expectation of growth in Qualitest and AMS offset by a decrease in Endo Pharmaceuticals revenues resulting from the entry of a single generic competitor to Lidoderm®, and by erosion in market share for Opana® ER due to competition from a single, non-AB-rated generic. Cost of revenues as a percent of total revenues is expected to increase when compared to 2012 as a result of the simultaneous growth in lower margin generic pharmaceutical product sales and decline in higher margin branded pharmaceutical sales in 2013. Selling, general and administrative expenses as a percentage of revenues are expected to decline in 2013 relative to 2012 reflecting continuing efficiency improvement efforts and the annualization of the effects of cost reductions initiated in 2012. Research and development expenses, excluding upfront and milestone payments, are expected to decrease as we streamline and integrate the R&D functions of our subsidiaries and focus our efforts on key products in development. There can be no assurance that the Company will achieve these results.

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

**Revenues.** Total revenues in 2011 increased 59% to \$2.73 billion from \$1.72 billion in 2010. This increase in revenues is primarily driven by our 2011 acquisition of AMS, Inc., from which we derived \$300.3 million in revenue, plus the full-year impact from our 2010 acquisitions, including \$446.2 million in revenues from Qualitest Pharmaceuticals products and \$205.2 million in revenues from HealthTronics, Inc. The remaining increase in total revenue was driven by organic growth in our Endo Pharmaceuticals product portfolio including Lidoderm®, Opana® ER and Voltaren® Gel. Sales growth of our Endo Pharmaceuticals segment was essentially volume driven.

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

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

\* Percentages may not add due to rounding.

**Lidoderm®.** Net sales of Lidoderm® in 2011 increased 5% to \$825.2 million from \$782.6 million in 2010. The increase in net sales was primarily attributable to increased volumes in 2011. In addition, we were required to pay Hind royalties based on net sales of Lidoderm® until this obligation expired on November 23, 2011. Hind royalties were recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm®. Due to the expiration of this obligation, these royalties decreased from \$86.8 million in 2010 to \$77.9 million in 2011, which had a favorable impact to 2011 net

sales. Lidoderm<sup>®</sup> had solid performance this year and continues to generate strong cash flow that we can use to invest in our business to continue to further diversify our revenue base.

*Opana<sup>®</sup> ER.* Net sales of Opana<sup>®</sup> ER in 2011 increased 60% to \$384.3 million from \$239.9 million in 2010. The increase in net sales was primarily attributable to continued prescription and market share growth of the product, as we continue to drive our promotional efforts through physician targeting. In addition, our strategy to contract with managed care organizations has resulted in increases in volume as we have broadened our access for the brand.

*Voltaren<sup>®</sup> Gel.* Net sales of Voltaren<sup>®</sup> Gel in 2011 increased 36% to \$142.7 million from \$104.9 million in 2010. The increase was driven by volume. The Company launched Voltaren<sup>®</sup> Gel in March 2008 and we believe the growth of Voltaren<sup>®</sup> Gel since its launch is driven by the product's proven clinical efficacy combined with our continued promotional activities aimed at increasing product awareness in the target audience.

*Percocet<sup>®</sup>.* Net sales of Percocet<sup>®</sup> in 2011 decreased 14% to \$104.6 million from \$121.3 million in 2010. The decrease was primarily attributable to decreased volumes during 2011 as compared to 2010.

*Frova<sup>®</sup>.* Net sales of Frova<sup>®</sup> in 2011 decreased 2% to \$58.2 million from \$59.3 million in 2010. The decrease in net sales was primarily attributable to reduced volumes during 2011 as compared to 2010, partially offset by price increases.

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

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

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

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

*HealthTronics.* Revenues from our HealthTronics segment in 2011 increased 101% to \$205.2 million from \$102.1 million in 2010. This increase was driven by the full-year impact of HealthTronics, Inc., which contributed six months of revenue in 2010 compared to a full year of revenue in 2011. The \$205.2 million consisted primarily of lithotripsy fees of \$110.2 million, cryosurgery treatment fees of \$26.0 million and other service revenues from our HealthTronics segment.

**Gross Margin, Costs and Expenses.** The following table sets forth costs and expenses for the years ended December 31 (dollars in thousands):

	2011		2010	
	\$	% of Revenues	\$	% of Revenues
Cost of revenues .....	\$ 1,065,208	39	\$ 504,757	29
Selling, general and administrative* .....	813,271	30	547,605	32
Research and development .....	182,286	7	144,525	8
Litigation-related and other contingencies* .....	11,263	—	—	—
Asset impairment charges .....	116,089	4	35,000	2
Acquisition-related and integration items, net .....	33,638	1	18,976	1
Total costs and expenses** .....	\$ 2,221,755	81	\$ 1,250,863	73

- \* \$11.3 million of costs incurred in 2011, associated primarily with an unfavorable court decision in the matter of Allmed Systems Inc. d/b/a Lisa Laser USA, Inc. and Lisa Laser Products OHG. vs. HealthTronics, Inc., which had previously been reported as a component of Selling, general and administrative expenses, have been reclassified as Litigation-related and other contingencies to conform to current year presentation.
- \*\* Percentages may not add due to rounding.

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

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses in 2011 increased 49% to \$813.3 million from \$547.6 million in 2010. The increase in Selling, general and administrative expenses was primarily attributable to our second half 2010 acquisitions and our June 2011 acquisition of AMS, Inc., which, on a combined basis, contributed approximately \$239.2 million of Selling, general and administrative expense during 2011 compared with \$24.7 million during 2010. The increase was also partially driven by certain integration costs and separation benefits incurred in connection with continued efforts to enhance the Company's operations and included in Selling, general and administrative expenses totaling \$19.7 million during 2011. The remaining increase is primarily attributable to the overall growth of our business and the related increases in costs. Selling, general and administrative expenses as a percentage of revenue decreased to 30% in 2011 from 32% in 2010.

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

**Litigation-Related and Other Contingencies.** Charges for Litigation-related and other contingencies in 2011 totaled \$11.3 million compared to zero in 2010. The 2011 charge relates primarily to an unfavorable court decision in the matter of Allmed Systems Inc. d/b/a Lisa Laser USA, Inc. and Lisa Laser Products OHG. vs. HealthTronics, Inc.

**Asset Impairment Charges.** Asset impairment charges in 2011 totaled \$116.1 million in 2011 compared to \$35.0 million in 2010. The impairment charges were related to intangibles and other miscellaneous assets and are further discussed below by segment. Our impairment review processes are described in further detail under the caption "CRITICAL ACCOUNTING ESTIMATES".

### **Endo Pharmaceuticals Segment**

In early 2012, the Company terminated Penwest's A0001 development program after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, during the fourth quarter of 2011 we recorded a pre-tax, non-cash impairment charge of \$1.6 million to write off this intangible asset in its entirety.

In May 2010, Teva Pharmaceutical Industries Ltd. terminated the pagoclone development and licensing arrangement with the Company upon the completion of the Phase IIb study. As a result, the Company concluded that there was a decline in the fair value of the corresponding indefinite-lived intangible asset. Accordingly, we recorded a \$13.0 million impairment charge in 2010.

On December 27, 2011, the Company terminated its pagoclone development program after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, we recorded a pre-tax, non-cash impairment charge of \$8.0 million to write off the remaining intangible asset in its entirety.

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

On November 11, 2011, the Company separately decided to terminate development of the octreotide implant for the treatment of acromegaly after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, we recorded a pre-tax non-cash impairment charge of \$9.0 million in 2011 to completely write-off the octreotide – acromegaly intangible asset.

### ***Qualitest Segment***

During the fourth quarter of 2011, the Company received a deficiency from the FDA on an ANDA submission for one of its lead assets in its Qualitest Pharmaceuticals IPR&D portfolio. Subsequently, in early 2012, the Company terminated its development program for this asset as a result of the regulatory challenges and changes in the development timeline resulting from the FDA's request. In addition, as a result of changes in market conditions since the acquisition date, there has been a significant deterioration in the commercial potential for this product. Accordingly, we recorded a pre-tax non-cash impairment charge of \$71.0 million in 2011 to write off the intangible asset in its entirety.

### ***Other***

In July 2008, the Company made a \$20 million investment in a privately-held company focused on the development of an innovative treatment for certain types of cancer. In September 2011, we impaired our investment in this privately-held company due to the negative clinical trial results related to its lead asset. Accordingly, we wrote off our investment in its entirety and recorded an impairment charge of \$22.7 million.

Remaining Asset impairment charges were not material to Consolidated Financial Statements in either 2011 or 2010.

***Acquisition-Related and Integration Items, net.*** Acquisition-related and integration items, net in 2011 were \$33.6 million of expense compared to \$19.0 million of expense in 2010. The increase is primarily a result of a decrease in the gain on the fair value of contingent consideration, which was \$51.4 million in 2010 compared to \$7.4 million in 2011. This increase in expense was partially offset by a decrease in transaction costs associated with the closing of acquisitions, which was \$25.8 million in 2011, related to the AMS acquisition, compared to \$61.7 million in 2010, related to the acquisitions of Qualitest Pharmaceuticals, Penwest and HealthTronics, Inc. The remaining change is the result of integration costs related to these acquisitions.

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

	2011	2010
Interest expense.....	\$ 148,623	\$ 47,956
Interest income.....	(599)	(1,355)
Interest expense, net.....	<u>\$ 148,024</u>	<u>\$ 46,601</u>

Interest expense in 2011 was \$148.6 million compared with \$48.0 million in 2010. The increase in interest expense was primarily attributable to increases to our average total indebtedness in 2011 compared to 2010. In 2011, we incurred \$66.6 million of interest expense on our \$1.3 billion of senior notes, of which \$400.0 million originated in November 2010 and the remaining \$900.0 million in June 2011. This compares to \$3.1 million of senior note interest in 2010. Our 2011 interest expense related to our credit facilities was \$51.3 million compared to \$5.4 million in 2010. This increase was largely attributable to the 2011 Credit Facility entered into in June 2011, which provided \$2.2 billion of term loan indebtedness compared to \$400.0 million of term loan indebtedness at December 31, 2010. These increases were partially offset by reduced interest expense on our 16% non-recourse notes due 2024, which incurred \$7.3 million of interest expense in 2010 until they were retired in the third quarter of 2010.

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

**Loss (Gain) on Extinguishment of Debt.** Upon the establishment of our 2011 Credit Facility, financing costs of \$56.2 million paid to establish the 2011 Credit Facility as well as financing costs of \$6.2 million associated with prior credit facilities, were deferred and are being amortized to interest expense over the life of the 2011 Credit Facility. Approximately \$8.5 million of the deferred financing costs associated with prior credit facilities was also written off at this time in accordance with the applicable accounting guidance for debt modifications and extinguishments and was included in the Consolidated Statements of Operations as a Net loss on extinguishment of debt. Additionally, in September 2011 and December 2011, we made prepayments of \$135.0 million and \$125.0 million, respectively, on our Term Loan B Facility. In accordance with the applicable accounting guidance for debt modifications and extinguishments, approximately \$3.4 million of the remaining unamortized financing costs was written off in connection with our 2011 prepayments and included in the Consolidated Statements of Operations as a Net loss on extinguishment of debt.

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

	2011	2010
Gain on trading securities .....	\$ —	\$ (15,420)
Loss on auction-rate securities rights.....	—	15,659
Other income, net.....	(3,268)	(2,172)
Other income, net.....	<u>\$ (3,268)</u>	<u>\$ (1,933)</u>

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

**Income Tax.** Income tax expense in 2011 decreased 18% to \$109.6 million from \$133.7 million in 2010. This fluctuation is due to a \$69.0 million decrease in income before income tax and the decrease in our effective income tax rate to 31.2% from 31.8% in 2010. The decrease in the effective income tax rate is primarily due to an increase in non-taxable income attributable to non-controlling interests in the current period as compared to 2010, the release of reserves related to uncertain tax positions due to statute of limitations expirations and audit settlements, an increase in the Domestic Production Activities deduction, and a decrease in transactions costs from acquisitions in the current period as compared to 2010. This decrease was partially offset by a lower benefit from non-taxable reductions in the fair value of contingent consideration in the current period as compared to 2010, the establishment of a valuation allowance in the current period against an anticipated capital loss on our cost method investment in a privately-held company and a charge for the non-deductible Branded Prescription Drug fee enacted in 2011.

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

## Business Segment Results Review

In the fourth quarter of 2011, as a result of our strategic planning process, the Company's executive leadership team reorganized the manner in which it views our various business activities. Management's intention was to enhance its level of understanding of the entity's performance, better assess its prospects and future cash flow potential and ultimately make more informed operating decisions



about resource allocation and the enterprise as a whole. Based on this change, we reassessed our reporting structure under the applicable accounting guidance and determined that the Company now has four reportable segments: (1) Endo Pharmaceuticals, (2) Qualitest, (3) AMS and (4) HealthTronics. We have retrospectively revised the segment presentation for all periods presented reflecting the change from three to four reportable segments. Additionally, concurrent with the Company's May 2012 enterprise-wide rebranding initiative and corporate name change, the Company changed the names of its reportable segments to better align with these efforts. These changes to our segments have no impact on the Company's Consolidated Financial Statements for all periods presented. Each segment derives revenue from the sales or licensing of their respective products or services and is discussed below.

We evaluate segment performance based on each segment's adjusted income before income tax, a financial measure not determined in accordance with GAAP. We define adjusted income before income tax as income (loss) before income tax before certain upfront and milestone payments to partners, acquisition-related and integration items, net, cost reduction and integration-related initiatives, asset impairment charges, amortization of intangible assets related to marketed products and customer relationships, inventory step-up recorded as part of our acquisitions, non-cash interest expense, litigation-related and other contingent matters and certain other items that the Company believes do not reflect its core operating performance.

Certain corporate general and administrative expenses are not allocated and are therefore included within Corporate unallocated. We calculate consolidated adjusted income before income tax by adding the adjusted income before income tax of each of our reportable segments to corporate unallocated adjusted income before income tax.

We refer to adjusted income before income tax in making operating decisions because we believe it provides meaningful supplemental information regarding the Company's operational performance. For instance, we believe that this measure facilitates its internal comparisons to its historical operating results and comparisons to competitors' results. The Company believes this measure is useful to investors in allowing for greater transparency related to supplemental information used by us in our financial and operational decision-making. In addition, we have historically reported similar financial measures to our investors and believe that the inclusion of comparative numbers provides consistency in our financial reporting at this time. Further, we believe that adjusted income before income tax may be useful to investors as we are aware that certain of our significant stockholders utilize adjusted income before income tax to evaluate our financial performance. Finally, adjusted income before income tax is utilized in the calculation of adjusted diluted net income per share, which is used by the Compensation Committee of Endo's Board of Directors in assessing the performance and compensation of substantially all of our employees, including our executive officers.

There are limitations to using financial measures such as adjusted income before income tax. Other companies in our industry may define adjusted income before income tax differently than we do. As a result, it may be difficult to use adjusted income before income tax or similarly named adjusted financial measures that other companies may use to compare the performance of those companies to our performance. Because of these limitations, adjusted income before income tax should not be considered as a measure of the income generated by our business or discretionary cash available to us to invest in the growth of our business. The Company compensates for these limitations by providing reconciliations of our consolidated adjusted income before income tax to our consolidated income before income tax, which is determined in accordance with U.S. GAAP and included in our Consolidated Statements of Operations.

### ***Endo Pharmaceuticals***

The Endo Pharmaceuticals segment includes a variety of branded prescription products related to treating and managing pain as well as our urology, endocrinology and oncology products. The marketed products that are included in this segment include Lidoderm<sup>®</sup>, Opana<sup>®</sup> ER, Percocet<sup>®</sup>, Voltaren<sup>®</sup> Gel, Frova<sup>®</sup>, Supprelin<sup>®</sup> LA, Vantas<sup>®</sup>, Valstar<sup>®</sup> and Fortesta<sup>®</sup> Gel.

### ***Qualitest***

The Qualitest segment is comprised of our legacy Endo non-branded generics portfolio and the portfolio from Qualitest Pharmaceuticals, which we acquired in 2010. Our Qualitest segment has historically focused on selective generics related to pain that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. With the addition of Qualitest Pharmaceuticals, the segment's product offerings now include products in the pain management, urology, central nervous system (CNS) disorders, immunosuppression, oncology, women's health and hypertension markets, among others.

### ***AMS***

The AMS segment currently 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 BPH therapy. These business lines are discussed in greater detail within Note 5. Acquisitions in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules". We distribute devices through our direct sales force and independent sales representatives in the U.S., Canada, Australia, and Western Europe. Additionally, we distribute devices through foreign independent distributors, primarily in Europe, Asia, and South America, who then sell the products to medical institutions. None of our AMS customers or distributors accounted for ten percent or more of our total revenues during any of the three years ended December 31, 2012 or 2011. Foreign subsidiary sales are predominantly to customers in Canada, Australia and Western Europe.

## HealthTronics

The HealthTronics segment provides urological services, products and support systems to urologists, hospitals, surgery centers and clinics across the U.S. These services are sold through the following business lines: lithotripsy services, prostate treatment services, anatomical pathology services, medical products manufacturing, sales and maintenance and electronic medical records services.

### Year Ended December 31, 2012 Compared to the Year Ended December 31, 2011

**Revenues.** The following table displays our revenue by reportable segment for the years ended December 31 (in thousands):

	2012	2011
Net revenues to external customers:		
Endo Pharmaceuticals.....	\$ 1,677,984	\$ 1,657,767
Qualitest.....	633,265	566,854
AMS(1).....	504,487	300,299
HealthTronics.....	211,627	205,201
Total consolidated net revenues to external customers.....	<u>\$ 3,027,363</u>	<u>\$ 2,730,121</u>

(1) The following table displays our AMS segment revenue by geography (in thousands). International revenues were not material to any of our other segments for any of the periods presented.

	2012	2011
AMS:		
United States.....	\$ 330,087	\$ 202,462
International.....	174,400	97,837
Total AMS revenues.....	<u>\$ 504,487</u>	<u>\$ 300,299</u>

**Endo Pharmaceuticals.** Revenues from our Endo Pharmaceuticals segment in 2012 increased 1% to \$1,678.0 million from \$1,657.8 million in 2011. This increase was primarily driven by increased revenues from Lidoderm<sup>®</sup>, partially offset by decreases from Voltaren<sup>®</sup> Gel and Opana<sup>®</sup> ER.

**Qualitest.** Net sales of our generic products in 2012 increased 12% to \$633.3 million from \$566.9 million in 2011. This increase was primarily driven by strong demand for Qualitest's diversified product portfolio and favorable pricing as a result of market opportunities, which drove gross profit of over 35%. During the year ended December 31, 2012, revenues from Qualitest's top 15 products increased 11% to \$373.1 million in 2012 from \$335.6 million in 2011. This increase, which was largely driven by increased volumes and pricing upside, was partially offset by reduced revenues from products impacted by the supply disruption associated with the previously disclosed shutdown of Novartis Consumer Health's Lincoln, Nebraska manufacturing facility.

**AMS.** Revenues from our AMS segment in 2012 increased 68% to \$504.5 million from \$300.3 million in 2011. This increase is attributable to the timing of our acquisition of AMS, Inc., which contributed revenue during the full twelve months ended December 31, 2012 compared to less than seven months of revenue during 2011. However, this increase was partially offset by lower than usual sales in AMS's women's health line, which relates primarily to a reduction in mesh procedural volumes, particularly as to pelvic organ prolapse (POP) repair procedures. This reduction in mesh procedural volumes may be in response to a July 2011 update to the October 2008 Public Health Notification issued by the FDA to further advise the public and medical community regarding potential complications associated with transvaginal placement of surgical mesh to treat POP and SUI, as well as to the attorney advertising associated with transvaginal mesh litigation.

**HealthTronics.** Revenues from our HealthTronics segment in 2012 increased 3% to \$211.6 million from \$205.2 million in 2011. This increase was primarily attributable to the revenues from the electronic medical records software companies, Intuitive Medical Software, LLC and meridianEMR, Inc. which we acquired in the second half of 2011, partially offset by the loss of sales from our IGRT business, which was sold in August 2011.

**Adjusted income before income tax.** The following table displays our adjusted income (loss) before income tax by reportable segment for the years ended December 31 (in thousands):

	<u>2012</u>	<u>2011</u>
Adjusted income before income tax:		
Endo Pharmaceuticals.....	\$ 906,839	\$ 890,951
Qualitest.....	171,418	107,204
AMS.....	119,852	82,418
HealthTronics.....	58,092	68,769
Corporate unallocated.....	<u>(338,826)</u>	<u>(318,100)</u>
Total consolidated adjusted income before income tax.....	<u>\$ 917,375</u>	<u>\$ 831,242</u>

*Endo Pharmaceuticals.* Adjusted income before income tax in 2012 increased 2% to \$906.8 million from \$891.0 million in 2011. This increase was primarily driven by increased revenues as described above as well as decreased operating expenses associated with our ongoing efforts to improve our operating efficiency.

*Qualitest.* Adjusted income before income tax in 2012 increased 60% to \$171.4 million from \$107.2 million in 2011. This increase was primarily driven by the continued revenue growth of our generics business. Additionally, favorable pricing as a result of market opportunities on certain of our generics products resulted in higher overall margins in our Qualitest segment.

*AMS.* Adjusted income before income tax in 2012 increased 45% to \$119.9 million from \$82.4 million in 2011. This increase was primarily driven by the timing of our June 2011 acquisition of AMS, Inc., which contributed a full period's results during the twelve months ended December 31, 2012, compared to less than seven months in 2011.

*HealthTronics.* Adjusted income before income tax in 2012 decreased 16% to \$58.1 million from \$68.8 million in 2011. Despite an increase in revenues as described above, this decrease was primarily driven by increased research and development expenses and costs incurred associated with the two electronic medical records software companies, Intuitive Medical Software, LLC and meridianEMR, Inc., that we acquired in the second half of 2011.

*Corporate unallocated.* Corporate unallocated adjusted loss before income tax in 2012 increased 7% to \$338.8 million from \$318.1 million in 2011. This increase was primarily driven by the previously discussed increase in interest expense, partially offset by decreased general and administrative expenses associated with our ongoing efforts to improve our operating efficiency.

*Reconciliation to GAAP.* The table below provides reconciliations of our consolidated adjusted income before income tax to our consolidated income (loss) before income tax, which is determined in accordance with U.S. GAAP, for the years ended December 31 (in thousands):

	<u>2012</u>	<u>2011</u>
Total consolidated adjusted income before income tax:	\$ 917,375	\$ 831,242
Upfront and milestone payments to partners.....	(60,778)	(28,098)
Asset impairment charges.....	(768,467)	(116,089)
Acquisition-related and integration items, net.....	(23,015)	(33,638)
Separation benefits and other cost reduction initiatives.....	(47,033)	(21,821)
Amortization of intangible assets.....	(227,260)	(190,969)
Inventory step-up.....	(880)	(49,438)
Non-cash interest expense.....	(20,762)	(18,952)
Net loss on extinguishment of debt.....	(7,215)	(11,919)
Accrual for payment to Impax related to sales of Opana® ER.....	(102,000)	—
Patent litigation settlement items, net.....	(85,123)	—
Litigation-related and other contingencies.....	(316,425)	(11,263)
Other income, net.....	—	2,636
Total consolidated (loss) income before income tax.....	<u>\$ (741,583)</u>	<u>\$ 351,691</u>

**Revenues.** The following table displays our revenue by reportable segment for the years ended December 31 (in thousands):

	2011	2010
Net revenues to external customers:		
Endo Pharmaceuticals.....	\$ 1,657,767	\$ 1,467,572
Qualitest.....	566,854	146,513
AMS(1).....	300,299	—
HealthTronics.....	205,201	102,144
Total consolidated net revenues to external customers.....	<u>\$ 2,730,121</u>	<u>\$ 1,716,229</u>

(1) The following table displays our AMS segment revenue by geography (in thousands). International revenues were not material to any of our other segments for any of the periods presented.

	2011	2010
AMS:		
United States.....	\$ 202,462	\$ —
International.....	97,837	—
Total AMS revenues.....	<u>\$ 300,299</u>	<u>\$ —</u>

**Endo Pharmaceuticals.** Net sales during 2011 increased 13% to \$1,657.8 million from \$1,467.6 million in 2010. This increase was primarily driven by increased revenues from Opana® ER, Lidoderm® and Voltaren® Gel, partially offset by decreased revenues from Percocet® and certain other brands.

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

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

**HealthTronics.** Revenues from our HealthTronics segment in 2011 increased 101% to \$205.2 million from \$102.1 million in 2010. This increase was driven by the full-year impact of HealthTronics, Inc., which contributed six months of revenue in 2010 compared to a full year of revenue in 2011. The \$205.2 million consisted primarily of lithotripsy fees of \$110.2 million, cryosurgery treatment fees of \$26.0 million and other service revenues from our HealthTronics segment.

**Adjusted income (loss) before income tax.** The following table displays our adjusted income (loss) before income tax by reportable segment and for the years ended December 31 (in thousands):

	2011	2010
Adjusted income before income tax:		
Endo Pharmaceuticals.....	\$ 890,951	\$ 757,453
Qualitest.....	107,204	24,722
AMS.....	82,418	—
HealthTronics.....	68,769	35,538
Corporate unallocated.....	(318,100)	(194,459)
Total consolidated adjusted income before income tax.....	<u>\$ 831,242</u>	<u>\$ 623,254</u>

**Endo Pharmaceuticals.** Adjusted income before income tax during 2011 increased 18% to \$891.0 million from \$757.5 million in 2010. This increase was primarily driven by increased revenues from our Endo Pharmaceuticals segment as well as the decrease in the royalty expense to Penwest from \$29.8 million during 2010 to zero during 2011. This royalty was eliminated upon our acquisition of Penwest in the third quarter of 2010.

*Qualitest.* Adjusted income before income tax during 2011 increased 334% to \$107.2 million from \$24.7 million in 2010. This increase was primarily driven by increased revenues from our Qualitest Pharmaceuticals acquisition as well as decreased research and development expense as a percentage of revenues.

*AMS.* Adjusted income before income tax during 2011 was \$82.4 million and was attributable to our AMS, Inc. subsidiary, which we acquired in June 2011.

*HealthTronics.* Adjusted income before income tax during 2011 was \$68.8 million compared to \$35.5 million in 2010. This increase was driven by our acquisition of HealthTronics, Inc., which contributed six months of results in 2010 compared to a full year in 2011.

*Corporate unallocated.* Corporate unallocated adjusted loss before income tax during 2011 increased 64% to \$318.1 million from \$194.5 million in 2010, which is primarily attributable to the overall growth of our business and the related increase in corporate costs, including increases in net interest expense of \$101.4 million.

*Reconciliation to GAAP.* The table below provides reconciliations of our consolidated adjusted income before income tax to our consolidated income before income tax, which is determined in accordance with U.S. GAAP, for the years ended December 31 (in thousands):

	2011	2010
Total consolidated adjusted income before income tax:	\$ 831,242	\$ 623,254
Upfront and milestone payments to partners	(28,098)	(23,850)
Asset impairment charges	(116,089)	(35,000)
Acquisition-related and integration items, net	(33,638)	(18,976)
Separation benefits and other cost reduction initiatives	(21,821)	(17,245)
Amortization of intangible assets	(190,969)	(83,974)
Inventory step-up	(49,438)	(6,289)
Non-cash interest expense	(18,952)	(16,983)
Net loss on extinguishment of debt	(11,919)	—
Litigation-related and other contingencies	(11,263)	—
Other income (expense), net	2,636	(239)
Total consolidated income before income tax	<u>\$ 351,691</u>	<u>\$ 420,698</u>

## LIQUIDITY AND CAPITAL RESOURCES

Our principal source of liquidity is cash generated from operations. Our principal liquidity requirements are for working capital for operations, licenses, milestone payments, capital expenditures and debt service payments. The Company continues to maintain a sufficient level of working capital, which was approximately \$241.2 million at December 31, 2012 compared to \$666.3 million and \$623.7 million at December 31, 2011 and 2010, respectively. Historically, we have generated positive cash flow from operating activities and have had broad access to financial markets that provide liquidity. Cash and cash equivalents were approximately \$547.9 million at December 31, 2012 compared to \$547.6 million and \$466.2 million at December 31, 2011 and 2010, respectively. Cash and cash equivalents at December 31, 2012, 2011 and 2010 primarily consisted of bank deposits, time deposits and/or money market funds.

In 2013, we expect that sales of our current portfolio of products and services will allow us to continue to generate positive cash flow from operations. We expect cash generated from operations together with our cash and cash equivalents to be sufficient to cover cash needs for working capital and general corporate purposes, including certain contingent liabilities, payment of contractual obligations, principal and interest payments on our indebtedness, capital expenditures, common stock repurchases and any regulatory and/or sales milestones that may become due.

We depend on patents or other forms of intellectual-property protection for most of our branded pharmaceutical revenues, cash flows, and earnings. Pursuant to our settlement and license agreement with Watson, we expect Watson to launch its lidocaine patch 5%, a generic version of Lidoderm<sup>®</sup> on September 15, 2013. Additionally, subject to FDA approval, we believe one or more competing products for Voltaren<sup>®</sup> Gel could potentially enter the market during the second quarter of 2014. The impact of such competition could cause a rapid decline in revenue from the affected products and have a material adverse effect on our liquidity and financial position. In addition, Impax's recently launched generic version of the non-crush resistant formulation Opana<sup>®</sup> ER adversely affected our results of operations since its launch on January 2, 2013 and will likely continue to do so in the future. However, the extent to which our revenues will be affected is subject to a number of uncertainties including the FDA's determination regarding whether the original formulation of Opana<sup>®</sup> ER was withdrawn for safety reasons, which we expect will be decided in May 2013, as well as certain other FDA actions that could impact the ability of both branded and generic competition for Opana<sup>®</sup> ER to enter the



market. Our goal is to mitigate the effect of these competitive activities by leveraging growth across the remainder of our portfolio and by acquiring and in-licensing additional products, product rights or technologies.

Beyond 2013, we expect cash generated from operations together with our cash, cash equivalents and marketable securities to continue to be sufficient to cover cash needs for working capital and general corporate purposes, including certain contingent liabilities, payment of contractual obligations, principal and interest payments on our indebtedness, capital expenditures, common stock repurchases and any regulatory and/or sales milestones that may become due. At this time, we cannot accurately predict the effect of certain developments on the rate of sales growth, such as the degree of market acceptance, patent protection and exclusivity of our products, the impact of competition, the effectiveness of our sales and marketing efforts and the outcome of our current efforts to develop, receive approval for and successfully launch our near-term product candidates. Any of the above could adversely affect our future cash flows. We may need to obtain additional funding for future strategic transactions, to repay our outstanding indebtedness, or for our future operational needs, and we cannot be certain that funding will be available on terms acceptable to us, or at all.

We may also elect to incur additional debt or issue equity or convertible securities to finance ongoing operations, acquisitions or to meet our other liquidity needs. Any issuances of equity securities or convertible securities could have a dilutive effect on the ownership interest of our current shareholders and may adversely impact net income per share in future periods. An acquisition may be accretive or dilutive and by its nature, involves numerous risks and uncertainties.

A description of our current debt agreements is below.

**Credit Facility.** On June 17, 2011, we terminated the 2010 Credit Facility. Concurrent with the termination of the 2010 Credit Facility, we established a \$1,500 million, 5-year senior secured term loan facility (the Term Loan A Facility), a \$700 million, 7-year senior secured term loan facility (the Term Loan B Facility, and, together with the Term Loan A Facility, the Term Loan Facilities), and a \$500 million, 5-year senior secured revolving credit facility (the 2011 Revolving Credit Facility and, together with the Term Loan Facilities, the 2011 Credit Facility) with Morgan Stanley Senior Funding, Inc., as administrative agent, Bank of America, N.A., as Syndication Agent, and certain other lenders. The 2011 Credit Facility was established primarily to finance our acquisition of AMS, Inc. and is available for working capital, general corporate purposes and lines of credit. The agreement governing the 2011 Credit Facility (the 2011 Credit Agreement) also permits up to \$500 million of additional revolving or term loan commitments from one or more of the existing lenders or other lenders with the consent of Morgan Stanley Senior Funding, Inc. (the administrative agent) without the need for consent from any of the existing lenders under the 2011 Credit Facility.

The obligations of the Company under the 2011 Credit Facility are guaranteed by certain of the Company's domestic subsidiaries and are secured by substantially all of the assets of the Company and the subsidiary guarantors. The 2011 Credit Facility contains certain usual and customary covenants, including, but not limited to covenants to maintain maximum leverage and minimum interest coverage ratios. Borrowings under the 2011 Credit Facility bear interest at an amount equal to a rate calculated based on the type of borrowing and the Company's Leverage Ratio. For term A loans and revolving loans (other than Swing Line Loans), the Company is permitted to elect to pay interest based on an adjusted LIBOR rate plus between 1.75% and 2.50% or an Alternate Base Rate (as defined in the 2011 Credit Agreement) plus between 0.75% and 1.50%. For term B loans, the Company may elect to pay interest based on an adjusted LIBOR rate plus 3.00% or an Alternate Base Rate plus 2.00%. The Company will pay a commitment fee of between 37.5 to 50 basis points, payable quarterly, on the average daily unused amount of the Revolving Credit Facility.

In September 2011 and December 2011, we made prepayments of \$135.0 million and \$125.0 million, respectively, on our Term Loan B Facility. Pursuant to our rights under the 2011 Credit Agreement, we elected to apply a portion of the September 2011 prepayment against all remaining contractual payments such that we had no remaining principal payment obligations until the maturity of the Term Loan B Facility on June 17, 2018. In February 2012, we made a prepayment of \$205.0 million on our Term Loan B Facility. We made additional prepayments of \$33.0 million and \$39.7 million in July 2012 and September 2012, respectively.

Based on current favorable conditions in the leveraged loan markets, we currently intend to seek amendments to the 2011 Credit Facility in order to, among other things, extend its term and modify its covenants to provide us with greater financial and operating flexibility. Any such amendment would require the consent of the lenders under the 2011 Credit Facility. There can be no assurance that we will be able to obtain any such amendment on favorable terms or at all.

**7.00% Senior Notes Due 2019.** On June 8, 2011, we entered into an indenture among the Company, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, which governs the terms of the Company's \$500 million aggregate principal amount of 7.00% Senior Notes due 2019 (the 2019 Notes). The 2019 Notes were issued in a private offering exempt from the registration requirements of the Securities Act of 1933, as amended (the Securities Act) to qualified institutional buyers in accordance with Rule 144A and to persons outside of the U.S. pursuant to Regulation S under the Securities Act. The 2019 Notes are senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain of the Company's domestic subsidiaries. The Company used the net proceeds of the 2019 Notes offering to partially finance the acquisition of AMS, Inc., and to pay related fees and expenses.

The 2019 Notes bear interest at a rate of 7.00% per year, accruing from June 8, 2011. Interest on the 2019 Notes is payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2012. The 2019 Notes will mature on July 15, 2019, subject to earlier repurchase or redemption in accordance with the terms of the indenture governing the 2019 Notes. The indenture governing the 2019 Notes contains covenants that, among other things, restrict the Company's ability and the ability of certain of its restricted subsidiaries to incur certain additional indebtedness and issue preferred stock; make certain dividends, distributions, investments and other restricted payments; sell certain assets; agree to any restrictions on the ability of restricted subsidiaries to make payments to the Company; create certain liens; enter into transactions with affiliates; designate subsidiaries as unrestricted subsidiaries; and consolidate, merge or sell substantially all of the Company's assets. These covenants are subject to a number of important exceptions and qualifications, including the fall away or revision of certain of these covenants upon the 2019 Notes receiving investment grade credit ratings.

**7.00% Senior Notes Due 2020.** On November 23, 2010, we entered into an indenture among the Company, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, which governs the terms of the Company's \$400 million aggregate principal amount of 7.00% Senior Notes due 2020 (the 2020 Notes). The 2020 Notes were issued in a private offering exempt from the registration requirements of the Securities Act of 1933, as amended (the Securities Act) to qualified institutional buyers in accordance with Rule 144A and to persons outside of the U.S. pursuant to Regulation S under the Securities Act. The 2020 Notes are senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain of the Company's domestic subsidiaries. The Company used the net proceeds of the 2020 Notes offering to partially finance the acquisition of Qualitest Pharmaceuticals, and to pay related fees and expenses.

The 2020 Notes bear interest at a rate of 7.00% per year, accruing from November 23, 2010. Interest on the 2020 Notes is payable semiannually in arrears on June 15 and December 15 of each year, beginning on June 15, 2011. The 2020 Notes will mature on December 15, 2020, subject to earlier repurchase or redemption in accordance with the terms of the indenture governing the 2020 Notes. The indenture governing the 2020 Notes contains covenants that, among other things, restrict the Company's ability and the ability of certain of its restricted subsidiaries to incur certain additional indebtedness and issue preferred stock; make certain dividends, distributions, investments and other restricted payments; sell certain assets; agree to any restrictions on the ability of restricted subsidiaries to make payments to the Company; create certain liens; enter into transactions with affiliates; designate subsidiaries as unrestricted subsidiaries; and consolidate, merge or sell substantially all of the Company's assets. These covenants are subject to a number of important exceptions and qualifications, including the fall away or revision of certain of these covenants upon the 2020 Notes receiving investment grade credit ratings.

**7.25% Senior Notes Due 2022.** On June 8, 2011, we entered into an indenture among the Company, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, which governs the terms of the Company's \$400 million aggregate principal amount of 7.25% Senior Notes due 2022 (the 2022 Notes). The 2022 Notes were issued in a private offering exempt from the registration requirements of the Securities Act of 1933, as amended (the Securities Act) to qualified institutional buyers in accordance with Rule 144A and to persons outside of the U.S. pursuant to Regulation S under the Securities Act. The 2022 Notes are senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain of the Company's domestic subsidiaries. The Company used the net proceeds of the 2022 Notes offering to partially finance the acquisition of AMS, Inc., and to pay related fees and expenses.

The 2022 Notes bear interest at a rate of 7.25% per year, accruing from June 8, 2011. Interest on the 2022 Notes is payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2012. The 2022 Notes will mature on January 15, 2022, subject to earlier repurchase or redemption in accordance with the terms of the indenture governing the 2022 Notes. The indenture governing the 2022 Notes contains covenants that, among other things, restrict the Company's ability and the ability of certain of its restricted subsidiaries to incur certain additional indebtedness and issue preferred stock; make certain dividends, distributions, investments and other restricted payments; sell certain assets; agree to any restrictions on the ability of restricted subsidiaries to make payments to the Company; create certain liens; enter into transactions with affiliates; designate subsidiaries as unrestricted subsidiaries; and consolidate, merge or sell substantially all of the Company's assets. These covenants are subject to a number of important exceptions and qualifications, including the fall away or revision of certain of these covenants upon the 2022 Notes receiving investment grade credit ratings.

**2011 Exchange Offer.** On October 14, 2011, the Company filed a Form S-4 Registration Statement with the Securities and Exchange Commission. On October 31, 2011, it filed a prospectus pursuant to Rule 424(b)(3). Pursuant to both filings, the Company offered to exchange the 2019 Notes, 2020 Notes and 2022 Notes for a like principal amount of new notes having identical terms that have been registered under the Securities Act of 1933, as amended. On November 30, 2011, all of the 2019 Notes, 2020 Notes and 2022 Notes had been properly tendered in the exchange offer and not withdrawn.

**1.75% Convertible Senior Subordinated Notes due 2015.** As discussed in Note 19. Debt in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules", in April 2008, we issued \$379.5 million in aggregate principal amount of 1.75% Convertible Senior Subordinated Notes due April 15, 2015 (the Convertible Notes) in a private offering for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended.

Holders of the Convertible Notes may convert their notes based on a conversion rate of 34.2466 shares of our common stock per \$1,000 principal amount of notes (the equivalent of \$29.20 per share), subject to adjustment upon certain events, only under the following circumstances as described in the indenture for the Convertible Notes: (1) during specified periods, if the price of our common stock reaches specified thresholds; (2) if the trading price of the Convertible Notes is below a specified threshold; (3) at any time after October 15, 2014; or (4) upon the occurrence of certain corporate transactions. We will be permitted to deliver cash, shares of Endo common stock or a combination of cash and shares, at our election, to satisfy any future conversions of the notes. It is our current intention to settle the principal amount of any conversion consideration in cash.

The Convertible Notes are only included in the dilutive net income per share calculation using the treasury stock method during periods in which the average market price of our common stock was above the applicable conversion price of the Convertible Notes, or \$29.20 per share. In these periods, under the treasury stock method, we calculated the number of shares issuable under the terms of these notes based on the average market price of the stock during the period, and included that number in the total diluted shares outstanding for the period.

We have entered into convertible note hedge and warrant agreements that, in combination, have the economic effect of reducing the dilutive impact of the Convertible Notes. However, we separately analyze the impact of the convertible note hedge and the warrant agreements on diluted weighted average shares outstanding. As a result, the purchases of the convertible note hedges are excluded because their impact would be anti-dilutive. The treasury stock method is applied when the warrants are in-the-money with the proceeds from the exercise of the warrant used to repurchase shares based on the average stock price in the calculation of diluted weighted average shares. Until the warrants are in-the-money, they have no impact to the diluted weighted average share calculation. The total number of shares that could potentially be included if the warrants were exercised is approximately 13.0 million.

The following table provides the range of shares that would be included in the dilutive net income per share calculation for the Convertible Notes and warrants based on share price sensitivity (in thousands except per share data):

	Three Months Ended March 31, 2012 (1)				Three Months Ended June 30, 2012			
	-5%	Actual	+5%	+10%	-5%	Actual	+5%	+10%
Average market price of Endo common stock: .....	\$ 34.66	\$ 36.48	\$ 38.30	\$ 40.13	\$ 31.58	\$ 33.24	\$ 34.90	\$ 36.56
Impact on dilutive shares:								
Convertible Notes.....	2,047	2,594	3,088	3,540	979	1,581	2,123	2,616
Warrants.....	—	—	—	42	—	—	—	—
	<u>2,047</u>	<u>2,594 (2)</u>	<u>3,088</u>	<u>3,582</u>	<u>979</u>	<u>1,581 (3)</u>	<u>2,123</u>	<u>2,616</u>
	Three Months Ended September 30, 2012				Three Months Ended December 31, 2012 (1)			
	-5%	Actual	+5%	+10%	-5%	Actual	+5%	+10%
Average market price of Endo common stock: .....	\$ 29.88	\$ 31.45	\$ 33.02	\$ 34.60	\$ 26.91	\$ 28.33	\$ 29.75	\$ 31.16
Impact on dilutive shares:								
Convertible Notes.....	296	929	1,504	2,028	—	—	240	817
Warrants.....	—	—	—	—	—	—	—	—
	<u>296</u>	<u>929 (3)</u>	<u>1,504</u>	<u>2,028</u>	<u>—</u>	<u>— (2)</u>	<u>240</u>	<u>817</u>

(1) Because the Company reported a Net loss attributable to Endo Health Solutions Inc. during the three month periods ended March 31, 2012 and December 31, 2012, the Convertible Notes and Warrants had no dilutive impact during these periods and would not have had a dilutive impact given any of the assumed share prices above. Therefore, these amounts are included for informational purposes only and are not indicative of actual results or results that would have occurred given the assumed share prices above.

- (2) Represents, for the three month periods ended March 31, 2012 and December 31, 2012, the amounts that would have been included in total diluted shares outstanding of 117.1 million and 112.8 million, respectively, had the Company reported Net income attributable to Endo Health Solutions Inc. as opposed to a Net loss attributable to Endo Health Solutions Inc.
- (3) Amounts included in total diluted shares outstanding of 121.1 million and 119.6 million for the three month periods ended June 30, 2012 and September 30, 2012, respectively.

**3.25% Convertible AMS Notes Due 2036 and 4.00% Convertible AMS Notes Due 2041.** As a result of our acquisition of AMS, Inc., the Company assumed AMS, Inc.'s 3.25% Convertible Notes due 2036 (the 2036 Notes) and 4.00% Convertible Notes due 2041 (the 2041 Notes and, together with the 2036 Notes, the AMS Notes). In accordance with the indentures governing the AMS Notes, the AMS Notes were immediately convertible upon the closing of Endo's acquisition of AMS, Inc. From the AMS, Inc. Acquisition Date until the make whole premium on the 2036 Notes expired on August 9, 2011, we paid \$95.7 million to redeem \$61.4 million of the 2036 Notes at a stated premium of 1.5571. From the AMS, Inc. Acquisition Date until the make whole premium on the 2041 Notes expired on August 1, 2011, we paid \$423.4 million to redeem \$249.9 million of the 2041 Notes at a stated premium of 1.6940. Our obligation remaining related to the AMS Notes is less than \$1.0 million at December 31, 2012, excluding accrued interest.

**Share Repurchase Programs.** In April 2008, our Board of Directors approved a share repurchase program (the 2008 Share Repurchase Program), authorizing the Company to repurchase in the aggregate up to \$750 million of shares of its outstanding common stock. In August 2012, our Board of Directors resolved to cancel and terminate the 2008 Share Repurchase Program, effective immediately, and approve a new share repurchase program (the 2012 Share Repurchase Program). The 2012 Share Repurchase Program authorizes the Company to repurchase in the aggregate up to \$450 million of shares of its outstanding common stock. Purchases under this program may be made from time to time in open market purchases, pre-set purchase programs, privately-negotiated transactions, and accelerated stock buyback agreements. This program does not obligate Endo to acquire any particular amount of common stock. Future repurchases, if any, will depend on factors such as levels of cash generation from operations, cash requirements for investment in the Company's business, repayment of future debt, if any, then current stock price, market conditions, securities law limitations and other factors. The share repurchase program may be suspended, modified or discontinued at any time. The 2012 Share Repurchase Program is set to expire on March 31, 2015.

Pursuant to our share repurchase programs, we purchased approximately 8.3 million shares of our common stock during 2012 totaling \$256.0 million, 0.9 million shares of our common stock during 2011 totaling \$34.7 million and 2.5 million shares of our common stock during 2010 totaling \$59.0 million.

**Employee Stock Purchase Plan.** At our Annual Meeting of Stockholders held in May of 2011, our shareholders approved the Endo Health Solutions Inc. Employee Stock Purchase Plan (the ESPP). The ESPP is a Company-sponsored plan that enables employees to voluntarily elect, in advance of any of the four quarterly offering periods ending March 31, June 30, September 30 and December 31 of each year, to contribute up to 10% of their eligible compensation, subject to certain limitations, to purchase shares of common stock at 85% of the lower of the closing price of Endo common stock on the first or last trading day of each offering period. The maximum number of shares that a participant may purchase in any calendar year is equal to \$25,000 divided by the closing selling price per share of our common stock on the first day of the offering period, subject to certain adjustments. Compensation expense is calculated in accordance with the applicable accounting guidance and is based on the share price at the beginning or end of each offering period and the purchase discount. Obligations under the ESPP may be satisfied by the reissuance of treasury stock, by the Company's purchase of shares on the open market or by the authorization of new shares. The maximum number of shares available under the ESPP, pursuant to the terms of the ESPP plan document, is one percent of the common shares outstanding on April 15, 2011 or approximately 1.2 million shares. The ESPP shall continue in effect until the earlier of (i) the date when no shares of stock are available for issuance under the ESPP, at which time the ESPP shall be suspended pursuant to the terms of the ESPP plan document, or (ii) December 31, 2022, unless earlier terminated. Compensation expense related to the ESPP totaled \$1.3 million during 2012. The Company issued 235,425 shares from treasury with a cost totaling \$6.1 million during 2012 pursuant to the ESPP.

**Marketable Securities.** In June 2012, our remaining auction-rate securities were called at par and we received proceeds of \$18.8 million. Prior to being sold, these auction-rate securities had been classified as available-for-sale securities and had therefore been maintained at their fair value, with changes in value being recorded as part of Other comprehensive income (loss), net. Due to the fact that we received proceeds equal to par, the auction-rate securities were adjusted to their fair value of \$18.8 million, with a corresponding gain to Other comprehensive income (loss), net. The previously recognized cumulative unrealized holding loss associated with these securities of \$1.5 million was reversed in its entirety. As a result, no gain or loss was realized.

**Working Capital.** The components of our working capital as of December 31, 2012, 2011 and 2010 are below (in thousands):

	December 31, 2012	December 31, 2011	December 31, 2010
Total current assets.....	\$ 1,969,234	\$ 1,788,096	\$ 1,359,534
Less: total current liabilities.....	(1,728,020)	(1,121,778)	(735,828)
Working capital.....	<u>\$ 241,214</u>	<u>\$ 666,318</u>	<u>\$ 623,706</u>

Working capital decreased by \$425.1 million from December 31, 2011 to December 31, 2012 primarily due to the establishment of accruals totaling \$316.4 million for litigation-related and other contingencies, \$102.0 million for the liability for our payment to Impax related to sales of Opana® ER and \$85.1 million for payments to Watson related to the Lidoderm® litigation settlement, the payment of \$277.7 million of our Term Loan indebtedness that had been classified as a non-current liability, net repurchases of Common stock totaling \$249.9 million, net purchases of property, plant and equipment of \$98.4 million and distributions to non-controlling interests of \$53.3 million. These decreases were partially offset by Net cash provided by operating activities of \$733.9 million.

Working capital increased by \$42.6 million from December 31, 2010 to December 31, 2011 primarily as a result of the current assets and liabilities assumed in connection with our second quarter 2011 acquisition of AMS and the net cash retained from our 2011 financings to acquire AMS. These amounts were partially offset by the use of cash to prepay \$260.0 million of our Term Loan indebtedness.

The following table summarizes our Consolidated Statements of Cash Flows and liquidity for the years ended December 31 (dollars in thousands):

	2012	2011	2010
Net cash flow provided by (used in):			
Operating activities.....	\$ 733,879	\$ 702,115	\$ 453,646
Investing activities.....	(88,467)	(2,374,092)	(896,323)
Financing activities.....	(645,547)	1,752,681	200,429
Effect of foreign exchange rate.....	431	702	—
Net increase (decrease) in cash and cash equivalents.....	\$ 296	\$ 81,406	\$ (242,248)
Cash and cash equivalents, beginning of period.....	\$ 547,620	\$ 466,214	\$ 708,462
Cash and cash equivalents, end of period.....	<u>\$ 547,916</u>	<u>\$ 547,620</u>	<u>\$ 466,214</u>
Current ratio .....	1.1:1	1.6:1	1.8:1
Days sales outstanding .....	45	45	46

**Net cash provided by operating activities.** Net cash provided by operating activities was \$733.9 million in 2012 compared to \$702.1 million provided by operating activities in 2011 and \$453.6 million provided by operating activities in 2010. Significant components of our operating cash flows for the years ended December 31 are as follows (in thousands):

	2012	2011	2010
<b>Cash Flow Data-Operating Activities:</b>			
Consolidated net (loss) income.....	\$ (688,021)	\$ 242,065	\$ 287,020
Depreciation and amortization.....	285,524	237,414	108,404
Stock-based compensation.....	59,395	46,013	22,909
Amortization of debt issuance costs and premium / discount .....	36,699	32,788	22,013
Deferred income taxes.....	(193,960)	(75,877)	(15,420)
Change in fair value of acquisition-related contingent consideration .....	237	(7,363)	(51,420)
Loss on auction-rate securities rights .....	—	—	15,659
Gain on trading securities .....	—	—	(15,420)
Net loss on extinguishment of debt .....	7,215	11,919	—
Asset impairment charges.....	768,467	116,089	35,000
Changes in assets and liabilities which provided (used) cash .....	454,393	99,581	43,672
Other, net .....	3,930	(514)	1,229
Net cash provided by operating activities.....	<u>\$ 733,879</u>	<u>\$ 702,115</u>	<u>\$ 453,646</u>

Net cash provided by operating activities represents the cash receipts and cash disbursements from all of our activities other than investing activities and financing activities. Operating cash flow is derived by adjusting our Consolidated net (loss) income for non-cash operating items, gains and losses attributed to investing and financing activities and changes in operating assets and liabilities resulting from timing differences between the receipts and payments of cash and when the transactions are recognized in our results of operations. As a result, changes in cash from operating activities reflect, among other things, the timing of cash collections from customers, payments to suppliers, managed care organizations and government agencies, collaborative partners, employees, and tax payments in the ordinary course of business.



The \$31.8 million increase in Net cash provided by operating activities in 2012 compared to 2011 was a result of a full-year of cash flow contribution from AMS and working capital initiatives, partially offset by operating performance, which was negatively impacted by the previously disclosed supply disruptions related to the shutdown of Novartis Consumer Health Inc.'s Lincoln, Nebraska manufacturing facility.

In 2011, our operating cash flow benefited from a full year of cash from operations from our Qualitest Pharmaceuticals acquisition and from a partial year of cash generated from our AMS, Inc. acquisition, when compared to 2010. In addition, Net cash provided by operating activities in 2011 was higher than in 2010 due in part to timing and an increasing lag in payments to managed care organizations attributed to government agencies' administrative delays.

**Net cash used in investing activities.** Net cash used in investing activities was \$88.5 million in 2012 compared to \$2.4 billion used in investing activities in 2011. This \$2.3 billion decrease in cash used relates primarily to net cash paid for acquisitions, which was \$3.2 million in 2012 compared to \$2.4 billion in 2011. The cash spent in 2011 was primarily for our acquisition of AMS, Inc.

Net cash used in investing activities was \$2.4 billion in 2011 compared to \$896.3 million used in investing activities in 2010. This \$1.5 billion increase in cash used relates primarily to cash paid for acquisitions, which was \$2.4 billion in 2011 compared to \$1.1 billion in 2010. The cash spent in 2011 was primarily for our acquisition of AMS, Inc. and the amounts spent in 2010 relate primarily to our acquisitions of Qualitest Pharmaceuticals, Penwest and HealthTronics, Inc.

**Net cash (used in) provided by financing activities.** Net cash used in financing activities was \$645.5 million in 2012 compared to \$1.8 billion provided by financing activities in 2011. This \$2.4 billion fluctuation was primarily attributable to our June 2011 debt restructuring related to our AMS acquisition, which provided net cash of \$1.8 billion in 2011, and the subsequent principal repayment activity related to the term loan portion of this debt, which used net cash of \$362.1 million in 2012. Additionally, in 2012, we completed net repurchases of Common stock totaling \$249.9 million.

Net cash provided by financing activities was \$1.8 billion in 2011 compared to \$200.4 million provided by financing activities in 2010. This \$1.6 billion increase resulted primarily from the previously described \$1.8 billion of cash provided by our 2011 debt restructuring, compared to \$266.4 million of cash provided by our 2010 debt-related activity, primarily related to our Qualitest Pharmaceuticals and HealthTronics, Inc. acquisitions.

**Research and Development.** Over the past few years, we have incurred significant expenditures related to conducting clinical studies to develop new products and exploring the value of our existing products in treating disorders beyond those currently approved in their respective labels. We may seek to mitigate the risk in, and expense of, our research and development programs by entering into collaborative arrangements with third parties. However, we intend to retain a portion of the commercial rights to these programs and, as a result, we still expect to spend significant funds on our share of the cost of these programs, including the costs of research, preclinical development, clinical research and manufacturing.

We expect to continue to incur significant levels of research and development expenditures as we focus on the development and advancement of our product pipeline. There can be no assurance that results of any ongoing or future preclinical or clinical trials related to these projects will be successful, that additional trials will not be required, that any drug or product under development will receive FDA approval in a timely manner or at all, or that such drug or product could be successfully manufactured in accordance with U.S. current Good Manufacturing Practices, or successfully marketed in a timely manner, or at all, or that we will have sufficient funds to develop or commercialize any of our products.

**Manufacturing, Supply and Other Service Agreements.** We contract with various third-party manufacturers and suppliers to provide us with raw materials used in our products, finished goods and certain services. Our most significant agreements are with Novartis Consumer Health, Inc. and Novartis AG, Teikoku Seiyaku Co., Ltd., Mallinckrodt Inc., Noramco, Inc., Grünenthal GMBH, Sharp Corporation, Ventiv Commercial Services, LLC and UPS Supply Chain Solutions. If, for any reason, we are unable to obtain sufficient quantities of any of the finished goods or raw materials or components required for our products, it could have a material adverse effect on our business, financial condition, results of operations and cash flows. For a complete description of commitments under manufacturing, supply and other service agreements, see Note 15. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

**License and Collaboration Agreements.** We have agreed to certain contingent payments in certain of our license, collaboration and other agreements. Payments under these agreements generally become due and payable only upon the achievement of certain developmental, regulatory, commercial and/or other milestones. Due to the fact that it is uncertain if and when these milestones will be achieved, such contingencies have not been recorded in our Consolidated Balance Sheets and are not reflected in the expected cash requirements for Contractual Obligations table below. In addition, under certain arrangements, we may have to make royalty payments based on a percentage of future sales of the products in the event regulatory approval for marketing is obtained. From a business perspective, we view these payments favorably as they signify that the products are moving successfully through the development phase toward commercialization. For a complete description of our contingent payments involving our license and collaboration

agreements, Note 7: License and Collaboration Agreements and Note 15. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

**Corporate Headquarters Lease.** On October 28, 2011, as part of our ongoing efforts to improve our operating efficiency and consolidate our Pennsylvania-based employees into one location, we entered into a lease agreement with RT/TC Atwater LP, a Delaware limited partnership, for a new Company headquarters to consist of approximately 300,000 square feet of office space located at 1400 Atwater Boulevard, Malvern, Pennsylvania (with a four-year option to lease up to approximately 150,000 additional square feet). The term of this triple net lease is 12 years and includes three renewal options, each for an additional 60-month period. The lease commenced on December 31, 2012 with a monthly lease rate for the initial year of \$0.5 million, increasing by 2.25% each year thereafter.

This lease is accounted for as a direct financing arrangement whereby the Company recorded, over the construction period, the full cost of the asset in Property, plant and equipment, net. At December 31, 2012 and 2011, the Company capitalized \$91.1 million and \$5.5 million, respectively, as Property, plant and equipment related to this arrangement. The building and leasehold improvements will be depreciated over the initial lease term. A corresponding liability was also recorded, net of leasehold improvements paid for by the Company and will be amortized over the expected lease term through monthly rental payments using an effective interest method. At December 31, 2012, the Company has recorded a liability of \$57.0 million related to this arrangement.

Effective upon the cease use date of the Chadds Ford, Pennsylvania properties in 2013, we expect to record a liability reflecting our remaining obligations under the respective lease agreements.

**Acquisitions.** As part of our business strategy, we plan to consider and, as appropriate, make acquisitions of other businesses, products, product rights or technologies. Our cash reserves and other liquid assets may be inadequate to consummate such acquisitions and it may be necessary for us to issue stock or raise substantial additional funds in the future to complete future transactions. In addition, as a result of our acquisition efforts, we are likely to experience significant charges to earnings for merger and related expenses (whether or not our efforts are successful) that may include transaction costs, closure costs or costs of restructuring activities.

#### **AMS, Inc.**

On June 17, 2011 (the AMS, Inc. Acquisition Date), the Company completed its acquisition of all outstanding shares of common stock of AMS, Inc. for approximately \$2.4 billion in aggregate consideration, including \$70.8 million related to existing AMS, Inc. stock-based compensation awards and certain other amounts, at which time AMS, Inc. became a wholly-owned, indirect subsidiary of the Company. AMS, Inc.'s shares were purchased at a price of \$30.00 per share.

AMS, Inc. is a worldwide developer and provider of technology solutions to physicians treating men's and women's pelvic health conditions. The AMS, Inc. business and applicable services include:

#### **Men's Health.**

AMS, Inc. supplies surgical solutions for the treatment of male urinary incontinence, the involuntary release of urine from the body. The fully implantable AMS 800® system 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. Since 2000, AMS, Inc. has also been selling the InVance® sling system, a less-invasive procedure for men with moderate incontinence, and in 2007, AMS, Inc. released the AdVance® sling system for the treatment of mild to moderate stress urinary incontinence. AMS, Inc. also offers the UroLume® endoprosthesis stent as a less invasive procedure for patients who may not be good surgical candidates, as well as for men suffering from bulbar urethral strictures.

AMS, Inc. also supplies penile implants to treat erectile dysfunction, the inability to achieve or maintain an erection sufficient for sexual intercourse, with a series of semi-rigid malleable prostheses and a complete range of more naturally functioning inflatable prostheses, including the AMS 700® MS. AMS, Inc. has refined its implants over the years with improvements to the AMS 700® series of inflatable prostheses, including the AMS 700 LGX® and the MS Pump®. Another key factor that distinguishes AMS, Inc.'s products is the use of the InhibiZone® antibiotic coating, which received FDA approval in July 2009 for AMS, Inc.'s product claim that InhibiZone® reduces the rate of revision surgery due to surgical infections.

#### **Women's Health.**

AMS, Inc. offers a broad range of systems, led by Monarc® and MiniArc®, 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. Monarc® incorporates unique helical needles to place a self-fixating, sub-fascial hammock through the obturator foramin. AMS, Inc.'s MiniArc® Single-Incision Sling for stress incontinence was released in 2007 and requires just one incision to surgically place a small sling under the urethra, which minimizes tissue disruption and potential for blood loss, thereby allowing the procedure to be

done with less anesthesia on an outpatient basis. In 2010, AMS, Inc. launched the MiniArc<sup>®</sup> Precise<sup>™</sup>, which is designed to enhance the ease and accuracy of placement of the MiniArc device.

AMS, Inc. also offers solutions for pelvic floor prolapse and other pelvic floor disorders, which may be caused by pregnancy, labor, and childbirth. In 2008, AMS, Inc. introduced the Elevate<sup>®</sup> transvaginal pelvic floor repair system, with no external incisions. Using an anatomically designed needle and self-fixating tips, Elevate<sup>®</sup> allows for safe, simple and precise mesh placement through a single vaginal incision. The posterior system was launched in 2008 and the anterior system was launched in 2009.

#### *BPH Therapy.*

AMS, Inc.'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. AMS, Inc. offers men experiencing a physical obstruction of the prostatic urethra an alternative to a transurethral resection of the prostate (TURP), with the GreenLight<sup>™</sup> photovaporization of the prostate. This laser therapy is designed to reduce the comorbidities associated with TURP. AMS, Inc.'s GreenLight<sup>™</sup> XPS and MoXy<sup>™</sup> Liquid Cooled Fiber provide shorter treatment times with similar long-term results compared to other laser systems. The GreenLight<sup>™</sup> laser system offers an optimal laser beam that balances vaporization of tissue with coagulation to prevent blood loss and providing enhanced surgical control compared to other laser systems. AMS, Inc. also offers the StoneLight<sup>®</sup> laser and SureFlex<sup>™</sup> fiber optics for the treatment of urinary stones. StoneLight<sup>®</sup> is a lightweight and portable 15-watt holmium laser that offers the right amount of power to effectively fragment most urinary stones. The SureFlex<sup>™</sup> fiber optic line is engineered to deliver more energy safely and effectively, even under maximum scope deflection, for high performance holmium laser lithotripsy.

AMS, Inc.'s TherMatrx<sup>®</sup> product is designed for those men not yet to the point of urethral obstruction, but for whom symptomatic relief is desired. It is a less-invasive tissue ablation technique that can be performed in a physician's office using microwave energy delivered to the prostate.

The acquisition of AMS, Inc. furthers Endo's evolution from a pharmaceutical product-driven company to a healthcare solutions provider, strengthens our leading core urology franchise and expands our presence in the medical devices market. We believe the combination of AMS, Inc. with Endo's existing platform will provide additional cost-effective solutions across the entire urology spectrum.

The operating results of AMS, Inc. from and including June 18, 2011 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheets as of December 31, 2012 and December 31, 2011 reflect the acquisition of AMS, Inc., effective June 18, 2011.

The following table summarizes the fair values of the assets acquired and liabilities assumed at the AMS, Inc. Acquisition Date (in thousands):

	<b>June 17, 2011</b> <b>(As adjusted)</b>
Cash and cash equivalents.....	\$ 47,289
Commercial paper .....	71,000
Accounts receivable .....	73,868
Other receivables.....	630
Inventories.....	74,988
Prepaid expenses and other current assets.....	7,133
Income taxes receivable .....	9,154
Deferred income taxes.....	15,432
Property, plant and equipment.....	56,413
Other intangible assets(1).....	1,260,000
Other assets .....	4,581
<b>Total identifiable assets.....</b>	<b>\$ 1,620,488</b>
Accounts payable .....	\$ 10,327
Accrued expenses .....	45,835
Deferred income taxes.....	416,745
Long-term debt.....	520,375
Other liabilities.....	25,891
<b>Total liabilities assumed .....</b>	<b>\$ 1,019,173</b>
<b>Net identifiable assets acquired .....</b>	<b>\$ 601,315</b>
Goodwill(2).....	1,798,661
<b>Net assets acquired.....</b>	<b>\$ 2,399,976</b>

- (1) Subsequent pre-tax non-cash impairment charges totaling \$135.5 million related to Other intangible assets were recorded in 2012. These impairment charges are further discussed in Note 9. Goodwill and Other Intangibles in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".
- (2) A subsequent pre-tax non-cash impairment charge of \$507.5 million related to this Goodwill was recorded in the fourth quarter of 2012. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the AMS, Inc. Acquisition Date to estimate the fair value of assets acquired and liabilities assumed. Our measurement period adjustments are complete.

The valuation of the intangible assets acquired and related amortization periods are as follows:

	Valuation (in millions)	Amortization Period (in years)
<b>Customer Relationships:</b>		
Men's Health.....	\$ 97.0	17
Women's Health.....	37.0	15
BPH.....	26.0	13
Total.....	<u>\$ 160.0</u>	16
<b>Developed Technology:</b>		
Men's Health.....	\$ 690.0	18
Women's Health(1).....	150.0	9
BPH.....	161.0	18
Total.....	<u>\$ 1,001.0</u>	16
<b>Tradenames:</b>		
AMS.....	\$ 45.0	30
GreenLight.....	12.0	15
Total.....	<u>\$ 57.0</u>	27
<b>In Process Research &amp; Development:</b>		
Oracle(2).....	\$ 12.0	n/a
Genesis.....	14.0	n/a
TOPAS.....	8.0	n/a
Other(3).....	8.0	n/a
Total.....	<u>\$ 42.0</u>	n/a
Total other intangible assets.....	<u>\$ 1,260.0</u>	n/a

- (1) A subsequent pre-tax non-cash impairment charge of \$128.5 million was recorded in the fourth quarter of 2012. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles.
- (2) A subsequent pre-tax non-cash impairment charge of \$4.0 million was recorded in the fourth quarter of 2012. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles.
- (3) A subsequent pre-tax non-cash impairment charge of \$3.0 million was recorded in the second quarter of 2012. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles.

The fair value of the developed technology, IPR&D and customer relationship assets were estimated using a discounted present value income approach. Under this method, an intangible asset's fair value is equal to the present value of the incremental after-tax cash flows (excess earnings) attributable solely to the intangible asset over its remaining useful life. To calculate fair value, the Company used cash flows discounted at rates considered appropriate given the inherent risks associated with each type of asset. The Company believes that the level and timing of cash flows appropriately reflect market participant assumptions. The fair value of the AMS and GreenLight tradenames were estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to license the AMS or GreenLight tradename. Thus, we derived the hypothetical royalty income from the projected revenues of AMS and GreenLight products, respectively. Cash flows were assumed to extend through the remaining economic useful life of each class of intangible asset.

The \$1,798.7 million of goodwill has been assigned to our AMS segment. The goodwill recognized is attributable primarily to strategic and synergistic opportunities across the entire urology spectrum, expected corporate synergies, the assembled workforce of AMS, Inc. and other factors. Approximately \$16.5 million of goodwill was expected to be deductible for income tax purposes.

Deferred tax assets of \$15.4 million are related primarily to federal net operating loss and credit carryforwards of AMS, Inc. and its subsidiaries. Deferred tax liabilities of \$416.7 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.



The Company recognized \$7.7 million and \$28.8 million of AMS, Inc. acquisition-related and integration costs that were expensed during the years ended December 31, 2012 and 2011, respectively. These costs are included in Acquisition-related and integration items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	2012	2011
Bank fees .....	\$ —	\$ 16,070
Legal, separation, integration, and other costs .....	7,672	12,684
<b>Total .....</b>	<b>\$ 7,672</b>	<b>\$ 28,754</b>

Transaction costs directly associated with the closing of the acquisition in 2011 and included in the table above totaled \$25.8 million.

The amounts of revenue and net loss of AMS, Inc. included in the Company's Consolidated Statements of Operations from and including June 18, 2011 to December 31, 2011 are as follows (in thousands, except per share data):

Revenue .....	\$ 300,299
Net loss attributable to Endo Health Solutions Inc. ....	\$ (329)
Basic and diluted net loss per share .....	\$ —

The following supplemental pro forma information presents the financial results as if the acquisition of AMS, Inc. had occurred on January 1, 2010 for the years ended December 31, 2011 and 2010. This supplemental pro forma information has been prepared for comparative purposes and does not purport to be indicative of what would have occurred had the acquisition been made on January 1, 2010, nor are they indicative of any future results.

	Twelve Months Ended December 31, 2011	Twelve Months Ended December 31, 2010
<b>Unaudited pro forma consolidated results (in thousands, except per share data):</b>		
Revenue.....	\$ 2,968,497	\$ 2,259,104
Net income attributable to Endo Health Solutions Inc. ....	\$ 214,487	\$ 199,776
Basic net income per share .....	\$ 1.84	\$ 1.72
Diluted net income per share .....	\$ 1.77	\$ 1.69

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of AMS, Inc. to reflect factually supportable adjustments that give effect to events that are directly attributable to the AMS, Inc. Acquisition, including borrowings to finance the acquisition as well as the additional depreciation and amortization that would have been charged assuming the fair value adjustments primarily to property, plant and equipment, inventory, and intangible assets, had been applied on January 1, 2010, together with the consequential tax effects.

### **Qualitest Pharmaceuticals**

On November 30, 2010 (the Qualitest Pharmaceuticals Acquisition Date), Endo completed its acquisition of all of the issued and outstanding capital stock of Generics International (US Parent), Inc. (Qualitest Pharmaceuticals) from an affiliate of Apax Partners, L.P. for approximately \$770.0 million. In addition, Endo paid \$406.8 million to retire Qualitest Pharmaceuticals' outstanding debt and related interest rate swap on November 30, 2010. In connection with the Qualitest Pharmaceuticals acquisition, \$108.0 million of the purchase price was placed into two separate escrow accounts. One of the escrow accounts was \$8.0 million, some of which was used to fund working capital adjustments, as defined in the Qualitest Pharmaceuticals Stock Purchase Agreement. This escrow was settled during the third quarter of 2011. There was also a \$100.0 million escrow account to be used to fund all claims arising out of or related to the Qualitest Pharmaceuticals acquisition. In connection with this \$100.0 million escrow account, to the extent that we realize tax benefits for costs that are funded by the escrow account, we will be required to share these tax benefits with Apax. The \$100.0 million escrow account was subsequently reduced to \$45.5 million pursuant to an October 2012 amendment to the Qualitest Pharmaceuticals Stock Purchase Agreement. This escrow fund was previously treated as a component of the Qualitest Pharmaceuticals purchase price and therefore this amendment does not have any impact on our cash or cash equivalents balances.

Qualitest Pharmaceuticals is a manufacturer and distributor of generic drugs and over-the-counter pharmaceuticals throughout the U.S. Qualitest Pharmaceuticals' product portfolio is comprised of 175 product families in various forms including tablets, capsules, creams, ointments, suppositories, and liquids. This acquisition has enabled us to gain critical mass in our generics business while strengthening our pain portfolio through a larger breadth of product offerings.

The operating results of Qualitest Pharmaceuticals from November 30, 2010 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheets as of December 31, 2012 and December 31, 2011 reflect the acquisition of Qualitest Pharmaceuticals, effective November 30, 2010, the date the Company obtained control of Qualitest Pharmaceuticals.

The following table summarizes the fair values of the assets acquired and liabilities assumed at the Qualitest Pharmaceuticals Acquisition Date (in thousands):

	<b>November 30, 2010</b> <b>(As adjusted)</b>
Cash and cash equivalents.....	\$ 21,828
Accounts receivable .....	93,228
Other receivables.....	1,483
Inventories.....	95,000
Prepaid expenses and other current assets.....	1,901
Deferred income taxes.....	71,040
Property, Plant and equipment.....	135,807
Other intangible assets(1).....	836,000
<b>Total identifiable assets.....</b>	<b>\$ 1,256,287</b>
Accounts payable .....	\$ 27,421
Accrued expenses.....	59,351
Deferred income taxes.....	207,321
Long-term debt.....	406,758
Other liabilities.....	9,487
<b>Total liabilities assumed.....</b>	<b>\$ 710,338</b>
Net identifiable assets acquired.....	\$ 545,949
Goodwill.....	224,098
Net assets acquired.....	<b>\$ 770,047</b>

(1) A subsequent pre-tax non-cash impairment charge of \$71.0 million related to Other intangible assets was recorded in the fourth quarter of 2011. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the Qualitest Pharmaceuticals Acquisition Date. Our measurement period adjustments are complete.

The valuation of the intangible assets acquired and related amortization periods are as follows:

	Valuation (in millions)	Amortization Period (in years)
<b>Developed Technology:</b>		
Hydrocodone and acetaminophen.....	\$ 119.0	17
Oxycodone and acetaminophen .....	30.0	17
Promethazine.....	46.0	16
Isosorbide Mononitrate ER .....	42.0	16
Multi Vitamins .....	38.0	16
Trazodone.....	17.0	16
Butalbital, acetaminophen, and caffeine .....	25.0	16
Tripnevifem.....	16.0	13
Spirolactone .....	13.0	17
Hydrocortisone.....	34.0	16
Hydrochlorothiazide.....	16.0	16
Controlled Substances.....	52.0	16
Oral Contraceptives.....	8.0	13
Others .....	162.0	17
Total .....	<u>\$ 618.0</u>	16
<b>In Process Research &amp; Development:</b>		
Generics portfolio with anticipated 2011 launch .....	\$ 63.0	n/a
Generics portfolio with anticipated 2012 launch .....	30.0	n/a
Generics portfolio with anticipated 2013 launch .....	17.0	n/a
Generics portfolio with anticipated 2014 launch(1).....	88.0	n/a
Total .....	<u>\$ 198.0</u>	n/a
<b>Tradename:</b>		
Qualitest tradename.....	\$ 20.0	15
Total .....	<u>\$ 20.0</u>	15
Total other intangible assets.....	<u>\$ 836.0</u>	n/a

(1) A subsequent pre-tax non-cash impairment charge of \$71.0 million was recorded in the fourth quarter of 2011. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

The fair value of the developed technology assets and IPR&D assets were estimated using an income approach. Under this method, an intangible asset's fair value is equal to the present value of the incremental after-tax cash flows (excess earnings) attributable solely to the intangible asset over its remaining useful life. To calculate fair value, the Company used probability-weighted cash flows discounted at rates considered appropriate given the inherent risks associated with each type of asset. The Company believes that the level and timing of cash flows appropriately reflect market participant assumptions. Cash flows were generally assumed to extend through the economic useful life of the developed technology, IPR&D asset or tradename. The fair value of the Qualitest tradename was estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to license the Qualitest tradename. Thus, we derived the hypothetical royalty income from the projected revenues of Qualitest Pharmaceuticals.

The \$224.1 million of goodwill was assigned to our Qualitest segment. The goodwill recognized is attributable primarily to expected purchasing, manufacturing and distribution synergies as well as its assembled workforce. Approximately \$170.4 million of goodwill was expected to be deductible for income tax purposes.

Deferred tax assets of \$71.0 million are related primarily to federal and state net operating loss and credit carryforwards of Qualitest Pharmaceuticals and its subsidiaries. Deferred tax liabilities of \$207.3 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

The Company recognized \$11.0 million, \$8.0 million and \$38.8 million of Qualitest Pharmaceuticals acquisition-related and integration items that were expensed during the years ended December 31, 2012, 2011 and 2010, respectively. These items are included in Acquisition-related and integration items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	2012	2011	2010
Bank fees.....	\$ —	\$ —	\$ 14,215
Legal, separation, integration, and other costs.....	10,776	8,284	24,572
Changes in fair value of acquisition-related contingent consideration ...	237	(313)	—
Total.....	<u>\$ 11,013</u>	<u>\$ 7,971</u>	<u>\$ 38,787</u>

Transaction costs directly associated with the closing of the acquisition in 2010 and included in the table above totaled \$36.1 million.

The amounts of revenue and net loss of Qualitest Pharmaceuticals included in the Company's Consolidated Statements of Operations from and including November 30, 2010 to December 31, 2010 are as follows (in thousands, except per share data):

Revenue.....	\$ 30,323
Net loss attributable to Endo Health Solutions Inc. ....	\$ (3,056)
Basic and diluted net loss per share .....	\$ (0.03)

The following supplemental pro forma information presents the financial results as if the acquisition of Qualitest Pharmaceuticals had occurred on January 1, 2010 for the year ended December 31, 2010. This supplemental pro forma information has been prepared for comparative purposes and does not purport to be indicative of what would have occurred had the acquisition been made on January 1, 2010, nor are they indicative of any future results.

	Twelve Months Ended December 31, 2010
<b>Unaudited pro forma consolidated results (in thousands, except per share data):</b>	
Revenue.....	\$ 2,038,761
Net income attributable to Endo Health Solutions Inc.....	\$ 243,710
Basic net income per share.....	\$ 2.10
Diluted net income per share.....	\$ 2.07

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of Qualitest Pharmaceuticals to reflect the additional depreciation and amortization that would have been charged assuming the fair value adjustments primarily to property, plant and equipment and intangible assets, had been applied on January 1, 2010, together with the consequential tax effects.

#### ***Penwest Pharmaceuticals Co.***

On September 20, 2010 (the Penwest Acquisition Date), the Company completed its tender offer for the outstanding shares of common stock of Penwest and on November 4, 2010, we closed this acquisition for approximately \$171.8 million in aggregate cash consideration, at which time Penwest became our wholly-owned subsidiary. On August 22, 2011, Penwest was merged into Endo Pharmaceuticals Inc., at which time Penwest ceased its existence as a separate legal entity.

This transaction contributes to Endo's core pain management franchise and permits us to maximize the value of our oxymorphone franchise.

The operating results of Penwest from September 20, 2010 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheets as of December 31, 2012 and December 31, 2011 reflect the acquisition of Penwest, effective September 20, 2010, the date the Company obtained control of Penwest.

The following table summarizes the fair values of the assets acquired and liabilities assumed at the Penwest Acquisition Date (in thousands):

	September 20, 2010 (As Adjusted)
Cash and cash equivalents.....	\$ 22,343
Marketable securities.....	800
Accounts receivable.....	10,866
Other receivables.....	131
Inventories.....	407
Prepaid expenses and other current assets.....	493
Deferred income taxes.....	29,765
Property, plant and equipment.....	915
Other intangible assets(1).....	111,200
Other assets.....	2,104
Total identifiable assets.....	<u>\$ 179,024</u>
Accounts payable.....	\$ 229
Income taxes payable.....	160
Penwest shareholder liability.....	—
Accrued expenses.....	1,542
Deferred income taxes.....	40,168
Other liabilities.....	4,520
Total liabilities assumed.....	<u>\$ 46,619</u>
Net identifiable assets acquired.....	<u>\$ 132,405</u>
Goodwill.....	39,361
Net assets acquired.....	<u><u>\$ 171,766</u></u>

(1) A subsequent pre-tax non-cash impairment charge of \$1.6 million related to Other intangible assets was recorded in the fourth quarter of 2011. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the Penwest Acquisition Date. Our measurement period adjustments are complete.

The valuation of the intangible assets acquired and related amortization periods are as follows (in millions):

	Valuation	Amortization Period (in years)
<b>In Process Research &amp; Development:</b>		
Otsuka.....	\$ 5.5	n/a
A0001(1).....	1.6	n/a
Total.....	<u>\$ 7.1</u>	n/a
<b>Developed Technology:</b>		
Opana® ER.....	\$ 104.1	10
Total.....	<u>\$ 104.1</u>	10
Total other intangible assets.....	<u>\$ 111.2</u>	n/a

(1) A subsequent pre-tax non-cash impairment charge of \$1.6 million was recorded in the fourth quarter of 2011. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

The fair values of the IPR&D assets and developed technology asset were estimated using an income approach. To calculate fair value, the Company used probability-weighted cash flows discounted at rates considered appropriate given the inherent risks associated with the asset. The Company believes that the level and timing of cash flows appropriately reflect market participant assumptions. Cash flows were generally assumed to extend through the economic useful life of our developed technology or IPR&D asset.



The \$39.4 million of goodwill was assigned to our Endo Pharmaceuticals segment. The goodwill recognized is attributable primarily to the control premium associated with our oxymorphone franchise and other factors. None of the goodwill was expected to be deductible for income tax purposes.

Deferred tax assets of \$29.8 million are related primarily to federal net operating loss and credit carryforwards of Penwest. Deferred tax liabilities of \$40.2 million are related primarily to the difference between the book basis and tax basis of the identifiable intangible assets.

The Company recognized \$0.3 million and \$10.7 million of Penwest acquisition-related and integration costs that were expensed during the years ended December 31, 2011 and 2010, respectively. These costs are included in Acquisition-related and integration items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	2011	2010
Bank fees .....	\$ —	\$ 3,865
Legal, separation, integration, and other costs .....	259	6,815
Total .....	<u>\$ 259</u>	<u>\$ 10,680</u>

Transaction costs directly associated with the closing of the acquisition in 2010 and included in the table above totaled \$5.6 million.

Due to the pro forma impacts of eliminating the pre-existing intercompany royalties between Penwest and Endo, which were determined to be at fair value, we have not provided supplemental pro forma information as amounts are not material to the Consolidated Statements of Operations. We have also considered the impacts of Penwest, since the date we obtained a majority interest, on our Consolidated Statement of Operations and concluded amounts were not material.

#### ***HealthTronics, Inc.***

On July 2, 2010 (the HealthTronics, Inc. Acquisition Date), the Company completed its initial tender offer for all outstanding shares of common stock of HealthTronics, Inc. and obtained effective control of HealthTronics, Inc. On July 12, 2010, Endo completed its acquisition of HealthTronics, Inc. for approximately \$214.8 million in aggregate cash consideration for 100% of the outstanding shares, at which time HealthTronics, Inc. became a wholly-owned subsidiary of the Company. HealthTronics, Inc.'s shares were purchased at a price of \$4.85 per HealthTronics, Inc. Share. In addition, Endo paid \$40.0 million to retire HealthTronics, Inc.'s debt that had been outstanding under its Senior Credit Facility. As a result of the acquisition, the HealthTronics, Inc. Senior Credit Facility was terminated.

HealthTronics, Inc. is a provider of healthcare services and manufacturer of certain related medical devices, primarily for the urology community. The HealthTronics, Inc. business and applicable services include:

#### ***Lithotripsy services.***

HealthTronics, Inc. provides lithotripsy services, which is a medical procedure where a device called a lithotripter transmits high energy shockwaves through the body to break up kidney stones. Lithotripsy services are provided principally through limited partnerships and other entities that HealthTronics, Inc. manages, which use lithotripters. In 2012, physician partners used our lithotripters to perform more than 50,000 procedures in the U.S. While the physicians render medical services, HealthTronics, Inc. does not. As the general partner of limited partnerships or the manager of other types of entities, HealthTronics, Inc. also provide services relating to operating its lithotripters, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting with payors, hospitals, and surgery centers.

#### ***Prostate treatment services.***

HealthTronics, Inc. provides treatments for benign and cancerous conditions of the prostate. In treating benign prostate disease, HealthTronics, Inc. deploys three technologies in a number of its partnerships above: (1) PVP, (2) TUNA, and (3) TUMT. All three technologies apply an energy source which reduces the size of the prostate gland. For treating prostate and other cancers, HealthTronics, Inc. uses a procedure called cryosurgery, a process which uses lethal ice to destroy tissue such as tumors for therapeutic purposes. In April 2008, HealthTronics, Inc. acquired Advanced Medical Partners, Inc., which significantly expanded its cryosurgery partnership base. In July 2009, HealthTronics, Inc. acquired Endocare, Inc., which manufactures both the medical devices and related consumables utilized by its cryosurgery operations and also provides cryosurgery treatments. The prostate treatment services are provided principally by using equipment that HealthTronics, Inc. leases from limited partnerships and other entities that HealthTronics, Inc. manages. Benign prostate disease and cryosurgery cancer treatment services are billed in the same manner as its

lithotripsy services under either retail or wholesale contracts. HealthTronics, Inc. also provides services relating to operating the equipment, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting.

*Anatomical pathology services.*

HealthTronics, Inc. provides anatomical pathology services primarily to the urology community. HealthTronics, Inc. has one pathology lab located in Georgia, which provides laboratory detection and diagnosis services to urologists throughout the U.S. In addition, in July 2008, HealthTronics, Inc. acquired Uropath LLC, now referred to as HealthTronics Laboratory Solutions, which managed pathology laboratories located at Uropath sites for physician practice groups located in Texas, Florida and Pennsylvania. Through HealthTronics Laboratory Solutions, HealthTronics, Inc. continues to provide administrative services to in-office pathology labs for practice groups and pathology services to physicians and practice groups with its lab equipment and personnel at the HealthTronics Laboratory Solutions laboratory sites.

*Medical products manufacturing, sales and maintenance.*

HealthTronics, Inc. manufactures and sells medical devices focused on minimally invasive technologies for tissue and tumor ablation through cryoablation, which is the use of lethal ice to destroy tissue, such as tumors, for therapeutic purposes. HealthTronics, Inc. develops and manufactures these devices for the treatment of prostate and renal cancers and our proprietary technologies also have applications across a number of additional markets, including the ablation of tumors in the lung, liver metastases and palliative intervention (treatment of pain associated with metastases). HealthTronics, Inc. manufactures the related spare parts and consumables for these devices. HealthTronics, Inc. also sells and maintains lithotripters and related spare parts and consumables.

The acquisition of HealthTronics, Inc. reflects Endo's desire to continue expanding our business beyond pain management into complementary medical areas where HealthTronics, Inc. can be innovative and competitive. We believe this expansion will enable us to be a provider of multiple healthcare solutions and services that fill critical gaps in patient care.

The operating results of HealthTronics, Inc. from July 2, 2010 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheets as of December 31, 2012 and December 31, 2011 reflect the acquisition of HealthTronics, Inc., effective July 2, 2010, the date the Company obtained control of HealthTronics, Inc.

The following table summarizes the fair values of the assets acquired and liabilities assumed at the HealthTronics, Inc. Acquisition Date (in thousands):

	July 2, 2010 (As Adjusted)
Cash and cash equivalents.....	\$ 6,769
Accounts receivable.....	33,388
Other receivables.....	1,006
Inventories.....	12,399
Prepaid expenses and other current assets.....	5,204
Deferred income taxes.....	46,489
Property, plant and equipment.....	30,687
Other intangible assets(1).....	73,124
Other assets.....	5,210
<b>Total identifiable assets.....</b>	<b>\$ 214,276</b>
Accounts payable.....	\$ 3,084
Accrued expenses.....	20,510
Deferred income taxes.....	22,376
Long-term debt.....	43,460
Other liabilities.....	1,785
<b>Total liabilities assumed.....</b>	<b>\$ 91,215</b>
<b>Net identifiable assets acquired.....</b>	<b>\$ 123,061</b>
Noncontrolling interests.....	(63,227)
Goodwill(2).....	155,009
<b>Net assets acquired.....</b>	<b>\$ 214,843</b>

(1) Other intangible assets includes a \$12.2 million intangible asset related to our IGRT business, which was sold in September 2011 for approximately \$13.0 million. Accordingly, the carrying amount of this asset was reduced to zero at the time of sale.

- (2) A subsequent pre-tax non-cash impairment charge of \$24.8 million related to this Goodwill was recorded in the fourth quarter of 2012. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the HealthTronics, Inc. Acquisition Date. Our measurement period adjustments are complete.

The valuation of the intangible assets acquired and related amortization periods are as follows (in millions):

	Valuation (in millions)	Amortization Period (in years)
Endocare Developed Technology .....	\$ 46.3	10
HealthTronics Tradename.....	14.6	15
Service Contract(1) .....	12.2	n/a
Total.....	<u>\$ 73.1</u>	n/a

- (1) This intangible asset relates to our IGRT business, which was sold in September 2011 for approximately \$13.0 million. Accordingly, the carrying amount of this asset was reduced to zero at the time of sale.

The fair value of the developed technology asset was estimated using a discounted present value income approach. Under this method, an intangible asset's fair value is equal to the present value of the incremental after-tax cash flows (excess earnings) attributable solely to the intangible asset over its remaining useful life. To calculate fair value, the Company used probability-weighted cash flows discounted at rates considered appropriate given the inherent risks associated with each type of asset. The Company believes that the level and timing of cash flows appropriately reflect market participant assumptions. Cash flows were assumed to extend through the economic useful life of the purchased technology. The fair value of the HealthTronics Tradename was estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to license the HealthTronics Tradename. Thus, we derived the hypothetical royalty income from the projected revenues of HealthTronics, Inc.'s services.

HealthTronics, Inc. has investments in partnerships and limited liability companies (LLCs) where we, as the general partner or managing member, exercise effective control. Accordingly, we consolidate various entities where we do not own 100% of the entity in accordance with the accounting consolidation principles. As a result, we are required to fair value the noncontrolling interests as part of our purchase price allocation. To calculate fair value, the Company used historical transactions which represented Level 2 data points within the fair value hierarchy to calculate applicable multiples of each respective noncontrolling interest in the partnerships and LLCs.

The \$155.0 million of goodwill has been assigned to our HealthTronics segment. The goodwill recognized is attributable primarily to strategic and synergistic opportunities across the HealthTronics, Inc. network of urology partnerships, expected corporate synergies, the assembled workforce of HealthTronics, Inc. and other factors. Approximately \$33.6 million of goodwill was expected to be deductible for income tax purposes.

Deferred tax assets of \$46.5 million are related primarily to federal net operating loss and credit carryforwards of HealthTronics, Inc. and its subsidiaries. Deferred tax liabilities of \$22.4 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

The Company recognized \$3.6 million, \$3.7 million and \$20.9 million of HealthTronics, Inc. acquisition-related and integration costs that were expensed during the years ended December 31, 2012, 2011 and 2010, respectively. These costs are included in Acquisition-related and integration items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	2012	2011	2010
Bank fees .....	\$ —	\$ —	\$ 2,017
Acceleration of outstanding HealthTronics, Inc. stock-based compensation.....	—	—	7,924
Legal, separation, integration, and other costs .....	3,569	3,704	10,988
Total.....	<u>\$ 3,569</u>	<u>\$ 3,704</u>	<u>\$ 20,929</u>

Transaction costs directly associated with the closing of the acquisition in 2010 and included in the table above totaled \$20.0 million.

The amounts of revenue and net loss of HealthTronics, Inc. included in the Company's Consolidated Statements of Operations from and including July 2, 2010 to December 31, 2010 are as follows (in thousands, except per share data):

Revenue .....	\$	102,144
Net loss attributable to Endo Health Solutions Inc.....	\$	(8,098)
Basic and diluted net loss per share.....	\$	(0.07)

The following supplemental pro forma information presents the financial results as if the acquisition of HealthTronics, Inc. had occurred on January 1, 2010 for the year ended December 31, 2010. This supplemental pro forma information has been prepared for comparative purposes and does not purport to be indicative of what would have occurred had the acquisition been made on January 1, 2010, nor are they indicative of any future results.

**Twelve Months Ended  
December 31, 2010**

**Unaudited pro forma consolidated results (in thousands, except per share data):**

Revenue.....	\$	1,814,918
Net income attributable to Endo Health Solutions Inc.....	\$	264,165
Basic net income per share.....	\$	2.27
Diluted net income per share.....	\$	2.24

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of HealthTronics, Inc. to reflect the additional depreciation and amortization that would have been charged assuming the fair value adjustments primarily to property, plant and equipment, and intangible assets, had been applied on January 1, 2010, together with the consequential tax effects.

**Other**

In the second half of 2011, as part of our effort to increase and broaden the relationships within the urology community, we acquired two electronic medical records software companies, Intuitive Medical Software, LLC and meridianEMR, Inc., which individually and combined represent immaterial acquisitions. These acquisitions provide electronic medical records for urologists. Together, these acquisitions provide access to more than 2,000 urology health care providers using data platforms that will enhance service offerings in urology practice management.

**Acquisition-Related Contingent Consideration.** As part of our consideration for the Qualitest Pharmaceuticals and Indevus acquisitions, we were initially contingently contractually obligated to pay certain consideration resulting from the outcome of future events. These amounts are updated for our current assumptions each reporting period based on new developments until such consideration is satisfied.

**Qualitest Pharmaceuticals**

On November 30, 2010 (the Qualitest Pharmaceuticals Acquisition Date), Endo acquired Qualitest Pharmaceuticals, which was party to an asset purchase agreement with Teva Pharmaceutical Industries Ltd (Teva) (the Teva Agreement). Pursuant to this agreement, Qualitest Pharmaceuticals purchased certain pipeline generic products from Teva and could be obligated to pay consideration to Teva upon the achievement of certain future regulatory milestones (the Teva Contingent Consideration).

The range of the undiscounted amounts the Company could pay under the Teva Agreement is between zero and \$12.5 million. The Company is accounting for the Teva Contingent Consideration in the same manner as if it had entered into that arrangement with respect to its acquisition of Qualitest Pharmaceuticals. Accordingly, the fair value was estimated based on a probability-weighted discounted cash flow model, or income approach. The resultant probability-weighted cash flows were then discounted using a discount rate of U.S. Prime plus 300 basis points. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. Using this valuation technique, the fair value of the contractual obligation to pay the Teva Contingent Consideration was determined to be \$8.9 million at December 31, 2012 and \$8.7 million at December 31, 2011.

The increase in the balance primarily, which was recorded as a loss and included in Acquisition-related and integration items, net in the accompanying Consolidated Statements of Operations, reflects changes of our present value assumptions associated with our valuation model.

As of December 31, 2012, there were no changes to the range of the undiscounted amounts the Company may be required to pay under the Teva Agreement.

## Indevus

The Indevus Contingent Consideration Agreements, which were contingent upon the achievement of commercial and regulatory milestones associated with certain of Indevus' key products in development at the Indevus Acquisition Date, were initially measured and recognized at fair value and were re-measured on a recurring basis, with changes to fair value recorded in Acquisition-related and integration items, net in the Consolidated Statements of Operations. The liability for the Indevus contingent consideration was reduced to zero off in 2011, reflecting management's 2011 probability assessment that it would not be obligated to make contingent consideration payments based on the progress and projected timeline for the related Indevus products in development. The last of the contingent obligations with respect to the Indevus contingent consideration expired in 2012.

**Legal Proceedings.** We are subject to various patent, product liability, government investigations and other legal proceedings in the ordinary course of business. Contingent accruals are recorded when we determine that a loss related to a litigation matter is both probable and reasonably estimable. Due to the fact that legal proceedings and other contingencies are inherently unpredictable, our assessments involve significant judgments regarding future events.

For a complete description of legal proceedings, see Note 15. Commitments and Contingencies in the Consolidated Financial Statements, included in Part IV, Item 15. of this report "Exhibits, Financial Statement Schedules".

**Contractual Obligations.** The following table lists our enforceable and legally binding noncancelable obligations as of December 31, 2012

Contractual Obligations	Payment Due by Period (in thousands)						
	Total	2013	2014	2015	2016	2017	Thereafter
Long-term debt obligations(1) .....	\$ 4,120,827	\$ 268,169	\$ 283,482	\$ 693,673	\$ 1,027,388	\$ 98,579	\$ 1,749,536
Capital lease obligations(2) .....	79,284	8,914	6,418	6,036	6,007	6,112	45,797
Operating lease obligations(3) .....	62,317	17,950	16,583	12,656	8,229	4,314	2,585
Minimum Voltaren® royalty obligations due to Novartis(4).....	47,178	32,178	15,000	—	—	—	—
Minimum purchase commitments to Teikoku(5) .....	40,256	40,256	—	—	—	—	—
Minimum advertising and promotion spend(6) ..	1,597	1,597	—	—	—	—	—
Other obligations and commitments(7) ..	17,850	3,479	1,371	1,000	1,000	1,000	10,000
<b>Total(8).....</b>	<b>\$ 4,369,309</b>	<b>\$ 372,543</b>	<b>\$ 322,854</b>	<b>\$ 713,365</b>	<b>\$ 1,042,624</b>	<b>\$ 110,005</b>	<b>\$ 1,807,918</b>

- (1) Includes minimum cash payments related to principal and interest, including commitment fees, associated with our indebtedness. Since future interest rates on our variable rate borrowings are unknown, for purposes of this contractual obligations table, amounts scheduled above were calculated using the greater of (i) the respective contractual interest rate spread corresponding to our current leverage ratios or (ii) the respective contractual interest rate floor, if any.
- (2) Includes minimum cash payments related to certain fixed assets, primarily related to technology. In addition, includes minimum cash payments related to the direct financing arrangement for the new company headquarters in Malvern, Pennsylvania.
- (3) Includes minimum cash payments related to our leased automobiles, machinery and equipment and facilities. Under the terms of our leases for our former headquarters' in Chadds Ford, Pennsylvania, we are required to continue to pay all future minimum lease payments to the landlord.
- (4) Under the terms of the five-year Voltaren® Gel Agreement, Endo has agreed to pay royalties to Novartis on annual Net Sales of the Licensed Product, subject to certain thresholds all as defined in the Voltaren® Gel Agreement. In addition, subject to certain limitations, Endo has agreed to make certain guaranteed minimum annual royalty payments beginning in the fourth year of the Voltaren® Gel Agreement, which may be reduced under certain circumstances, including Novartis's failure to supply the Licensed Product. These guaranteed minimum royalties will be creditable against royalty payments on a Voltaren® Gel Agreement year basis such that Endo's obligation with respect to each Voltaren® Gel Agreement year is to pay the greater of (i) royalties payable based on annual net sales of the Licensed Product or (ii) the guaranteed minimum royalty for such Agreement year. In December 2012, pursuant to the provisions of this Voltaren® Gel Agreement, the term was automatically renewed for an additional one year period.

- (5) On April 24, 2007, we amended our Supply and Manufacturing Agreement with Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc. (collectively, Teikoku) dated as of November 23, 1998, pursuant to which Teikoku manufactures and supplies Lidoderm® (lidocaine patch 5%) (the Product) to Endo. This amendment is referred to as the Amended Agreement. Under the terms of the Amended Agreement, Endo agreed to purchase a minimum number of Lidoderm® patches per year through 2012, representing the noncancelable portion of the Amended Agreement. The minimum purchase requirement remains in effect subsequent to 2012, except that Endo has the right to terminate the Amended Agreement if we fail to meet the annual minimum requirement in subsequent years. The supply price of Lidoderm® is adjusted annually based on a price index defined in the Amended Agreement. Since future price changes are unknown, for purposes of this contractual obligations table, all amounts scheduled above represent the minimum patch quantities at the price currently existing under the Amended Agreement. Effective November 1, 2010, the parties amended the Amended Agreement. Pursuant to this amendment, Teikoku has agreed to supply additional Product at no cost to Endo in each of 2011, 2012 and 2013 in the event Endo's firm orders of Product exceed certain thresholds in those years. We will update the Teikoku purchase commitments upon future price changes made in accordance with the Amended Agreement.
- (6) Under the terms of the five-year Voltaren® Gel Agreement, Endo has agreed to certain minimum advertising and promotional spending, subject to certain thresholds as defined in the Voltaren® Gel Agreement. Future minimum advertising and promotional spending are determined based on a percentage of net sales of the licensed product. On December 31, 2012, Endo and Novartis entered into an amendment to the Voltaren® Gel Agreement which reduced the minimum amount of annual advertising and promotional expenses required to be spent by Endo on the commercialization of Voltaren® Gel during each year of the Voltaren® Gel Agreement.
- (7) Other obligations and commitments include agreements to purchase third-party assets, products and services.
- (8) Total does not include contractual obligations already included in current liabilities on our Consolidated Balance Sheet (except for current portion of long-term debt, short-term capital lease obligations and short-term royalty obligations) or certain purchase obligations, which are discussed below.

For purposes of the table above, obligations for the purchase of goods or services are included only for significant noncancelable purchase orders that are enforceable, legally binding and specify all significant terms including fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the timing of the obligation. Our purchase orders are based on our current manufacturing needs and are typically fulfilled by our suppliers within a relatively short period. At December 31, 2012, we have open purchase orders that represent authorizations to purchase rather than binding agreements that are not included in the table above.

As of December 31, 2012, our liability for unrecognized tax benefits amounted to \$65.7 million (including interest and penalties). Due to the nature and timing of the ultimate outcome of these uncertain tax positions, we cannot make a reasonably reliable estimate of the amount and period of related future payments. Therefore, our liability has been excluded from the above contractual obligations table.

**Enterprise Resource Planning System Project.** As part of our integration efforts, we have decided to implement our historical enterprise resource planning (ERP) system, SAP, at certain of our key subsidiaries which currently use a variety of ERP systems. We expect this ERP system to be implemented no later than 2015. During the implementation process, management will review and evaluate the design and operating effectiveness of key controls within SAP, as well as the accuracy of the data conversion process.

**Fluctuations.** Our quarterly results have fluctuated in the past, and may continue to fluctuate. These fluctuations may be due to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products, the impact of competitive products and pricing, asset impairment charges, separation benefits, business combination transaction costs, upfront, milestone and certain other payments made or accrued pursuant to licensing agreements and changes in the fair value of financial instruments and contingent assets and liabilities recorded as part of a business combination. Further, a substantial portion of our total revenues are through three wholesale drug distributors who in turn supply our products to pharmacies, hospitals and physicians. Accordingly, we are potentially subject to a concentration of credit risk with respect to our trade receivables.

**Growth Opportunities.** We continue to evaluate growth opportunities including strategic investments, licensing arrangements, acquisitions of businesses, product rights or technologies, and strategic alliances and promotional arrangements which could require significant capital resources. We intend to continue to focus our business development activities on further diversifying our revenue base through product licensing and company acquisitions, as well as other opportunities to enhance stockholder value. Through execution of our business strategy we intend to focus on developing new products through both an internal and a virtual research and development organization with greater scientific and clinical capabilities; expanding the Company's product line by acquiring new products and technologies in existing therapeutic and complementary areas; increasing revenues and earnings through sales and marketing programs for our innovative product offerings and effectively using the Company's resources; and providing additional resources to support our generics business.

**Non-U.S. Operations.** Our operations outside of the U.S. were not material during 2012. As a result, fluctuations in foreign currency exchange rates did not have a material effect on our Consolidated Financial Statements.



In general, it is the practice and intention of the Company to reinvest the earnings of its non-U.S. subsidiaries in those operations. As of December 31, 2012, the Company has not made a provision for U.S. or additional foreign withholding taxes on approximately \$85.7 million of the excess of the amount for financial reporting over the tax basis of investments in foreign subsidiaries that are essentially permanent in duration. Generally, such amounts become subject to U.S. taxation upon the remittance of dividends and under certain other circumstances. It is not practicable to estimate the amount of deferred tax liability related to investments in these foreign subsidiaries.

**Inflation.** We do not believe that inflation had a material adverse effect on our financial statements for the periods presented.

**Off-Balance Sheet Arrangements.** We have no off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

## CRITICAL ACCOUNTING ESTIMATES

To understand our financial statements, it is important to understand our critical accounting estimates. The preparation of our financial statements in conformity with accounting principles generally accepted in the U.S. requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in the determination of revenue recognition and sales deductions for estimated chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and allowances. Significant estimates and assumptions are also required when determining the fair value of financial instruments, the valuation of long-lived assets, income taxes, contingencies and stock-based compensation. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption made by us, there may also be other estimates or assumptions that are reasonable. Although we believe that our estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made. Actual results may differ significantly from our estimates.

We consider an accounting estimate to be critical if: (1) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (2) changes in the estimate that are reasonably likely to occur from period to period, or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition results of operations or cash flows. Our most critical accounting estimates are described below:

### **Revenue recognition**

#### **Pharmaceutical Products**

Our net pharmaceutical product sales consist of revenues from sales of our pharmaceutical products, less estimates for chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and allowances as well as fees for services. We recognize revenue for product sales when title and risk of loss has passed to the customer, which is typically upon delivery to the customer, when estimated provisions for chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and allowances are reasonably determinable, and when collectability is reasonably assured. Revenue from the launch of a new or significantly unique product, for which we are unable to develop the requisite historical data on which to base estimates of returns and allowances due to the uniqueness of the therapeutic area or delivery technology as compared to other products in our portfolio and in the industry, may be deferred until such time that an estimate can be determined and all of the conditions above are met and when the product has achieved market acceptance, which is typically based on dispensed prescription data and other information obtained during the period following launch.

Decisions made by wholesaler customers and large retail chain customers regarding the levels of inventory they hold (and thus the amount of product they purchase from us) can materially affect the level of our sales in any particular period and thus may not correlate to the number of prescriptions written for our products based on external third-party data. We believe that speculative buying of product, particularly in anticipation of possible price increases, has been the historic practice of many pharmaceutical wholesalers. In recent years, our wholesaler customers, as well as others in the industry, began modifying their business models from arrangements where they derive profits from price arbitrage, to arrangements where they charge a fee for their services. Accordingly, we have entered into Distribution Service Agreements (DSAs) with six of our significant wholesaler customers. These agreements, which pertain to branded products only, obligate the wholesalers to provide us with specific services, including the provision of periodic retail demand information and current inventory levels for our branded products held at their warehouse locations; additionally, under these DSAs, the wholesalers have agreed to manage the variability of their purchases and inventory levels within specified limits based on product demand.

Under the DSAs, we received information from our six wholesaler customers about the levels of inventory they held for our branded products as of December 31, 2012. Based on this information, which we have not independently verified, we believe that total branded inventory held at these wholesalers is within normal levels. In addition, we also evaluate market conditions for products primarily through the analysis of wholesaler and other third party sell-through and market research data, as well as internally-generated information.

## *Devices*

As a result of our acquisition of AMS, Inc., we sell products in this market through a direct sales force. A portion of our revenue is generated from consigned inventory or from inventory with field representatives. For these products, revenue is recognized at the time the product has been used or implanted. For all other transactions, we recognize revenue when title to the goods and risk of loss transfer to our customers providing there are no remaining performance obligations required from us or any matters requiring customer acceptance. In cases where we utilize distributors or ship product directly to the end user, we recognize revenue upon shipment provided all revenue recognition criteria have been met. We record estimated sales returns, discounts and rebates as a reduction of net sales in the period the related revenue is recognized.

We provide incentives to customers, including volume based rebates. Customers are not required to provide documentation that would allow us to reasonably estimate the fair value of the benefit received and we do not receive an identifiable benefit in exchange for the consideration. Accordingly, the incentives are recorded as a reduction of revenue.

Our AMS customers have rights of return for the occasional ordering or shipping error. We maintain an allowance for these returns and reduce reported revenue for expected returns from shipments during each reporting period. This allowance is based on historical and current trends in product returns.

## *Services*

In our HealthTronics segment, we recognize revenue generally when services are provided or, in the case of fees for product sales and licensing applications, revenues are generally recognized upon delivery or for licensing fees, when the patient is treated. In our HealthTronics segment, revenue is recognized based on the type of product or service sold, as follows:

- Fees for urology treatments—A substantial majority of our HealthTronics revenues are derived from fees related to lithotripsy treatments performed using our lithotripters. For lithotripsy and prostate treatment services, we, through our partnerships and other entities, facilitate the use of our equipment and provide other support services in connection with these treatments at hospitals and other health care facilities. The professional fee payable to the physician performing the procedure is generally billed and collected by the physician.
- Fees for managing the operation of our lithotripters and prostate treatment devices—Through our partnerships and otherwise directly by us, we provide services related to operating our lithotripters and prostate treatment equipment and receive a management fee for performing these services. We recognize revenue for these services as the services are provided.
- Fees for maintenance services—We provide equipment maintenance services to our partnerships as well as outside parties. These services are billed either on a time and material basis or at a fixed contractual rate, payable monthly, quarterly, or annually. Revenues from these services are recorded when the related maintenance services are performed.
- Fees for equipment sales, consumable sales and licensing applications—We manufacture and sell medical devices focused on minimally invasive technologies for tissue and tumor ablation through cryosurgery, and their related consumables. We also sell and maintain lithotripters and manufacture and sell consumables related to the lithotripters. With respect to some lithotripter sales, in addition to the original sales price, we receive a licensing fee from the buyer of the lithotripter for each patient treated with such lithotripter. In exchange for this licensing fee, we provide the buyer of the lithotripter with certain consumables. All the sales for equipment and consumables are recognized when the related items are delivered. Revenues from licensing fees are recorded when the patient is treated. In some cases, we lease certain equipment to our partnerships as well as third parties. Revenues from these leases are recognized on a monthly basis or as procedures are performed.
- Fees for anatomical pathology services—We provide anatomical pathology services primarily to the urology community. Revenues from these services are recorded when the related laboratory procedures are performed.

## Sales deductions

When we recognize revenue from the sale of our products, we simultaneously record an adjustment to revenue for estimated chargebacks, rebates, sales incentives and allowances, certain royalties, DSA fees, returns and allowances. These provisions, as described in greater detail below, are estimated based on historical experience, estimated future trends, estimated customer inventory levels, current contract sales terms with our wholesale and indirect customers and other competitive factors. If the assumptions we used to calculate these adjustments do not appropriately reflect future activity, our financial position, results of operations and cash flows could be materially impacted. The following table presents the activity and ending balances for our product sales provisions for the last three years (in thousands):

	Returns and Allowances	Rebates	Chargebacks	Other Sales Deductions	Total
Balance at January 1, 2010 .....	\$ 48,274	\$ 124,443	\$ 51,904	\$ 6,060	\$ 230,681
Additions related to acquisitions.....	11,000	11,175	9,703	7,833	39,711
Current year provision .....	20,019	632,034	519,537	54,969	1,226,559
Prior year provision.....	(2,520)	(1,791)	21	—	(4,290)
Payments or credits .....	(11,752)	(562,636)	(493,345)	(53,542)	(1,121,275)
Balance at December 31, 2010 .....	\$ 65,021	\$ 203,225	\$ 87,820	\$ 15,320	\$ 371,386
Additions related to acquisitions.....	3,594	194	—	—	3,788
Current year provision .....	52,027	842,674	801,543	85,147	1,781,391
Prior year provision.....	3,697	2,312	—	—	6,009
Payments or credits .....	(34,264)	(739,494)	(772,542)	(79,125)	(1,625,425)
Balance at December 31, 2011.....	\$ 90,075	\$ 308,911	\$ 116,821	\$ 21,342	\$ 537,149
Current year provision .....	39,909	872,709	716,982	87,437	1,717,037
Prior year provision.....	(15,556)	(9,163)	(100)	(709)	(25,528)
Payments or credits .....	(28,613)	(844,531)	(772,401)	(90,290)	(1,735,835)
Balance at December 31, 2012 .....	\$ 85,815	\$ 327,926	\$ 61,302	\$ 17,780	\$ 492,823

### Returns and Allowances

Our provision for returns and allowances consists of our estimates of future product returns, pricing adjustments and delivery errors. Consistent with industry practice, we maintain a return policy that allows our customers to return product within a specified period of time both prior and subsequent to the product's expiration date. Our return policy allows customers to receive credit for expired products within six months prior to expiration and within one year after expiration. The primary factors we consider in estimating our potential product returns include:

- the shelf life or expiration date of each product;
- historical levels of expired product returns;
- external data with respect to inventory levels in the wholesale distribution channel;
- external data with respect to prescription demand for our products; and
- estimated returns liability to be processed by year of sale based on analysis of lot information related to actual historical returns.

In determining our estimates for returns and allowances, we are required to make certain assumptions regarding the timing of the introduction of new products and the potential of these products to capture market share. In addition, we make certain assumptions with respect to the extent and pattern of decline associated with generic competition. To make these assessments we utilize market data for similar products as analogs for our estimations. We use our best judgment to formulate these assumptions based on past experience and information available to us at the time. We continually reassess and make the appropriate changes to our estimates and assumptions as new information becomes available to us.

Our estimate for returns and allowances may be impacted by a number of factors, but the principal factor relates to the level of inventory in the distribution channel. When we are aware of an increase in the level of inventory of our products in the distribution channel, we consider the reasons for the increase to determine if the increase may be temporary or other-than-temporary. Increases in inventory levels assessed as temporary will not result in an adjustment to our provision for returns and allowances. Other-than-temporary increases in inventory levels, however, may be an indication that future product returns could be higher than originally anticipated and, accordingly, we may need to adjust our estimate for returns and allowances. Some of the factors that may be an indication that an increase in inventory levels will be temporary include:

- recently implemented or announced price increases for our products; and
- new product launches or expanded indications for our existing products.

Conversely, factors that may be an indication that an increase in inventory levels will be other-than-temporary include:

- declining sales trends based on prescription demand;
- recent regulatory approvals to extend the shelf life of our products, which could result in a period of higher returns related to older product with the shorter shelf life;
- introduction of new product or generic competition;
- increasing price competition from generic competitors; and
- recent changes to the National Drug Codes (NDCs) of our products, which could result in a period of higher returns related to product with the old NDC, as our customers generally permit only one NDC per product for identification and tracking within their inventory systems.

### *Rebates*

We establish contracts with wholesalers, chain stores and indirect customers that provide for rebates, sales incentives, DSA fees, and other allowances. Some customers receive rebates upon attaining established sales volumes. We estimate rebates, sales incentives and other allowances based upon the terms of the contracts with our customers, historical experience, estimated inventory levels of our customers and estimated future trends. Our rebate programs can generally be categorized into the following four types:

- direct rebates;
- indirect rebates;
- managed care rebates; and
- Medicaid and Medicare Part D rebates.

Direct rebates are generally rebates paid to direct purchasing customers based on a percentage applied to a direct customer's purchases from us, including DSA fees paid to wholesalers under our DSA agreements, as described above. Indirect rebates are rebates paid to "indirect customers" which have purchased our products from a wholesaler under a contract with us.

We are subject to rebates on sales made under governmental and managed-care pricing programs. In estimating our provisions for these types of rebates, we consider relevant statutes with respect to governmental pricing programs and contractual sales terms with managed-care providers and group purchasing organizations. We estimate an accrual for managed-care, Medicaid and Medicare Part D rebates as a reduction of revenue at the time product sales are recorded. These rebate reserves are estimated based upon the historical utilization levels, historical payment experience, historical relationship to revenues and estimated future trends. Changes in the level of utilization of our products through private or public benefit plans and group purchasing organizations will affect the amount of rebates that we owe.

We participate in state government-managed Medicaid programs, as well as certain other qualifying federal and state government programs whereby discounts and rebates are provided to participating government entities. Medicaid rebates are amounts owed based upon contractual agreements or legal requirements with public sector (Medicaid) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. Medicaid reserves are based on expected payments, which are driven by patient usage, contract performance, as well as field inventory that will be subject to a Medicaid rebate. Medicaid rebates are typically billed up to 180 days after the product is shipped, but can be as much as 270 days after the quarter in which the product is dispensed to the Medicaid participant. As a result, our Medicaid rebate provision includes an estimate of outstanding claims for end-customer sales that occurred but for which the related claim has not been billed, and an estimate for future claims that will be made when inventory in the distribution channel is sold through to plan participants. Our calculation also requires other estimates, such as estimates of sales mix, to determine which sales are subject to rebates and the amount of such rebates. Periodically, we adjust the Medicaid rebate provision based on actual claims paid. Due to the delay in billing, adjustments to actual claims paid may incorporate revisions of this provision for several periods. Medicaid pricing programs involve particularly difficult interpretations of statutes and regulatory guidance, which are complex and thus our estimates could differ from actual experience.

We continually update these factors based on new contractual or statutory requirements, and significant changes in sales trends that may impact the percentage of our products subject to rebates.

### *Chargebacks*

The provision for chargebacks is one of the most significant and the most complex estimates used in the recognition of our revenue. We market and sell products directly to wholesalers, distributors, warehousing pharmacy chains, and other direct purchasing groups. We also market products indirectly to independent pharmacies, non-warehousing chains, managed care organizations, and group purchasing organizations, collectively referred to as "indirect customers." We enter into agreements with some indirect customers to establish contract pricing for certain products. These indirect customers then independently select a wholesaler from which to purchase the products at these contracted prices. Alternatively, we may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, we provide credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price. Such credit is called a chargeback. The primary factors we consider in developing and evaluating our provision for chargebacks include:

- the average historical chargeback credits;

- estimated future sales trends; and
- an estimate of the inventory held by our wholesalers, based on internal analysis of a wholesaler's historical purchases and contract sales.

#### *Other sales deductions*

We offer our customers 2.0% prompt pay cash discounts. Provisions for prompt pay discounts are estimated and recorded at the time of sale. We estimate provisions for cash discounts based on contractual sales terms with customers, an analysis of unpaid invoices and historical payment experience. Estimated cash discounts have historically been predictable and less subjective, due to the limited number of assumptions involved, the consistency of historical experience and the fact that we generally settle these amounts within thirty to sixty days.

Shelf-stock adjustments are credits issued to our customers to reflect decreases in the selling prices of our products. These credits are customary in the industry and are intended to reduce a customer's inventory cost to better reflect current market prices. The determination to grant a shelf-stock credit to a customer following a price decrease is at our discretion rather than contractually required. The primary factors we consider when deciding whether to record a reserve for a shelf-stock adjustment include:

- the estimated number of competing products being launched as well as the expected launch date, which we determine based on market intelligence;
- the estimated decline in the market price of our product, which we determine based on historical experience and input from customers; and
- the estimated levels of inventory held by our customers at the time of the anticipated decrease in market price, which we determine based upon historical experience and customer input.

#### *Valuation of long-lived assets*

Long-lived assets, including property, plant and equipment, licenses, developed technology, tradenames and patents are assessed for impairment whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Recoverability of assets that will continue to be used in our operations is measured by comparing the carrying amount of the asset to the forecasted undiscounted future cash flows related to the asset. In the event the carrying value of the asset exceeds its undiscounted future cash flows and the carrying value is not considered recoverable, impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value, generally based on a discounted future cash flow method, independent appraisals or preliminary offers from prospective buyers. An impairment loss would be recognized in the Consolidated Statements of Operations in the period that the impairment occurs. As a result of the significance of our amortizable intangibles, any recognized impairment loss could have a material adverse impact on our financial position and/or results of operations.

Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. Factors that we consider in deciding when to perform an impairment review include significant under-performance of a product line in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in our use of the assets.

Our reviews of long-lived assets during the three years ended December 31, 2012 resulted in certain asset impairment charges, which are described above under the caption "RESULTS OF OPERATIONS".

The cost of licenses are either expensed immediately or, if capitalized, are stated at cost, less accumulated amortization and are amortized using the straight-line method over their estimated useful lives ranging from 1 to 15 years, with a weighted average useful life of approximately 9 years. We determine amortization periods for licenses based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental and regulatory issues, and contractual terms. Significant changes to any of these factors may result in a reduction in the useful life of the license and an acceleration of related amortization expense, which could cause our operating income, net income and net income per share to decrease. The value of these licenses is subject to continuing scientific, medical and marketplace uncertainty.

Acquired customer relationships are recorded at fair value upon acquisition and are amortized using estimated useful lives ranging from 13 to 17 years, with a weighted average useful life of approximately 16 years. We determine amortization periods for customer relationships based on our assessment of various factors impacting estimated useful lives and cash flows from the acquired assets. Such factors include the strength of the customer relationships, contractual terms and our plans regarding our future relations with our customers. Significant changes to any of these factors may result in a reduction in the useful life of the asset and an acceleration of related amortization expense, which could cause our operating income, net income and net income per share to decrease.

Acquired tradenames are recorded at fair value upon acquisition and, if deemed to have definite lives, are amortized using estimated useful lives ranging from 15 to 30 years, with a weighted average useful life of approximately 22 years. We determine amortization periods for tradenames based on our assessment of various factors impacting estimated useful lives and cash flows from

the acquired assets. Such factors include the strength of the tradename and our plans regarding the future use of the tradename. Significant changes to any of these factors may result in a reduction in the useful life of the asset and an acceleration of related amortization expense, which could cause our operating income, net income and net income per share to decrease.

Acquired developed technology is recorded at fair value upon acquisition and amortized using estimated useful lives ranging from 3 to 20 years, with a weighted average useful life of approximately 16 years. We determine amortization periods for developed technology based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired assets. Such factors include the strength of the intellectual property protection of the product and various other competitive and regulatory issues, and contractual terms. Significant changes to any of these factors may result in a reduction in the useful life of the asset and an acceleration of related amortization expense, which could cause our operating income, net income and net income per share to decrease. The value of these assets is subject to continuing scientific, medical and marketplace uncertainty.

### *Goodwill and indefinite-lived intangible assets*

Endo tests goodwill and indefinite-lived intangible assets for impairment annually, or more frequently whenever events or changes in circumstances indicate that the asset might be impaired. Our annual assessment has historically been performed as of January 1<sup>st</sup>. However, during the third quarter of 2012, we changed our annual goodwill and indefinite-lived intangible assets impairment test date from January 1<sup>st</sup> to October 1<sup>st</sup>, which necessitated completing a test as of October 1, 2012 so that no more than 12 months elapsed between annual tests. The goodwill test consists of a Step I analysis that requires a comparison between the respective reporting unit's fair value and carrying amount. A Step II analysis would be required if the fair value of the reporting unit is lower than its carrying amount. If the fair value of the reporting unit exceeds its carrying amount, an impairment does not exist and no further analysis is required. The indefinite-lived intangible asset impairment test consists of a one-step analysis that compares the fair value of the intangible asset with its carrying amount. If the carrying amount of an intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. Although the Company has four operating segments, Endo Pharmaceuticals, Qualitest, AMS and HealthTronics, we have determined that the Company has seven reporting units; (1) Pain, (2) Generics, (3) Urology, Endocrinology and Oncology (UEO), (4) Anatomical Pathology Services, (5) Urology Services, (6) HealthTronics Information Technology Solutions (HITS) and (7) American Medical Systems (AMS).

As noted above, we completed our annual impairment tests as of October 1, 2012. Based upon recent market conditions, and, in some cases, a lack of comparable market transactions for similar assets, Endo determined that an income approach using a discounted cash flow model was an appropriate valuation methodology to determine each reporting unit's fair value for goodwill impairment testing and each asset's fair value for indefinite-lived intangible asset impairment testing. Our discounted cash flow models are highly reliant on various assumptions, including estimates of future cash flow (including long-term growth rates), discount rate, and expectations about variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. Discount rates applied to the estimated cash flows for our October 1, 2012 annual goodwill and indefinite-lived intangible assets impairment test ranged from 9.5% to 17.5%, depending on the overall risk associated with the particular assets and other market factors. We believe the discount rates and other inputs and assumptions are consistent with those that a market participant would use.

In order to assess the reasonableness of the calculated fair values of our reporting units, we also compare the sum of the reporting units' fair values to Endo's market capitalization and calculate an implied control premium (the excess sum of the reporting unit's fair values over the market capitalization). The Company evaluates the control premium by comparing it to control premiums of recent comparable market transactions, as applicable. If the control premium is not reasonable in light of comparable recent transactions, we reevaluate the fair value estimates of the reporting units by adjusting discount rates and/or other assumptions. This reevaluation could correlate to lower implied fair values for certain or all of the Company's reporting units.

The results of our Step I analyses showed that the fair values of the Pain, UEO and Generics reporting units exceeded their respective carrying amounts. The excess of fair value over carrying amount for each of these reporting units as of October 1, 2012 ranged from approximately 70% to more than 100% of carrying amount or \$355.8 million to \$1.5 billion, respectively. The results of the analysis for the Urology Services reporting unit, which held \$139.9 million of goodwill as of October 1, 2012, showed fair value that exceeded its carrying amount by 8% or \$16.4 million. An increase of 50 basis points to our assumed discount rates used in testing any of these reporting units would not have changed the results of our Step I analyses. However, we believe there is a risk of potential failure of Step I of the impairment test for the Urology Services reporting unit in future periods given the minimal excess fair value over carrying amount.

The results of the Step I analyses for the AMS, Anatomical Pathology Services, and HITS reporting units showed that the fair values of those reporting units were lower than their respective carrying amounts, thus requiring a Step II analysis for each reporting unit. The declines in these fair values, as well as fair value changes for other assets and liabilities in the Step II goodwill impairment test, resulted in an implied fair value of goodwill below the carrying amount of the goodwill for these reporting units. Accordingly, we recorded combined pre-tax non-cash goodwill impairment charges in the Consolidated Statement of Operations totaling \$557.4 million in 2012. A 50 basis point increase in the assumed discount rates utilized would have resulted in an increased goodwill impairment of approximately \$150 million and \$2 million for the AMS and HITS reporting units, respectively.



These impairment charges are further described above under the caption "RESULTS OF OPERATIONS". Other than these charges, there were no additional impairments of goodwill recorded as a result of performing our annual goodwill assessments during the three years ended December 31, 2012.

Our annual review of indefinite-lived intangible assets during the three years ended December 31, 2012 resulted in certain asset impairment charges, which are described above under the caption "RESULTS OF OPERATIONS". Other than these charges, there were no additional impairments recorded as a result of performing our annual assessments.

#### ***Acquisition-related in-process research and development***

Acquired businesses are accounted for using the acquisition method of accounting, which requires that the purchase price be allocated to the net assets acquired at their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill. Amounts allocated to acquired IPR&D are recorded to the balance sheet at the date of acquisition based on their relative fair values. The judgments made in determining the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact our results of operations.

There are several methods that can be used to determine the fair value of assets acquired and liabilities assumed. For intangible assets, including IPR&D, we typically use the "income method." This method starts with our forecast of all of the expected future net cash flows. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams. Some of the more significant estimates and assumptions inherent in the income method or other methods include: the amount and timing of projected future cash flows; the amount and timing of projected costs to develop the IPR&D into commercially viable products; the discount rate selected to measure the risks inherent in the future cash flows; and the assessment of the asset's life cycle and the competitive trends impacting the asset, including consideration of any technical, legal, regulatory, or economic barriers to entry, as well as expected changes in standards of practice for indications addressed by the asset.

Determining the useful life of an intangible asset also requires judgment, as different types of intangible assets will have different useful lives. Acquired IPR&D is designated as an indefinite-lived intangible asset until the associated research and development activities are completed or abandoned.

#### ***Income taxes***

Provisions for income taxes are calculated on reported pre-tax income based on current tax laws, statutory tax rates and available tax incentives and planning opportunities in various jurisdictions in which we operate. Such provisions differ from the amounts currently receivable or payable because certain items of income and expense are recognized in different time periods for financial reporting purposes than for income tax purposes. We recognize deferred taxes by the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred income taxes are recognized for differences between the financial statement and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. Significant judgment is required in determining income tax provisions and evaluating tax positions. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The factors used to assess the likelihood of realization are the Company's forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. Failure to achieve forecasted taxable income in applicable tax jurisdictions could affect the ultimate realization of deferred tax assets and could result in an increase in the Company's effective tax rate on future earnings.

At December 31, 2012, we had \$503.1 million of gross deferred tax assets, which included federal and state net operating loss carryforwards (NOLs) of approximately \$125.0 million, research and development credit carryforwards of \$16.2 million, impairment losses that are capital in nature of \$9.6 million, alternative minimum tax and foreign tax credits of \$2.6 million and temporary differences of approximately \$349.7 million. At December 31, 2012, our NOLs and research and development credit carryforwards were related to multiple tax jurisdictions, including federal and various state jurisdictions, which expire at intervals between 2013 and 2033. We evaluate the potential realization of our deferred tax benefits on a jurisdiction-by-jurisdiction basis. Our analysis of the realization considers the probability of generating taxable income or other sources of income as defined within the applicable income tax authoritative guidance, which could be utilized to support the assets over the permitted carryforward period in each jurisdiction. Where we have determined under the more likely than not standard that we do not have a better-than-50% probability of realization, we establish a valuation allowance against that portion of the deferred tax asset where our analysis and judgment indicates a less-than-50% probability of realization. Based on our forecasted taxable income within these jurisdictions, we believe we will generate sufficient future taxable income to realize a significant portion of our deferred tax assets associated with our NOLs and research and development credit carryforwards. However, the Company does not anticipate future capital gains that would be required to obtain the tax benefit of our impairment capital losses. Accordingly, this deferred tax asset is offset by a valuation allowance of \$9.4 million at December 31, 2012. In addition, due to our historical losses in certain state jurisdictions and the absence of sources of income, we have established a \$9.1 million valuation allowance for our state NOL carryforwards.

On a periodic basis, we evaluate the realizability of our deferred tax assets and liabilities and will adjust such amounts in light of changing facts and circumstances, including but not limited to future projections of taxable income, tax legislation, rulings by relevant tax authorities, tax planning strategies and the progress of ongoing tax audits. Settlement of filing positions that may be challenged by tax authorities could impact the income tax position in the year of resolution.

### **Contingencies**

The Company is subject to various patent, product liability, government investigations and other legal proceedings in the ordinary course of business. Legal fees and other expenses related to litigation are expensed as incurred and included in Selling, general and administrative expenses. Contingent accruals are recorded in the Consolidated Statements of Operations when the Company determines that a loss related to a litigation matter is both probable and reasonably estimable. Due to the fact that legal proceedings and other contingencies are inherently unpredictable, our assessments involve significant judgments regarding future events.

### **Stock-based compensation**

The Company accounts for its stock-based compensation plans in accordance with FASB Codification Topic 718, Stock Compensation. Accordingly, stock-based compensation for employees and non-employee directors is measured at the grant date, based on the estimated fair value of the award, and is recognized as an expense over the requisite service period. Determining the appropriate fair-value model and calculating the fair value of share-based awards at the date of grant requires judgment. We use the Black-Scholes option pricing model to estimate the fair value of employee stock options.

The Black-Scholes option pricing model utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield (which is expected to be zero, as the Company has not paid cash dividends to date and does not currently expect to pay cash dividends) and the expected term of the option. Expected volatilities utilized in the model are based mainly on the historical volatility of the Company's stock price and other factors. To the extent volatility of our stock price increases in the future, our estimates of the fair value of stock options granted in the future could increase, thereby increasing stock-based compensation expense in future periods. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. We estimate the expected term of options granted based on our historical experience with our employees' exercise of stock options and other factors, including an estimate of the number of share-based awards which will be forfeited due to employee turnover. Changes in the estimated forfeiture rate may have a significant effect on share-based compensation, as the effect of adjusting the rate for all expense amortization is recognized in the period the forfeiture estimate is changed. If the actual forfeiture rate is higher than the estimated forfeiture rate, then an adjustment is made to increase the estimated forfeiture rate, which will result in a decrease to the expense recognized in the financial statements. If the actual forfeiture rate is lower than the estimated forfeiture rate, then an adjustment is made to decrease the estimated forfeiture rate, which will result in an increase to the expense recognized in the financial statements. Changes in the inputs and assumptions can materially affect the measurement of the estimated fair value of our employee stock options. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense. Also, the accounting estimate of stock-based compensation expense is reasonably likely to change from period to period as further stock options are granted and adjustments are made for stock option forfeitures and cancellations.

The fair value of our restricted stock grants to employees and non-employee directors is based on the fair market value of our common stock on the date of grant discounted for expected future dividends.

### **RECENT ACCOUNTING PRONOUNCEMENTS**

In June 2011, the Financial Accounting Standards Board (FASB or the Board) issued Accounting Standards Update (ASU) 2011-05 on the presentation of comprehensive income. This ASU amends FASB Codification Topic 220, Comprehensive Income, to require an entity to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2011 and early adoption is permitted. In December 2011, the FASB issued ASU 2011-12 which amends ASU 2011-05 to defer only those changes in ASU 2011-05 that relate to the presentation of reclassification adjustments to allow the Board time to re-deliberate whether to present on the face of the financial statements the effects of reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income for all periods presented. The Company has adopted all current required provisions of ASU 2011-05 and ASU 2011-12.

In July 2012, the FASB issued ASU 2012-02 on impairment testing for indefinite-lived intangible assets. This ASU amends FASB Codification Topic 350, Intangibles-Goodwill and Other to allow, but not require, an entity, when performing its annual or more frequent indefinite-lived intangible asset impairment test, to first assess qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that the indefinite-lived intangible asset is impaired. If, after assessing the totality of events and circumstances, an entity concludes that it is not more likely than not that the indefinite-lived

intangible asset is impaired, then the entity is not required to take further action. However, if an entity concludes otherwise, then it is required to determine the fair value of the indefinite-lived intangible asset and perform the quantitative impairment test by comparing the fair value with the carrying amount. ASU 2012-02 is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. The Company has adopted ASU 2012-02 and determined that the adoption of this ASU did not have a significant impact on the Company's Consolidated Financial Statements.

In February 2013, the FASB issued ASU 2013-02, which established the effective date for the requirement to present components of reclassifications out of accumulated other comprehensive income on the face of the income statement. The standard is effective for reporting periods beginning after December 15, 2012. The adoption of this ASU is not expected to have a significant impact on the Company's Consolidated Financial Statements.

#### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

Market risk is the potential loss arising from adverse changes in the financial markets, including interest rates and foreign currency exchange rates.

##### *Interest Rate Risk*

Our exposure to interest rate risk relates primarily to our Term Loan Facility, money market funds, and long-term marketable debt securities portfolio. Additionally, if we were to utilize amounts under our Revolving Credit Facility, we could be exposed to interest rate risk. At December 31, 2012, our Term Loan Facility includes floating-rate debt of approximately \$1.5 billion. Based on this amount, a 1% rise in interest rates would result in approximately \$15 million in incremental annual interest expense.

In general, our investments in marketable securities are governed by our investment policy, which has been approved by our Board of Directors. Our investment policy seeks to preserve the value of capital, consistent with maximizing return on the Company's investment, while maintaining adequate liquidity. To achieve this objective, we maintain our portfolio in a variety of high credit quality debt securities. Generally, our interest rate risk with respect to these investments is limited due to yields earned, which approximate current interest rates. We attempt to mitigate default risk by maintaining our portfolio investments in diversified, high-quality investment grade securities with limited time to maturity. We constantly monitor our investment portfolio and position our portfolio to respond appropriately to a reduction in credit rating of any investment issuer, guarantor or depository.

As of December 31, 2012 and 2011, we had no other assets or liabilities with significant interest rate sensitivity.

##### *Investment Risk*

At December 31, 2012 and 2011, we had publicly traded equity securities totaling \$1.7 million and \$1.6 million, respectively, included in long-term marketable securities. The fair values of our investments are subject to significant fluctuations due to the volatility of the stock market, changes in general economic conditions and changes in the financial condition of the companies we invest in. Based on the fair value of the publicly traded equity securities we held at December 31, 2012, an assumed 25%, 40% and 50% adverse change in the market prices of these securities would result in a corresponding decline in total fair value of approximately \$0.4 million, \$0.7 million and \$0.9 million, respectively. Based on the fair value of the publicly traded equity securities we held at December 31, 2011, an assumed 25%, 40% and 50% adverse change in the market prices of these securities would result in a corresponding decline in total fair value of approximately \$0.4 million, \$0.7 million and \$0.8 million, respectively. Any decline in value below our original investments will be evaluated to determine if the decline in value is considered temporary or other-than-temporary. An other-than-temporary decline in fair value would be included as a charge to earnings.

##### *Foreign Currency Risk*

Our operations outside of the U.S. are maintained primarily in their local currency. All assets and liabilities of our international subsidiaries, which maintain their financial statements in local currency, are translated to U.S. dollars at period-end exchange rates. Translation adjustments arising from the use of differing exchange rates are included in accumulated other comprehensive income in stockholders' equity. Gains and losses on foreign currency transactions and short term inter-company receivables from foreign subsidiaries are included in Other income, net.

The reported results of our foreign operations will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. We have entered into various foreign exchange forward contracts to manage a portion of our exposure to foreign exchange rate fluctuations on our forecasted sales to and receivables from certain subsidiaries, denominated in euros, British pounds, Canadian dollars, Australian dollars, and Swedish krona.

In addition, we purchase Lidoderm<sup>®</sup>, in U.S. dollars, from Teikoku Seiyaku Co., Ltd., a Japanese manufacturer. As part of the purchase agreement with Teikoku, there is a price adjustment feature that prevents the cash payment in U.S. dollars from falling outside of a certain pre-defined range in Japanese yen even if the spot rate is outside of that range. In addition, we have certain licensing arrangements which could require us to make payments upon certain regulatory and sales milestones, denominated in euros.

A 10% change in foreign currency exchange rates would not have a material impact on our financial condition, results of operations or cash flows.

#### *Inflation*

We do not believe that inflation has had a significant impact on our revenues or operations.

#### **Item 8. *Financial Statements and Supplementary Data***

The information required by this item is contained in the financial statements set forth in Item 15(a) under the caption "Consolidated Financial Statements" as part of this Annual Report on Form 10-K.

#### **Item 9. *Changes In and Disagreements With Accountants on Accounting and Financial Disclosure***

Not applicable.

#### **Item 9A. *Controls and Procedures***

##### *(a) Evaluation of Disclosure Controls and Procedures*

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as of December 31, 2012. Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of December 31, 2012.

##### *(b) Management's Report on Internal Control over Financial Reporting*

The report of management of the Company regarding internal control over financial reporting is set forth in Item 15(a) of this Annual Report on Form 10-K under the caption "Management's Report on Internal Control Over Financial Reporting" and incorporated herein by reference.

##### *(c) Attestation Report of Independent Registered Public Accounting Firm*

The attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting is set forth in Item 15(a) of this Annual Report on Form 10-K under the caption "Report of Independent Registered Public Accounting Firm" and incorporated herein by reference.

##### *(d) Changes in Internal Control over Financial Reporting*

There were no changes in the Company's internal control over financial reporting during 2012 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. During the third quarter of 2012, the Company established a global shared services center in Austin, Texas as part of its ongoing efforts to integrate the operations of its various subsidiaries. At this time, certain financial transaction-processing activities were moved to this newly-established shared services center. The establishment of this shared services center was not in response to any identified deficiency or weakness in our internal control over financial reporting. This initiative is expected to continue to enhance our internal controls over financial reporting over time.

#### **Item 9B. *Other Information***

Effective December 19, 2012, EPI and Grünenthal GMBH (Grünenthal) amended the existing License, Development and Supply Agreement between EPI and Grünenthal (the Grünenthal Agreement) whereby, among other provisions, Grünenthal supplies to Endo a crush-resistant formulation of Opana<sup>®</sup> ER. Pursuant to the December 19, 2012 amendment, EPI shall be responsible for planning the packaging of finished product and certain other routine packaging quality obligations and Grünenthal shall reimburse EPI for the third-party costs incurred related to packaging as well as pay EPI a periodic packaging fee. The amendment also changed certain of the terms with respect to the floor price required to be paid by EPI in consideration for product supplied by Grünenthal.

On December 21, 2012, EPI and Bioniche entered into a termination agreement (the Bioniche Termination Agreement) to terminate the Bioniche License Agreement. As a result, EPI agreed to return rights to Urocidin<sup>™</sup> to Bioniche in consideration for Bioniche paying EPI a royalty equal to 5% of global net sales of Urocidin<sup>™</sup> for a period commencing on the date of the first commercial sale and continuing for the later of ten years or the expiration of the last valid patent covering the product. Pursuant to the Bioniche Termination Agreement, the parties ceased performing activities under the Bioniche License Agreement, excluding wind-up activities, effective December 21, 2012. Further, all terms and requirements of the Bioniche License Agreement, including future contingent milestone and royalty payments to Bioniche, as well as all rights and licenses granted to EPI pursuant to the Bioniche License Agreement will terminate effective March 31, 2013.

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

**Directors**

The information concerning our directors required under this Item is incorporated herein by reference from our proxy statement, which will be filed with the Securities and Exchange Commission, relating to our 2013 Annual Meeting of Stockholders (2013 Proxy Statement).

**Executive Officers**

For information concerning Endo's executive officers, see Part I, Item 1. of this report "Business", under the caption "Executive Officers of the Registrant" and our 2013 Proxy Statement.

**Code of Ethics**

The information concerning our Code of Conduct, which was recently updated in early 2013, is incorporated herein by reference from our 2013 Proxy Statement and can be viewed on our website, the internet address for which is <http://www.endo.com>.

**Audit Committee**

The information concerning our Audit Committee is incorporated herein by reference from our 2013 Proxy Statement.

**Audit Committee Financial Experts**

The information concerning our Audit Committee Financial Experts is incorporated herein by reference from our 2013 Proxy Statement.

**Item 11. Executive Compensation**

The information required under this Item is incorporated herein by reference from our 2013 Proxy Statement.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

*Equity Compensation Plan Information.* The following information relates to plans in effect as of December 31, 2012 under which equity securities of Endo may be issued to employees and directors. The Endo Health Solutions Inc. 2004, 2007 and 2010 Stock Incentive Plans and the Endo Health Solutions Inc. Assumed Stock Incentive Plan (formerly known as the American Medical Systems Holdings, Inc. 2005 Stock Incentive Plan) provide that stock options may be granted thereunder to non-employee consultants.

Plan Category	Column A	Column B	Column C
	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights (1)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column A)
<b>Equity compensation plans approved by security holders</b>			
Endo Health Solutions Inc. Assumed Stock Incentive Plan.....	1,171,482	\$ 24.56	3,370,862
Endo Health Solutions Inc. 2004 Stock Incentive Plan .....	1,697,695	\$ 23.87	—
Endo Health Solutions Inc. 2007 Stock Incentive Plan .....	2,305,115	\$ 21.24	—
Endo Health Solutions Inc. 2010 Stock Incentive Plan .....	5,714,694	\$ 33.99	5,470,320

(1) Excludes shares of restricted stock units outstanding

The other information required under this Item is incorporated herein by reference from our 2013 Proxy Statement.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information required under this Item is incorporated herein by reference from our 2013 Proxy Statement.

**Item 14. Principal Accounting Fees and Services**

Information about the fees for 2012 and 2011 for professional services rendered by our independent registered public accounting firm is incorporated herein by reference from our 2013 Proxy Statement. Our Audit Committee's policy on pre-approval of audit and permissible non-audit services of our independent registered public accounting firm is incorporated by reference from our 2013 Proxy Statement.

The information required under this Item is incorporated herein by reference from our 2013 Proxy Statement.



**PART IV**

**Item 15. Exhibits, Financial Statement Schedules**

*Documents filed as part of this Annual Report on Form 10-K*

1. Consolidated Financial Statements: See accompanying Index to Consolidated Financial Statements.
2. Consolidated Financial Statement Schedule:

**SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS**

(in thousands)

	<u>Balance at Beginning of Period</u>	<u>Additions, Costs and Expenses</u>	<u>Deductions, Write-offs</u>	<u>Balance at End of Period</u>
<b>Allowance For Doubtful Accounts:</b>				
Year Ended December 31, 2010 .....	\$ 1,023	\$ 855	\$ (748)	\$ 1,130
Year Ended December 31, 2011 .....	<u>\$ 1,130</u>	<u>\$ 4,170</u>	<u>\$ (1,092)</u>	<u>\$ 4,208</u>
Year Ended December 31, 2012 .....	<u>\$ 4,208</u>	<u>\$ 3,402</u>	<u>\$ (1,752)</u>	<u>\$ 5,858</u>

All other financial statement schedules have been omitted because they are not applicable or the required information is included in the Consolidated Financial Statements or notes thereto.

3. Exhibits: The information called for by this Item is incorporated by reference to the Exhibit Index of this Report.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**ENDO HEALTH SOLUTIONS INC.**  
**(Registrant)**

**/S/ DAVID P. HOLVECK**

**Name: David P. Holveck**  
**Title: President and Chief Executive Officer**

**Date: March 1, 2013**

Pursuant to the requirements of the Securities Exchange of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/S/ DAVID P. HOLVECK</u> David P. Holveck	Director, President and Chief Executive Officer (Principal Executive Officer)	March 1, 2013
<u>/S/ ALAN G. LEVIN</u> Alan G. Levin	Executive Vice President, Chief Financial Officer (Principal Financial Officer)	March 1, 2013
<u>/S/ DANIEL A. RUDIO</u> Daniel A. Rudio	Vice President, Controller (Principal Accounting Officer)	March 1, 2013
<u>*</u> Roger H. Kimmel	Chairman and Director	March 1, 2013
<u>*</u> John J. Delucca	Director	March 1, 2013
<u>*</u> Nancy J. Hutson, Ph.D.	Director	March 1, 2013
<u>*</u> Michael Hyatt	Director	March 1, 2013
<u>*</u> William P. Montague	Director	March 1, 2013
<u>*</u> David B. Nash, M.D., M.B.A.	Director	March 1, 2013
<u>*</u> Joseph C. Scodari	Director	March 1, 2013
<u>*</u> Jill D. Smith	Director	March 1, 2013
<u>*</u> William F. Spengler	Director	March 1, 2013
*By: <u>/S/ CAROLINE B. MANOGUE</u> Caroline B. Manogue	Attorney-in-fact pursuant to a Power of Attorney filed with this Report as Exhibit 24	March 1, 2013

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## MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The management of Endo Health Solutions Inc. is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Endo Health Solutions Inc.'s internal control system was designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation and fair presentation of its published financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Endo Health Solutions Inc.'s management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2012. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on our assessment we believe that, as of December 31, 2012, the Company's internal control over financial reporting is effective based on those criteria.

Endo Health Solutions Inc.'s independent registered public accounting firm has issued its report on the effectiveness of the Company's internal control over financial reporting as of December 31, 2012. This report appears on page F-4.

/S/ DAVID P. HOLVECK

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David P. Holveck

President and Chief Executive Officer

/S/ ALAN G. LEVIN

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Alan G. Levin

Executive Vice President, Chief Financial Officer

March 1, 2013

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of  
Endo Health Solutions Inc.  
Malvern, Pennsylvania

We have audited the accompanying consolidated balance sheets of Endo Health Solutions Inc. (formerly known as Endo Pharmaceuticals Holdings Inc.) and subsidiaries (the "Company") as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Endo Health Solutions Inc. and subsidiaries as of December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2012, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 1, 2013 expressed an unqualified opinion on the Company's internal control over financial reporting.

/S/ DELOITTE & TOUCHE LLP

Philadelphia, Pennsylvania  
March 1, 2013



## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of  
Endo Health Solutions Inc.  
Malvern, Pennsylvania

We have audited the internal control over financial reporting of Endo Health Solutions Inc. (formerly known as Endo Pharmaceuticals Holdings Inc.) and subsidiaries (the "Company") as of December 31, 2012, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended December 31, 2012 of the Company and our report dated March 1, 2013 expressed an unqualified opinion on those financial statements and financial statement schedule.

/S/ DELOITTE & TOUCHE LLP

Philadelphia, Pennsylvania

March 1, 2013

**ENDO HEALTH SOLUTIONS INC.**  
**CONSOLIDATED BALANCE SHEETS**  
**DECEMBER 31, 2012 AND 2011**  
(In thousands, except share and per share data)

	<u>December 31, 2012</u>	<u>December 31, 2011</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents .....	\$ 547,916	\$ 547,620
Accounts receivable, net of allowance of \$5,858 and \$4,208 at December 31, 2012 and 2011, respectively .....	690,850	733,222
Inventories, net .....	357,638	262,419
Prepaid expenses and other current assets .....	27,750	29,732
Income taxes receivable .....	36,489	—
Deferred income taxes .....	308,591	215,103
Total current assets .....	<u>\$ 1,969,234</u>	<u>\$ 1,788,096</u>
MARKETABLE SECURITIES .....	1,746	19,105
PROPERTY, PLANT AND EQUIPMENT, NET .....	385,668	297,731
GOODWILL .....	2,014,351	2,558,041
OTHER INTANGIBLES, NET .....	2,098,973	2,504,124
OTHER ASSETS .....	98,587	125,486
<b>TOTAL ASSETS .....</b>	<b><u>\$ 6,568,559</u></b>	<b><u>\$ 7,292,583</u></b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable .....	\$ 416,882	\$ 260,385
Accrued expenses .....	1,170,945	732,831
Current portion of long-term debt .....	133,998	88,265
Acquisition-related contingent consideration .....	6,195	4,925
Income taxes payable .....	—	35,372
Total current liabilities .....	<u>\$ 1,728,020</u>	<u>\$ 1,121,778</u>
DEFERRED INCOME TAXES .....	516,565	617,677
ACQUISITION-RELATED CONTINGENT CONSIDERATION .....	2,729	3,762
LONG-TERM DEBT, LESS CURRENT PORTION, NET .....	3,037,947	3,424,329
OTHER LIABILITIES .....	150,092	85,446
COMMITMENTS AND CONTINGENCIES (NOTE 15)		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock, \$0.01 par value; 40,000,000 shares authorized; none issued .....	—	—
Common stock, \$0.01 par value; 350,000,000 shares authorized; 140,040,882 and 138,337,002 shares issued; 110,793,855 and 117,158,880 shares outstanding at December 31, 2012 and 2011, respectively .....	1,400	1,383
Additional paid-in capital .....	1,035,115	952,325
Retained earnings .....	811,573	1,551,910
Accumulated other comprehensive loss .....	(6,802)	(9,436)
Treasury stock, 29,247,027 and 21,178,122 shares at December 31, 2012 and 2011, respectively .....	(768,430)	(518,492)
Total Endo Health Solutions Inc. stockholders' equity .....	<u>\$ 1,072,856</u>	<u>\$ 1,977,690</u>
Noncontrolling interests .....	60,350	61,901
Total stockholders' equity .....	<u>\$ 1,133,206</u>	<u>\$ 2,039,591</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY .....</b>	<b><u>\$ 6,568,559</u></b>	<b><u>\$ 7,292,583</u></b>

See Notes to Consolidated Financial Statements.

**ENDO HEALTH SOLUTIONS INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**YEARS ENDED DECEMBER 31, 2012, 2011 AND 2010**  
(In thousands, except per share data)

	2012	2011	2010
<b>REVENUES:</b>			
Net pharmaceutical product sales .....	\$ 2,297,685	\$ 2,209,089	\$ 1,601,192
Devices revenues .....	504,487	300,299	—
Service and other revenues .....	225,191	220,733	115,037
<b>TOTAL REVENUES .....</b>	<b>\$ 3,027,363</b>	<b>\$ 2,730,121</b>	<b>\$ 1,716,229</b>
<b>COSTS AND EXPENSES:</b>			
Cost of revenues .....	1,261,093	1,065,208	504,757
Selling, general and administrative .....	898,847	813,271	547,605
Research and development .....	226,120	182,286	144,525
Patent litigation settlement, net .....	85,123	—	—
Litigation-related and other contingencies .....	316,425	11,263	—
Asset impairment charges .....	768,467	116,089	35,000
Acquisition-related and integration items, net .....	23,015	33,638	18,976
<b>OPERATING (LOSS) INCOME .....</b>	<b>\$ (551,727)</b>	<b>\$ 508,366</b>	<b>\$ 465,366</b>
INTEREST EXPENSE, NET .....	182,834	148,024	46,601
NET LOSS ON EXTINGUISHMENT OF DEBT .....	7,215	11,919	—
OTHER INCOME, NET .....	(193)	(3,268)	(1,933)
<b>(LOSS) INCOME BEFORE INCOME TAX .....</b>	<b>\$ (741,583)</b>	<b>\$ 351,691</b>	<b>\$ 420,698</b>
INCOME TAX .....	(53,562)	109,626	133,678
<b>CONSOLIDATED NET (LOSS) INCOME .....</b>	<b>\$ (688,021)</b>	<b>\$ 242,065</b>	<b>\$ 287,020</b>
Less: Net income attributable to noncontrolling interests .....	52,316	54,452	28,014
<b>NET (LOSS) INCOME ATTRIBUTABLE TO ENDO HEALTH SOLUTIONS INC.....</b>	<b>\$ (740,337)</b>	<b>\$ 187,613</b>	<b>\$ 259,006</b>
<b>NET (LOSS) INCOME PER SHARE ATTRIBUTABLE TO ENDO HEALTH SOLUTIONS INC.</b>			
Basic .....	\$ (6.40)	\$ 1.61	\$ 2.23
Diluted .....	\$ (6.40)	\$ 1.55	\$ 2.20
<b>WEIGHTED AVERAGE SHARES:</b>			
Basic .....	115,719	116,706	116,164
Diluted .....	115,719	121,178	117,951

See Notes to Consolidated Financial Statements.

**ENDO HEALTH SOLUTIONS INC.**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME**  
**YEARS ENDED DECEMBER 31, 2012, 2011 AND 2010**  
(In thousands)

	2012	2011	2010
CONSOLIDATED NET (LOSS) INCOME .....	\$ (688,021)	\$ 242,065	\$ 287,020
OTHER COMPREHENSIVE INCOME (LOSS), NET OF TAX:			
Net unrealized gain (loss) on securities:			
Unrealized gains (losses) arising during the period.....	\$ 1,403	\$ (2,334)	\$ 720
Less: reclassification adjustments for losses realized in net (loss) income.....	—	1,403	(419)
Foreign currency translation gain (loss) .....	2,164	(8,071)	—
Fair value adjustment on derivatives designated as cash flow hedges:			
Fair value adjustment on derivatives designated as cash flow hedges arising during the period.....	\$ (1,212)	\$ 216	\$ —
Less: reclassification adjustments for cash flow hedges settled and included in net (loss) income.....	279	(933)	(1)
215			—
OTHER COMPREHENSIVE INCOME (LOSS).....	\$ 2,634	\$ (8,275)	\$ 720
CONSOLIDATED COMPREHENSIVE (LOSS) INCOME.....	\$ (685,387)	\$ 233,790	\$ 287,740
Less: Comprehensive income attributable to noncontrolling interests .....	52,316	54,452	28,014
COMPREHENSIVE (LOSS) INCOME ATTRIBUTABLE TO ENDO HEALTH SOLUTIONS INC.....	\$ (737,703)	\$ 179,338	\$ 259,726

See Notes to Consolidated Financial Statements.

**ENDO HEALTH SOLUTIONS INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**YEARS ENDED DECEMBER 31, 2012, 2011 AND 2010**  
(In thousands, except share data)

Endo Health Solutions Inc. Shareholders

	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive (Loss) Income	Treasury Stock		Total Endo Health Solutions Inc. Stockholders' Equity	Noncontrolling Interests	Total Stockholders' Equity
	Number of Shares	Amount				Number of Shares	Amount			
BALANCE, JANUARY 1, 2010.....	134,986,612	\$ 1,350	\$ 817,467	\$ 1,105,291	\$ (1,881)	(17,716,303)	\$ (424,816)	\$ 1,497,411	\$ —	\$ 1,497,411
Net income .....	—	—	—	259,006	—	—	—	259,006	28,014	287,020
Other comprehensive income.....	—	—	—	—	720	—	—	720	—	720
Compensation related to stock-based awards.....	—	—	22,909	—	—	—	—	22,909	—	22,909
Exercise of options .....	965,013	9	20,874	—	—	—	—	20,883	—	20,883
Tax benefits of stock awards .....	—	—	(805)	—	—	—	—	(805)	—	(805)
Common stock issued.....	358,292	4	437	—	—	—	—	441	—	441
Treasury stock acquired.....	—	—	—	—	—	(2,535,719)	(58,974)	(58,974)	—	(58,974)
Noncontrolling interests acquired in business combinations .....	—	—	—	—	—	—	—	—	63,227	63,227
Distributions to noncontrolling interests .....	—	—	—	—	—	—	—	—	(28,870)	(28,870)
Buy-out of noncontrolling interests, net.....	—	—	—	—	—	—	—	—	(633)	(633)
<b>BALANCE, DECEMBER 31, 2010 .....</b>	<b>136,309,917</b>	<b>\$ 1,363</b>	<b>\$ 860,882</b>	<b>\$ 1,364,297</b>	<b>\$ (1,161)</b>	<b>(20,252,022)</b>	<b>\$ (483,790)</b>	<b>\$ 1,741,591</b>	<b>\$ 61,738</b>	<b>\$ 1,803,329</b>
Net income .....	—	—	—	187,613	—	—	—	187,613	54,452	242,065
Other comprehensive loss .....	—	—	—	—	(8,275)	—	—	(8,275)	—	(8,275)
Compensation related to stock-based awards.....	—	—	46,013	—	—	—	—	46,013	—	46,013
Forfeiture of restricted stock awards .....	(8,009)	—	—	—	—	—	—	—	—	—
Exercise of options .....	1,274,280	12	28,946	—	—	—	—	28,958	—	28,958
Tax benefits of stock awards, net .....	—	—	3,780	—	—	—	—	3,780	—	3,780
Common stock issued.....	760,814	8	479	—	—	—	—	487	—	487
Treasury stock acquired.....	—	—	—	—	—	(926,100)	(34,702)	(34,702)	—	(34,702)
Distributions to noncontrolling interests .....	—	—	—	—	—	—	—	—	(53,997)	(53,997)
Buy-out of noncontrolling interests, net.....	—	—	—	—	—	—	—	—	(292)	(292)
Replacement equity issued in connection with the AMS acquisition.....	—	—	12,220	—	—	—	—	12,220	—	12,220
Other .....	—	—	5	—	—	—	—	5	—	5
<b>BALANCE, DECEMBER 31, 2011 .....</b>	<b>138,337,002</b>	<b>\$ 1,383</b>	<b>\$ 952,325</b>	<b>\$ 1,551,910</b>	<b>\$ (9,436)</b>	<b>(21,178,122)</b>	<b>\$ (518,492)</b>	<b>\$ 1,977,690</b>	<b>\$ 61,901</b>	<b>\$ 2,039,591</b>

**Endo Health Solutions Inc. Shareholders**

	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive (Loss) Income	Treasury Stock		Total Endo Health Solutions Inc. Stockholders' Equity	Noncontrolling Interests	Total Stockholders' Equity
	Number of Shares	Amount				Number of Shares	Amount			
Net (loss) income.....	—	—	—	(740,337)	—	—	—	(740,337)	52,316	(688,021)
Other comprehensive income.....	—	—	—	—	2,634	—	—	2,634	—	2,634
Compensation related to stock-based awards.....	—	—	59,395	—	—	—	—	59,395	—	59,395
Forfeiture of restricted stock awards.....	(19,624)	—	—	—	—	—	—	—	—	—
Exercise of options.....	853,794	8	19,350	—	—	—	—	19,358	—	19,358
Tax benefits of stock awards, net.....	—	—	2,537	—	—	—	—	2,537	—	2,537
Common stock issued.....	869,710	9	469	—	—	—	—	478	—	478
Treasury stock acquired.....	—	—	—	—	—	(8,304,330)	(256,000)	(256,000)	—	(256,000)
Issuance of common stock from treasury.....	—	—	—	—	—	235,425	6,062	6,062	—	6,062
Distributions to noncontrolling interests.....	—	—	—	—	—	—	—	—	(53,269)	(53,269)
Buy-out of noncontrolling interests, net.....	—	—	—	—	—	—	—	—	(598)	(598)
Other.....	—	—	1,039	—	—	—	—	1,039	—	1,039
<b>BALANCE, DECEMBER 31, 2012.....</b>	<b>140,040,882</b>	<b>\$ 1,400</b>	<b>\$ 1,035,115</b>	<b>\$ 811,573</b>	<b>\$ (6,802)</b>	<b>(29,247,027)</b>	<b>\$ (768,430)</b>	<b>\$ 1,072,856</b>	<b>\$ 60,350</b>	<b>\$ 1,133,206</b>

See Notes to Consolidated Financial Statements.



**ENDO HEALTH SOLUTIONS INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**YEARS ENDED DECEMBER 31, 2012, 2011 AND 2010**  
(In thousands)

	2012	2011	2010
<b>OPERATING ACTIVITIES:</b>			
Consolidated net (loss) income .....	\$ (688,021)	\$ 242,065	\$ 287,020
Adjustments to reconcile consolidated net (loss) income to Net cash provided by operating activities			
Depreciation and amortization .....	285,524	237,414	108,404
Stock-based compensation .....	59,395	46,013	22,909
Amortization of debt issuance costs and premium / discount .....	36,699	32,788	22,013
Provision for bad debts .....	3,402	—	855
Selling, general and administrative expenses paid in shares of common stock .....	478	234	220
Deferred income taxes .....	(193,960)	(75,877)	(15,420)
Net loss on disposal of property, plant and equipment .....	50	76	154
Change in fair value of acquisition-related contingent consideration .....	237	(7,363)	(51,420)
Loss on auction-rate securities rights .....	—	—	15,659
Gain on trading securities .....	—	—	(15,420)
Net loss on extinguishment of debt .....	7,215	11,919	—
Asset impairment charges .....	768,467	116,089	35,000
Gain on sale of business .....	—	(824)	—
Changes in assets and liabilities which provided (used) cash:			
Accounts receivable .....	40,395	(107,609)	(84,659)
Inventories .....	(95,438)	(8,703)	13,894
Prepaid and other assets .....	18,227	(2,156)	(4,003)
Accounts payable .....	142,609	(30,269)	30,145
Accrued expenses .....	424,340	205,020	93,346
Other liabilities .....	(809)	(3,029)	(5,612)
Income taxes payable/receivable .....	(74,931)	46,327	561
Net cash provided by operating activities .....	<u>\$ 733,879</u>	<u>\$ 702,115</u>	<u>\$ 453,646</u>
<b>INVESTING ACTIVITIES:</b>			
Purchases of property, plant and equipment .....	(99,818)	(59,383)	(19,891)
Proceeds from sale of property, plant and equipment .....	1,426	1,626	356
Acquisitions, net of cash acquired .....	(3,175)	(2,393,397)	(1,105,040)
Proceeds from investments .....	18,800	85,025	—
Proceeds from sales of trading securities .....	—	—	231,125
Purchases of investments .....	—	(14,025)	—
Other investments .....	—	(4,628)	(2,473)
License fees .....	(5,700)	(2,300)	(400)
Proceeds from sale of business .....	—	12,990	—
Net cash used in investing activities .....	<u>\$ (88,467)</u>	<u>\$ (2,374,092)</u>	<u>\$ (896,323)</u>

	2012	2011	2010
<b>FINANCING ACTIVITIES:</b>			
Capital lease obligations repayments .....	(859)	(1,444)	(313)
Proceeds from issuance of 2019 and 2022 Notes .....	—	900,000	—
Proceeds from issuance of 2020 Notes .....	—	—	386,576
Proceeds from issuance of Term Loans .....	—	2,200,000	400,000
Proceeds from other indebtedness .....	—	500	1,696
Principal payments on Term Loans .....	(362,075)	(689,876)	—
Payment on AMS Convertible Notes .....	(66)	(519,040)	—
Principal payments on HealthTronics, Inc. senior credit facility .....	—	—	(40,000)
Principal payments on Qualitest Pharmaceuticals debt .....	—	—	(406,758)
Principal payments on other indebtedness .....	(899)	—	(61,559)
Deferred financing fees .....	—	(82,504)	(13,563)
Payment for contingent consideration .....	—	(827)	—
Tax benefits of stock awards .....	4,949	5,909	1,944
Exercise of Endo Health Solutions Inc. stock options .....	19,358	28,954	20,883
Purchase of common stock .....	(256,000)	(34,702)	(58,974)
Issuance of common stock from treasury .....	6,062	—	—
Cash distributions to noncontrolling interests .....	(53,269)	(53,997)	(28,870)
Cash buy-out of noncontrolling interests, net of cash contributions .....	(2,748)	(292)	(633)
Net cash (used in) provided by financing activities .....	<u>\$ (645,547)</u>	<u>\$ 1,752,681</u>	<u>\$ 200,429</u>
Effect of foreign exchange rate .....	431	702	—
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS .....	<u>\$ 296</u>	<u>\$ 81,406</u>	<u>\$ (242,248)</u>
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD .....	<u>547,620</u>	<u>466,214</u>	<u>708,462</u>
CASH AND CASH EQUIVALENTS, END OF PERIOD .....	<u><u>\$ 547,916</u></u>	<u><u>\$ 547,620</u></u>	<u><u>\$ 466,214</u></u>
<b>SUPPLEMENTAL INFORMATION:</b>			
Cash paid for interest .....	<u>\$ 152,097</u>	<u>\$ 81,458</u>	<u>\$ 22,187</u>
Cash paid for income taxes .....	<u>\$ 192,647</u>	<u>\$ 150,299</u>	<u>\$ 143,529</u>
<b>SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES</b>			
Purchases of property, plant and equipment financed by capital leases .....	<u>\$ 1,373</u>	<u>\$ 4,279</u>	<u>\$ 689</u>
Purchases of property, plant and equipment financed by direct financing arrangement .....	<u>\$ 57,008</u>	<u>\$ —</u>	<u>\$ —</u>
Accrual for purchases of property, plant and equipment .....	<u>\$ 12,237</u>	<u>\$ 11,704</u>	<u>\$ 6,793</u>

See Notes to Consolidated Financial Statements.

**ENDO HEALTH SOLUTIONS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**YEARS ENDED DECEMBER 31, 2012, 2011 AND 2010**

**NOTE 1. DESCRIPTION OF BUSINESS**

On May 23, 2012, we changed our name from Endo Pharmaceuticals Holdings Inc. to Endo Health Solutions Inc., which we refer to herein as the Company, we, our, us, or Endo. Endo Health Solutions Inc., together with its subsidiaries is a U.S. based, specialty healthcare solutions company focused on branded and generic pharmaceuticals, devices and services. We aim to partner with healthcare professionals and payment providers to deliver a suite of complementary branded and generic drugs, devices and clinical data to meet the needs of patients in areas such as pain management, urology, oncology and endocrinology. The Company was incorporated on November 18, 1997 under the laws of the State of Delaware.

On July 2, 2010, we acquired HealthTronics, Inc. a provider of healthcare services and manufacturer of certain related medical devices, primarily for the urology community. On September 20, 2010, we acquired Penwest, a drug development company. On November 30, 2010, we acquired Qualitest Pharmaceuticals, a privately-held generics company in the U.S. On June 17, 2011, we acquired AMS, Inc., a worldwide developer and provider of technology solutions to physicians treating men's and women's pelvic health conditions.

In the fourth quarter of 2011, as a result of our strategic planning process, the Company's executive leadership team reorganized the manner in which it views our various business activities. Management's intention was to enhance its level of understanding of the entity's performance, better assess its prospects and future cash flow potential and ultimately make more informed operating decisions about resource allocation and the enterprise as a whole. Based on this change, we reassessed our reporting structure under the applicable accounting guidance and determined that the Company had four reportable segments. We have retrospectively revised the segment presentation for all periods presented reflecting the change from three to four reportable segments. This change in our segments had no impact on the Company's Consolidated Financial Statements for all years presented. For a complete description of our segment results, see Note 6. Segment Results.

**NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Consolidation and Basis of Presentation*—The Company's Consolidated Financial Statements are prepared in accordance with accounting principles generally accepted in the U.S. (GAAP). The Consolidated Financial Statements include the accounts of wholly owned subsidiaries, after elimination of intercompany accounts and transactions. Certain prior period amounts have been reclassified to conform to the current period presentation.

As a result of the HealthTronics, Inc. acquisition, we now own interests in various partnerships and limited liability corporations, or LLCs. We consolidate our investments in these partnerships or LLCs, where we, as the general partner or managing member, exercise effective control, even though our ownership is less than 50%. The related governing agreements provide us with broad powers, and the other parties do not participate in the management of the entity and do not have the substantial ability to remove us. We have reviewed each of the underlying agreements and determined we have effective control. If circumstances changed and it was determined this control did not exist, these investments would be reflected using the equity method of accounting. Although this would change individual line items within our Consolidated Financial Statements, it would have no effect on our net income attributable to Endo Health Solutions Inc. and/or total stockholders' equity attributable to Endo Health Solutions Inc.

*Use of Estimates*—The preparation of our Consolidated Financial Statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the Consolidated Financial Statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in the determination of revenue recognition and sales deductions for estimated chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and allowances. Significant estimates and assumptions are also required when determining the fair value of marketable securities and other financial instruments, the valuation of long-lived and indefinite-lived assets, income taxes, contingencies and stock-based compensation. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. Our estimates often are based on complex judgments, probabilities and assumptions that we believe to be reasonable but that are inherently uncertain and unpredictable. For any given individual estimate or assumption made by us, there may also be other estimates or assumptions that are reasonable.

We regularly evaluate our estimates and assumptions using historical experience and other factors, including the economic environment. As future events and their effects cannot be determined with precision, our estimates and assumptions may prove to be incomplete or inaccurate, or unanticipated events and circumstances may occur that might cause us to change those estimates and assumptions. Market conditions, such as illiquid credit markets, volatile equity markets, dramatic fluctuations in foreign currency rates and economic downturn, can increase the uncertainty already inherent in our estimates and assumptions. We adjust our estimates and assumptions when facts and circumstances indicate the need for change. Those changes generally will be reflected in our consolidated

financial statements on a prospective basis unless they are required to be treated retrospectively under the relevant accounting standard. It is possible that other professionals, applying reasonable judgment to the same facts and circumstances, could develop and support a range of alternative estimated amounts. We also are subject to other risks and uncertainties that may cause actual results to differ from estimated amounts, such as changes in the healthcare environment, competition, litigation, legislation and regulations.

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

	2012	2011	2010
Cardinal Health, Inc. ....	23%	25%	33%
McKesson Corporation .....	25%	24%	28%
AmerisourceBergen Corporation .....	11%	13%	15%

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

The Company derives a majority of its total revenues from a limited number of products. Products that accounted for 10% or more of our total revenues during the years ended December 31 were as follows:

	2012	2011	2010
Lidoderm® .....	31%	30%	46%
Opana® ER .....	10%	14%	14%

We have agreements with Novartis Consumer Health, Inc., Novartis Consumer Health, Inc. and Novartis AG, Teikoku Seiyaku Co., Ltd., Mallinckrodt Inc., Noramco, Inc., Grünenthal GMBH and Sharp Corporation for the manufacture and supply of a substantial portion of our existing pharmaceutical products. Additionally, we utilize UPS Supply Chain Solutions, Inc. for certain customer service support, warehouse and distribution services, see Note 15. Commitments and Contingencies.

*Revenue Recognition*—

*Pharmaceutical Products*

Our net pharmaceutical product sales consist of revenues from sales of our pharmaceutical products, less estimates for chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and allowances. We recognize revenue for product sales when title and risk of loss has passed to the customer, which is typically upon delivery to the customer, when estimated provisions for chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and allowances are reasonably determinable, and when collectability is reasonably assured. Revenue from the launch of a new or significantly unique product, for which we are unable to develop the requisite historical data on which to base estimates of returns and allowances due to the uniqueness of the therapeutic area or delivery technology as compared to other products in our portfolio and in the industry, may be deferred until such time that an estimate can be determined and all of the conditions above are met and when the product has achieved market acceptance, which is typically based on dispensed prescription data and other information obtained during the period following launch.

*Devices*

For inventory on consignment or with field representatives, revenue is recognized at the time the product has been used or implanted. For all other transactions, we recognize revenue when title to the goods and risk of loss transfer to our customers providing there are no remaining performance obligations required from us or any matters requiring customer acceptance. In cases where we utilize distributors or ship product directly to the end user, we recognize revenue upon shipment provided all revenue recognition criteria have been met.

*Services*

Our fees for the urology and pathology services performed by our HealthTronics segment are recorded when the procedure is performed and are based on contracted rates. Management fees from our HealthTronics, Inc. limited partnerships are recorded monthly when earned.

*Sales Deductions*—When we recognize net sales from the sale of our pharmaceutical products, we simultaneously record an adjustment to revenue for estimated chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and allowances. These provisions, are estimated based on historical experience, estimated future trends, estimated customer inventory levels, current contract sales terms with our wholesale and indirect customers and other competitive factors, if the

assumptions we used to calculate these adjustments do not appropriately reflect future activity, our financial position, results of operations and cash flows could be materially impacted.

*Research and Development*—Expenditures for research and development are expensed as incurred. Property, plant and equipment that are acquired or constructed for research and development activities and that have alternate future uses are capitalized and depreciated over their estimated useful lives on a straight-line basis. Upfront and milestone payments made to third parties in connection with agreements with third parties are generally expensed as incurred up to the point of regulatory approval. Payments made to third parties subsequent to regulatory approval are generally capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in Other intangibles, net on the Consolidated Balance Sheets.

*Cash and Cash Equivalents*—The Company considers all highly liquid money market instruments with an original maturity of three months or less when purchased to be cash equivalents. At December 31, 2012, cash equivalents were deposited in financial institutions and consisted of immediately available fund balances. The Company maintains its cash deposits and cash equivalents with well-known and stable financial institutions.

*Cost of Revenues*—Cost of revenues includes all costs directly related to bringing both purchased and manufactured products to their final selling destination, as well as providing our services to our customers. It includes purchasing and receiving costs, direct and indirect costs to manufacture products, including direct materials, direct labor, and direct overhead expenses necessary to acquire and convert purchased materials and supplies into finished goods. Cost of revenues also includes royalties on certain licensed products, inspection costs, depreciation, amortization of intangible assets, warehousing costs, freight charges, costs to operate our equipment, and other shipping and handling activity.

*Concentrations of Credit Risk*—Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash equivalents, marketable debt securities and accounts receivable. We invest our excess cash in high-quality, liquid money market instruments maintained by major U.S. banks and financial institutions. We have not experienced any losses on our cash equivalents.

We perform ongoing credit evaluations of our customers and generally do not require collateral. We have no history of significant losses from uncollectible accounts. Approximately 64% and 62% of our trade accounts receivable balance represent amounts due from three customers at December 31, 2012 and 2011, respectively.

We do not expect our current or future credit risk exposures to have a significant impact on our operations. However, there can be no assurance that our business will not experience any adverse impact from credit risk in the future.

*Inventories*—Inventories consist of finished goods held for distribution, raw materials and work-in-process. Our inventories are stated at the lower of cost or market. Cost is determined by the first-in, first-out method. We write-down inventories to net realizable value based on forecasted demand and market conditions, which may differ from actual results.

*Property, plant and equipment*—Property, plant and equipment are stated at cost less accumulated depreciation. Depreciation is computed over the estimated useful life of the related assets, ranging from 1 year to 35 years, on a straight-line basis. Leasehold improvements and capital lease assets are depreciated on a straight-line basis over the shorter of their estimated useful lives or the terms of their respective leases.

*Lease Accounting*—The Company accounts for operating lease transactions by recording rent expense on a straight-line basis over the expected life of the lease, commencing on the date it gains possession of leased property. The Company includes tenant improvement allowances and rent holidays received from landlords and the effect of any rent escalation clauses as adjustments to straight-line rent expense over the expected life of the lease.

Capital lease transactions are reflected as a liability at the inception of the lease based on the present value of the minimum lease payments or, if lower, the fair value of the property. Assets under capital leases are recorded in Property, plant and equipment, net on the Consolidated Balance Sheets and depreciated in a manner similar to other Property, plant and equipment.

Certain construction projects may be accounted for as direct financing arrangements, whereby the Company records, over the construction period, the full cost of the asset in Property, plant and equipment, net on the Consolidated Balance Sheets. A corresponding liability is also recorded, net of leasehold improvements paid for by the Company, and is amortized over the expected lease term through monthly rental payments using an effective interest method. Assets recorded under direct financing arrangements are depreciated in the same manner as owned property.

*License Rights*—The cost of licenses are either expensed immediately or, if capitalized, are stated at cost, less accumulated amortization and are amortized using the straight-line method over their estimated useful lives ranging from 1 year to 15 years, with a weighted average useful life of approximately 9 years. We determine amortization periods for licenses based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of

the product, the strength of the intellectual property protection of the product and various other competitive, developmental and regulatory issues, and contractual terms.

*Customer Relationships*—Acquired customer relationships are recorded at fair value upon acquisition and are amortized using estimated useful lives ranging from 13 years to 17 years, with a weighted average useful life of approximately 16 years. We determine amortization periods for customer relationships based on our assessment of various factors impacting estimated useful lives and cash flows from the acquired assets. Such factors include the strength of the customer relationships, contractual terms and our plans regarding our future relations with our customers. Significant changes to any of these factors may result in a reduction in the useful life of the asset and an acceleration of related amortization expense, which could cause our operating income, net income and net income per share to decrease.

*Tradenames*—Acquired tradenames are recorded at fair value upon acquisition and, if deemed to have definite lives, are amortized using estimated useful lives ranging from 15 years to 30 years, with a weighted average useful life of approximately 22 years. We determine amortization periods for tradenames based on our assessment of various factors impacting estimated useful lives and cash flows from the acquired assets. Such factors include the strength of the tradename and our plans regarding the future use of the tradename. Significant changes to any of these factors may result in a reduction in the useful life of the asset and an acceleration of related amortization expense, which could cause our operating income, net income and net income per share to decrease.

*Developed Technology*—Acquired developed technology is recorded at fair value upon acquisition and amortized using estimated useful lives ranging from 3 years to 20 years, with a weighted average useful life of approximately 16 years. We determine amortization periods for developed technology based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired assets. Such factors include the strength of the intellectual property protection of the product and various other competitive and regulatory issues, and contractual terms. Significant changes to any of these factors may result in a reduction in the useful life of the asset and an acceleration of related amortization expense, which could cause our operating income, net income and net income per share to decrease. The value of these assets is subject to continuing scientific, medical and marketplace uncertainty.

*Long-Lived Asset Impairment Testing*—Long-lived assets, which includes property, plant and equipment, and definite-lived intangible assets, are assessed for impairment whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows generated by that asset. In the event the carrying amount of the asset exceeds the undiscounted future cash flows generated by that asset and the carrying amount is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset's carrying amount over its fair value. An impairment loss is recognized in net income in the period that the impairment occurs.

*In-Process Research and Development Assets (IPR&D)*—The fair value of IPR&D acquired in a business combination is determined based on the present value of each research project's projected cash flows using an income approach. Future cash flows are predominately based on the net income forecast of each project, consistent with historical pricing, margins and expense levels of similar products. Revenues are estimated based on relevant market size and growth factors, expected industry trends, individual project life cycles and the life of each research project's underlying patent. In determining the fair value of each research project, expected cash flows are adjusted for the technical and regulatory risk of completion.

IPR&D is initially capitalized and considered indefinite-lived intangible assets subject to impairment reviews. The reviews, which occur annually on October 1st of each year or more frequently upon the occurrence of certain events, requires the determination of the fair value of the respective intangible assets. If the fair value of the intangible assets is less than its carrying amount, an impairment loss is recognized for the difference. For those assets that reach commercialization, the assets are amortized over the expected useful lives.

*Goodwill*—Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is carried at cost. Goodwill is not amortized; rather, it is subject to a periodic assessment for impairment by applying a fair value based test. Goodwill is assessed for impairment on an annual basis as of October 1st of each year or more frequently if events or changes in circumstances indicate that the asset might be impaired. The impairment model permits, and we utilize, a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our seven reporting units ((1) Pain, (2) Generics, (3) Urology, (4) Endocrinology and Oncology (UEO), (5) Anatomical Pathology Services, (6) Urology Services, (7) HealthTronics Information Technology Solutions (HITS) and (8) American Medical Systems (AMS)) using a discounted cash flow analysis. If the net book values of a reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting units' fair value to all of its assets and liabilities using the acquisition method prescribed under authoritative guidance for business combinations with any residual fair value being allocated to goodwill. An impairment charge is recognized only when the implied fair value of our reporting unit's goodwill is less than its carrying amount.

*Advertising Costs*—Advertising costs are expensed as incurred and included in Selling, general and administrative expenses and amounted to \$43.5 million, \$55.1 million and \$44.3 million for the years ended December 31, 2012, 2011 and 2010, respectively.



*Income Taxes*—Provisions for income taxes are calculated on reported pre-tax income based on current tax laws, statutory tax rates and available tax incentives and planning opportunities in various jurisdictions in which we operate. Such provisions differ from the amounts currently receivable or payable because certain items of income and expense are recognized in different time periods for financial reporting purposes than for income tax purposes. We recognize deferred taxes by the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred income taxes are recognized for differences between the financial statement and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. Significant judgment is required in determining income tax provisions and evaluating tax positions. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The factors used to assess the likelihood of realization are the Company's forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. Failure to achieve forecasted taxable income in applicable tax jurisdictions could affect the ultimate realization of deferred tax assets and could result in an increase in the Company's effective tax rate on future earnings.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate resolution.

*Contingencies*—The Company is subject to various patent, product liability, government investigations and other legal proceedings in the ordinary course of business. Legal fees and other expenses related to litigation are expensed as incurred and included in Selling, general and administrative expenses. Contingent accruals are recorded with a corresponding charge to Litigation-related and other contingencies in the Consolidated Statements of Operations when the Company determines that a loss is both probable and reasonably estimable. Due to the fact that legal proceedings and other contingencies are inherently unpredictable, our assessments involve significant judgment regarding future events.

*Stock-Based Compensation*—The Company accounts for its stock-based compensation plans in accordance with FASB Codification Topic 718, Stock Compensation. Accordingly, stock-based compensation for employees and non-employee directors is measured at the grant date, based on the estimated fair value of the award, and is recognized as an expense over the requisite service period. Stock-based compensation expense is reduced for estimated future forfeitures. These estimates are revised in future periods if actual forfeitures differ from the estimates. Changes in forfeiture estimates impact compensation expense in the period in which the change in estimate occurs.

*Segment Information*—The Company operates in four reportable segments. These segments are: (1) Endo Pharmaceuticals (formerly Branded Pharmaceuticals), (2) Qualitest (formerly Generics), (3) AMS (formerly Devices) and (4) HealthTronics (formerly Services). A summary of our total revenues to external customers and adjusted income before income tax for each of our segments is found in Note 6. Segment Results.

*Comprehensive Income*—Comprehensive income includes all changes in equity during a period except those that resulted from investments by or distributions to a company's stockholders. Other comprehensive income or loss refers to revenues, expenses, gains and losses that are included in comprehensive income, but excluded from net income as these amounts are recorded directly as an adjustment to stockholders' equity.

*Treasury Stock*—Treasury stock consists of shares of Endo Health Solutions Inc. that have been issued but subsequently reacquired. We account for treasury stock purchases under the cost method. In accordance with the cost method, we account for the entire cost of acquiring shares of our stock as treasury stock, which is a contra equity account. When these shares are reissued, we use an average cost method for determining cost. Proceeds in excess of cost are then credited to Additional paid-in capital.

*Foreign Currency Translation*—The financial statements for operations outside the U.S. are maintained primarily in their local currency. All assets and liabilities of our international subsidiaries are translated to U.S. dollars at year-end exchange rates, while elements of the statement of operations are translated at average exchange rates in effect during the year. Translation adjustments arising from the use of differing exchange rates are included in accumulated other comprehensive income in stockholders' equity with the exception of inter-company balances not considered permanently invested which are included in Other income, net. The balance of cumulative translation adjustments included in accumulated other comprehensive income was a loss of \$6.2 million at December 31, 2012 and a loss of \$8.1 million at December 31, 2011. Gains and losses on foreign currency transactions are also included in Other income, net.

*Derivatives and Hedging Activities*—All derivatives are recorded in the Consolidated Balance Sheets at fair value. Changes in the fair value of derivatives are recorded each period in earnings or other comprehensive income depending on the type of hedging instrument and the effectiveness of those hedges. See Note 20. Derivative Instruments and Hedging Activities for a description of our derivative instruments and hedging activities.

*Convertible Senior Subordinated Notes*—We accounted for the issuance of our 1.75% Convertible Senior Subordinated Notes due April 2015 (the Convertible Notes) in accordance with the guidance regarding the accounting for convertible debt instruments that may be settled in cash upon conversion, which among other items, specifies that contracts issued or held by an entity that are both (1) indexed to the entities own common stock and (2) classified in stockholders' equity in its statement of financial position are not considered to be derivative financial instruments if the appropriate provisions are met. Accordingly, we have recorded the Convertible Notes as long-term debt in the accompanying Consolidated Balance Sheets.

Concurrent with the issuance of the Convertible Notes we entered into privately negotiated common stock call options with affiliates of the initial purchasers. In addition, we sold warrants to affiliates of certain of the initial purchasers. In addition to entering into the convertible note hedge transaction and the warrant transaction, we entered into a privately-negotiated accelerated share repurchase agreement with the same counterparty, as part of our broader share repurchase program described in Note 14. Stockholders' Equity. We accounted for the call options, warrants, and accelerated share repurchase agreement in accordance with the guidance regarding the accounting derivative financial instruments indexed to, and potentially settled in, a company's own stock. The call options, warrants, and accelerated share repurchase agreement meet the requirements to be accounted for as equity instruments. The cost of the call options and the proceeds related to the sale of the warrants are included in additional paid-in capital in the accompanying Consolidated Balance Sheets.

#### *Recent Accounting Pronouncements*

In June 2011, the Financial Accounting Standards Board (FASB or the Board) issued Accounting Standards Update (ASU) 2011-05 on the presentation of comprehensive income. This ASU amends FASB Codification Topic 220, Comprehensive Income, to require an entity to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2011 and early adoption is permitted. In December 2011, the FASB issued ASU 2011-12 which amends ASU 2011-05 to defer only those changes in ASU 2011-05 that relate to the presentation of reclassification adjustments to allow the Board time to re-deliberate whether to present on the face of the financial statements the effects of reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income for all periods presented. The Company has adopted all current required provisions of ASU 2011-05 and ASU 2011-12.

In July 2012, the FASB issued ASU 2012-02 on impairment testing for indefinite-lived intangible assets. This ASU amends FASB Codification Topic 350, Intangibles-Goodwill and Other to allow, but not require, an entity, when performing its annual or more frequent indefinite-lived intangible asset impairment test, to first assess qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that the indefinite-lived intangible asset is impaired. If, after assessing the totality of events and circumstances, an entity concludes that it is not more likely than not that the indefinite-lived intangible asset is impaired, then the entity is not required to take further action. However, if an entity concludes otherwise, then it is required to determine the fair value of the indefinite-lived intangible asset and perform the quantitative impairment test by comparing the fair value with the carrying amount. ASU 2012-02 is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. The Company has adopted ASU 2012-02 and determined that the adoption of this ASU did not have a significant impact on the Company's Consolidated Financial Statements.

In February 2013, the FASB issued ASU 2013-02, which established the effective date for the requirement to present components of reclassifications out of accumulated other comprehensive income on the face of the income statement. The standard is effective for reporting periods beginning after December 15, 2012. The adoption of this ASU is not expected to have a significant impact on the Company's Consolidated Financial Statements.

### **NOTE 3. FAIR VALUE MEASUREMENTS**

The financial instruments recorded in our Consolidated Balance Sheets include cash and cash equivalents, accounts receivable, marketable securities, equity and cost method investments, accounts payable and accrued expenses, acquisition-related contingent consideration, debt obligations, and derivative instruments. Included in cash and cash equivalents are money market funds representing a type of mutual fund required by law to invest in low-risk securities (for example, U.S. government bonds, U.S. Treasury Bills and commercial paper). Money market funds are structured to maintain the fund's net asset value at \$1 per unit, which assists in ensuring adequate liquidity upon demand by the holder. Money market funds pay dividends that generally reflect short-term interest rates. Thus, only the dividend yield fluctuates. Due to their short-term maturity, the carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate their fair values.

The following table presents the carrying amounts and estimated fair values of our other financial instruments (in thousands):

	December 31, 2012		December 31, 2011	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
<b>Current assets:</b>				
Derivative instruments.....	\$ —	\$ —	\$ 1,471	\$ 1,471
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,471</u>	<u>\$ 1,471</u>
<b>Long-term assets:</b>				
Auction-rate securities.....	\$ —	\$ —	\$ 17,463	\$ 17,463
Equity securities.....	1,746	1,746	1,642	1,642
Equity and cost method investments.....	15,195	N/A	20,661	N/A
	<u>\$ 16,941</u>		<u>\$ 39,766</u>	
<b>Current liabilities:</b>				
Acquisition-related contingent consideration—short-term.....	\$ 6,195	\$ 6,195	\$ 4,925	\$ 4,925
Current portion of Term Loan A Facility Due 2016.....	131,250	131,250	84,375	84,375
3.25% AMS Convertible Notes due 2036.....	795	795	841	841
4.00% AMS Convertible Notes due 2041.....	111	111	131	131
Current portion of other long-term debt.....	1,842	1,842	2,918	2,918
Derivative instruments.....	602	602	119	119
Minimum Voltaren® Gel royalties due to Novartis—short-term.....	31,878	31,878	30,000	30,000
Other.....	1,000	1,000	—	—
	<u>\$ 173,673</u>	<u>\$ 173,673</u>	<u>\$ 123,309</u>	<u>\$ 123,309</u>
<b>Long-term liabilities:</b>				
Acquisition-related contingent consideration—long-term.....	\$ 2,729	\$ 2,729	\$ 3,762	\$ 3,762
1.75% Convertible Senior Subordinated Notes Due 2015, net.....	321,332	364,444	299,222	330,950
Term Loan A Facility Due 2016, less current portion.....	1,256,250	1,259,094	1,387,500	1,372,119
Term Loan B Facility Due 2018.....	160,550	162,260	438,250	439,017
7.00% Senior Notes Due 2019.....	500,000	536,563	500,000	532,500
7.00% Senior Notes Due 2020, net.....	396,899	429,000	396,618	424,750
7.25% Senior Notes Due 2022.....	400,000	431,500	400,000	422,500
Other long-term debt, less current portion.....	2,916	2,916	2,739	2,739
Minimum Voltaren® Gel royalties due to Novartis—long-term.....	13,846	13,846	20,100	20,100
Other.....	5,775	5,775	—	—
	<u>\$ 3,060,297</u>	<u>\$ 3,208,127</u>	<u>\$ 3,448,191</u>	<u>\$ 3,548,437</u>

Equity securities consist of publicly traded common stock, the value of which is based on a quoted market price and thus represent Level 1 measurements within the fair value hierarchy. These securities are not held to support current operations and are therefore classified as non-current assets.

The acquisition-related contingent consideration, which is required to be measured at fair value on a recurring basis, consists primarily of contingent cash consideration related to the November 2010 acquisition of Generics International (US Parent), Inc. (doing business as Qualitest Pharmaceuticals). The fair value of our acquisition-related contingent consideration is determined using an income approach (present value technique), which is discussed in more detail below. The fair value of our 1.75% Convertible Senior Subordinated Notes (Convertible Notes) is based on an income approach known as the binomial lattice model which incorporated certain inputs and assumptions, including scheduled coupon and principal payments, the conversion feature inherent in the Convertible Notes, the put feature inherent in the Convertible Notes, and stock price volatility assumptions of 32% at December 31, 2012 and 33% at December 31, 2011 that were based on historic volatility of the Company's common stock and other factors. These fair value measurements are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy.

The fair values of the Term Loan Facilities and 2019, 2020, and 2022 Notes were based on market quotes and transactions proximate to the valuation date. The Company had previously used an income approach to value these debt instruments; however, the valuation methodology was subsequently transitioned to a market-based approach given the volume of observable market transactions

and quoted prices for these debt instruments. Based on this valuation methodology, we determined these debt instruments represent Level 2 measurements within the fair value hierarchy.

The total fair value of various foreign exchange forward contracts as of December 31, 2012 includes liabilities of \$0.6 million, reported in Accrued expenses. We measure our derivative instruments at fair value on a recurring basis using significant observable inputs, hence these instruments represent Level 2 measurements within the fair value hierarchy. Refer to Note 20. Derivative Instruments and Hedging Activities for more information regarding our derivative instruments.

At the inception of our License and Supply Agreement with Novartis AG in 2008, we recorded a liability representing the fair value of the minimum Voltaren<sup>®</sup> Gel royalty due to Novartis AG. In December 2012, pursuant to the provisions of this agreement, the term was automatically renewed for an additional one year period. At this time, an additional liability of \$21.3 million was recorded, representing the fair value of the incremental minimum royalty we expect to pay to Novartis AG over the renewal term. The fair values of these liabilities were determined using an income approach (present value technique) taking into consideration the level and timing of expected cash flows and an assumed discount rate. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The liability is currently being accreted up to the expected minimum payments, less payments made to date. We believe the carrying amount of this minimum royalty guarantee at December 31, 2012 and December 31, 2011 represents a reasonable approximation of the price that would be paid to transfer the liability in an orderly transaction between market participants at the measurement date. Accordingly, the carrying value approximates fair value as of December 31, 2012 and December 31, 2011.

The fair value of equity method and cost method investments is not readily available nor have we estimated the fair value of these investments and disclosure is not required. The Company is not aware of any identified events or changes in circumstances that would have a significant adverse effect on the carrying value of any of our equity or cost method investments included in our Consolidated Balance Sheets at December 31, 2012 and December 31, 2011. However, the Company did record a pre-tax non-cash impairment charge of \$22.7 million in September 2011 to completely impair its cost method investment in a privately-held company focused on the development of an innovative treatment for certain types of cancer. This impairment was recorded due to the negative clinical trial results related to this company's lead asset. It was included in the Asset impairment charges line of the Company's Consolidated Statements of Operations and related to our Endo Pharmaceuticals segment.

As of December 31, 2012, the Company held certain assets and liabilities that are required to be measured at fair value on a recurring basis. Fair value guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company's financial assets and liabilities measured at fair value on a recurring basis at December 31, 2012 and December 31, 2011, were as follows (in thousands):

	Fair Value Measurements at Reporting Date using			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
<b>December 31, 2012</b>				
<b>Assets:</b>				
Equity securities.....	\$ 1,746	\$ —	\$ —	\$ 1,746
Total.....	<u>\$ 1,746</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,746</u>
<b>Liabilities:</b>				
Derivative instruments.....	\$ —	\$ 602	\$ —	\$ 602
Acquisition-related contingent consideration—short-term....	—	—	6,195	6,195
Acquisition-related contingent consideration—long-term....	—	—	2,729	2,729
Total.....	<u>\$ —</u>	<u>\$ 602</u>	<u>\$ 8,924</u>	<u>\$ 9,526</u>

**Fair Value Measurements at Reporting Date using**

<b>December 31, 2011</b>	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>	<b>Total</b>
<b>Assets:</b>				
Money market funds.....	\$ 110,816	\$ —	\$ —	\$ 110,816
Equity securities.....	1,642	—	—	1,642
Derivative instruments.....	—	1,471	—	1,471
Auction-rate securities.....	—	—	17,463	17,463
Total.....	<u>\$ 112,458</u>	<u>\$ 1,471</u>	<u>\$ 17,463</u>	<u>\$ 131,392</u>
<b>Liabilities:</b>				
Derivative instruments.....	\$ —	\$ 119	\$ —	\$ 119
Acquisition-related contingent consideration—short-term ....	—	—	4,925	4,925
Acquisition-related contingent consideration—long-term .....	—	—	3,762	3,762
Total.....	<u>\$ —</u>	<u>\$ 119</u>	<u>\$ 8,687</u>	<u>\$ 8,806</u>

***Auction-Rate Securities***

In June 2012, our remaining auction-rate securities were called at par and we received proceeds of \$18.8 million. Prior to being sold, these auction-rate securities had been classified as available-for-sale securities and had therefore been maintained at their fair value, with changes in value being recorded as part of Other comprehensive income (loss), net. Due to the fact that we received proceeds equal to par, the auction-rate securities were adjusted to their fair value of \$18.8 million, with a corresponding gain to Other comprehensive income (loss), net. The previously recognized cumulative unrealized holding loss associated with these securities of \$1.5 million was reversed in its entirety. As a result, no gain or loss was realized.

***Acquisition-Related Contingent Consideration***

***Qualitest Pharmaceuticals***

On November 30, 2010 (the Qualitest Pharmaceuticals Acquisition Date), Endo acquired Qualitest Pharmaceuticals, which was party to an asset purchase agreement with Teva Pharmaceutical Industries Ltd (Teva) (the Teva Agreement). Pursuant to this agreement, Qualitest Pharmaceuticals purchased certain pipeline generic products from Teva and could be obligated to pay consideration to Teva upon the achievement of certain future regulatory milestones (the Teva Contingent Consideration).

The range of the undiscounted amounts the Company could pay under the Teva Agreement is between zero and \$12.5 million. The Company is accounting for the Teva Contingent Consideration in the same manner as if it had entered into that arrangement with respect to its acquisition of Qualitest Pharmaceuticals. Accordingly, the fair value was estimated based on a probability-weighted discounted cash flow model, or income approach. The resultant probability-weighted cash flows were then discounted using a discount rate of U.S. Prime plus 300 basis points. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. Using this valuation technique, the fair value of the contractual obligation to pay the Teva Contingent Consideration was determined to be \$8.9 million at December 31, 2012 and \$8.7 million at December 31, 2011. The increase in the balance, which was recorded as a loss and included in Acquisition-related and integration items, net in the accompanying Consolidated Statements of Operations, primarily reflects changes to the present value assumptions associated with our valuation model.

As of December 31, 2012, there were no changes to the range of the undiscounted amounts the Company may be required to pay under the Teva Agreement.

*Indevus Pharmaceuticals (Indevus)*

The Indevus Contingent Consideration Agreements, which were contingent upon the achievement of commercial and regulatory milestones associated with certain of Indevus' key products in development at the Indevus Acquisition Date, were initially measured and recognized at fair value and were re-measured on a recurring basis, with changes to fair value recorded in Acquisition-related and integration items, net in the Consolidated Statements of Operations. The liability for the Indevus contingent consideration was reduced to zero in 2011, reflecting management's 2011 probability assessment that it would not be obligated to make contingent consideration payments based on the progress and projected timeline for the related Indevus products in development. The last of the contingent obligations with respect to the Indevus contingent consideration expired in 2012.

**Fair Value Measurements Using Significant Unobservable Inputs**

The following table presents changes to the Company's financial liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the year ended December 31, 2012 (in thousands):

	<u>Auction-rate Securities</u>
<b>Assets:</b>	
January 1, 2012.....	\$ 17,463
Securities sold or redeemed.....	(18,800)
Securities purchase or acquired.....	—
Transfers in and/or (out) of Level 3.....	—
Changes in fair value recorded in earnings.....	—
Unrealized gains included in Other comprehensive income (loss), net.....	1,337
December 31, 2012.....	<u>\$ —</u>
	<u>Acquisition- related Contingent Consideration</u>
<b>Liabilities:</b>	
January 1, 2012.....	\$ (8,687)
Amounts (acquired) sold or (issued) settled, net.....	—
Transfers in and/or (out) of Level 3.....	—
Changes in fair value recorded in earnings.....	(237)
December 31, 2012.....	<u>\$ (8,924)</u>

The following table presents changes to the Company's financial assets and liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the year ended December 31, 2011 (in thousands):

	<u>Auction-rate Securities</u>
<b>Assets:</b>	
January 1, 2011.....	\$ 17,332
Securities sold or redeemed.....	—
Transfers in and/or (out) of Level 3.....	—
Changes in fair value recorded in earnings.....	—
Unrealized gains included in Other comprehensive income (loss), net.....	131
December 31, 2011.....	<u>\$ 17,463</u>



	Acquisition-related Contingent Consideration
<b>Liabilities:</b>	
January 1, 2011.....	\$ (16,050)
Amounts (acquired) sold / (issued) settled, net .....	—
Transfers in and/or (out) of Level 3.....	—
Changes in fair value recorded in earnings .....	7,363
December 31, 2011.....	<u>\$ (8,687)</u>

The following is a summary of available-for-sale securities held by the Company as of December 31, 2012 and December 31, 2011 (in thousands):

	Available-for-sale			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Value
<b>December 31, 2012</b>				
Equity securities.....	\$ 1,766	\$ —	\$ (20)	\$ 1,746
<i>Long-term available-for-sale securities</i> .....	\$ 1,766	\$ —	\$ (20)	\$ 1,746
<i>Total available-for-sale securities</i> .....	<u>\$ 1,766</u>	<u>\$ —</u>	<u>\$ (20)</u>	<u>\$ 1,746</u>

	Available-for-sale			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Value
<b>December 31, 2011</b>				
Money market funds.....	\$ 110,816	\$ —	\$ —	\$ 110,816
<i>Total included in cash and cash equivalents</i> .....	\$ 110,816	\$ —	\$ —	\$ 110,816
Auction-rate securities.....	18,800	—	(1,337)	17,463
Equity securities.....	1,766	—	(124)	1,642
<i>Long-term available-for-sale securities</i> .....	\$ 20,566	\$ —	\$ (1,461)	\$ 19,105
<i>Total available-for-sale securities</i> .....	<u>\$ 131,382</u>	<u>\$ —</u>	<u>\$ (1,461)</u>	<u>\$ 129,921</u>

At December 31, 2011, our investments in auction-rate securities consisted of two securities which, as of that date, had been in unrealized loss positions for more than twelve months. The Company had determined that, as of December 31, 2011, the gross unrealized losses associated with the auction-rate securities were not other-than-temporary.

At December 31, 2012 and December 31, 2011, our equity securities consisted of investments in the stock of three publicly traded companies. As of December 31, 2012, one investment had been in an unrealized loss position for less than twelve months and one investment had been in an unrealized loss position for more than twelve months. As of December 31, 2011, two investments had been in an unrealized loss position for less than twelve months and one had been in an unrealized loss position for more than twelve months. Due to changes in circumstances surrounding one of our equity securities in the second half of 2011, we recorded a non-cash, other-than-temporary impairment charge of \$3.8 million to reduce the cost basis of this investment to its fair value. This impairment was recorded in the Asset impairment charges line in our Consolidated Statements of Operations. The Company does not believe the remaining unrealized losses are other-than-temporary at December 31, 2012 or December 31, 2011 primarily because the Company has both the ability and intent to hold these investments for a period of time we believe will be sufficient to recover such losses.

## Nonrecurring Fair Value Measurements

The Company's financial assets measured at fair value on a nonrecurring basis during the year ended December 31, 2012 were as follows (in thousands):

	Fair Value Measurements at Measurement Date using			Total Expense for the Year Ended December 31, 2012
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>Assets:</b>				
Supprelin® Asia and Europe intangible assets .....	—	—	—	(2,000)
Vantas® Asia and Latin America intangible assets .....	—	—	—	(3,689)
Valstar® Europe intangible asset .....	—	—	—	(2,000)
Sanctura® Asia intangible asset .....	—	—	—	(8,000)
Sanctura XR® intangible asset .....	—	—	5,000	(51,163)
AMS developed technology intangible assets .....	—	—	—	(128,472)
AMS IPR&D intangible assets .....	—	—	9,000	(7,000)
HITS other intangible assets .....	—	—	900	(3,025)
Goodwill .....	—	—	2,012,438	(557,420)
Property, plant and equipment (See Note 8) .....	—	—	—	(5,698)
<b>Total .....</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 2,027,338</b>	<b>\$ (768,467)</b>
<b>Liabilities:</b>				
Patent litigation settlement liability(1) (See Note 15) ..	—	—	131,361	(131,361)
Minimum Voltaren® Gel royalties due to Novartis .....	—	—	21,346	—
<b>Total .....</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 152,707</b>	<b>\$ (131,361)</b>

(1) As a result of a subsequent change in estimate with respect to this obligation, the Company reduced its liability associated with the Watson Settlement Agreement by \$46.2 million to \$85.1 million during the third quarter of 2012.

See Note 9. Goodwill and Other Intangibles for a discussion of goodwill and other intangible asset impairment charges.

## NOTE 4. INVENTORIES

Inventories are comprised of the following at December 31 (in thousands):

	2012	2011
Raw materials .....	\$ 108,460	\$ 103,064
Work-in-process .....	59,763	51,063
Finished goods .....	189,415	108,292
<b>Total .....</b>	<b>\$ 357,638</b>	<b>\$ 262,419</b>

Inventory amounts in the table above are shown net of obsolescence. Our reserve for obsolescence is not material to the Consolidated Balance Sheets and therefore has not been separately disclosed.

## NOTE 5. ACQUISITIONS

### AMS, Inc.

On June 17, 2011 (the AMS, Inc. Acquisition Date), the Company completed its acquisition of all outstanding shares of common stock of AMS, Inc. for approximately \$2.4 billion in aggregate consideration, including \$70.8 million related to existing AMS, Inc. stock-based compensation awards and certain other amounts, at which time AMS, Inc. became a wholly-owned, indirect subsidiary of the Company. AMS, Inc.'s shares were purchased at a price of \$30.00 per share.

AMS, Inc. is a worldwide developer and provider of technology solutions to physicians treating men's and women's pelvic health conditions. The AMS, Inc. business and applicable services include:

### *Men's Health.*

AMS, Inc. supplies surgical solutions for the treatment of male urinary incontinence, the involuntary release of urine from the body. The fully implantable AMS 800<sup>®</sup> system 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. Since 2000, AMS, Inc. has also been selling the InVance<sup>®</sup> sling system, a less-invasive procedure for men with moderate incontinence, and in 2007, AMS, Inc. released the AdVance<sup>®</sup> sling system for the treatment of mild to moderate stress urinary incontinence. AMS, Inc. also offers the UroLume<sup>®</sup> endoprosthesis stent as a less invasive procedure for patients who may not be good surgical candidates, as well as for men suffering from bulbar urethral strictures.

AMS, Inc. also supplies penile implants to treat erectile dysfunction, the inability to achieve or maintain an erection sufficient for sexual intercourse, with a series of semi-rigid malleable prostheses and a complete range of more naturally functioning inflatable prostheses, including the AMS 700<sup>®</sup> MS. AMS, Inc. has refined its implants over the years with improvements to the AMS 700<sup>®</sup> series of inflatable prostheses, including the AMS 700 LGX<sup>®</sup> and the MS Pump<sup>®</sup>. Another key factor that distinguishes AMS, Inc.'s products is the use of the InhibiZone<sup>®</sup> antibiotic coating, which received FDA approval in July 2009 for AMS, Inc.'s product claim that InhibiZone<sup>®</sup> reduces the rate of revision surgery due to surgical infections.

### *Women's Health.*

AMS, Inc. offers a broad range of systems, led by Monarc<sup>®</sup> and MiniArc<sup>®</sup>, 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. Monarc<sup>®</sup> incorporates unique helical needles to place a self-fixating, sub-fascial hammock through the obturator foramin. AMS, Inc.'s MiniArc<sup>®</sup> Single-Incision Sling for stress incontinence was released in 2007 and requires just one incision to surgically place a small sling under the urethra, which minimizes tissue disruption and potential for blood loss, thereby allowing the procedure to be done with less anesthesia on an outpatient basis. In 2010, AMS, Inc. launched the MiniArc<sup>®</sup> Precise™, which is designed to enhance the ease and accuracy of placement of the MiniArc device.

AMS, Inc. also offers solutions for pelvic floor prolapse and other pelvic floor disorders, which may be caused by pregnancy, labor, and childbirth. In 2008, AMS, Inc. introduced the Elevate<sup>®</sup> transvaginal pelvic floor repair system, with no external incisions. Using an anatomically designed needle and self-fixating tips, Elevate<sup>®</sup> allows for safe, simple and precise mesh placement through a single vaginal incision. The posterior system was launched in 2008 and the anterior system was launched in 2009.

### *BPH Therapy.*

AMS, Inc.'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. AMS, Inc. offers men experiencing a physical obstruction of the prostatic urethra an alternative to a transurethral resection of the prostate (TURP), with the GreenLight™ photovaporization of the prostate. This laser therapy is designed to reduce the comorbidities associated with TURP. AMS, Inc.'s GreenLight™ XPS and MoXy™ Liquid Cooled Fiber 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 providing enhanced surgical control compared to other laser systems. AMS, Inc. also offers the StoneLight<sup>®</sup> laser and SureFlex™ fiber optics for the treatment of urinary stones. StoneLight<sup>®</sup> is a lightweight and portable 15-watt holmium laser that offers the right amount of power to effectively fragment most urinary stones. The SureFlex™ fiber optic line is engineered to deliver more energy safely and effectively, even under maximum scope deflection, for high performance holmium laser lithotripsy.

AMS, Inc.'s TherMatrx<sup>®</sup> product is designed for those men not yet to the point of urethral obstruction, but for whom symptomatic relief is desired. It is a less-invasive tissue ablation technique that can be performed in a physician's office using microwave energy delivered to the prostate.

The acquisition of AMS, Inc. furthers Endo's evolution from a pharmaceutical product-driven company to a healthcare solutions provider, strengthens our leading core urology franchise and expands our presence in the medical devices market. We believe the combination of AMS, Inc. with Endo's existing platform will provide additional cost-effective solutions across the entire urology spectrum.

The operating results of AMS, Inc. from and including June 18, 2011 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheets as of December 31, 2012 and December 31, 2011 reflect the acquisition of AMS, Inc., effective June 18, 2011.

The following table summarizes the fair values of the assets acquired and liabilities assumed at the AMS, Inc. Acquisition Date (in thousands):

	<b>June 17, 2011</b> <b>(As adjusted)</b>
Cash and cash equivalents.....	\$ 47,289
Commercial paper .....	71,000
Accounts receivable .....	73,868
Other receivables.....	630
Inventories.....	74,988
Prepaid expenses and other current assets.....	7,133
Income taxes receivable .....	9,154
Deferred income taxes.....	15,432
Property, plant and equipment.....	56,413
Other intangible assets(1).....	1,260,000
Other assets .....	4,581
<b>Total identifiable assets.....</b>	<b>\$ 1,620,488</b>
Accounts payable .....	\$ 10,327
Accrued expenses.....	45,835
Deferred income taxes.....	416,745
Long-term debt.....	520,375
Other liabilities .....	25,891
<b>Total liabilities assumed .....</b>	<b>\$ 1,019,173</b>
<b>Net identifiable assets acquired .....</b>	<b>\$ 601,315</b>
Goodwill(2).....	1,798,661
<b>Net assets acquired.....</b>	<b>\$ 2,399,976</b>

- (1) Subsequent pre-tax non-cash impairment charges totaling \$135.5 million related to Other intangible assets were recorded in 2012. These impairment charges are further discussed in Note 9. Goodwill and Other Intangibles.
- (2) A subsequent pre-tax non-cash impairment charge of \$507.5 million related to this Goodwill was recorded in the fourth quarter of 2012. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles.

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the AMS, Inc. Acquisition Date to estimate the fair value of assets acquired and liabilities assumed. Our measurement period adjustments are complete.

The valuation of the intangible assets acquired and related amortization periods are as follows:

	Valuation (in millions)	Amortization Period (in years)
<b>Customer Relationships:</b>		
Men's Health.....	\$ 97.0	17
Women's Health.....	37.0	15
BPH.....	26.0	13
Total.....	<u>\$ 160.0</u>	16
<b>Developed Technology:</b>		
Men's Health.....	\$ 690.0	18
Women's Health(1).....	150.0	9
BPH.....	161.0	18
Total.....	<u>\$ 1,001.0</u>	16
<b>Tradenames:</b>		
AMS.....	\$ 45.0	30
GreenLight.....	12.0	15
Total.....	<u>\$ 57.0</u>	27
<b>In Process Research &amp; Development:</b>		
Oracle(2).....	\$ 12.0	n/a
Genesis.....	14.0	n/a
TOPAS.....	8.0	n/a
Other(3).....	8.0	n/a
Total.....	<u>\$ 42.0</u>	n/a
Total other intangible assets.....	<u>\$ 1,260.0</u>	n/a

- (1) A subsequent pre-tax non-cash impairment charge of \$128.5 million was recorded in the fourth quarter of 2012. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles.
- (2) A subsequent pre-tax non-cash impairment charge of \$4.0 million was recorded in the fourth quarter of 2012. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles.
- (3) A subsequent pre-tax non-cash impairment charge of \$3.0 million was recorded in the second quarter of 2012. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles.

The fair value of the developed technology, IPR&D and customer relationship assets were estimated using a discounted present value income approach. Under this method, an intangible asset's fair value is equal to the present value of the incremental after-tax cash flows (excess earnings) attributable solely to the intangible asset over its remaining useful life. To calculate fair value, the Company used cash flows discounted at rates considered appropriate given the inherent risks associated with each type of asset. The Company believes that the level and timing of cash flows appropriately reflect market participant assumptions. The fair value of the AMS and GreenLight tradenames were estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to license the AMS or GreenLight tradename. Thus, we derived the hypothetical royalty income from the projected revenues of AMS and GreenLight products, respectively. Cash flows were assumed to extend through the remaining economic useful life of each class of intangible asset.

The \$1,798.7 million of goodwill has been assigned to our AMS segment. The goodwill recognized is attributable primarily to strategic and synergistic opportunities across the entire urology spectrum, expected corporate synergies, the assembled workforce of AMS, Inc. and other factors. Approximately \$16.5 million of goodwill was expected to be deductible for income tax purposes.

Deferred tax assets of \$15.4 million are related primarily to federal net operating loss and credit carryforwards of AMS, Inc. and its subsidiaries. Deferred tax liabilities of \$416.7 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

The Company recognized \$7.7 million and \$28.8 million of AMS, Inc. acquisition-related and integration costs that were expensed during the years ended December 31, 2012 and 2011, respectively. These costs are included in Acquisition-related and integration items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	2012	2011
Bank fees .....	\$ —	\$ 16,070
Legal, separation, integration, and other costs .....	7,672	12,684
Total .....	<u>\$ 7,672</u>	<u>\$ 28,754</u>

Transaction costs directly associated with the closing of the acquisition in 2011 and included in the table above totaled \$25.8 million.

The amounts of revenue and net loss of AMS, Inc. included in the Company's Consolidated Statements of Operations from and including June 18, 2011 to December 31, 2011 are as follows (in thousands, except per share data):

Revenue .....	\$ 300,299
Net loss attributable to Endo Health Solutions Inc. ....	\$ (329)
Basic and diluted net loss per share .....	\$ —

The following supplemental pro forma information presents the financial results as if the acquisition of AMS, Inc. had occurred on January 1, 2010 for the years ended December 31, 2011 and 2010. This supplemental pro forma information has been prepared for comparative purposes and does not purport to be indicative of what would have occurred had the acquisition been made on January 1, 2010, nor are they indicative of any future results.

	Twelve Months Ended December 31, 2011	Twelve Months Ended December 31, 2010
<b>Unaudited pro forma consolidated results (in thousands, except per share data):</b>		
Revenue.....	\$ 2,968,497	\$ 2,259,104
Net income attributable to Endo Health Solutions Inc. ....	\$ 214,487	\$ 199,776
Basic net income per share .....	\$ 1.84	\$ 1.72
Diluted net income per share .....	\$ 1.77	\$ 1.69

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of AMS, Inc. to reflect factually supportable adjustments that give effect to events that are directly attributable to the AMS, Inc. Acquisition, including borrowings to finance the acquisition as well as the additional depreciation and amortization that would have been charged assuming the fair value adjustments primarily to property, plant and equipment, inventory, and intangible assets, had been applied on January 1, 2010, together with the consequential tax effects.

### ***Qualitest Pharmaceuticals***

On November 30, 2010 (the Qualitest Pharmaceuticals Acquisition Date), Endo completed its acquisition of all of the issued and outstanding capital stock of Generics International (US Parent), Inc. (Qualitest Pharmaceuticals) from an affiliate of Apax Partners, L.P. for approximately \$770.0 million. In addition, Endo paid \$406.8 million to retire Qualitest Pharmaceuticals' outstanding debt and related interest rate swap on November 30, 2010. In connection with the Qualitest Pharmaceuticals acquisition, \$108.0 million of the purchase price was placed into two separate escrow accounts. One of the escrow accounts was \$8.0 million, some of which was used to fund working capital adjustments, as defined in the Qualitest Pharmaceuticals Stock Purchase Agreement. This escrow was settled during the third quarter of 2011. There was also a \$100.0 million escrow account to be used to fund all claims arising out of or related to the Qualitest Pharmaceuticals acquisition. In connection with this \$100.0 million escrow account, to the extent that we realize tax benefits for costs that are funded by the escrow account, we will be required to share these tax benefits with Apax. The \$100.0 million escrow account was subsequently reduced to \$45.5 million pursuant to an October 2012 amendment to the Qualitest Pharmaceuticals Stock Purchase Agreement. This escrow fund was previously treated as a component of the Qualitest Pharmaceuticals purchase price and therefore this amendment does not have any impact on our cash or cash equivalents balances.

Qualitest Pharmaceuticals is a manufacturer and distributor of generic drugs and over-the-counter pharmaceuticals throughout the U.S. Qualitest Pharmaceuticals' product portfolio is comprised of 175 product families in various forms including tablets, capsules, creams, ointments, suppositories, and liquids. This acquisition has enabled us to gain critical mass in our generics business while strengthening our pain portfolio through a larger breadth of product offerings.



The operating results of Qualitest Pharmaceuticals from November 30, 2010 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheets as of December 31, 2012 and December 31, 2011 reflect the acquisition of Qualitest Pharmaceuticals, effective November 30, 2010, the date the Company obtained control of Qualitest Pharmaceuticals.

The following table summarizes the fair values of the assets acquired and liabilities assumed at the Qualitest Pharmaceuticals Acquisition Date (in thousands):

	<b>November 30, 2010</b> <b>(As adjusted)</b>
Cash and cash equivalents.....	\$ 21,828
Accounts receivable .....	93,228
Other receivables.....	1,483
Inventories.....	95,000
Prepaid expenses and other current assets.....	1,901
Deferred income taxes.....	71,040
Property, Plant and equipment.....	135,807
Other intangible assets(1).....	836,000
Total identifiable assets.....	<u>\$ 1,256,287</u>
Accounts payable .....	\$ 27,421
Accrued expenses .....	59,351
Deferred income taxes.....	207,321
Long-term debt.....	406,758
Other liabilities.....	9,487
Total liabilities assumed.....	<u>\$ 710,338</u>
Net identifiable assets acquired.....	<u>\$ 545,949</u>
Goodwill.....	224,098
Net assets acquired.....	<u><u>\$ 770,047</u></u>

(1) A subsequent pre-tax non-cash impairment charge of \$71.0 million related to Other intangible assets was recorded in the fourth quarter of 2011. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles.

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the Qualitest Pharmaceuticals Acquisition Date. Our measurement period adjustments are complete.

The valuation of the intangible assets acquired and related amortization periods are as follows:

	Valuation (in millions)	Amortization Period (in years)
<b>Developed Technology:</b>		
Hydrocodone and acetaminophen .....	\$ 119.0	17
Oxycodone and acetaminophen .....	30.0	17
Promethazine .....	46.0	16
Isosorbide Mononitrate ER .....	42.0	16
Multi Vitamins .....	38.0	16
Trazodone .....	17.0	16
Butalbital, acetaminophen, and caffeine .....	25.0	16
Triprevifem .....	16.0	13
Spironolactone .....	13.0	17
Hydrocortisone .....	34.0	16
Hydrochlorothiazide .....	16.0	16
Controlled Substances .....	52.0	16
Oral Contraceptives .....	8.0	13
Others .....	162.0	17
Total .....	<u>\$ 618.0</u>	16
<b>In Process Research &amp; Development:</b>		
Generics portfolio with anticipated 2011 launch .....	\$ 63.0	n/a
Generics portfolio with anticipated 2012 launch .....	30.0	n/a
Generics portfolio with anticipated 2013 launch .....	17.0	n/a
Generics portfolio with anticipated 2014 launch(1) .....	88.0	n/a
Total .....	<u>\$ 198.0</u>	n/a
<b>Tradename:</b>		
Qualitest tradename .....	\$ 20.0	15
Total .....	<u>\$ 20.0</u>	15
Total other intangible assets .....	<u>\$ 836.0</u>	n/a

(1) A subsequent pre-tax non-cash impairment charge of \$71.0 million was recorded in the fourth quarter of 2011. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles.

The fair value of the developed technology assets and IPR&D assets were estimated using an income approach. Under this method, an intangible asset's fair value is equal to the present value of the incremental after-tax cash flows (excess earnings) attributable solely to the intangible asset over its remaining useful life. To calculate fair value, the Company used probability-weighted cash flows discounted at rates considered appropriate given the inherent risks associated with each type of asset. The Company believes that the level and timing of cash flows appropriately reflect market participant assumptions. Cash flows were generally assumed to extend through the economic useful life of the developed technology, IPR&D asset or tradename. The fair value of the Qualitest tradename was estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to license the Qualitest tradename. Thus, we derived the hypothetical royalty income from the projected revenues of Qualitest Pharmaceuticals.

The \$224.1 million of goodwill was assigned to our Qualitest segment. The goodwill recognized is attributable primarily to expected purchasing, manufacturing and distribution synergies as well as its assembled workforce. Approximately \$170.4 million of goodwill was expected to be deductible for income tax purposes.

Deferred tax assets of \$71.0 million are related primarily to federal and state net operating loss and credit carryforwards of Qualitest Pharmaceuticals and its subsidiaries. Deferred tax liabilities of \$207.3 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

The Company recognized \$11.0 million, \$8.0 million and \$38.8 million of Qualitest Pharmaceuticals acquisition-related and integration items that were expensed during the years ended December 31, 2012, 2011 and 2010, respectively. These items are included in Acquisition-related and integration items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	2012	2011	2010
Bank fees.....	\$ —	\$ —	\$ 14,215
Legal, separation, integration, and other costs.....	10,776	8,284	24,572
Changes in fair value of acquisition-related contingent consideration ...	237	(313)	—
Total.....	<u>\$ 11,013</u>	<u>\$ 7,971</u>	<u>\$ 38,787</u>

Transaction costs directly associated with the closing of the acquisition in 2010 and included in the table above totaled \$36.1 million.

The amounts of revenue and net loss of Qualitest Pharmaceuticals included in the Company's Consolidated Statements of Operations from and including November 30, 2010 to December 31, 2010 are as follows (in thousands, except per share data):

Revenue.....	\$ 30,323
Net loss attributable to Endo Health Solutions Inc. ....	\$ (3,056)
Basic and diluted net loss per share .....	\$ (0.03)

The following supplemental pro forma information presents the financial results as if the acquisition of Qualitest Pharmaceuticals had occurred on January 1, 2010 for the year ended December 31, 2010. This supplemental pro forma information has been prepared for comparative purposes and does not purport to be indicative of what would have occurred had the acquisition been made on January 1, 2010, nor are they indicative of any future results.

	Twelve Months Ended December 31, 2010
<b>Unaudited pro forma consolidated results (in thousands, except per share data):</b>	
Revenue.....	\$ 2,038,761
Net income attributable to Endo Health Solutions Inc.....	\$ 243,710
Basic net income per share.....	\$ 2.10
Diluted net income per share.....	\$ 2.07

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of Qualitest Pharmaceuticals to reflect the additional depreciation and amortization that would have been charged assuming the fair value adjustments primarily to property, plant and equipment and intangible assets, had been applied on January 1, 2010, together with the consequential tax effects.

#### ***Penwest Pharmaceuticals Co.***

On September 20, 2010 (the Penwest Acquisition Date), the Company completed its tender offer for the outstanding shares of common stock of Penwest and on November 4, 2010, we closed this acquisition for approximately \$171.8 million in aggregate cash consideration, at which time Penwest became our wholly-owned subsidiary. On August 22, 2011, Penwest was merged into Endo Pharmaceuticals Inc., at which time Penwest ceased its existence as a separate legal entity.

This transaction contributes to Endo's core pain management franchise and permits us to maximize the value of our oxymorphone franchise.

The operating results of Penwest from September 20, 2010 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheets as of December 31, 2012 and December 31, 2011 reflect the acquisition of Penwest, effective September 20, 2010, the date the Company obtained control of Penwest.

The following table summarizes the fair values of the assets acquired and liabilities assumed at the Penwest Acquisition Date (in thousands):

	<u>September 20, 2010 (As Adjusted)</u>
Cash and cash equivalents.....	\$ 22,343
Marketable securities.....	800
Accounts receivable.....	10,866
Other receivables.....	131
Inventories.....	407
Prepaid expenses and other current assets.....	493
Deferred income taxes.....	29,765
Property, plant and equipment.....	915
Other intangible assets(1).....	111,200
Other assets.....	2,104
Total identifiable assets.....	<u>\$ 179,024</u>
Accounts payable.....	\$ 229
Income taxes payable.....	160
Penwest shareholder liability.....	—
Accrued expenses.....	1,542
Deferred income taxes.....	40,168
Other liabilities.....	4,520
Total liabilities assumed.....	<u>\$ 46,619</u>
Net identifiable assets acquired.....	<u>\$ 132,405</u>
Goodwill.....	39,361
Net assets acquired.....	<u><u>\$ 171,766</u></u>

(1) A subsequent pre-tax non-cash impairment charge of \$1.6 million related to Other intangible assets was recorded in the fourth quarter of 2011. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles.

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the Penwest Acquisition Date. Our measurement period adjustments are complete.

The valuation of the intangible assets acquired and related amortization periods are as follows (in millions):

	<u>Valuation</u>	<u>Amortization Period (in years)</u>
<b>In Process Research &amp; Development:</b>		
Otsuka.....	\$ 5.5	n/a
A0001(1).....	1.6	n/a
Total.....	<u>\$ 7.1</u>	n/a
<b>Developed Technology:</b>		
Opana® ER.....	\$ 104.1	10
Total.....	<u>\$ 104.1</u>	10
Total other intangible assets.....	<u><u>\$ 111.2</u></u>	n/a

(1) A subsequent pre-tax non-cash impairment charge of \$1.6 million was recorded in the fourth quarter of 2011. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles.

The fair values of the IPR&D assets and developed technology asset were estimated using an income approach. To calculate fair value, the Company used probability-weighted cash flows discounted at rates considered appropriate given the inherent risks associated with the asset. The Company believes that the level and timing of cash flows appropriately reflect market participant assumptions. Cash flows were generally assumed to extend through the economic useful life of our developed technology or IPR&D asset.

The \$39.4 million of goodwill was assigned to our Endo Pharmaceuticals segment. The goodwill recognized is attributable primarily to the control premium associated with our oxymorphone franchise and other factors. None of the goodwill was expected to be deductible for income tax purposes.

Deferred tax assets of \$29.8 million are related primarily to federal net operating loss and credit carryforwards of Penwest. Deferred tax liabilities of \$40.2 million are related primarily to the difference between the book basis and tax basis of the identifiable intangible assets.

The Company recognized \$0.3 million and \$10.7 million of Penwest acquisition-related and integration costs that were expensed during the years ended December 31, 2011 and 2010, respectively. These costs are included in Acquisition-related and integration items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	2011	2010
Bank fees .....	\$ —	\$ 3,865
Legal, separation, integration, and other costs .....	259	6,815
Total .....	<u>\$ 259</u>	<u>\$ 10,680</u>

Transaction costs directly associated with the closing of the acquisition in 2010 and included in the table above totaled \$5.6 million.

Due to the pro forma impacts of eliminating the pre-existing intercompany royalties between Penwest and Endo, which were determined to be at fair value, we have not provided supplemental pro forma information as amounts are not material to the Consolidated Statements of Operations. We have also considered the impacts of Penwest, since the date we obtained a majority interest, on our Consolidated Statement of Operations and concluded amounts were not material.

***HealthTronics, Inc.***

On July 2, 2010 (the HealthTronics, Inc. Acquisition Date), the Company completed its initial tender offer for all outstanding shares of common stock of HealthTronics, Inc. and obtained effective control of HealthTronics, Inc. On July 12, 2010, Endo completed its acquisition of HealthTronics, Inc. for approximately \$214.8 million in aggregate cash consideration for 100% of the outstanding shares, at which time HealthTronics, Inc. became a wholly-owned subsidiary of the Company. HealthTronics, Inc.'s shares were purchased at a price of \$4.85 per HealthTronics, Inc. Share. In addition, Endo paid \$40.0 million to retire HealthTronics, Inc.'s debt that had been outstanding under its Senior Credit Facility. As a result of the acquisition, the HealthTronics, Inc. Senior Credit Facility was terminated.

HealthTronics, Inc. is a provider of healthcare services and manufacturer of certain related medical devices, primarily for the urology community. The HealthTronics, Inc. business and applicable services include:

*Lithotripsy services.*

HealthTronics, Inc. provides lithotripsy services, which is a medical procedure where a device called a lithotripter transmits high energy shockwaves through the body to break up kidney stones. Lithotripsy services are provided principally through limited partnerships and other entities that HealthTronics, Inc. manages, which use lithotripters. In 2012, physician partners used our lithotripters to perform more than 50,000 procedures in the U.S. While the physicians render medical services, HealthTronics, Inc. does not. As the general partner of limited partnerships or the manager of other types of entities, HealthTronics, Inc. also provide services relating to operating its lithotripters, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting with payors, hospitals, and surgery centers.

*Prostate treatment services.*

HealthTronics, Inc. provides treatments for benign and cancerous conditions of the prostate. In treating benign prostate disease, HealthTronics, Inc. deploys three technologies in a number of its partnerships above: (1) PVP, (2) TUNA, and (3) TUMT. All three technologies apply an energy source which reduces the size of the prostate gland. For treating prostate and other cancers, HealthTronics, Inc. uses a procedure called cryosurgery, a process which uses lethal ice to destroy tissue such as tumors for therapeutic purposes. In April 2008, HealthTronics, Inc. acquired Advanced Medical Partners, Inc., which significantly expanded its cryosurgery partnership base. In July 2009, HealthTronics, Inc. acquired Endocare, Inc., which manufactures both the medical devices and related consumables utilized by its cryosurgery operations and also provides cryosurgery treatments. The prostate treatment services are provided principally by using equipment that HealthTronics, Inc. leases from limited partnerships and other entities that HealthTronics, Inc. manages. Benign prostate disease and cryosurgery cancer treatment services are billed in the same manner as its

lithotripsy services under either retail or wholesale contracts. HealthTronics, Inc. also provides services relating to operating the equipment, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting.

*Anatomical pathology services.*

HealthTronics, Inc. provides anatomical pathology services primarily to the urology community. HealthTronics, Inc. has one pathology lab located in Georgia, which provides laboratory detection and diagnosis services to urologists throughout the U.S. In addition, in July 2008, HealthTronics, Inc. acquired Uropath LLC, now referred to as HealthTronics Laboratory Solutions, which managed pathology laboratories located at Uropath sites for physician practice groups located in Texas, Florida and Pennsylvania. Through HealthTronics Laboratory Solutions, HealthTronics, Inc. continues to provide administrative services to in-office pathology labs for practice groups and pathology services to physicians and practice groups with its lab equipment and personnel at the HealthTronics Laboratory Solutions laboratory sites.

*Medical products manufacturing, sales and maintenance.*

HealthTronics, Inc. manufactures and sells medical devices focused on minimally invasive technologies for tissue and tumor ablation through cryoablation, which is the use of lethal ice to destroy tissue, such as tumors, for therapeutic purposes. HealthTronics, Inc. develops and manufactures these devices for the treatment of prostate and renal cancers and our proprietary technologies also have applications across a number of additional markets, including the ablation of tumors in the lung, liver metastases and palliative intervention (treatment of pain associated with metastases). HealthTronics, Inc. manufactures the related spare parts and consumables for these devices. HealthTronics, Inc. also sells and maintains lithotripters and related spare parts and consumables.

The acquisition of HealthTronics, Inc. reflects Endo's desire to continue expanding our business beyond pain management into complementary medical areas where HealthTronics, Inc. can be innovative and competitive. We believe this expansion will enable us to be a provider of multiple healthcare solutions and services that fill critical gaps in patient care.

The operating results of HealthTronics, Inc. from July 2, 2010 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheets as of December 31, 2012 and December 31, 2011 reflect the acquisition of HealthTronics, Inc., effective July 2, 2010, the date the Company obtained control of HealthTronics, Inc.

The following table summarizes the fair values of the assets acquired and liabilities assumed at the HealthTronics, Inc. Acquisition Date (in thousands):

	<u>July 2, 2010 (As Adjusted)</u>
Cash and cash equivalents.....	\$ 6,769
Accounts receivable .....	33,388
Other receivables .....	1,006
Inventories .....	12,399
Prepaid expenses and other current assets.....	5,204
Deferred income taxes.....	46,489
Property, plant and equipment.....	30,687
Other intangible assets(1).....	73,124
Other assets .....	5,210
Total identifiable assets.....	<u>\$ 214,276</u>
Accounts payable .....	\$ 3,084
Accrued expenses .....	20,510
Deferred income taxes.....	22,376
Long-term debt.....	43,460
Other liabilities.....	1,785
Total liabilities assumed.....	<u>\$ 91,215</u>
Net identifiable assets acquired.....	<u>\$ 123,061</u>
Noncontrolling interests .....	(63,227)
Goodwill(2).....	155,009
Net assets acquired .....	<u><u>\$ 214,843</u></u>

(1) Other intangible assets includes a \$12.2 million intangible asset related to our IGRT business, which was sold in September 2011 for approximately \$13.0 million. Accordingly, the carrying amount of this asset was reduced to zero at the time of sale.



- (2) A subsequent pre-tax non-cash impairment charge of \$24.8 million related to this Goodwill was recorded in the fourth quarter of 2012. This impairment charge is further discussed in Note 9. Goodwill and Other Intangibles.

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the HealthTronics, Inc. Acquisition Date. Our measurement period adjustments are complete.

The valuation of the intangible assets acquired and related amortization periods are as follows (in millions):

	Valuation (in millions)	Amortization Period (in years)
Endocare Developed Technology .....	\$ 46.3	10
HealthTronics Tradename .....	14.6	15
Service Contract(1) .....	12.2	n/a
Total .....	<u>\$ 73.1</u>	n/a

- (1) This intangible asset relates to our IGRT business, which was sold in September 2011 for approximately \$13.0 million. Accordingly, the carrying amount of this asset was reduced to zero at the time of sale.

The fair value of the developed technology asset was estimated using a discounted present value income approach. Under this method, an intangible asset's fair value is equal to the present value of the incremental after-tax cash flows (excess earnings) attributable solely to the intangible asset over its remaining useful life. To calculate fair value, the Company used probability-weighted cash flows discounted at rates considered appropriate given the inherent risks associated with each type of asset. The Company believes that the level and timing of cash flows appropriately reflect market participant assumptions. Cash flows were assumed to extend through the economic useful life of the purchased technology. The fair value of the HealthTronics Tradename was estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to license the HealthTronics Tradename. Thus, we derived the hypothetical royalty income from the projected revenues of HealthTronics, Inc.'s services.

HealthTronics, Inc. has investments in partnerships and limited liability companies (LLCs) where we, as the general partner or managing member, exercise effective control. Accordingly, we consolidate various entities where we do not own 100% of the entity in accordance with the accounting consolidation principles. As a result, we are required to fair value the noncontrolling interests as part of our purchase price allocation. To calculate fair value, the Company used historical transactions which represented Level 2 data points within the fair value hierarchy to calculate applicable multiples of each respective noncontrolling interest in the partnerships and LLCs.

The \$155.0 million of goodwill has been assigned to our HealthTronics segment. The goodwill recognized is attributable primarily to strategic and synergistic opportunities across the HealthTronics, Inc. network of urology partnerships, expected corporate synergies, the assembled workforce of HealthTronics, Inc. and other factors. Approximately \$33.6 million of goodwill was expected to be deductible for income tax purposes.

Deferred tax assets of \$46.5 million are related primarily to federal net operating loss and credit carryforwards of HealthTronics, Inc. and its subsidiaries. Deferred tax liabilities of \$22.4 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

The Company recognized \$3.6 million, \$3.7 million and \$20.9 million of HealthTronics, Inc. acquisition-related and integration costs that were expensed during the years ended December 31, 2012, 2011 and 2010, respectively. These costs are included in Acquisition-related and integration items, net in the accompanying Consolidated Statements of Operations and are comprised of the following items (in thousands):

	2012	2011	2010
Bank fees .....	\$ —	\$ —	\$ 2,017
Acceleration of outstanding HealthTronics, Inc. stock-based compensation .....	—	—	7,924
Legal, separation, integration, and other costs .....	3,569	3,704	10,988
Total .....	<u>\$ 3,569</u>	<u>\$ 3,704</u>	<u>\$ 20,929</u>

Transaction costs directly associated with the closing of the acquisition in 2010 and included in the table above totaled \$20.0 million.

The amounts of revenue and net loss of HealthTronics, Inc. included in the Company's Consolidated Statements of Operations from and including July 2, 2010 to December 31, 2010 are as follows (in thousands, except per share data):

Revenue .....	\$	102,144
Net loss attributable to Endo Health Solutions Inc.....	\$	(8,098)
Basic and diluted net loss per share.....	\$	(0.07)

The following supplemental pro forma information presents the financial results as if the acquisition of HealthTronics, Inc. had occurred on January 1, 2010 for the year ended December 31, 2010. This supplemental pro forma information has been prepared for comparative purposes and does not purport to be indicative of what would have occurred had the acquisition been made on January 1, 2010, nor are they indicative of any future results.

	<u>Twelve Months Ended December 31, 2010</u>	
<b>Unaudited pro forma consolidated results (in thousands, except per share data):</b>		
Revenue .....	\$	1,814,918
Net income attributable to Endo Health Solutions Inc.....	\$	264,165
Basic net income per share.....	\$	2.27
Diluted net income per share.....	\$	2.24

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of HealthTronics, Inc. to reflect the additional depreciation and amortization that would have been charged assuming the fair value adjustments primarily to property, plant and equipment, and intangible assets, had been applied on January 1, 2010, together with the consequential tax effects.

**Other**

In the second half of 2011, as part of our effort to increase and broaden the relationships within the urology community, we acquired two electronic medical records software companies, Intuitive Medical Software, LLC and meridianEMR, Inc., which individually and combined represent immaterial acquisitions. These acquisitions provide electronic medical records for urologists. Together, these acquisitions provide access to more than 2,000 urology health care providers using data platforms that will enhance service offerings in urology practice management.

**NOTE 6. SEGMENT RESULTS**

In the fourth quarter of 2011, as a result of our strategic planning process, the Company's executive leadership team reorganized the manner in which it views our various business activities. Management's intention was to enhance its level of understanding of the entity's performance, better assess its prospects and future cash flow potential and ultimately make more informed operating decisions about resource allocation and the enterprise as a whole. Based on this change, we reassessed our reporting structure under the applicable accounting guidance and determined that the Company had four reportable segments. We have retrospectively revised the segment presentation for all periods presented reflecting the change from three to four reportable segments. Additionally, concurrent with the Company's May 2012 enterprise-wide rebranding initiative and corporate name change, the Company changed the names of its reportable segments to better align with these efforts. These changes to our segments have no impact on the Company's Consolidated Financial Statements for all periods presented.

The four reportable business segments in which the Company now operates are: (1) Endo Pharmaceuticals, (2) Qualitest, (3) AMS and (4) HealthTronics. Each segment derives revenue from the sales or licensing of their respective products or services.

We evaluate segment performance based on each segment's adjusted income before income tax. We define adjusted income before income tax as income (loss) before income tax before certain upfront and milestone payments to partners, acquisition-related and integration items, net, cost reduction and integration-related initiatives, asset impairment charges, amortization of intangible assets related to marketed products and customer relationships, inventory step-up recorded as part of our acquisitions, non-cash interest expense, litigation-related and other contingent matters and certain other items that the Company believes do not reflect its core operating performance.

Certain corporate general and administrative expenses are not allocated and are therefore included within Corporate unallocated. We calculate consolidated adjusted income before income tax by adding the adjusted income before income tax of each of our reportable segments to Corporate unallocated adjusted income before income tax.

### ***Endo Pharmaceuticals***

The Endo Pharmaceuticals segment includes a variety of branded prescription products related to treating and managing pain as well as our urology, endocrinology and oncology products. The marketed products that are included in this segment include Lidoderm<sup>®</sup>, Opana<sup>®</sup> ER, Percocet<sup>®</sup>, Voltaren<sup>®</sup> Gel, Frova<sup>®</sup>, Supprelin<sup>®</sup> LA, Vantas<sup>®</sup>, Valstar<sup>®</sup> and Fortesta<sup>®</sup> Gel.

### ***Qualitest***

The Qualitest segment is comprised of our legacy Endo non-branded generics portfolio and the portfolio from Qualitest Pharmaceuticals, which we acquired in 2010. The Qualitest segment has historically focused on selective generics related to pain that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. With the addition of Qualitest Pharmaceuticals, the segment's product offerings now include products in the pain management, urology, central nervous system (CNS) disorders, immunosuppression, oncology, women's health and hypertension markets, among others.

### ***AMS***

The AMS segment currently 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 BPH therapy. These business lines are discussed in greater detail within Note 5. Acquisitions. We distribute devices through our direct sales force and independent sales representatives in the U.S., Canada, Australia and Western Europe. Additionally, we distribute devices through foreign independent distributors, primarily in Europe, Asia, and South America, who then sell the products to medical institutions. None of our AMS customers or distributors accounted for ten percent or more of our total revenues during the years ended December 31, 2012, 2011 or 2010. Foreign subsidiary sales are predominantly to customers in Canada, Australia and Western Europe.

### ***HealthTronics***

The HealthTronics segment provides urological services, products and support systems to urologists, hospitals, surgery centers and clinics across the U.S. These services are sold through the following business lines: lithotripsy services, prostate treatment services, anatomical pathology services, medical products manufacturing, sales and maintenance and electronic medical records services.

The following represents selected information for the Company's reportable segments for the years ended December 31 (in thousands):

	2012	2011	2010
Net revenues to external customers:			
Endo Pharmaceuticals .....	\$ 1,677,984	\$ 1,657,767	\$ 1,467,572
Qualitest .....	633,265	566,854	146,513
AMS(1) .....	504,487	300,299	—
HealthTronics .....	211,627	205,201	102,144
Total consolidated net revenues to external customers .....	<u>\$ 3,027,363</u>	<u>\$ 2,730,121</u>	<u>\$ 1,716,229</u>
Adjusted income before income tax:			
Endo Pharmaceuticals .....	\$ 906,839	\$ 890,951	\$ 757,453
Qualitest .....	171,418	107,204	24,722
AMS .....	119,852	82,418	—
HealthTronics .....	58,092	68,769	35,538
Corporate unallocated .....	(338,826)	(318,100)	(194,459)
Total consolidated adjusted income before income tax .....	<u>\$ 917,375</u>	<u>\$ 831,242</u>	<u>\$ 623,254</u>

(1) The following table displays our AMS segment revenue by geography (in thousands). International revenues were not material to any of our other segments for any of the periods presented.

	2012	2011	2010
AMS:			
United States .....	\$ 330,087	\$ 202,462	\$ —
International .....	174,400	97,837	—
Total AMS revenues .....	<u>\$ 504,487</u>	<u>\$ 300,299</u>	<u>\$ —</u>

The table below provides reconciliations of our consolidated adjusted income before income tax to our consolidated (loss) income before income tax, which is determined in accordance with U.S. GAAP, for the years ended December 31 (in thousands):

	2012	2011	2010
Total consolidated adjusted income before income tax: .....	\$ 917,375	\$ 831,242	\$ 623,254
Upfront and milestone payments to partners .....	(60,778)	(28,098)	(23,850)
Asset impairment charges .....	(768,467)	(116,089)	(35,000)
Acquisition-related and integration items, net .....	(23,015)	(33,638)	(18,976)
Separation benefits and other cost reduction initiatives(1) .....	(47,033)	(21,821)	(17,245)
Amortization of intangible assets .....	(227,260)	(190,969)	(83,974)
Inventory step-up .....	(880)	(49,438)	(6,289)
Non-cash interest expense .....	(20,762)	(18,952)	(16,983)
Net loss on extinguishment of debt .....	(7,215)	(11,919)	—
Accrual for payment to Impax related to sales of Opana® ER .....	(102,000)	—	—
Patent litigation settlement items, net .....	(85,123)	—	—
Litigation-related and other contingencies .....	(316,425)	(11,263)	—
Other income (expense), net .....	—	2,636	(239)
Total consolidated (loss) income before income tax .....	<u>\$ (741,583)</u>	<u>\$ 351,691</u>	<u>\$ 420,698</u>

(1) During the year ended December 31, 2012, the Company recorded \$43.6 million of employee separation costs, \$18.2 million of which is included in Accrued expenses on the Consolidated Balance Sheets as of December 31, 2012. The cash related portion of these charges is \$37.8 million. Approximately \$19.7 million of the \$37.8 million was paid in 2012. A majority of the remaining \$18.2 million is expected to be paid in 2013.

The following represents additional selected financial information for our reportable segments for the years ended December 31 (in thousands):

	2012	2011	2010
<b>Depreciation expense:</b>			
Endo Pharmaceuticals .....	\$ 15,540	\$ 13,264	\$ 13,259
Qualitest .....	12,343	11,468	1,676
AMS .....	10,667	4,984	—
HealthTronics .....	14,081	12,330	6,000
Corporate unallocated .....	5,033	3,799	2,894
<b>Total depreciation expense .....</b>	<b>\$ 57,664</b>	<b>\$ 45,845</b>	<b>\$ 23,829</b>
	<b>2012</b>	<b>2011</b>	<b>2010</b>
<b>Amortization expense:</b>			
Endo Pharmaceuticals .....	\$ 105,974	\$ 104,439	\$ 78,647
Qualitest .....	41,524	39,078	3,068
AMS .....	73,422	42,099	—
HealthTronics .....	6,940	5,953	2,860
<b>Total amortization expense .....</b>	<b>\$ 227,860</b>	<b>\$ 191,569</b>	<b>\$ 84,575</b>

Interest income and expense are considered corporate items and are not allocated to our segments. Asset information is not accounted for at the segment level and consequently is not reviewed or included within our internal management reporting. Therefore, the Company has not disclosed asset information for each reportable segment.

## NOTE 7. LICENSE AND COLLABORATION AGREEMENTS

### Commercial Products

#### *Novartis AG and Novartis Consumer Health, Inc.*

On March 4, 2008, we entered into a License and Supply Agreement (the Voltaren<sup>®</sup> Gel Agreement) with and among Novartis AG and Novartis Consumer Health, Inc. (Novartis) to obtain the exclusive U.S. marketing rights for the prescription medicine Voltaren<sup>®</sup> Gel (Voltaren<sup>®</sup> Gel or Licensed Product). Voltaren<sup>®</sup> 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<sup>®</sup> Gel was granted marketing exclusivity in the U.S. as a prescription medicine until October 2010.

Under the terms of the five-year Voltaren<sup>®</sup> Gel Agreement, Endo made an upfront cash payment of \$85 million. Endo agreed to pay royalties to Novartis on annual Net Sales of the Licensed Product, subject to certain thresholds as defined in the Voltaren<sup>®</sup> Gel Agreement. In addition, Endo agreed to make certain guaranteed minimum annual royalty payments of \$30 million per year payable in the 4th and 5th year of the Voltaren<sup>®</sup> Gel Agreement, which may be reduced under certain circumstances, including Novartis's failure to supply the Licensed Product, subject to certain limitations including the launch of a generic to the Licensed Product in the U.S. These guaranteed minimum royalties will be creditable against royalty payments on an annual basis such that Endo's obligation with respect to each year is to pay the greater of (i) royalties payable based on annual net sales of the Licensed Product or (ii) the guaranteed minimum royalty for such Voltaren<sup>®</sup> Gel Agreement year. Novartis is also eligible to receive a one-time milestone payment of \$25 million if annual net sales of Voltaren<sup>®</sup> Gel exceed \$300 million in the U.S. To date, annual net sales have not exceeded this threshold and, therefore, this milestone payment has not been paid.

The \$85 million upfront payment and the present value of the guaranteed minimum royalties was initially capitalized as an intangible asset in the amount of \$129 million, representing the fair value of the exclusive license to market Voltaren<sup>®</sup> Gel over the initial contract term. We are amortizing this intangible asset into Cost of revenues over an estimated five-year useful life. Due to Novartis's failure to supply Voltaren<sup>®</sup> Gel during the first quarter of 2012 resulting from the shutdown of its Lincoln, Nebraska manufacturing facility, we were not obligated to make any first quarter royalty payment, including the \$7.5 million minimum royalty. Accordingly, during the first quarter of 2012, we recorded a reduction to the associated liability and a decrease in the intangible asset. Subsequent to the first quarter of 2012, royalties in the amount of \$21.6 million were incurred representing either a percentage of actual net sales of Voltaren<sup>®</sup> Gel or minimum royalties pursuant to the Voltaren<sup>®</sup> Gel Agreement. Voltaren<sup>®</sup> Gel royalties incurred during the year ended December 31, 2011 were \$17.7 million. There were no Voltaren<sup>®</sup> Gel royalties incurred during the year ended December 31, 2010.

Endo is solely responsible to commercialize the Licensed Product during the term of the Voltaren<sup>®</sup> Gel Agreement. With respect to each year during the term of the Voltaren<sup>®</sup> Gel Agreement, subject to certain limitations, Endo is required to incur a minimum amount of annual advertising and promotional expenses (A&P Expenditures) on the commercialization of the Licensed Product, which may be reduced under certain circumstances including Novartis's failure to supply the Licensed Product. In addition, Endo is required to perform a minimum number of face-to-face one-on-one discussions with physicians and other healthcare practitioners (Details) for the purpose of promoting the Licensed Product within its approved indication during each year of the Voltaren<sup>®</sup> Gel Agreement which may be reduced under certain circumstances including Novartis's failure to supply the Licensed Product. Further, during the term of the Voltaren<sup>®</sup> Gel Agreement, Endo will share in the costs of certain clinical studies and development activities initiated at the request of the FDA or as considered appropriate by Novartis and Endo. On December 31, 2012, Endo and Novartis entered into an amendment to the Voltaren<sup>®</sup> Gel Agreement (the Voltaren<sup>®</sup> Gel Amendment) which reduced the minimum number of Details required to be conducted by Endo and the minimum amount of annual advertising and promotional expenses required to be spent by Endo on the commercialization of Voltaren<sup>®</sup> Gel during each year of the Voltaren<sup>®</sup> Gel Agreement.

During the third Voltaren<sup>®</sup> Gel Agreement Year beginning on July 1, 2010 and extending through June 30, 2011, we agreed to spend 15% of prior year sales or approximately \$13 million on A&P Expenditures. During the fourth Voltaren<sup>®</sup> Gel Agreement Year beginning on July 1, 2011 and extending through June 30, 2012, we agreed to spend 13% of prior year sales or approximately \$16 million on A&P Expenditures. On December 31, 2012, we entered into an amendment that reduced the amount of minimum A&P Expenditures for the fifth Agreement Year beginning on July 1, 2012 and extending through June 30, 2013 to approximately \$4.5 million. In subsequent Agreement Years, the minimum A&P Expenditures set forth in the Voltaren<sup>®</sup> Gel Agreement are determined based on a percentage of net sales of Voltaren<sup>®</sup> Gel, which may be reduced under certain circumstances, including Novartis's failure to supply Voltaren<sup>®</sup> Gel.

Amounts incurred by Endo for such A&P Expenditures were \$9.4 million, \$18.7 million and \$18.0 million for the years ended December 31, 2012, 2011 and 2010, respectively.

During the term of the Voltaren<sup>®</sup> Gel Agreement, Endo has agreed to purchase all of its requirements for the Licensed Product from Novartis. The price was fixed for the first year and subject to annual changes based upon changes in the producer price index and raw materials. The Voltaren<sup>®</sup> Gel Amendment reduced the supply price of Voltaren<sup>®</sup> Gel otherwise payable under the Agreement.

Novartis has the exclusive right, at its sole discretion, to effect a switch of the Licensed Product from a prescription product to an over-the-counter (OTC) product in the U.S. (an OTC Switch) by filing an amendment or supplement to the Licensed Product New Drug Application or taking any other action necessary or advisable in connection therewith to effect the OTC Switch, and thereafter to commercialize such OTC product. Notwithstanding the foregoing, Novartis shall not launch an OTC equivalent product prior to a time specified in the Voltaren<sup>®</sup> Gel Agreement, and Novartis shall not take any action that results in the loss of the prescription product status for the Licensed Product prior to such time. Novartis is obligated to notify Endo if it submits a filing to the FDA in respect of an OTC equivalent product. In the event that Novartis gains approval of an OTC equivalent product that results in the Licensed Product being declassified as a prescription product, then Novartis will make certain royalty payments to Endo on net sales of such OTC equivalent product in the U.S. by Novartis, its affiliates and their respective licensees or sublicensees as set forth in the Voltaren<sup>®</sup> Gel Agreement. As a condition to the payment of any and all such royalties, net sales of the Licensed Product in the U.S. must have exceeded a certain threshold prior to the launch of the OTC equivalent product by Novartis or its affiliates.

The initial term of the Voltaren<sup>®</sup> Gel Agreement will expire on June 30, 2013, and we have the option to extend it for three successive one year terms. In December 2012, pursuant to the provisions of the Voltaren<sup>®</sup> Gel Agreement, the term was automatically renewed for an additional one year period. As a result, we capitalized, as an intangible asset, \$21.3 million, representing the present value of the guaranteed minimum royalties we expect to pay to Novartis AG over the renewal term. The Voltaren<sup>®</sup> Gel Agreement will remain in place unless either (i) Endo provides written notice of non-renewal to the other party at least six months prior to the expiration of any renewal term after the first renewal term (ii) Novartis provides written notice of non-renewal to the other party at least six months prior to the expiration of any renewal term after the second renewal term or (iii) the Voltaren<sup>®</sup> Gel Agreement is otherwise terminated in accordance with its terms. Upon extension, Endo is again obligated to make certain guaranteed minimum annual royalty payments of \$30 million per year during each successive one-year renewal term, subject to certain limitations including the launch of a generic to the Licensed Product in the U.S. These guaranteed minimum annual royalty payments may be reduced under certain circumstances, including Novartis's failure to supply the Licensed Product. These guaranteed minimum royalties will be creditable against royalty payments on an annual basis such that Endo's obligation with respect to each year is to pay the greater of (i) royalties payable based on annual net sales of the Licensed Product or (ii) the guaranteed minimum royalty for such Voltaren<sup>®</sup> Gel Agreement year. Among other standard and customary termination rights granted under the Voltaren<sup>®</sup> Gel Agreement, the Voltaren<sup>®</sup> Gel Agreement can be terminated by either party upon reasonable written notice and if either party has committed a material breach that has not been remedied within 90 days from the giving of written notice. Endo may terminate the Voltaren<sup>®</sup> Gel Agreement by written notice upon the occurrence of several events, including the launch in the U.S. of a generic to the Licensed Product. Novartis may terminate the Voltaren<sup>®</sup> Gel Agreement upon reasonable written notice (1) if Endo fails to deliver a set percentage of the minimum Details in a certain six-month period under the Voltaren<sup>®</sup> Gel Agreement; or (2) on or after the launch in the U.S. of an OTC



equivalent product by Novartis, its affiliates or any third party that does not result in the declassification of the Licensed Product as a prescription product, following which net sales in a six-month period under the Voltaren® Gel Agreement are less than a certain defined dollar amount.

#### *Hind Healthcare Inc.*

In November 1998, Endo entered into a license agreement (the Hind License Agreement) with Hind Healthcare Inc. (Hind), for the sole and exclusive right to develop, use, market, promote and sell Lidoderm® in the U.S. Under the terms of the Hind License Agreement, Endo paid Hind approximately \$10 million based upon the achievement of certain milestones and capitalized this amount as an intangible asset representing the fair value of these exclusive rights. In addition, we were required to pay Hind nonrefundable royalties based on net sales of Lidoderm® until this obligation expired on November 23, 2011 pursuant to the terms of the Hind License Agreement. Royalties were recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm®. The royalty rate was 10% of net sales including a minimum royalty of at least \$500,000 per year. There were no royalties recorded in 2012. During the years ended December 31, 2011 and 2010, we recorded \$77.9 million and \$86.8 million in royalties to Hind which we recorded as a reduction to net sales.

#### *Vernalis Development Limited*

In July 2004, we entered into a License Agreement with Vernalis Development Limited (Vernalis) under which Vernalis agreed to license, exclusively to us, rights to market frovatriptan succinate (Frova®) in North America (the Vernalis License Agreement). Frova® was launched June 2002 in the U.S. and indicated for the acute treatment of migraine headaches in adults. Under the terms of the Vernalis License Agreement, we paid Vernalis an upfront fee of \$30 million and annual \$15 million payments each in 2005 and 2006. We capitalized the \$30 million up-front payment and the present value of the two \$15 million anniversary payments. We are amortizing this intangible asset into Cost of revenues on a straight-line basis over its estimated life of 12.5 years.

In addition, Vernalis could receive one-time milestone payments for the achievement of defined annual net sales targets. These sales milestone payments increase based on increasing net sales targets ranging from a milestone of \$10 million on \$200 million in net sales to a milestone of \$75 million on \$1.2 billion in net sales. These sales milestones could total up to \$255.0 million if all of the defined net sales targets are achieved. Beginning on January 1, 2007, we began paying royalties to Vernalis based on the net sales of Frova®. The term of the license agreement is for the shorter of the time (i) that there are valid claims on the Vernalis patents covering Frova® or there is market exclusivity granted by a regulatory authority, whichever is longer, or (ii) until the date on which a generic version of Frova® is first offered, but in no event longer than 20 years. We can terminate the license agreement under certain circumstances, including upon one year's written notice. In July 2007, Vernalis and Endo entered into an Amendment (Amendment No. 3) to the License Agreement dated July 14, 2004. Under Amendment No. 3, Vernalis granted an exclusive license to Endo to make, have made, use, commercialize and have commercialized Frova® in Canada, under the Canadian Trademark.

In February 2008, we entered into Amendment No. 4 to the Vernalis License Agreement (Amendment No. 4). In addition to amending certain specific terms and conditions of the License Agreement, Amendment No. 4 sets forth an annual minimum net sales threshold such that no royalties will be due on annual U.S. net sales of Frova® less than \$85 million. Prior to this amendment, royalties were payable by us to Vernalis on all net sales of Frova® in the U.S. Now, once the annual minimum net sales amount is reached, royalty payments will be due only on the portion of annual net sales that exceed the \$85 million threshold. To date, annual net sales have not exceeded the \$85 million threshold and, therefore, no royalties have been paid.

On August 15, 2011, the parties amended the Vernalis License Agreement (Amendment No. 5). Pursuant to Amendment No. 5, Vernalis assigned to the Company certain patents which were previously exclusively licensed by the Company. Amendment No. 5 did not alter the financial arrangement between the parties.

#### *The Population Council*

The Company markets certain of its products utilizing the hydrogel polymer technology pursuant to an agreement between Indevus (now, Endo Pharmaceuticals Solutions Inc.) and The Population Council. Unless earlier terminated by either party in the event of a material breach by the other party, the term of the agreement is the shorter of 25 years from October 1997 or until the date on which The Population Council receives approximately \$40 million in payments from the Company. To date, we have made payments of \$10.2 million to the Population Council. The Company is required to pay to The Population Council 3% of its net sales of Vantas® and any polymer implant containing a luteinizing hormone-releasing hormone (LHRH) analog. We are also obligated to pay royalties to The Population Council ranging from 0.5% of net sales to 4% of net sales under certain conditions. In addition, we are obligated to pay the Population Council 30% of certain profits and payments received in certain territories by the Company from the licensing of Vantas® or any other polymer implant containing an LHRH analog and 5% for other implants.

### *Strakan International Limited*

In August 2009, we entered into a License and Supply Agreement with Strakan International Limited, a subsidiary of ProStrakan Group plc. (ProStrakan), which was subsequently acquired by Kyowa Hakko Kirin Co. Ltd., for the exclusive right to commercialize Fortesta<sup>®</sup> Gel in the U.S. (the ProStrakan Agreement). Fortesta<sup>®</sup> Gel is a patented two percent testosterone transdermal gel for testosterone replacement therapy in male hypogonadism. A metered dose delivery system permits accurate dose adjustment to increase the ability to individualize patient treatment. Under the terms of the ProStrakan Agreement, Endo paid ProStrakan an up-front cash payment of \$10 million, which was recorded as Research and development expense.

The Company received FDA approval for Fortesta<sup>®</sup> Gel in December 2010, which triggered a one-time approval milestone to ProStrakan for \$12.5 million. The approval milestone was recorded as an intangible asset and is being amortized into Cost of revenues on a straight-line basis over its estimated useful life. An additional milestone payment of \$7.5 million was triggered during the second quarter of 2011 pursuant to the terms of the ProStrakan Agreement, at which time it was recorded to Cost of revenues. ProStrakan could potentially receive up to approximately \$167.5 million in additional payments linked to the achievement of future commercial milestones related to Fortesta<sup>®</sup> Gel.

ProStrakan will exclusively supply Fortesta<sup>®</sup> Gel to Endo at a supply price based on a percentage of annual net sales subject to a minimum floor price as defined in the ProStrakan Agreement. Endo may terminate the ProStrakan Agreement upon 6 months' prior written notice at no cost to the Company.

### *Grünenthal GMBH*

In December 2007, we entered into a License, Development and Supply Agreement (the Grünenthal Agreement) with Grünenthal for the exclusive clinical development and commercialization rights in Canada and the U.S. for an oral formulation of Opana<sup>®</sup> ER, which is designed to be crush-resistant. Under the terms of the Grünenthal Agreement, we paid approximately \$4.9 million for the successful completion of a clinical milestone in 2010, which was recorded as Research and development expense. In December 2011, the FDA approved a formulation of Opana<sup>®</sup> ER designed to be crush-resistant, which is called Opana<sup>®</sup> ER.

In the fourth quarter of 2011, the Company capitalized a one-time approval milestone to Grünenthal for \$4.9 million. We are amortizing this intangible asset into Cost of revenues over its estimated useful life. We made an additional payment of \$4.9 million in August 2012 related to a commercial milestone which was recorded as Cost of revenues. Additional payments of approximately 50.8 million euros (approximately \$67.1 million at December 31, 2012) may become due upon achievement of additional future predetermined regulatory and commercial milestones. Endo will also make payments to Grünenthal based on net sales of any such product or products commercialized under this agreement, including the formulation of Opana<sup>®</sup> ER approved by the FDA in December 2011.

Effective December 19, 2012, EPI and Grünenthal amended the Grünenthal Agreement whereby EPI became responsible for planning of packaging of finished product and certain other routine packaging quality obligations and Grünenthal agreed to reimburse EPI for the third-party costs incurred related to packaging as well as pay EPI a periodic packaging fee. The amendment also changed certain of the terms with respect to the floor price required to be paid by EPI in consideration for product supplied by Grünenthal.

### *Products in Development*

#### *Impax Laboratories, Inc.*

In June 2010, the Company entered into a Development and Co-Promotion Agreement (the Impax Development Agreement) with Impax Laboratories, Inc. (Impax), whereby the Company was granted a royalty-free license for the co-exclusive rights to co-promote a next generation Parkinson's disease product. Under the terms of the Impax Development Agreement, Endo paid Impax an upfront payment of \$10 million in 2010, which was recorded as Research and development expense. The Company could be obligated to pay up to approximately \$30.0 million in additional payments linked to the achievement of future clinical, regulatory, and commercial milestones related to the development product. Prior to the completion of Phase III trials, Endo may only terminate the Impax Development Agreement upon a material breach.

#### *Bioniche Life Sciences Inc.*

In July 2009, the Company entered into a License, Development and Supply Agreement (the Bioniche License Agreement) with Bioniche Life Sciences Inc. and Bioniche Urology Inc. (collectively, Bioniche), whereby the Company licensed from Bioniche the exclusive rights to develop and market Bioniche's proprietary formulation of Mycobacterial Cell Wall-DNA Complex (MCC), known as Urocidin<sup>™</sup>, in the U.S. with an option for global rights, which we exercised in the first quarter of 2010. Urocidin<sup>™</sup> is a patented formulation of MCC developed by Bioniche for the treatment of non-muscle-invasive bladder cancer that had been previously been undergoing Phase III clinical testing.

During the third quarter of 2012, as a result of discussions with the FDA regarding our Urocidin™ Phase III clinical trial, the Company's subsidiary, Endo Pharmaceuticals Inc. (EPI), decided to end the study before its scheduled completion. On December 21, 2012, EPI and Bioniche entered into a termination agreement (the Bioniche Termination Agreement) to terminate the Bioniche License Agreement. As a result, EPI agreed to return rights to Urocidin™ to Bioniche in consideration for Bioniche paying EPI a royalty equal to 5% of global net sales of Urocidin™ for a period commencing on the date of the first commercial sale and continuing for the later of ten years or the expiration of the last valid patent covering the product. Pursuant to the Bioniche Termination Agreement, the parties ceased performing activities under the Bioniche License Agreement, excluding wind-up activities, effective December 21, 2012. Further, all terms and requirements of the Bioniche License Agreement, including future contingent milestone and royalty payments to Bioniche, as well as all rights and licenses granted to EPI pursuant to the Bioniche License Agreement will terminate effective March 31, 2013.

Prior to the termination, under the terms of the Bioniche License Agreement, Endo had paid Bioniche an up-front cash payment of \$20.0 million in July 2009 and milestone payments of \$11.0 million in 2009 and \$4.0 million in 2010 resulting from the achievement of contractual milestones, which were recorded as Research and development expense.

#### *BayerSchering*

In July 2005, Indevus (now, Endo Pharmaceuticals Solutions Inc.) licensed exclusive U.S. rights from Schering AG, Germany, now BayerSchering Pharma AG (BayerSchering) to market a long-acting injectable testosterone preparation for the treatment of male hypogonadism that we refer to as Aveed™ (the BayerSchering Agreement). The Company is responsible for the development and commercialization of Aveed™ in the U.S. BayerSchering is responsible for manufacturing and supplying the Company with finished product. As part of the BayerSchering Agreement, Indevus agreed to pay to BayerSchering up to \$30.0 million in up-front, regulatory milestone, and commercialization milestone payments, including a \$5.0 million payment due upon approval by the FDA to market Aveed™. Indevus also agreed to pay to BayerSchering 25% of net sales of Aveed™ to cover both the cost of finished product and royalties. The BayerSchering Agreement expires ten years from the first commercial sale of Aveed™. Either party may also terminate the BayerSchering Agreement in the event of a material breach by the other party.

In October 2006, Indevus entered into a supply agreement with BayerSchering pursuant to which BayerSchering agreed to manufacture and supply Indevus with all of its requirements for Aveed™ for a supply price based on net sales of Aveed™. The supply price is applied against the 25% of net sales owed to BayerSchering pursuant to the BayerSchering Agreement. The BayerSchering Agreement expires 10 years after the first commercial sale of Aveed™.

#### *Hydron Technologies, Inc.*

In November 1989, GP Strategies Corporation (GP Strategies), then known as National Patent Development Corporation, entered into an agreement (the Hydron Agreement) with Dento-Med Industries, Inc., now known as Hydron Technologies, Inc. In June 2000, Valera Pharmaceuticals, Inc. (Valera, now a wholly-owned, indirect subsidiary of the Company known as Endo Pharmaceuticals Valera Inc.) entered into a contribution agreement with GP Strategies, pursuant to which Valera acquired the assets of GP Strategies' drug delivery business, including all intellectual property, and all of GP Strategies' rights under the Hydron Agreement, and certain other agreements with The Population Council and Shire US, Inc.

Pursuant to the Hydron Agreement, the Company has the exclusive right to manufacture, sell and distribute any prescription drug or medical device and certain other products made with the hydrogel polymer technology. Hydron Technologies retained an exclusive, worldwide license to manufacture, market or use products composed of, or produced with the use of, the hydrogel polymer technology in certain consumer and oral health fields. Neither party is prohibited from manufacturing, exploiting, using or transferring the rights to any new non-prescription drug product containing the hydrogel polymer technology, subject to certain exceptions, for limited exclusivity periods. Subject to certain conditions and exceptions, the Company is obligated to supply certain types of polymer to Hydron Technologies and Hydron Technologies is obligated to purchase such products from the Company. Under the Hydron Agreement, the Company also had the title to the Hydron® trademark. Recently, the Company decided to stop using the Hydron® trademark and transferred the title to such trademark to Hydron Technologies pursuant to the Hydron Agreement. This agreement continues indefinitely, unless terminated earlier by the parties. Each party may owe royalties up to 5% to the other party on certain products under certain conditions.

#### *BioDelivery Sciences International, Inc.*

In January 2012, the Company signed a worldwide license and development agreement (the BioDelivery Agreement) with BioDelivery Sciences International, Inc. (BioDelivery) for the exclusive rights to develop and commercialize BEMA® Buprenorphine. BEMA® Buprenorphine is a transmucosal form of buprenorphine, a partial mu-opiate receptor agonist, which incorporates a bioerodible mucoadhesive (BEMA®) technology. BEMA® Buprenorphine is currently in Phase III trials for the treatment of moderate to severe chronic pain. The Company made an upfront payment to BioDelivery for \$30.0 million, which was expensed as Research and development in the first quarter of 2012. During the first quarter of 2012, \$15.0 million of additional costs were incurred related to

the achievement of certain regulatory milestones and were recorded as Research and development expense. We paid this amount in the second quarter of 2012. In the future, Endo could be obligated to pay royalties based on net sales of BEMA<sup>®</sup> Buprenorphine and commercial and regulatory milestone payments of up to approximately \$135.0 million. Endo may terminate the BioDelivery Agreement at any time upon six months written notice. Unless terminated earlier, the BioDelivery Agreement shall expire, on a country by country basis, upon the later to occur of 10 years from the date of first commercial sale in a particular country or the date on which the last valid claim of the applicable BioDelivery patents in a particular country has expired or been invalidated or found unenforceable.

#### *Orion Corporation*

In January 2011, the Company entered into a Discovery, Development and Commercialization Agreement (the 2011 Orion Agreement) with Orion Corporation (Orion) to exclusively co-develop products for the treatment of certain cancers and solid tumors. Under the terms of the 2011 Orion Agreement, Endo and Orion each contributed four research programs to the collaboration to be conducted pursuant to the agreement. The development of each research program shall initially be the sole responsibility of the contributing party. However, upon the achievement of certain milestones, the non-contribution party shall have the opportunity to, at its option, obtain a license to jointly develop and commercialize any research program contributed by the other party for amounts defined in the 2011 Orion Agreement. Subject to certain limitations, upon the first commercial sale of any successfully launched jointly developed product, Endo shall be obligated to pay royalties to Orion based on net sales of the corresponding product in North America (the Endo territory) and Orion shall be obligated to pay royalties to Endo on net sales of the corresponding product in certain European countries (the Orion territory). The 2011 Orion Agreement shall expire in January 2016, unless terminated early or extended pursuant to the terms of the agreement. In January 2011, Endo exercised its option to obtain a license to jointly develop and commercialize Orion's Anti-Androgen program focused on castration-resistant prostate cancer, one of Orion's four contributed research programs, and made a corresponding payment to Orion for \$10.0 million, which was expensed as Research and development in the first quarter of 2011.

#### *EpiCept Corp.*

In December 2003, we entered into a license granting us exclusive, worldwide rights to certain patents of EpiCept Corp. (EpiCept) as well as exclusive, worldwide commercialization rights to EpiCept's LidoPAIN<sup>®</sup> BP product (EpiCept Agreement). The EpiCept Agreement provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept's LidoPAIN<sup>®</sup> BP product. Under this Agreement, we made an upfront payment to EpiCept of \$7.5 million which we capitalized as an intangible asset representing the fair value of the exclusive right and the patents. We are amortizing this intangible asset over its useful life of thirteen years. EpiCept has also retained an option to co-promote the LidoPAIN<sup>®</sup> BP product. Milestone payments made by Endo under this agreement, including regulatory milestones and sales thresholds, could total up to \$82.5 million. In addition, the EpiCept Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The EpiCept Agreement generally lasts until the underlying patents expire. In January 2009, EpiCept announced that it was discontinuing all drug discovery activities including the development of LidoPAIN<sup>®</sup> BP. However, the Company intends to maintain its patent rights conveyed by the EpiCept Agreement.

#### *Other*

We have entered into certain other collaboration and discovery agreements with third parties for the development of pain management and other products. These agreements require us to share in the development costs of such products and grant marketing rights to us for such products.

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

## NOTE 8. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment is comprised of the following for the years ended December 31 (in thousands):

	2012	2011
Land and buildings .....	\$ 214,860	\$ 121,573
Machinery and equipment .....	127,060	113,992
Leasehold improvements .....	31,214	36,233
Computer equipment and software .....	92,582	73,302
Assets under capital lease .....	6,607	5,461
Furniture and fixtures .....	9,378	16,365
Assets under construction .....	50,217	42,516
Property, plant and equipment, gross .....	531,918	409,442
Less accumulated depreciation .....	(146,250)	(111,711)
Property, plant and equipment, net .....	<u>\$ 385,668</u>	<u>\$ 297,731</u>

Depreciation expense, including expense related to assets under capital lease, was \$57.7 million, \$45.8 million and \$23.8 million for the years ended December 31, 2012, 2011 and 2010, respectively.

In the fourth quarter of 2012, the Company recorded impairment charges totaling \$5.7 million to completely write off certain miscellaneous property, plant and equipment where the Company deemed the carrying amounts to no longer be recoverable. These charges were related to our ongoing efforts to improve our operating efficiency and to consolidate certain locations, including our generics research and development operations and our corporate headquarters. These charges are included in the Asset impairment charges line item in our 2012 Consolidated Statement of Operations.

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

This lease is accounted for as a direct financing arrangement whereby the Company recorded, over the construction period, the full cost of the asset in Property, plant and equipment, net. At December 31, 2012 and 2011, the Company capitalized \$91.1 million and \$5.5 million, respectively, as Property, plant and equipment related to this arrangement. The lease asset was included as a component of Land and buildings in the table above at December 31, 2012 and as Assets under construction at December 31, 2011. The building and leasehold improvements will be depreciated over the initial lease term of 12 years. See Note 15. Commitments and Contingencies for further details on the lease agreement.

## NOTE 9. GOODWILL AND OTHER INTANGIBLES

Goodwill represents the excess of purchase price over the fair value of net assets acquired. Other indefinite-lived intangible assets consist primarily of the fair value of in-process research and development assets acquired in a business combination.

### Goodwill

Changes in the carrying amount of our goodwill for the year ended December 31, 2012 were as follows:

	Carrying Amount				Total Consolidated
	Endo Pharmaceuticals	Qualitest	AMS	HealthTronics	
December 31, 2011 .....	\$ 290,793	\$ 275,201	\$ 1,791,876	\$ 200,171	\$ 2,558,041
Goodwill acquired during the period .....	—	—	—	7,717	7,717
Measurement period adjustments .....	—	—	2,225	2,789	5,014
Effect of currency translation .....	—	—	999	—	999
Goodwill impairment charges .....	—	—	(507,528)	(49,892)	(557,420)
December 31, 2012 .....	<u>\$ 290,793</u>	<u>\$ 275,201</u>	<u>\$ 1,287,572</u>	<u>\$ 160,785</u>	<u>\$ 2,014,351</u>

The goodwill acquired during the period relates to immaterial acquisitions in 2012.

## Other Intangible Assets

Our other intangible assets consist of the following at December 31, (in thousands):

	2012	2011
Indefinite-lived intangibles:		
In-process research and development .....	\$ 165,400	\$ 221,400
<i>Total indefinite-lived intangibles</i> .....	<u>\$ 165,400</u>	<u>\$ 221,400</u>
Definite-lived intangibles:		
Licenses (weighted average life of 9 years) .....	\$ 605,850	\$ 647,239
Less accumulated amortization .....	(329,120)	(256,903)
Licenses, net .....	<u>\$ 276,730</u>	<u>\$ 390,336</u>
Customer relationships (weighted average life of 16 years) .....	160,210	159,632
Less accumulated amortization .....	(15,682)	(5,460)
Customer relationships, net .....	<u>\$ 144,528</u>	<u>\$ 154,172</u>
Tradenames (weighted average life of 22 years) .....	91,600	91,600
Less accumulated amortization .....	(8,742)	(4,142)
Tradenames, net .....	<u>\$ 82,858</u>	<u>\$ 87,458</u>
Developed technology (weighted average life of 16 years) .....	1,694,336	1,774,300
Less accumulated amortization .....	(266,350)	(125,695)
Developed technology, net .....	<u>\$ 1,427,986</u>	<u>\$ 1,648,605</u>
Other (weighted average life of 13 years) .....	1,742	2,200
Less accumulated amortization .....	(271)	(47)
Other, net .....	<u>\$ 1,471</u>	<u>\$ 2,153</u>
<i>Total definite-lived intangibles, net (weighted average life of 15 years)</i> .....	<u>\$ 1,933,573</u>	<u>\$ 2,282,724</u>
Other intangibles, net .....	<u>\$ 2,098,973</u>	<u>\$ 2,504,124</u>

As of December 31, 2012, the weighted average amortization period for our definite-lived intangible assets in total was approximately 15 years.

Amortization expense for the twelve month periods ended December 31, 2012, 2011 and 2010 was \$227.9 million, \$191.6 million and \$84.6 million, respectively. Estimated amortization of intangibles for the 5 years subsequent to December 31, 2012 is as follows (in thousands):

2013 .....	\$ 182,302
2014 .....	\$ 156,473
2015 .....	\$ 151,187
2016 .....	\$ 149,959
2017 .....	\$ 138,488

Changes in the gross carrying amount of our other intangible assets for the year ended December 31, 2012 were as follows:

	Gross Carrying Amount
December 31, 2011 .....	\$ 2,896,371
Voltaren® Gel license extension .....	21,346
Patents acquired .....	12,075
Asset impairment charges .....	(205,349)
Effect of currency translation .....	579
Other .....	(5,884)
December 31, 2012 .....	<u>\$ 2,719,138</u>

## **Impairments**

We assess goodwill and other indefinite-lived intangible assets for impairment annually, or more frequently whenever events or changes in circumstances indicate that the asset may be impaired. For goodwill, the assessment considers if the carrying amount of a reporting unit exceeds its fair value. If so, an impairment charge is recognized for the excess of the carrying amount of the reporting unit's goodwill over its implied fair value. For indefinite-lived intangible assets, the assessment considers if the carrying amount of the asset exceeds its fair value. If so, an impairment charge is recognized for the excess. Any such impairments are recorded in the Asset impairment charges line of our Consolidated Statements of Operations.

During the third quarter of 2012, we changed our annual goodwill impairment test date from January 1 to October 1. The change in the annual date for impairment testing required a test as of October 1, 2012 so that no more than 12 months elapsed between annual tests. We completed this test and the new date did not have an effect on delaying, accelerating or avoiding an impairment charge. The selection of October 1 as the annual testing date for the impairment of goodwill is preferable as it aligns the timing of the annual impairment test with the completion of our planning and budgeting process, which will allow us to utilize the updated business plans that result from the budget process to estimate the fair value of our reporting units and do so on a more timely basis. The selection of October 1 as the annual testing date will also move the testing outside of our annual year-end financial reporting process when our resources are more constrained. During the third quarter of 2012, we also changed our annual indefinite-lived intangible asset test date to October 1.

Due to significant judgments and estimates that are utilized in an impairment analysis, we determined it was impracticable to objectively determine, without the use of hindsight, the assumptions that would have been used as of each October 1 for periods before October 1, 2012. As such, we will prospectively apply the changes in the annual goodwill and indefinite-lived intangible asset impairment testing dates beginning on October 1, 2012.

As of October 1, 2012, we completed our annual impairment tests. Based upon recent market conditions, and, in some cases, a lack of comparable market transactions for similar assets, Endo determined that an income approach using a discounted cash flow model was an appropriate valuation methodology to determine each reporting unit's fair value for goodwill impairment testing and each asset's fair value for indefinite-lived intangible asset impairment testing. Our discounted cash flow models are highly reliant on various assumptions, including estimates of future cash flows (including long-term growth rates), discount rates, and expectations about variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. Discount rates applied to the estimated cash flows for our October 1, 2012 annual goodwill and indefinite-lived intangible assets impairment test ranged from 9.5% to 17.5%, depending on the overall risk associated with the particular assets and other market factors. We believe the discount rates and other inputs and assumptions are consistent with those that a market participant would use.

In order to assess the reasonableness of the calculated fair values of our reporting units, we also compare the sum of the reporting units' fair values to Endo's market capitalization and calculate an implied control premium (the excess sum of the reporting unit's fair values over the market capitalization). The Company evaluates the control premium by comparing it to control premiums of recent comparable market transactions, as applicable. If the control premium is not reasonable in light of comparable recent transactions, we reevaluate the fair value estimates of the reporting units by adjusting discount rates and/or other assumptions. This reevaluation could correlate to lower implied fair values for certain or all of the Company's reporting units.

The results of our Step I analyses showed that the fair values of the Pain, UEO and Generics reporting units exceeded their respective carrying amounts. The excess of fair value over carrying amount for each of these reporting units as of October 1, 2012, ranged from approximately 70% to more than 100% of carrying amount or \$355.8 million to \$1.5 billion, respectively. The results of the analysis for the Urology Services reporting unit, which held \$139.9 million of goodwill as of October 1, 2012, showed fair value that exceeded its carrying amount by 8% or \$16.4 million. The Urology Services reporting unit is part of the HealthTronics segment.

The results of the Step I analyses for the AMS, Anatomical Pathology Services, and HITS reporting units showed that the fair values of those reporting units were lower than their respective carrying amounts, thus requiring a Step II analysis for each reporting unit. The declines in the fair values of the AMS, Anatomical Pathology Services, and HITS reporting units, as well as fair value changes for other assets and liabilities in the Step II goodwill impairment test, resulted in an implied fair value of goodwill below the carrying amount of the goodwill for these reporting units. Accordingly, we recorded combined pre-tax non-cash goodwill impairment charges in the Consolidated Statement of Operations totaling \$557.4 million in 2012.

A summary of goodwill and other intangible asset impairment charges recognized for the three years ended December 31, 2012 is included below by reportable segment.



## ***Endo Pharmaceuticals Segment***

As part of our year-end financial close and reporting process, the Company concluded that impairment assessments were required to evaluate the recoverability of certain definite-lived intangible assets associated with our Supprelin<sup>®</sup> and Vantas<sup>®</sup> franchises in certain non-U.S. markets. After performing these assessments, we recorded pre-tax non-cash impairment charges of \$2.0 million and \$3.7 million, respectively, representing the remaining carrying amounts of these assets.

The Company also reviewed its in-process research and development indefinite-lived intangible assets in connection with its annual impairment testing. As a result of market and potential regulatory changes in certain non-U.S. markets, we determined that our European Valstar<sup>®</sup> asset and our Asian Sanctura<sup>®</sup> asset were not recoverable. In the fourth quarter of 2012, we recorded pre-tax non-cash impairment charges of \$2.0 million, and \$8.0 million, respectively, representing the carrying amounts of these assets.

Pursuant to the Sanctura XR<sup>®</sup> Amended and Restated License, Commercialization and Supply Agreement with Allergan USA, Inc. (Allergan), the Company receives royalties based on net sales of Sanctura XR<sup>®</sup> made by Allergan. In March 2009, Watson Pharmaceuticals, Inc. (now doing business as Actavis, Inc. and referred to herein as Watson or Actavis) filed an Abbreviated New Drug Application (ANDA) seeking FDA approval to market generic versions of Sanctura XR<sup>®</sup> before the expiration of Allergan's patents listed in the Orange Book. Subsequent to Watson's ANDA filing, Sandoz Inc. and Paddock Laboratories, Inc. (acquired by Perrigo Company in August 2011) also filed ANDAs for a generic version of Sanctura XR<sup>®</sup>. In April 2012, the U.S. District Court for the District of Delaware ruled that five patents covering Allergan's Sanctura XR<sup>®</sup> (trospium chloride) extended-release capsules were invalid. The Company appealed this ruling, and subsequently in June 2012, our appeal was dismissed.

As part of our first quarter 2012 financial close and reporting process, the Company concluded that an impairment assessment was required to evaluate the recoverability of the indefinite-lived intangible asset. The Company assessed the recoverability of this asset and determined the fair value of the Sanctura XR<sup>®</sup> intangible asset to be \$21.6 million at March 31, 2012. Accordingly, the Company recorded a pre-tax non-cash impairment charge of \$40.0 million in March 2012, representing the difference between the carrying amount of the intangible asset and its estimated fair value.

In October 2012, Watson announced that it had received FDA approval for its generic version of Sanctura XR<sup>®</sup> and that it intended to begin shipping its product immediately. As a result, the Company reevaluated the recoverability of the asset and determined that an impairment existed. The fair value of the Sanctura XR<sup>®</sup> intangible asset was determined to be \$5.0 million at September 30, 2012. Accordingly, the Company recorded an additional pre-tax non-cash impairment charge of \$11.2 million in September 2012. The remaining net book value was amortized in its entirety by December 31, 2012, commensurate with the expected rate of erosion due to generic competition.

In early 2012, the Company terminated Penwest's A0001 development program after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, during the fourth quarter of 2011 we recorded a pre-tax, non-cash impairment charge of \$1.6 million to write off this intangible asset in its entirety.

In May 2010, Teva Pharmaceutical Industries Ltd. terminated the pagoclone development and licensing arrangement with the Company upon the completion of the Phase IIb study. As a result, the Company concluded that there was a decline in the fair value of the corresponding indefinite-lived intangible asset. Accordingly, we recorded a \$13.0 million impairment charge in 2010.

On December 27, 2011, the Company terminated its pagoclone development program after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, we recorded a pre-tax, non-cash impairment charge of \$8.0 million in 2011 to write off the remaining intangible asset in its entirety.

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

On November 11, 2011, the Company separately decided to terminate development of the octreotide implant for the treatment of acromegaly after conducting an in-depth review of the Company's research and development activities, including an analysis of research and development priorities, focus and available resources for current and future projects and the commercial potential for the product. Accordingly, we recorded a pre-tax non-cash impairment charge of \$9.0 million in 2011 to completely write-off the octreotide – acromegaly intangible asset.

### ***Qualitest Segment***

During the fourth quarter of 2011, the Company received a deficiency from the FDA on an ANDA submission for one of its lead assets in its Qualitest Pharmaceuticals IPR&D portfolio. Subsequently, in early 2012, the Company terminated its development program for this asset as a result of the regulatory challenges and changes in the development timeline resulting from the FDA's request. In addition, as a result of changes in market conditions since the acquisition date, there has been a significant deterioration in the commercial potential for this product. Accordingly, we recorded a pre-tax non-cash impairment charge of \$71.0 million in 2011 to write off the intangible asset in its entirety.

### ***AMS Segment***

Based on the results of the Company's Step II analysis for the AMS reporting unit, we recorded a pre-tax, non-cash goodwill impairment charge in the Consolidated Statement of Operations for \$507.5 million, representing the difference between the implied fair value of the reporting unit's goodwill and its carrying amount as of October 1, 2012. The decline in the fair value for the AMS reporting unit is the result of lower projected revenue growth and profitability levels. The lower projected operating results reflect changes in the assumptions related to organic revenue growth, market trends, business mix, cost structure and other expectations about the anticipated short-term and long-term operating results of the AMS reporting unit identified as part of our fourth quarter 2012 strategic planning and budgeting processes.

As a result of the Step II analysis, we also determined that the carrying amounts of the women's health developed technology intangible asset and one of the AMS, Inc. IPR&D intangible assets were impaired. This determination was based primarily on lower than initially expected revenue and profitability levels over a sustained period of time and downward revisions to management's short-term and long-term forecasts for the AMS women's health product line. Accordingly, we recorded a pre-tax non-cash impairment charge of \$128.5 million to impair the women's health developed technology intangible asset in its entirety. We also recorded a pre-tax non-cash impairment charge of \$4.0 million to impair the IPR&D asset, representing the difference between the fair value and the carrying amount.

During the second quarter of 2012, as a result of market and potential regulatory changes affecting the commercial potential in the U.S. for one of the AMS, Inc. IPR&D assets, the Company determined that the asset's carrying amount was no longer fully recoverable. Accordingly, in the second quarter of 2012, we recorded a pre-tax non-cash impairment charge of \$3.0 million, representing the difference between the fair value and the carrying amount.

### ***HealthTronics Segment***

Based on the results of the Company's Step II analysis for the Anatomical Pathology Services and HITS reporting units, we recorded pre-tax, non-cash goodwill impairment charges in the Consolidated Statement of Operations for \$24.8 million and \$25.1 million, respectively, representing the difference between the implied fair value of each reporting unit's goodwill and the respective carrying amounts as of October 1, 2012. The declines in the fair values for these reporting units resulted from lower projected revenue growth and profitability levels for each respective business. The lower projected operating results reflect changes in the assumptions related to organic revenue growth, new product development, strategic business changes, cost structure, market trends, business mix and other expectations about the anticipated short-term and long-term operating results of these reporting units identified as part of our fourth quarter 2012 strategic planning and budgeting processes.

As a result of the HITS Step II analysis, we also determined that the carrying amounts of certain HITS intangible assets were impaired. This determination was based primarily on lower than initially expected revenue and profitability levels over an expected sustained period of time and downward revisions to management's short-term and long-term forecasts for the HITS reporting unit. Accordingly, we recorded pre-tax non-cash impairment charges of \$3.0 million on these intangible assets, representing the difference between the fair values and the carrying amounts.

## NOTE 10. OTHER COMPREHENSIVE INCOME (LOSS)

The following table presents the tax effects allocated to each component of Other comprehensive income (loss) for the years ended December 31, (in thousands):

	2012			2011			2010		
	Before-Tax Amount	Tax (Expense) Benefit	Net-of-Tax Amount	Before-Tax Amount	Tax Benefit (Expense)	Net-of-Tax Amount	Before-Tax Amount	Tax (Expense) Benefit	Net-of-Tax Amount
Net unrealized gain (loss) on securities:									
Unrealized gains (losses) arising during the period.....	\$ 1,441	\$ (38)	\$ 1,403	\$ (3,796)	\$ 1,462	\$ (2,334)	\$ 1,347	\$ (627)	\$ 720
Less: reclassification adjustments for losses realized in net (loss) income.....	—	—	—	3,190	(1,275)	1,915	—	—	—
Net unrealized gains (losses).....	1,441	(38)	1,403	(606)	187	(419)	1,347	(627)	720
Foreign currency translation gain (loss).....	2,104	60	2,164	(7,751)	(320)	(8,071)	—	—	—
Fair value adjustment on derivatives designated as cash flow hedges:									
Fair value adjustment on derivatives designated as cash flow hedges arising during the period.....	(1,892)	680	(1,212)	517	(301)	216	—	—	—
Less: reclassification adjustments for cash flow hedges settled and included in net (loss) income.....	436	(157)	279	(2)	1	(1)	—	—	—
Net unrealized fair value adjustment on derivatives designated as cash flow hedges.....	(1,456)	523	(933)	515	(300)	215	—	—	—
Other comprehensive income (loss).....	<u>\$ 2,089</u>	<u>\$ 545</u>	<u>\$ 2,634</u>	<u>\$ (7,842)</u>	<u>\$ (433)</u>	<u>\$ (8,275)</u>	<u>\$ 1,347</u>	<u>\$ (627)</u>	<u>\$ 720</u>

## NOTE 11. ACCRUED EXPENSES

Accrued expenses are comprised of the following for each of the years ended December 31 (in thousands):

	2012	2011
Chargebacks.....	\$ 61,302	\$ 116,821
Returns and allowances.....	85,815	90,075
Rebates.....	327,926	308,911
Other sales deductions.....	17,780	21,342
Accruals for litigation-related and other contingencies.....	484,378	11,263
Other.....	193,744	184,419
Total.....	<u>\$ 1,170,945</u>	<u>\$ 732,831</u>

**NOTE 12. OTHER INCOME, NET**

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

	2012	2011	2010
Gain on trading securities .....	—	—	(15,420)
Loss on auction-rate securities rights.....	—	—	15,659
Other income, net.....	(193)	(3,268)	(2,172)
Other income, net.....	<u>\$ (193)</u>	<u>\$ (3,268)</u>	<u>\$ (1,933)</u>

**NOTE 13. INCOME TAXES**

The components of our (loss) income before income tax by geography were as follows (in thousands):

	2012	2011	2010
United States .....	\$ (735,381)	\$ 349,174	\$ 420,698
International .....	(6,202)	2,517	—
Total (loss) income before income tax.....	<u>\$ (741,583)</u>	<u>\$ 351,691</u>	<u>\$ 420,698</u>

Income tax consists of the following for each of the years ended December 31 (in thousands):

	2012	2011	2010
<b>Current:</b>			
Federal .....	\$ 120,543	\$ 153,421	\$ 128,793
Foreign.....	2,398	1,954	—
State .....	14,420	27,140	22,451
Total current income tax .....	<u>137,361</u>	<u>182,515</u>	<u>151,244</u>
<b>Deferred:</b>			
Federal .....	(181,608)	(68,110)	(8,139)
Foreign.....	(1,025)	(815)	—
State .....	(7,841)	(18,546)	(6,871)
Total deferred income tax .....	<u>(190,474)</u>	<u>(87,471)</u>	<u>(15,010)</u>
Excess tax benefits (shortfall) of stock options exercised .....	2,537	4,015	(1,051)
Valuation allowance.....	(2,986)	10,567	(1,505)
Total income tax.....	<u>\$ (53,562)</u>	<u>\$ 109,626</u>	<u>\$ 133,678</u>

A reconciliation of income tax at the federal statutory income tax rate to the total income tax provision for each of the years ended December 31 (in thousands):

	2012	2011	2010
Federal income tax at the statutory rate .....	\$ (259,554)	\$ 123,092	\$ 147,245
Noncontrolling interests.....	(18,311)	(19,058)	(9,805)
State income tax, net of federal benefit .....	7,407	7,590	8,447
Research and development credit .....	—	(3,883)	(3,667)
Orphan drug credit .....	—	(2,013)	(904)
Uncertain tax positions .....	15,617	(6,741)	1,148
Foreign rate differential .....	4,181	577	—
Goodwill asset impairment charges .....	187,320	—	—
Change in valuation allowance .....	(5,771)	8,984	—
Effect of permanent items:			
Branded prescription drug fee .....	6,108	6,307	—
Changes in contingent consideration .....	—	(2,215)	(15,673)
Domestic production activities deduction .....	(5,194)	(10,626)	(4,357)
Transaction-related expenses .....	349	2,843	9,612
Fines and penalties.....	11,202	17	5
Other .....	3,084	4,752	1,627
Total income tax.....	<u>\$ (53,562)</u>	<u>\$ 109,626</u>	<u>\$ 133,678</u>

The tax effects of temporary differences that comprise the current and non-current deferred income tax amounts shown on the balance sheets for the years ended December 31 are as follows (in thousands):

	2012	2011
Deferred tax assets:		
Accrued expenses.....	\$ 261,234	\$ 167,565
Compensation related to stock options .....	33,148	26,125
Purchased in-process research and development.....	—	673
Net operating loss carryforward.....	125,000	178,524
Impairment on capital assets .....	9,590	16,047
Research and development credit carryforward.....	16,188	18,206
Uncertain tax positions.....	9,584	8,684
Prepaid royalties.....	1,811	5,524
Other.....	46,547	23,496
Total gross deferred income tax assets.....	<u>503,102</u>	<u>444,844</u>
Deferred tax liabilities:		
Property, plant, equipment, and intangibles.....	(684,194)	(815,566)
Non-cash interest expense.....	(8,331)	(10,315)
Total gross deferred income tax liabilities.....	<u>(692,525)</u>	<u>(825,881)</u>
Valuation allowance .....	(18,551)	(21,537)
Net deferred income tax liability.....	<u>\$ (207,974)</u>	<u>\$ (402,574)</u>

At December 31, 2012, our NOLs and research and development credit carryforwards were related to multiple tax jurisdictions, including federal and various state jurisdictions, which expire at intervals between 2013 and 2033. At December 31, 2012, we had gross federal net operating loss carry forwards of \$324.9 million.

In general, it is the practice and intention of the Company to reinvest the earnings of its non-U.S. subsidiaries in those operations. As of December 31, 2012, the Company has not made a provision for U.S. or additional foreign withholding taxes on approximately \$85.7 million of the excess of the amount for financial reporting over the tax basis of investments in foreign subsidiaries that are essentially permanent in duration. Generally, such amounts become subject to U.S. taxation upon the remittance of dividends and under certain other circumstances. It is not practicable to estimate the amount of deferred tax liability related to investments in these foreign subsidiaries.

We evaluate our tax positions using the prescribed two-step process. Step 1 – Recognition, requires the Company to determine whether a tax position, based solely on its technical merits, has a likelihood of more than 50 percent (more-likely-than-not) that the tax position taken will be sustained upon examination. Step 2 – Measurement, which is only addressed if Step 1 has been satisfied, requires the Company to measure the tax benefit as the largest amount of benefit, determined on a cumulative probability basis that is more-likely-than-not to be realized upon ultimate settlement.

The Company records accrued interest and penalties related to unrecognized tax benefits in income tax expense. Interest and penalties resulted in an income tax expense of \$0.5 million in 2012, income tax benefit of \$3.4 million in 2011 and income tax expense of \$1.0 million in 2010.

A reconciliation of the change in the unrecognized tax benefits (UTB) balance from January 1, 2010 to December 31, 2012 is as follows (in thousands):

	<b>Unrecognized Tax Benefit Federal, State, and Foreign Tax</b>
UTB Balance at January 1, 2010 .....	\$ 27,103
Gross additions for current year positions .....	6,293
Gross additions for prior period positions .....	—
Gross reductions for prior period positions .....	(2,887)
Decrease due to settlements .....	(351)
Decrease due to lapse of statute of limitations .....	(679)
Additions related to acquisitions .....	9,702
UTB Balance at December 31, 2010 .....	<u>\$ 39,181</u>
Gross additions for current year positions .....	2,082
Gross additions for prior period positions .....	133
Gross reductions for prior period positions .....	(1,078)
Decrease due to settlements .....	(13,790)
Decrease due to lapse of statute of limitations .....	(4,220)
Additions related to acquisitions .....	18,320
UTB Balance at December 31, 2011 .....	<u>\$ 40,628</u>
Gross additions for current year positions .....	24,088
Gross additions for prior period positions .....	285
Gross reductions for prior period positions .....	(632)
Decrease due to lapse of statute of limitations .....	(5,452)
UTB Balance at December 31, 2012 .....	<u><u>\$ 58,917</u></u>
Accrued interest and penalties .....	<u>6,763</u>
Total UTB balance including accrued interest and penalties .....	<u><u>\$ 65,680</u></u>
Current portion (included in accrued expenses) .....	\$ —
Non-current portion (included in other liabilities) .....	\$ 65,680

The Company and its subsidiaries are routinely examined by various taxing authorities, which have proposed adjustments to tax for issues such as certain tax credits and the deductibility of certain expenses. While it is possible that one or more of these examinations may be resolved within the next twelve months, it is not anticipated that the total amount of unrecognized tax benefits will significantly increase or decrease within the next twelve months. In addition, the expiration of statutes of limitations for various jurisdictions is expected to reduce the unrecognized tax benefits balance by an insignificant amount.

The Company files income tax returns in the U.S. Federal jurisdiction, and various state and foreign jurisdictions. The Company is subject to U.S. Federal, state and local, and non-U.S. income tax examinations by tax authorities. In general, the Company is no longer subject to U.S. Federal, state and local, and foreign income tax examinations by tax authorities for years before 2005. The Company believes that it has provided adequately for uncertain tax positions relating to all open tax years by tax jurisdiction.

The total amount of gross unrecognized tax benefits as of December 31, 2012 is \$65.7 million, including interest and penalties, of which \$54.9 million, if recognized, would affect the Company's effective tax rate. This liability is included in Other liabilities in the

Consolidated Balance Sheets. The change in the total amount of unrecognized tax benefits impacted the Company's results of operations for the year ended December 31, 2012 due to the establishment of an uncertainty on certain litigation-related and other contingent matters, partially offset by a release of reserves due to the expiration of statutes of limitation. The change in the total amount of unrecognized tax benefits did not have a material impact on our financial position as of December 31, 2012. Any future adjustments to our uncertain tax position liability will result in an impact to our income tax provision and effective tax rate.

It is expected that the amount of unrecognized tax benefits will change during the next twelve months; however, the Company does not anticipate any adjustments that would lead to a material impact on our results of operations or our financial position.

## **NOTE 14. STOCKHOLDERS' EQUITY**

### ***Common Stock***

The total number of shares of common stock, \$0.01 par value, that the Company is authorized to issue is 350,000,000.

Subject to certain limitations, we are permitted to pay dividends under our indebtedness. See Note 19. Debt for further details.

### ***Preferred Stock***

The Board of Directors may, without further action by the stockholders, issue a series of Preferred Stock and fix the rights and preferences of those shares, including the dividend rights, dividend rates, conversion rights, exchange rights, voting rights, terms of redemption, redemption price or prices, liquidation preferences, the number of shares constituting any series and the designation of such series. As of December 31, 2012, no shares of Preferred Stock have been issued.

### ***Stock-Based Compensation***

#### ***Endo Health Solutions Inc. 2000, 2004, 2007, and 2010 Stock Incentive Plans and the Endo Health Solutions Inc. Assumed Stock Incentive Plan***

On August 11, 2000, we established the Endo Health Solutions Inc. 2000 Stock Incentive Plan. The 2000 Stock Incentive Plan reserved an aggregate of 4,000,000 shares of common stock of the Company for issuance to employees, officers, directors and consultants. The 2000 Stock Incentive Plan provided for the issuance of stock options, restricted stock, stock bonus awards, stock appreciation rights or performance awards. The 2000 Stock incentive Plan expired in 2010.

In May 2004, our stockholders approved the Endo Health Solutions Inc. 2004 Stock Incentive Plan. The maximum number of shares of Company stock reserved for issuance under the 2004 Stock Incentive Plan is 4,000,000 shares. The 2004 Plan provides for the grant of stock options, stock appreciation rights, shares of restricted stock, performance shares, performance units or other share-based awards that may be granted to executive officers and other employees of the Company, including officers and directors who are employees, to non-employee directors and to consultants to the Company.

In May 2007, our stockholders approved the Endo Health Solutions Inc. 2007 Stock Incentive Plan. The maximum number of shares of Company stock reserved for issuance under the 2007 Stock Incentive Plan is 7,000,000 shares (subject to adjustment for certain transactions), but in no event may the total number of shares of Company stock subject to awards awarded to any one participant during any tax year of the Company exceed 750,000 shares (subject to adjustment for certain transactions).

In May 2010, our stockholders approved the Endo Health Solutions Inc. 2010 Stock Incentive Plan. The maximum number of shares of Company stock reserved for issuance under the Plan includes 8,000,000 shares plus the number of shares of Company stock reserved but unissued under the Company's 2004 and 2007 Stock Incentive Plans as of April 28, 2010 and may be increased to include the number of shares of Company stock that become available for reuse under these plans following April 28, 2010, subject to adjustment for certain transactions. Notwithstanding the foregoing, of the 8,000,000 shares originally reserved for issuance under this Plan, no more than 4,000,000 of such shares shall be issued as awards, other than options, that are settled in the Company's stock. In no event may the total number of shares of Company stock subject to awards awarded to any one participant during any tax year of the Company, exceed 1,000,000 shares (subject to adjustment for certain transactions).

In June 2011, in connection with our acquisition of AMS, Inc., we assumed the AMS 2005 Stock Incentive Plan (now known as the Endo Health Solutions Inc. Assumed Stock Incentive Plan). As of the AMS, Inc. Acquisition Date, the number of shares of Company stock reserved for issuance under the Plan was 5,269,152.

At December 31, 2012, approximately 20.1 million shares were reserved for future issuance upon exercise of options granted or to be granted under the Endo 2004, 2007, and 2010 Stock Incentive Plans and the Endo Health Solutions Inc. Assumed Stock Incentive Plan. As of December 31, 2012, stock options, restricted stock awards, performance stock units and restricted stock units have been granted under the Stock Incentive Plans.

All stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as an expense in the income statement over the requisite service period.



The Company recognized stock-based compensation expense of \$59.4 million, \$46.0 million and \$22.9 million during the years ended December 31, 2012, 2011 and 2010, respectively. As of December 31, 2012, the total remaining unrecognized compensation cost related to all non-vested stock-based compensation awards amounted to \$81.8 million. This expected cost does not include the impact of any future stock-based compensation awards.

Presented below is the allocation of stock-based compensation as recorded in our Consolidated Statements of Operations for the years ended December 31 (in thousands).

	2012	2011	2010
Selling, general and administrative expenses .....	\$ 51,846	\$ 39,305	\$ 19,229
Research and development expenses .....	6,672	6,214	3,680
Cost of revenues.....	877	494	—
Total stock-based compensation expense.....	<u>\$ 59,395</u>	<u>\$ 46,013</u>	<u>\$ 22,909</u>

### Stock Options

During the years ended December 31, 2012, 2011 and 2010, the Company granted stock options to employees of the Company as part of their annual stock compensation award and, in certain circumstances, upon their commencement of service with the Company. For all of the Company's stock-based compensation plans, the fair value of each option grant was estimated at the date of grant using the Black-Scholes option-pricing model. Black-Scholes utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield (which is assumed to be zero, as the Company has not paid cash dividends to date and does not currently expect to pay cash dividends) and the expected term of the option. Expected volatilities utilized in the model are based mainly on the historical volatility of the Company's stock price over a period commensurate with the expected life of the share option as well as other factors. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. We estimate the expected term of options granted based on our historical experience with our employees' exercise of stock options and other factors.

A summary of the activity under the Endo 2000, 2004, 2007, and 2010 Stock Incentive Plans and the Endo Health Solutions Inc. Assumed Stock Incentive Plan (since June 18, 2011) for the three-year period ended December 31, 2012 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding as of January 1, 2010.....	5,158,541	\$ 22.84		
Granted .....	2,210,537	\$ 22.23		
Exercised.....	(965,013)	\$ 21.64		
Forfeited.....	(305,033)	\$ 21.72		
Expired.....	(207,632)	\$ 30.44		
Outstanding as of December 31, 2010.....	5,891,400	\$ 22.60		
Granted .....	3,865,575	\$ 29.66		
Exercised.....	(1,274,280)	\$ 22.80		
Forfeited.....	(335,049)	\$ 26.54		
Expired.....	(32,179)	\$ 26.49		
Outstanding as of December 31, 2011.....	8,115,467	\$ 25.79		
Granted .....	2,237,081	\$ 34.58		
Exercised.....	(853,794)	\$ 22.66		
Forfeited.....	(613,613)	\$ 31.31		
Expired.....	(60,436)	\$ 27.61		
Outstanding as of December 31, 2012.....	8,824,705	\$ 27.92	6.60	\$ 18,070,054
Vested and expected to vest as of December 31, 2012.....	8,360,315	\$ 27.67	6.49	\$ 17,817,892
Exercisable as of December 31, 2012.....	3,932,954	\$ 24.79	4.86	\$ 11,332,566

The total intrinsic value of options exercised during the years ended December 31, 2012, 2011 and 2010 was \$19.3 million, \$29.0 million and \$9.0 million, respectively. The weighted average grant date fair value of the stock options granted in the twelve months ended December 31, 2012, 2011 and 2010 was \$10.50, \$11.97 and \$7.66 per option, respectively, determined using the following assumptions:

	December 31, 2012	December 31, 2011	December 31, 2010
Average expected term (years).....	5.00	5.00	5.25
Risk-free interest rate.....	0.9%	2.0%	2.4%
Dividend yield.....	—	—	—
Expected volatility.....	33%	32%	34%

As of December 31, 2012, the weighted average remaining requisite service period of the non-vested stock options was 2.2 years. As of December 31, 2012, the total remaining unrecognized compensation cost related to non-vested stock options amounted to \$36.5 million. This unrecognized compensation cost does not include the impact of any future stock-based compensation awards.

The following table summarizes information about stock options outstanding under our 2000, 2004, 2007, and 2010 Stock Incentive Plans and the Endo Health Solutions Inc. Assumed Stock Incentive Plan at December 31, 2012:

Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Exercisable Weighted Average Exercise Price	Range of Exercise Prices
8,824,705	6.60	\$27.92	3,932,954	\$24.79	\$11.05 - \$41.83

#### Restricted Stock Units

During the years ended December 31, 2012, 2011 and 2010, the Company granted restricted stock units to employees and non-employee directors of the Company as part of their annual stock compensation award and, in certain circumstances, upon their commencement of service with the Company. We recognize expense for our restricted stock units using the straight-line method over the requisite service period. The total value of compensation expense for restricted stock units is equal to the closing price of Endo shares on the date of grant.

A summary of our restricted stock units for the three-year period ended December 31, 2012 is presented below:

	Number of Shares	Aggregate Intrinsic Value
Outstanding as of January 1, 2010.....	1,477,241	
Granted.....	1,411,140	
Forfeited.....	(357,546)	
Vested.....	(319,532)	
Outstanding as of December 31, 2010.....	2,211,303	
Granted.....	1,158,562	
Forfeited.....	(181,752)	
Vested.....	(558,331)	
Outstanding as of December 31, 2011.....	2,629,782	
Granted.....	1,087,171	
Forfeited.....	(362,682)	
Vested.....	(930,659)	
Outstanding as of December 31, 2012.....	2,423,612	\$ 62,736,926
Vested and expected to vest as of December 31, 2012.....	2,206,714	\$ 55,823,733

As of December 31, 2012, the weighted average remaining requisite service period of the non-vested restricted stock units was 2.0 years. The weighted average grant date fair value of the restricted stock units granted during the years ended December 31, 2012, 2011 and 2010 was \$34.76, \$33.51 and \$21.39 per unit, respectively. As of December 31, 2012, the total remaining unrecognized compensation cost related to non-vested restricted stock units amounted to \$40.1 million. This unrecognized compensation cost does not include the impact of any future stock-based compensation awards.

### Restricted Stock Awards

We recognize expense for our restricted stock using the straight-line method over the requisite service period. The total value of compensation expense for restricted stock is equal to the closing price of Endo shares on the date of grant.

A summary of our restricted stock awards for the three-year period ended December 31, 2012 is presented below:

	Number of Shares	Weighted Average Fair Value Per Share	Aggregate Intrinsic Value
Non-vested as of January 1, 2010 .....	—	\$ —	
Granted .....	—	\$ —	
Forfeited .....	—	\$ —	
Vested .....	—	\$ —	\$ —
Non-vested as of December 31, 2010 .....	—	\$ —	
Granted .....	199,413	\$ 30.40	
Forfeited .....	(8,009)	\$ 27.51	
Vested .....	(17,787)	\$ 32.96	\$ 276,551
Non-vested as of December 31, 2011 .....	173,617	\$ 30.27	
Granted .....	—	\$ —	
Forfeited .....	(19,624)	\$ 29.34	
Vested .....	(72,342)	\$ 29.19	\$ 1,897,531
Non-vested as of December 31, 2012 .....	81,651	\$ 31.45	

As of December 31, 2012, the weighted average remaining requisite service period of the non-vested restricted stock awards was approximately 1.6 years.

### Performance Shares

Beginning in the first quarter ended March 31, 2010, the Company began to award performance stock units (PSU) to certain key employees as part of their annual stock compensation award. These PSUs are tied to both Endo's overall financial performance and Endo's financial performance relative to the financial performance of a selected industry group. Awards are granted annually, with each award covering a three-year performance cycle. Each PSU is convertible to one share of Endo common stock. Performance measures used to determine the actual number of performance shares issuable upon vesting include an equal weighting of Endo's total shareholder return (TSR) performance compared to the performance group over the three-year performance cycle and Endo's three-year cumulative revenue performance as compared to a three-year revenue target. TSR relative to peers is considered a market condition while cumulative revenue performance is considered a performance condition under applicable authoritative guidance. The PSUs linked to revenue performance are marked to market on a recurring basis based on management's expectations of future revenues. PSUs granted during the years ended December 31, 2012, 2011 and 2010 totaled approximately 193,000, 160,000 and 163,000, respectively. On December 31, 2012, all remaining PSUs granted during 2010 were converted to shares of common stock in accordance with the provisions of underlying PSU award agreements. Subsequently, holders of the PSUs received approximately 143,000 shares of common stock, net of shares withheld for tax purposes. As of December 31, 2012, there was approximately \$5.1 million of total unrecognized compensation costs related to PSUs. That cost is expected to be recognized over a weighted average period of 3.0 years.

### Share Repurchase Programs

In April 2008, our Board of Directors approved a share repurchase program (the 2008 Share Repurchase Program), authorizing the Company to repurchase in the aggregate up to \$750 million of shares of its outstanding common stock. In August 2012, our Board of Directors resolved to cancel and terminate the 2008 Share Repurchase Program, effective immediately, and approve a new share repurchase program (the 2012 Share Repurchase Program). The 2012 Share Repurchase Program authorizes the Company to repurchase in the aggregate up to \$450 million of shares of its outstanding common stock. Purchases under this program may be made from time to time in open market purchases, pre-set purchase programs, privately-negotiated transactions, and accelerated stock buyback agreements. This program does not obligate Endo to acquire any particular amount of common stock. Future repurchases, if any, will depend on factors such as levels of cash generation from operations, cash requirements for investment in the Company's business, repayment of future debt, if any, then current stock price, market conditions, securities law limitations and other factors. The share repurchase program may be suspended, modified or discontinued at any time. The 2012 Share Repurchase Program is set to expire on March 31, 2015.

Pursuant to our share repurchase programs, we purchased approximately 8.3 million shares of our common stock during 2012 totaling \$256.0 million, 0.9 million shares of our common stock during 2011 totaling \$34.7 million and 2.5 million shares of our common stock during 2010 totaling \$59.0 million.

### ***Employee Stock Purchase Plan***

At our Annual Meeting of Stockholders held in May of 2011, our shareholders approved the Endo Health Solutions Inc. Employee Stock Purchase Plan (the ESPP). The ESPP is a Company-sponsored plan that enables employees to voluntarily elect, in advance of any of the four quarterly offering periods ending March 31, June 30, September 30 and December 31 of each year, to contribute up to 10% of their eligible compensation, subject to certain limitations, to purchase shares of common stock at 85% of the lower of the closing price of Endo common stock on the first or last trading day of each offering period. The maximum number of shares that a participant may purchase in any calendar year is equal to \$25,000 divided by the closing selling price per share of our common stock on the first day of the offering period, subject to certain adjustments. Compensation expense is calculated in accordance with the applicable accounting guidance and is based on the share price at the beginning or end of each offering period and the purchase discount. Obligations under the ESPP may be satisfied by the reissuance of treasury stock, by the Company's purchase of shares on the open market or by the authorization of new shares. The maximum number of shares available under the ESPP, pursuant to the terms of the ESPP plan document, is one percent of the common shares outstanding on April 15, 2011 or approximately 1.2 million shares. The ESPP shall continue in effect until the earlier of (i) the date when no shares of stock are available for issuance under the ESPP, at which time the ESPP shall be suspended pursuant to the terms of the ESPP plan document, or (ii) December 31, 2022, unless earlier terminated. Compensation expense related to the ESPP totaled \$1.3 million during 2012. The Company issued 235,425 shares from treasury with a cost totaling \$6.1 million during 2012 pursuant to the ESPP.

## **NOTE 15. COMMITMENTS AND CONTINGENCIES**

### **Manufacturing, Supply and Other Service Agreements**

We contract with various third party manufacturers, suppliers and service providers to provide us with raw materials used in our products and semi-finished and finished goods, as well as certain packaging and labeling and sales and marketing services. Our most significant agreements are with Novartis Consumer Health, Inc. and Novartis AG (collectively, Novartis), Teikoku Seiyaku Co., Ltd., Mallinckrodt Inc., Noramco, Inc., Grünenthal GMBH, Sharp Corporation Ventiv Commercial Services, LLC and UPS Supply Chain Solutions. If for any reason we are unable to obtain sufficient quantities of any of the finished goods or raw materials or components required for our products or services needed to conduct our business, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

#### *Novartis Manufacturing Agreement*

On May 3, 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc. whereby Novartis Consumer Health, Inc. agreed to manufacture certain of our commercial products and products in development and Endo agreed to purchase, on an annual basis, a minimum amount of product from Novartis Consumer Health, Inc. for the purchase price equal to a predetermined amount per unit, subject to periodic adjustments. This agreement had a five-year initial term, with automatic five-year renewals thereafter. In August 2005, we extended this agreement until 2011. On February 23, 2011, we gave notice to Novartis Consumer Health, Inc. that we would terminate this agreement effective February 2014. On December 31, 2012, the parties mutually agreed to terminate the agreement effective December 31, 2012. The termination did not give rise to any early termination penalties. Amounts purchased pursuant to this agreement were \$1.8 million, \$66.3 million and \$54.9 million for the years ended December 31, 2012, 2011 and 2010, respectively.

In December 2011, Novartis Consumer Health, Inc.'s Lincoln, Nebraska manufacturing facility was shut down to facilitate its implementation of certain manufacturing process improvements. These improvements were intended to address the possibility of rare instances of errors in the packaging of the tablets, potentially resulting in product mix-ups. The supply disruption was not related to the efficacy or safety of Endo's products. However, we experienced short-term supply constraints of certain Endo analgesic products which had been manufactured at this facility prior to the shutdown, including Opana<sup>®</sup>, Voltaren<sup>®</sup> Gel, oxymorphone hydrochloride, Percodan<sup>®</sup>, Endodan<sup>®</sup>, morphine sulfate ER and Zydone<sup>®</sup>. 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<sup>®</sup> Gel to an alternate Novartis manufacturing site.

In the first quarter of 2012, Endo began production of the formulation of Opana<sup>®</sup> ER, designed to be crush-resistant, at a third party manufacturing facility managed by Endo's development partner, Grünenthal. The Company began shipping this formulation in March 2012 and completed the transition to this formulation in the second quarter of 2012. Endo also began production of Voltaren<sup>®</sup> Gel at an alternative Novartis manufacturing source and resumed sales of Voltaren<sup>®</sup> Gel in April 2012. Endo had already initiated the manufacturing of Percocet<sup>®</sup> and Endocet<sup>®</sup> at its Huntsville, Alabama facility as a result of its acquisition of Qualitest Pharmaceuticals in 2010 and, as a result, there was minimal disruption to patients on these products.

### *Novartis License and Supply Agreement*

Pursuant to the March 2008 Voltaren<sup>®</sup> Gel License and Supply Agreement (the Voltaren<sup>®</sup> Gel Agreement) with Novartis AG and Novartis Consumer Health, Inc. Endo has agreed to purchase from Novartis all of its requirements for Voltaren<sup>®</sup> Gel during the entire term of the Voltaren<sup>®</sup> Gel Agreement. The price of product purchased under the Voltaren<sup>®</sup> Gel Agreement is fixed for the first year and subject to annual changes based upon changes in the producer price index and raw materials. Amounts purchased pursuant to the Voltaren<sup>®</sup> Gel Agreement were \$34.0 million, \$30.4 million and \$27.1 million for the years ended December 31, 2012, 2011 and 2010, respectively.

### *Teikoku Seiyaku Co., Ltd.*

Under the terms of our agreement (the Teikoku Agreement) with Teikoku Seiyaku Co. Ltd. (Teikoku), a Japanese manufacturer, Teikoku manufactures Lidoderm<sup>®</sup> at its two Japanese facilities, located on adjacent properties, for commercial sale by us in the U.S. We also have an option to extend the supply area to other territories. On April 24, 2007, we amended the Teikoku agreement (the Amended Agreement). The material components of the Amended Agreement are as follows:

- We agreed to purchase a minimum number of patches per year through 2012, representing the noncancelable portion of the Amended Agreement.
- Teikoku agreed to fix the supply price of Lidoderm<sup>®</sup> for a period of time after which the price will be adjusted at future dates certain based on a price index defined in the Amended Agreement. The minimum purchase requirement shall remain in effect subsequent to 2012, except that Endo has the right to terminate the Amended Agreement if we fail to meet the annual minimum requirement in subsequent years. Using prices currently existing under the Amended Agreement we have estimated our minimum purchase requirement to be approximately \$40.3 million in 2013.
- Following cessation of our obligation to pay royalties to Hind Healthcare Inc. (Hind) under the Sole and Exclusive License Agreement dated as of November 23, 1998, as amended, between Hind and Endo (the Hind Agreement), we began to pay to Teikoku annual royalties based on our annual net sales of Lidoderm<sup>®</sup>.
- The Amended Agreement will expire on December 31, 2021, unless terminated in accordance with its terms. Either party may terminate this Agreement, upon 30 days' written notice, in the event that Endo fails to purchase the annual minimum quantity for each year after 2012 (e.g., 2013 through 2021). Notwithstanding the foregoing, after December 31, 2021, the Amended Agreement shall be automatically renewed on the first day of January each year unless (i) we and Teikoku agree to terminate the Amended Agreement upon mutual written agreement or (ii) either we or Teikoku terminates the Amended Agreement with 180-day written notice to the other party, which notice shall not in any event be effective prior to July 1, 2022.
- Endo is the exclusive licensee for any authorized generic for Lidoderm<sup>®</sup>.

On January 6, 2010, the parties amended the Teikoku Agreement, effective December 16, 2009. Pursuant to the amendment, Teikoku has agreed to supply Lidoderm<sup>®</sup> at a fixed price for a period of time after which the price will be adjusted at certain future dates based on a price index defined in the amendment.

Effective November 1, 2010, the parties again amended the Teikoku Agreement. Pursuant to this amendment, Teikoku agreed to supply additional Lidoderm<sup>®</sup> at no cost to Endo in each of 2011, 2012 and 2013 in the event Endo's firm orders of Product exceeded certain thresholds in those years.

Amounts purchased pursuant to the Teikoku Agreement, as amended, were \$179.5 million, \$203.4 million and \$172.3 million for the years ended December 31, 2012, 2011 and 2010, respectively.

On November 23, 2011, our obligation to pay royalties to Hind under the Hind Agreement ceased. Accordingly, on November 23, 2011, pursuant to the terms of the Teikoku Agreement, we began to incur royalties to Teikoku based on annual net sales of Lidoderm<sup>®</sup>. The royalty rate is 6% of branded Lidoderm<sup>®</sup> net sales. During the twelve months ended December 31, 2012, we recorded \$55.7 million for these royalties to Teikoku, which was included in our Consolidated Statements of Operations as Cost of revenues. At December 31, 2012, \$55.7 million is recorded as a royalty payable and included in Accounts payable in the accompanying Consolidated Balance Sheets.

On August 3, 2012, Teikoku agreed to provide to Endo, at a discount, any branded Lidoderm<sup>®</sup> product that is required to be provided to the wholesaler affiliates of Watson Laboratories, Inc. pursuant to the Watson Settlement Agreement (discussed below). The discount will be equal to a 50% reduction to the regular prices that Endo would otherwise be obligated to pay for this product.

### *Mallinckrodt Inc.*

Under the terms of our agreement (the Mallinckrodt Agreement) with Mallinckrodt Inc. (Mallinckrodt), Mallinckrodt manufactures and supplies to us certain narcotic active drug substances, in bulk form, and raw materials for inclusion in our controlled

substance pharmaceutical products. There is no minimum annual purchase commitment under the Mallinckrodt Agreement. However, we are required to purchase a fixed percentage of our annual requirements of each narcotic active drug substance covered by the Mallinckrodt Agreement from Mallinckrodt. The purchase price for these substances is equal to a fixed amount, adjusted on an annual basis. The initial term of this agreement was July 1, 1998 until September 30, 2013, with an automatic renewal provision for unlimited successive one-year periods. On September 30, 2011, we provided written notice to Mallinckrodt that the Company intends to let the Mallinckrodt Agreement expire effective September 30, 2013. The Company chose to allow the Mallinckrodt Agreement to expire in connection with its ongoing initiatives relating to the sourcing of active pharmaceutical ingredients. In April 2012, the Company entered into an agreement with Noramco, Inc. as described below. The Company will continue to purchase certain narcotic active drug substances, in bulk form, under the terms of the Mallinckrodt Agreement through the expiration date.

Amounts purchased pursuant to this agreement were \$37.6 million, \$51.3 million and \$26.1 million for the years ended December 31, 2012, 2011 and 2010, respectively.

#### *Noramco, Inc.*

Under the terms of our agreement (the Noramco Agreement) with Noramco, Inc. (Noramco), Noramco manufactured and supplied to us certain narcotic active drug substances, in bulk form, and raw materials for inclusion in our controlled substance pharmaceutical products. There were no minimum annual purchase commitments under the Noramco Agreement. However, we were required to purchase a fixed percentage of our annual requirements of each narcotic active drug substance covered by the Noramco Agreement from Noramco. The purchase price for these substances was equal to a fixed amount, adjusted on an annual basis. Originally, the Noramco Agreement was to expire on December 31, 2011, with automatic renewal provisions for unlimited successive one-year periods. In September 2011, we extended the Noramco Agreement through early 2012. On April 27, 2012, we entered into a new supply agreement with Noramco (the 2012 Noramco Agreement). Under the terms of this supply agreement, Noramco manufactures and supplies to us certain narcotic active drug substances, in bulk form, for inclusion in our controlled substance pharmaceutical products. There are no minimum annual purchase commitments under the 2012 Noramco Agreement. However, we are required to purchase from Noramco a fixed percentage of our annual requirements of each narcotic active drug substance covered by the 2012 Noramco Agreement. The purchase price for these substances is equal to a fixed amount, adjusted on an annual basis based on volume. The term of the 2012 Noramco Agreement is for four years with automatic renewal provisions for unlimited successive one-year periods.

Amounts purchased from Noramco were \$52.9 million, \$55.5 million and \$13.9 million for the years ended December 31, 2012, 2011 and 2010, respectively.

#### *Grünenthal GMBH*

Under the terms of our December 2007 License, Development and Supply Agreement with Grünenthal (the Grünenthal Agreement), Grünenthal agreed to manufacture and supply to Endo a crush-resistant formulation of Opana<sup>®</sup> ER based on a supply price equal to a certain percentage of net sales of Opana<sup>®</sup> ER, subject to a floor price. In the first quarter of 2012, Endo began production of the crush-resistant formulation of Opana<sup>®</sup> ER at a third party manufacturing facility managed by Grünenthal. The Grünenthal Agreement will expire on the later of (i) the 15th anniversary of the date of first commercial sale of the product, (ii) the expiration of the last issued patent in the territory claiming or covering products, or (iii) the expiration of exclusivity granted by the FDA for the last product developed under the Grünenthal Agreement. Effective December 19, 2012, EPI and Grünenthal amended the Grünenthal Agreement whereby EPI became responsible for planning of packaging of finished product and certain other routine packaging quality obligations and Grünenthal agreed to reimburse EPI for the third-party costs incurred related to packaging as well as pay EPI a periodic packaging fee. The amendment also changed certain of the terms with respect to the floor price required to be paid by EPI in consideration for product supplied by Grünenthal.

Our license and supply payments made to Grünenthal pursuant to the Grünenthal Agreement are recorded in Cost of revenues in our Consolidated Financial Statements and must be paid in U.S. dollars within 45 days after each calendar quarter. We incurred \$35.7 million during the year ended December 31, 2012 for these payments. We incurred no such costs during the year ended December 31, 2011 and no such costs during the year ended December 31, 2010.

#### *Sharp Corporation*

Under the terms of our agreement (the Sharp Agreement) with Sharp Corporation (Sharp), a U.S. manufacturer, Sharp performs certain packaging and labeling services for Endo, including the packaging and labeling of Lidoderm<sup>®</sup> at its facilities in Allentown, Pennsylvania and Conshohocken, Pennsylvania, for commercial sale by us in the U.S. Effective June 1, 2012, the parties amended the Sharp Agreement to include several new products that Sharp will package and label. These products include our formulation of Opana<sup>®</sup> ER designed to be crush-resistant, Vantas<sup>®</sup>, Supprelin<sup>®</sup> LA, Valstar<sup>®</sup> and several SKUs of generic prednisone and methylprednisolone. The Sharp Agreement is effective until March 1, 2015 and is subject to renewal for additional one-year periods

upon mutual agreement by both parties. Endo has the right to terminate the Sharp Agreement at any time upon 90 days' written notice to Sharp.

Amounts purchased pursuant to the Sharp agreement were \$9.5 million, \$6.3 million and \$6.9 million for the years ended December 31, 2012, 2011 and 2010, respectively.

#### *Ventiv Commercial Services, LLC*

On December 27, 2011, we entered into a Sales and Promotional Services Agreement (the Ventiv Agreement) with Ventiv, effective as of December 30, 2011. Under the terms of the Ventiv Agreement, Ventiv provided to Endo certain sales and promotional services through a contracted field force of 228 sales representatives, 24 district managers, one project manager, one trainer and one national sales director, collectively referred to as the Ventiv Field Force. The Ventiv Field Force promotes Voltaren<sup>®</sup> Gel, Lidoderm<sup>®</sup>, Frova<sup>®</sup>, Opana<sup>®</sup> ER, Fortesta<sup>®</sup> Gel and any additional products added by Endo. The sales representatives are required to perform face-to-face, one-on-one discussions with physicians and other health care practitioners promoting these products.

Endo pays to Ventiv a monthly fixed fee during the term of the Ventiv Agreement based on a budget that has been approved by both Endo and Ventiv. During the term of the Ventiv Agreement, Ventiv will also be eligible to earn, in addition to the fixed management fee, an at-risk management fee. This at-risk management fee is payable upon the achievement of certain performance metrics that have been mutually agreed upon by the parties.

On September 26, 2012, the Ventiv Agreement was amended to decrease the Ventiv Field Force from 228 to 170 sales representatives and decrease the number of district managers from 24 to 17, as well as to retain one project manager, one trainer and one national sales director, starting on October 5, 2012. In addition, the amendment decreased the fees payable to Ventiv as a result of the decrease in the Ventiv Field Force.

The Ventiv Agreement shall continue until December 30, 2013. Endo may extend the current term for an additional period by written notice delivered to Ventiv prior to the expiration of the then current term.

The expenses incurred with respect to Ventiv were \$37.2 million, \$38.4 million and \$10.9 million for the years ended December 31, 2012, 2011 and 2010, respectively. These amounts were included within Selling, general and administrative expense in the accompanying Consolidated Statements of Operations.

#### *UPS Supply Chain Solutions*

Under the terms of this agreement, we utilize UPS Supply Chain Solutions to provide customer service support and warehouse, freight and distribution services for certain of our products in the U.S. The initial term of the agreement will extend to March 31, 2015. The agreement may be terminated by either party (1) without cause upon prior written notice to the other party; (2) with cause in the event of an uncured material breach by the other party and (3) if the other party become insolvent or bankrupt. In the event of termination of services provided under the Warehouse Distribution Services Schedule to the agreement (i) by Endo without cause or (ii) by UPS due to Endo's breach, failure by Endo to make payments when due, or Endo's insolvency, we would be required to pay UPS certain termination costs. Such termination costs would not exceed \$0.9 million. On February 21, 2012, we amended this agreement to provide for a reduced pricing structure, which includes new monthly fees, new variable fees and new termination fees.

#### *General*

In addition to the manufacturing and supply agreements described above, we have agreements with various companies for clinical development services. Although we have no reason to believe that the parties to these agreements will not meet their obligations, failure by any of these third parties to honor their contractual obligations may have a materially adverse effect on our business, financial condition, results of operations and cash flows.

#### **Milestones and Royalties**

See Note 7. License and Collaboration Agreements for a complete description of future milestone and royalty commitments pursuant to our acquisitions, license and collaboration agreements.

#### **Employment Agreements**

We have entered into employment agreements with certain members of management.



## Research Contracts

We routinely contract with universities, medical centers, contract research organizations and other institutions for the conduct of research and clinical studies on our behalf. These agreements are generally for the duration of the contracted study and contain provisions that allow us to terminate prior to completion.

## Legal Proceedings

We and certain of our subsidiaries are involved in various claims, legal proceedings and governmental investigations that arise from time to time in the ordinary course of our business, including relating to product liability, intellectual property, regulatory compliance and commercial matters. While we cannot predict the outcome of our ongoing legal proceedings and we intend to vigorously defend our position, an adverse outcome in any of these proceedings could have a material adverse effect on our current and future financial position, results of operations and cash flows.

In view of the inherent difficulty of predicting the outcome of our various claims, legal proceedings and governmental investigations, particularly where there are many claimants, each with their own unique circumstances that give rise to their alleged claims, and the claimants seek indeterminate damages and particularly given the various stages of our proceedings, unless specified otherwise below, we are unable to predict the outcome of these matters or the ultimate legal and financial liability, and at this time cannot reasonably estimate the possible loss or range of loss. Accordingly, there are claims, legal proceedings and governmental investigations in which we are involved where a loss is reasonably possible in future periods and for which we have not accrued a related liability. Likewise, it is reasonably possible that a future loss could exceed the related accrued liability.

### *Product Liability*

We and certain of our subsidiaries have been named as defendants in numerous lawsuits in various federal and state courts, as well as in Canada, alleging personal injury resulting from the use of certain our products and the products of our subsidiaries. These matters are described in more detail below. At December 31, 2012, the Company has established a product liability accrual totaling \$92.0 million for all known pending and estimated future claims, which the Company believes represents the minimum possible amount we will be required to pay with respect to these cases. The amount of this accrual was recorded in our Consolidated Statements of Operations as Litigation-related and other contingencies. No better estimate is available and the Company cannot estimate the range of loss at this time. We will continue to monitor each related legal claim and adjust the accrual for new information and further developments. It is not possible at this time to determine with certainty the ultimate outcome of these matters or the effect of potential future claims. Nevertheless, 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.

**MCP Cases.** Qualitest Pharmaceuticals, and in certain cases the Company or certain of its subsidiaries, along with several other pharmaceutical manufacturers, have been named as defendants in numerous lawsuits in various federal and state courts alleging personal injury resulting from the use of the prescription medicine metoclopramide. Plaintiffs in these suits allege various personal injuries including tardive dyskinesia, other movement disorders, and death. The Company intends to contest these cases vigorously and to explore other options as appropriate in the best interests of the Company. Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any additional litigation will be brought against the Company or its subsidiaries. Subject to certain terms and conditions, we will be indemnified by the former owners of Qualitest Pharmaceuticals with respect to metoclopramide litigation arising out of the sales of the product by Qualitest Pharmaceuticals between January 1, 2006 and the date on which the acquisition was completed, subject to an overall liability cap for all claims arising out of or related to the acquisition, including the claims described above. As of February 20, 2013, approximately 843 MCP cases are currently pending against Qualitest Pharmaceuticals and/or the Company.

**Propoxyphene Cases.** Qualitest Pharmaceuticals and, in certain cases, the Company or certain of its subsidiaries, along with several other pharmaceutical manufacturers, have been named as defendants in numerous lawsuits originally filed in various federal and state courts alleging personal injury resulting from the use of prescription pain medicines containing propoxyphene. Plaintiffs in these suits allege various personal injuries including cardiac impairment and damage. In August 2011, a multidistrict litigation (MDL) was formed, and certain transferable cases pending in federal court are now coordinated in the Eastern District of Kentucky as part of MDL No. 2226. On March 5, 2012 and June 22, 2012, the MDL Judge issued orders dismissing with prejudice certain claims against generic manufacturers, including Qualitest Pharmaceuticals and the Company. Certain plaintiffs have appealed those decisions to the U.S. Court of Appeals for the Sixth Circuit. A consolidated appeal is pending before the Sixth Circuit in certain of these cases. Some of these cases have already been remanded, although appeals are being sought or are pending. In November 2012, additional cases were filed in various California state courts, and removed to corresponding federal courts. The Company intends to contest all of these cases vigorously and to explore other options as appropriate in the best interests of the Company. Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any additional litigation will be brought against the Company or its subsidiaries. Subject to certain terms and

conditions, we will be indemnified by the former owners of Qualitest Pharmaceuticals with respect to propoxyphene litigation arising out of the sales of the product by Qualitest Pharmaceuticals between January 1, 2006 and the date on which the acquisition was completed, subject to an overall liability cap for all claims arising out of or related to the acquisition, including the claims described above. As of February 20, 2013, approximately 39 propoxyphene cases are currently pending against Qualitest Pharmaceuticals and/or the Company. There are also approximately 69 propoxyphene cases on appeal to the Sixth Circuit.

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

In July 2011, FDA issued an update to the October 2008 Public Health Notification regarding mesh to further advise the public and the medical community of the potential complications associated with transvaginal placement of surgical mesh to treat POP and SUI. In this July 2011 update, the FDA maintained that adverse events are not rare, as previously reported, and questioned the relative effectiveness of transvaginal mesh as a treatment for POP as compared to non-mesh surgical repair. The July 2011 notification continued to encourage physicians to seek specialized training in mesh procedures, to consider and to advise their patients about the risks associated with these procedures and to be diligent in diagnosing and reporting complications. FDA also convened an advisory panel which met on September 8-9, 2011 to further address the safety and effectiveness of transvaginal surgical mesh used to treat POP and SUI. At the conclusion of the meetings, the advisory panel recommended reclassifying transvaginal mesh products used to treat POP to Class III devices (premarket approval) and recommended that manufacturers of these products be required to conduct additional post-market surveillance studies. The advisory panel recommended that transvaginal surgical mesh products used to treat SUI remain as Class II devices. Regarding retropubic and transobturator (TOT) slings, the advisory panel recommended that no additional post-market surveillance studies are necessary. Regarding mini-slings, the advisory panel recommended premarket study for new devices and additional post-market surveillance studies.

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, Inc., to conduct post-market safety studies and to monitor adverse event rates relating to the use of these products. AMS, Inc. received a total of nineteen class-wide post-market study orders regarding its pelvic floor repair and mini-sling products; however sixteen of these study orders have been placed on hold for a variety of commercial reasons. Three of these post-market study orders remain active and AMS, Inc. is continuing the process of complying with these orders. In these orders, the FDA also noted that it is still considering the recommendation of the September 9, 2011 advisory committee that urogynecological surgical mesh for transvaginal repair of pelvic organ prolapse be reclassified from Class II to Class III.

Since 2008, AMS, Inc., and more recently, in certain cases the Company or certain of its 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 pelvic organ prolapse and stress urinary incontinence. 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, a multidistrict litigation (MDL) was formed, and cases pending in federal courts are now consolidated in the Southern District of West Virginia as part of MDL No. 2325. Similar cases in various state courts around the country are also currently pending. More specifically, as of February 20, 2013, approximately 5,100 mesh cases are currently pending against AMS, Inc. and/or the Company or certain of its subsidiaries. Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions. The majority of the currently pending cases are in the MDL.

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 pelvic organ prolapse and stress urinary incontinence. We have not yet received a subpoena relating to this investigation, and 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.

AMS, Inc. and the Company intend to vigorously contest all currently pending cases and any future cases that may be brought, if any, and to explore other options as appropriate in the best interests of AMS, Inc. and the Company. It is not possible at this time to determine with certainty the ultimate outcome of these matters or the effect of potential future claims. Nevertheless, 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.

As previously reported, in January 2007 and April 2011, the Company received subpoenas issued by the United States Department of Health and Human Services (HHS), Office of Inspector General (OIG) and the United States Department of Justice (DOJ), respectively. The subpoenas request documents relating to Lidoderm® (lidocaine patch 5%), focused primarily on the sale, marketing and promotion of Lidoderm®.

In October 2012, preliminary discussions to resolve potential claims arising from this matter advanced to a point where the Company believed a loss to be probable. Endo recorded a charge of \$53.0 million in the third quarter of 2012, which at that time the Company believed was the minimum possible settlement. Since that time, discussions have progressed and, without admitting any liability or wrongdoing, the Company reached a tentative agreement with the HHS-OIG, DOJ and participating state entities in the fourth quarter of 2012 to resolve this matter for a total of approximately \$194.0 million. Accordingly, we recorded a corresponding charge in our 2012 Consolidated Statement of Operations as Litigation-related and other contingencies. The settlement remains subject to further negotiation of specific terms and to final approval by the federal government and participating state entities, and accordingly, there is no assurance that a resolution will occur. Endo has cooperated fully and continues to cooperate with the government's investigation. Settlements of these investigations have commonly resulted in the payment of substantial damages and fines to the government for alleged civil and criminal violations, and have commonly included a corresponding plea agreement or deferred prosecution agreement, and entry into a Corporate Integrity Agreement with the HHS-OIG.

#### *Pricing Litigation*

A number of cases were brought by state government entities that allege generally that our wholly-owned subsidiary, Endo Pharmaceuticals Inc. (EPI), and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid. These cases generally seek damages, treble damages, disgorgement of profits, restitution and attorneys' fees.

As previously reported, a case pending in the 19th Judicial District, Parish of East Baton Rouge, Louisiana against EPI and numerous other pharmaceutical companies: *State of Louisiana v. Abbott Laboratories, Inc., et al.* contained allegations similar to the those described above. Without admitting any liability or wrongdoing, in the third quarter of 2012, EPI and the State of Louisiana have reached an agreement to resolve this case for a total of approximately \$4.6 million. On July 1, 2011, the Texas Attorney General's Office issued a Civil Investigative Demand (CID) to Qualitest Pharmaceuticals, Inc. and to EPI inquiring into activities in Texas that are similar to those contained in the allegations described above. Without admitting any liability or wrongdoing, in the third quarter of 2012, Qualitest Pharmaceuticals, EPI and the State of Texas have reached an agreement to resolve this matter for a total of \$25.0 million. We recorded corresponding charges for these amounts in our 2012 Consolidated Statement of Operations as Litigation-related and other contingencies.

Additionally, there is a previously reported case pending in the Third Judicial District Court of Salt Lake County, Utah against EPI and numerous other pharmaceutical companies: *State of Utah v. Actavis US, Inc., et al.*

EPI intends to contest the above unresolved case vigorously and to explore other options as appropriate in the best interests of the Company. Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against the Company or its subsidiaries.

#### *Paragraph IV Certifications on Lidoderm®*

As previously reported, on January 15, 2010, the Company's subsidiary, Endo Pharmaceuticals Inc. (EPI or Endo) and the holders of the Lidoderm® NDA and relevant patents, Teikoku Seiyaku Co., Ltd., and Teikoku Pharma USA, Inc. (collectively, Teikoku) received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) (a Paragraph IV Notice) from Watson Laboratories, Inc. (Watson) advising of its filing of an Abbreviated New Drug Application (ANDA) for a generic version of Lidoderm® (lidocaine topical patch 5%). The Paragraph IV Notice refers to U.S. Patent No. 5,827,529, which covers the formulation of Lidoderm®, a topical patch to relieve the pain of post herpetic neuralgia launched in 1999. This patent is listed in the FDA's Orange Book and expires in October 2015. As a result of this Notice, on February 19, 2010, EPI and Teikoku filed a lawsuit against Watson in the U.S. District Court of the District of Delaware. This lawsuit was heard by the court and the trial concluded on February 14, 2012. In October 2010, Teikoku Pharma USA listed U.S. Patent No. 5,741,510 in the FDA Orange Book, and this patent expires in March 2014. On June 30, 2011, EPI and Teikoku filed a second lawsuit against Watson in the U.S. District Court of the District of Delaware alleging infringement of U.S. Patent Nos. 5,741,510, 6,096,333, and 6,096,334 which cover lidocaine patch formulations and manufacturing processes.

On May 28, 2012, EPI entered into a Settlement and License Agreement (the Watson Settlement Agreement) among EPI and Teikoku, on the one hand, and Watson, on the other hand. The Watson Settlement Agreement settled all ongoing patent litigation among the parties relating to Watson's generic version of Lidoderm®. Under the terms of the Watson Settlement Agreement, the parties dismissed their respective claims and counterclaims without prejudice. As part of the settlement, Watson agreed not to challenge the validity or enforceability of Endo's and Teikoku's patents relating to Lidoderm® with respect to Watson's generic version of

Lidoderm®. Watson also agreed not to sell its generic version of Lidoderm® until it received FDA approval and, in any event, no sooner than September 15, 2013, except in limited specific circumstances (such date being the Start Date). Endo and Teikoku agreed to grant Watson a license permitting the sale of generic Lidoderm® upon the Start Date in the U.S. The license to Watson is exclusive as to Endo's launch of an authorized generic version of Lidoderm® until the earlier of 1) the introduction of a generic version of Lidoderm® by a company other than Watson, or 2) seven and a half months after Watson launches its generic version of Lidoderm®. Endo will receive an at market royalty equal to 25% of the gross profit generated on Watson's sales of its generic version of Lidoderm® during Watson's period of exclusivity.

Additionally, the Watson Settlement Agreement provides that Endo and Teikoku will provide, at no cost, to Watson's wholesaler affiliate branded Lidoderm® product for Watson's wholesaler affiliate's distribution, subject to certain terms and conditions. Given that Watson received FDA approval of its generic version of Lidoderm® in August 2012,

Endo and Teikoku will provide branded Lidoderm® of value totaling \$12.0 million each month (\$96.0 million in total for 2013) (valued at the then-prevailing wholesale acquisition cost) beginning on January 1, 2013 through August 1, 2013. The obligation of Endo and Teikoku to provide this branded product at no cost terminates immediately upon the launch of a third party's generic version of Lidoderm® in the U.S., including its territories, possessions and the Commonwealth of Puerto Rico (the Territory).

Endo will be responsible for the payment of all gross to net adjustments arising from Watson's sale of the branded Lidoderm® product.

Teikoku has agreed to provide a rebate to Endo equal to 50% of the cost of branded Lidoderm® product that is required to be provided to Watson's wholesaler affiliate pursuant to Section 3(b), 3(c) and 3(d) of the Watson Settlement Agreement.

The Company has concluded that the Watson Settlement Agreement is a multiple-element arrangement and during the second quarter of 2012 recognized a liability and corresponding charge of \$131.4 million in Patent litigation settlement, net in the Consolidated Statements of Operations, representing the initial estimated fair value of the settlement component. Fair value of the settlement component was estimated using the probability adjusted expected value of branded Lidoderm® product to be provided to Watson at the anticipated wholesaler acquisition cost (WAC) expected to be in place at the time of shipment, less a reasonable estimate of Watson's selling costs. The resultant probability-weighted values were then discounted using a discount rate of 5.1%.

The Company believes that the level and timing of branded Lidoderm® product to be shipped, discount rate, and probabilities used in the model appropriately reflect market participant assumptions. Because the liability is recorded at fair value using WAC, the net charge recognized in 2012 is comprised of several elements, including our cost of product to be shipped, estimated gross-to-net deductions to be paid by the Company and the estimated product profit margin. We believe this is the most appropriate measure of fair value as these components combined represent the value accruing to Watson. As a result of using a fair value measurement, the charge will be greater than the actual cost to the Company. As such, relief of the liability in subsequent periods through shipments of branded Lidoderm® product will result in income, which we expect to record as a component of Other income, net in the Company's Consolidated Statements of Operations. We intend to reclassify the portion of the settlement liability related to the gross-to-net component into our gross-to-net reserves as product is shipped to Watson, the effect of which will be to offset a portion of the income that will be recognized into Other income, net in the Company's Consolidated Statements of Operations, as the settlement liability is relieved. The rebate arrangement with Teikoku will also be accounted for prospectively as product purchased from Teikoku will be recorded into inventory at the discounted purchase price and relieved as shipments are made to Watson. The benefit associated with this rebate will be recorded as a component of Other income, net in the Company's Consolidated Statements of Operations.

On August 23, 2012, Watson announced it received FDA approval on its ANDA for its lidocaine patch 5%, a generic version of Lidoderm®. The Company anticipates Watson will launch its generic version of Lidoderm® on September 15, 2013 pursuant to the terms of the Watson Settlement Agreement. In light of Watson's anticipated September 2013 launch, the Company reassessed its obligation to Watson and believes it will not be obligated to provide to Watson's wholesaler affiliate branded Lidoderm® product beyond September 2013. Accordingly, in the third quarter of 2012, the Company recognized a change in estimate with respect to its obligation and reduced its liability associated with the Watson Settlement Agreement by \$46.2 million to \$85.1 million. The corresponding gain of \$46.2 million was recorded in Patent litigation settlement, net in the Consolidated Statements of Operations. Future changes, if any, resulting from revisions to the timing or the amount of the original estimate will be recognized as an increase or a decrease in the carrying amount of the litigation settlement liability and the related Patent litigation settlement, net during the period of change. Future changes in estimates to the settlement liability could have a material impact on our results of operations.

As previously reported, in January 2011, EPI and Teikoku received a Paragraph IV Notice from Mylan Technologies Inc. (Mylan) advising of its filing of an ANDA for a generic version of Lidoderm®. The Paragraph IV Notice refers to U.S. Patent Nos. 5,827,529 and 5,741,510, which cover the formulation of Lidoderm®. These patents are listed in the FDA's Orange Book and expire in October 2015 and March 2014, respectively. On March 14, 2011, EPI filed a lawsuit against Mylan in the U.S. District Court for the District of Delaware, claiming that the Paragraph IV Notice served by Mylan failed to comply with the requirements of 21 U.S.C. sec. 355(b)(3)(C)(1) and 21 C.F.R. 214.95(a). In that suit, EPI sought a declaration that Mylan's Paragraph IV Notice is null, void and without legal effect, and that as a result, Mylan has failed to properly trigger the ANDA litigation process. In the alternative, EPI alleged that Mylan's submission of its ANDA constitutes infringement of the '510 patent under 35 U.S.C. sec. 271(e)(2)(A). On March 30, 2012, the Court dismissed this complaint without prejudice. On April 13, 2012, Endo and Teikoku filed a motion to amend this Complaint and reinstate the suit. That motion is currently pending before the court.

On May 16, 2012, EPI and Teikoku received a Paragraph IV Notice from Noven Pharmaceuticals, Inc. (Noven) advising of its filing of an ANDA for a generic version of Lidoderm<sup>®</sup> (lidocaine topical patch 5%). The Paragraph IV Notice refers to U.S. Patent No. 5,827,529, which covers the formulation of Lidoderm<sup>®</sup>. This patent is listed in the FDA's Orange Book and expires in October 2015. On June 29, 2012, EPI filed a lawsuit against Noven in the U.S. District Court for the District of Delaware. Because the suit was filed within the 45-day period under the Hatch-Waxman Act for filing a patent infringement action, we believe that it triggered an automatic 30-month stay of approval under the Act.

On May 24, 2012, EPI and Teikoku received a Paragraph IV Notice from TWi Pharmaceuticals, Inc. (TWi) advising of its filing of an ANDA for a generic version of Lidoderm<sup>®</sup> (lidocaine topical patch 5%). The Paragraph IV Notice refers to U.S. Patent Nos. 5,827,529 and 5,741,510, which cover the formulation of Lidoderm<sup>®</sup>. These patents are listed in the FDA's Orange Book and expire in October 2015 and March 2014, respectively. On July 5, 2012, EPI filed a lawsuit against TWi in the U.S. District Court for the District of Delaware. Because the suit was filed within the 45-day period under the Hatch-Waxman Act for filing a patent infringement action, we believe that it triggered an automatic 30-month stay of approval under the Act.

Endo intends, and has been advised by Teikoku that they too intend, to vigorously defend the intellectual property rights relating to Lidoderm<sup>®</sup> and to pursue all available remaining legal and regulatory avenues in defense of Lidoderm<sup>®</sup>, including enforcement of the product's intellectual property rights and approved labeling. However, there can be no assurance that we will be successful. If we are unsuccessful and any one of the above generic manufacturers is able to obtain FDA approval of its product, that generic manufacturer may be able to launch its generic version of Lidoderm<sup>®</sup> prior to the applicable patents' expirations in 2014 and 2015. Additionally, we cannot predict or determine the timing or outcome of ongoing litigation but will explore all options as appropriate in the best interests of the Company. In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of Lidoderm<sup>®</sup> and challenge the applicable patents.

#### *Paragraph IV Certifications on Opana<sup>®</sup> ER*

As previously reported, starting in December 2007 through December 2011, EPI received Paragraph IV Notices from various generic drug manufacturers, including Impax Laboratories, Inc. (Impax), Actavis South Atlantic LLC (Actavis), Sandoz, Inc. (Sandoz), Barr Laboratories, Inc. (Teva), Watson Laboratories, Inc. (Watson), Roxane Laboratories, Inc. (Roxane) and most recently, Ranbaxy Inc. (Ranbaxy) advising of the filing by each such company of an ANDA for a generic version of the non-crush resistant formulation of Opana<sup>®</sup> ER (oxymorphone hydrochloride extended-release tablets CII). To date, EPI settled all of the Paragraph IV litigation relating to the non-crush resistant formulation of Opana<sup>®</sup> ER. Under the terms of the settlements, each generic manufacturer agreed not to challenge the validity or enforceability of patents relating to the non-crush resistant formulation of Opana<sup>®</sup> ER. As a result, Actavis launched its generic non-crush resistant Opana<sup>®</sup> ER 7.5 and 15 mg tablets on July 15, 2011, and Impax launched its generic non-crush resistant Opana<sup>®</sup> ER 5, 10, 20, 30 and 40 mg tablets on January 2, 2013. We expect Sandoz, Teva, Watson, Roxane and Actavis to launch production and sale of all strengths of their respective versions of generic non-crush resistant Opana<sup>®</sup> ER during the third quarter of 2013. We evaluated Ranbaxy's Paragraph IV Notice and concluded that we will not sue Ranbaxy at this time. As a result, and because Ranbaxy filed a Paragraph III notice against two patents expiring September 9, 2013, we expect Ranbaxy to launch all strengths of its generic non-crush resistant Opana<sup>®</sup> ER on September 9, 2013.

On December 11, 2012, EPI filed a Complaint against Actavis South Atlantic LLC (Actavis) in the United States District Court for the District of New Jersey claiming false advertising and calling for Actavis to cease and desist promoting its non-crush resistant formulation of Opana<sup>®</sup> ER product as AB rated, or bioequivalent, to the crush-resistant formulation of Opana<sup>®</sup> ER. On February 5, 2013, Endo filed a Motion for Preliminary Injunction with the court requesting the court enjoin Actavis from further false advertising. That Motion is pending before the court.

Pursuant to the June 2010 Settlement and License Agreement (the Impax Settlement Agreement) with Impax, EPI agreed to provide a payment to Impax should prescription sales of the non-crush resistant formulation of Opana<sup>®</sup> ER, as defined in the Impax Settlement Agreement, fall below a predetermined contractual threshold in the quarter immediately prior to the date on which Impax was authorized to launch its generic version of the non-crush resistant formulation of Opana<sup>®</sup> ER, which occurred on January 2, 2013. During the first quarter of 2012, the Novartis shut-down of its Lincoln, Nebraska manufacturing facility and resulting lack of 2012 oxymorphone active pharmaceutical ingredient (API) quota granted by the DEA to Novartis caused EPI to attempt an accelerated launch of the crush-resistant formulation of Opana<sup>®</sup> ER. While significant uncertainties existed throughout the first quarter of 2012 about our ability to rapidly ramp up production of the formulation designed to be crush-resistant and produce finished goods at a new, untested manufacturing facility in a very short period of time, we were able to do so in March 2012. Accordingly, the Company recognized a liability under the Impax Settlement Agreement upon the Company's sale of the formulation designed to be crush-resistant, which occurred in March 2012. The total charge of \$102.0 million was recorded in Cost of revenues in our 2012 Consolidated Financial Statements.

From September 21, 2012 through February 6, 2013, EPI and its partner Grünenthal received Paragraph IV Notices from each of Teva Pharmaceuticals USA, Inc. (Teva), Amneal Pharmaceuticals, LLC, Sandoz Inc., ThoRx Laboratories, Inc. (ThoRx), Par Pharmaceuticals (Par), Actavis South Atlantic LLC (Actavis), and Impax Pharmaceuticals (Impax), advising of the filing by each such company of an ANDA for a generic version of the formulation of Opana<sup>®</sup> ER designed to be crush-resistant. These Paragraph IV Notices refer to U.S. Patent Nos. 8,075,872, 8,114,383, 8,192,722, 7,851,482, 8,309,060, 8,309,122 and 8,329,216, which variously cover the formulation of Opana<sup>®</sup> ER, a highly pure version of the active pharmaceutical ingredient and the release profile of Opana<sup>®</sup> ER. EPI filed lawsuits against each of these filers in the US District Court for the Southern District of New York. Each lawsuit was filed within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. EPI intends, and has been advised by Grünenthal that they too intend, to vigorously defend the intellectual property rights covering Opana<sup>®</sup> ER and to pursue all available legal and regulatory avenues in defense of Opana<sup>®</sup> ER, including enforcement of the product's intellectual property rights and approved labeling. However, there can be no assurance that we will be successful. If we are unsuccessful and Teva, Amneal, Sandoz, ThoRx, Par, Actavis or Impax is able to obtain FDA approval of its product, it may be able to launch a generic version of Opana<sup>®</sup> ER prior to the applicable patents' expirations in 2023 through 2029. Additionally, we cannot predict or determine the timing or outcome of this defense but will explore all options as appropriate in the best interests of the Company. In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of Opana<sup>®</sup> ER and challenge the applicable patents.

#### *Paragraph IV Certification on Fortesta<sup>®</sup> Gel*

On January 18, 2013, EPI and its licensor Strakan Limited received a notice from Watson advising of the filing by Watson of an ANDA for a generic version of Fortesta<sup>®</sup> (testosterone) Gel. On February 28, 2013, EPI filed a lawsuit against Watson in the U.S. District Court for the Eastern District of Texas, Marshall division. Because the suit was filed within the 45-day period under the Hatch-Waxman Act for filing a patent infringement action, we believe that it triggered an automatic 30-month stay of approval under the Act.

Endo intends to vigorously defend Fortesta<sup>®</sup> Gel and to pursue all available legal and regulatory avenues in defense of Fortesta<sup>®</sup> Gel, including enforcement of the product's intellectual property rights and approved labeling. However, there can be no assurance that we will be successful. If we are unsuccessful and Watson is able to obtain FDA approval of its product, Watson may be able to launch its generic version of Fortesta<sup>®</sup> Gel prior to the applicable patents' expirations in 2018. Additionally, we cannot predict or determine the timing or outcome of this litigation but will explore all options as appropriate in the best interests of the Company. In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of Fortesta<sup>®</sup> Gel and challenge the applicable patents.

#### *Paragraph IV Certification on Frova<sup>®</sup>*

As previously reported, in July 2011, EPI and its licensor, Vernalis Development Limited received a notice from Mylan Technologies Inc. (Mylan) advising of the filing by Mylan of an ANDA for a generic version of Frova<sup>®</sup> (frovatriptan succinate) 2.5 mg tablets. Mylan's notice included a Paragraph IV Notice with respect to U.S. Patent Nos. 5,464,864, 5,561,603, 5,637,611, 5,827,871 and 5,962,501, which cover Frova<sup>®</sup>. These patents are listed in the FDA's Orange Book and expire between 2013 and 2015. As a result of this Paragraph IV Notice, on August 16, 2011, EPI filed a lawsuit against Mylan in the U.S. District Court for the District of Delaware alleging infringement of U.S. Patent Nos. 5,464,864, 5,637,611 and 5,827,871. Because the suit was filed within the 45-day period under the Hatch-Waxman Act for filing a patent infringement action, we believe that it triggered an automatic 30-month stay of approval under the Act. On September 22, 2011, Mylan filed an Answer and Counterclaims, claiming the asserted patents are invalid or not infringed.

Endo intends to vigorously defend its intellectual property rights and to pursue all available legal and regulatory avenues in defense of Frova<sup>®</sup>, including enforcement of the product's intellectual property rights and approved labeling. However, there can be no assurance that we will be successful. If we are unsuccessful and Mylan is able to obtain FDA approval of its product, Mylan may be able to launch its generic version of Frova<sup>®</sup> prior to the applicable patents' expirations in 2014 and 2015. Additionally, we cannot predict or determine the timing or outcome of this litigation but will explore all options as appropriate in the best interests of the Company. In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of Frova<sup>®</sup> and challenge the applicable patents.

#### *Other Legal Proceedings*

In addition to the above proceedings, we are involved in, or have been involved in, arbitrations or various other legal proceedings that arise from the normal course of our business. We cannot predict the timing or outcome of these claims and other proceedings. Currently, we are not involved in any arbitration and/or other legal proceeding that we expect to have a material effect on our business, financial condition, results of operations and cash flows.

## Leases

We lease certain fixed assets under capital leases that expire through 2014. We lease automobiles, machinery and equipment and facilities under certain noncancelable operating leases that expire through 2024. These leases are renewable at our option.

On October 28, 2011, our subsidiary EPI entered into a lease agreement with RT/TC Atwater LP, a Delaware limited partnership, for a new Company headquarters to consist of approximately 300,000 square feet of office space located at 1400 Atwater Boulevard, Malvern, Pennsylvania (with a four-year option to lease up to approximately 150,000 additional square feet). The term of this triple net lease is 12 years and includes three renewal options, each for an additional 60-month period. The lease commenced on December 31, 2012 with a monthly lease rate for the initial year of \$0.5 million, increasing by 2.25% each year thereafter.

This lease is accounted for as a direct financing arrangement whereby the Company recorded, over the construction period, the full cost of the asset in Property, plant and equipment, net. A corresponding liability was also recorded, net of leasehold improvements paid for by the Company, and will be amortized over the expected lease term through monthly rental payments using an effective interest method. At December 31, 2012, the Company recorded a liability of \$57.0 million related to this arrangement, \$5.1 million of which is included in Accounts payable and \$51.9 million of which is included in Other liabilities in the accompanying Consolidated Balance Sheet.

A summary of minimum future rental payments required under capital and operating leases as of December 31, 2012 are as follows (in thousands):

	<u>Capital Leases(1)</u>	<u>Operating Leases</u>
2013 .....	\$ 8,914	\$ 17,950
2014 .....	\$ 6,418	\$ 16,583
2015 .....	\$ 6,036	\$ 12,656
2016 .....	\$ 6,007	\$ 8,229
2017 .....	\$ 6,112	\$ 4,314
Thereafter .....	\$ 45,797	\$ 2,585
Total minimum lease payments.....	<u>\$ 79,284</u>	<u>\$ 62,317</u>
Less: Amount representing interest .....	<u>11,306</u>	
Total present value of minimum payments.....	<u>\$ 67,978</u>	
Less: Current portion of such obligations .....	<u>6,701</u>	
Long-term capital lease obligations.....	<u>\$ 61,277</u>	

(1) The direct financing arrangement is included under Capital Leases.

Expense incurred under operating leases was \$25.5 million, \$22.5 million and \$17.2 million for the years ended December 31, 2012, 2011 and 2010, respectively.

## NOTE 16. SAVINGS AND INVESTMENT PLAN AND DEFERRED COMPENSATION PLANS

### *Savings and Investment Plan*

On September 1, 1997, we established a defined contribution Savings and Investment Plan (the Endo 401(k) Plan) covering all employees. Employee contributions are made on a pre-tax basis under section 401(k) of the Internal Revenue Code (the Code). We match up to 6% of the participants' contributions subject to limitations under section 401(k) of the Code. Participants are fully vested with respect to their own contributions and the Company's matching contributions.

On July 2, 2010, the Company acquired HealthTronics, Inc., which sponsored the HealthTronics, Inc. and Subsidiaries 401(k) Plan (the HealthTronics Plan). The HealthTronics Plan was a defined contribution profit-sharing plan with a 401(k) option covering all employees of HealthTronics, Inc. In June 2011, former HealthTronics, Inc. employees began to participate in the Endo 401(k) Plan and the HealthTronics Plan assets were transferred into the Endo 401(k) Plan.

On November 30, 2010, the Company acquired Qualitest Pharmaceuticals, which sponsored the Qualitest Pharmaceuticals 401(k) Plan (the Qualitest Plan). The Qualitest Plan is a defined contribution profit-sharing plan with a 401(k) option covering all employees of Qualitest Pharmaceuticals. In January 2012, former Qualitest Pharmaceuticals employees began to participate in the Endo 401(k) Plan and the Qualitest Plan assets were transferred into the Endo 401(k) Plan.

On June 17, 2011, the Company acquired AMS, Inc., which sponsors the AMS Savings and Investment Plan (the AMS Plan). The AMS Plan is a defined contribution profit-sharing plan with a 401(k) option covering all employees of AMS, Inc. The Company merged the AMS Plan into the Endo 401(k) Plan in 2013.



Costs incurred for contributions made by us to the various 401(k) plans amounted to \$17.7 million, \$15.0 million and \$9.8 million for the years ended December 31, 2012, 2011 and 2010, respectively.

#### *Executive Deferred Compensation Plan*

In December 2007, the Board of Directors (the Board) of Endo Health Solutions Inc. adopted the Endo Pharmaceuticals Holdings Inc. Executive Deferred Compensation Plan (now known as the Endo Health Solutions Inc. Executive Deferred Compensation Plan and referred to herein as the Deferred Compensation Plan) and the Endo Pharmaceuticals Holdings Inc. 401(k) Restoration Plan (now known as the Endo Health Solutions Inc. 401(k) Restoration Plan and referred to herein as the 401(k) Restoration Plan) both effective as of January 1, 2008. Both plans cover employees earning over the Internal Revenue Code plan compensation limit, which would include the chief executive officer, chief financial officer and other named executive officers. The Deferred Compensation Plan allows for deferral of up to 50% of the bonus, with payout to occur as elected, either in a lump sum or in installments, and up to 100% of restricted stock units granted, with payout to occur as a lump sum. Under the 401(k) Restoration Plan the participant may defer the amount of base salary and bonus that would have been deferrable under the Company's Savings and Investment Plan (up to 50% of salary and bonus) if not for the qualified plan statutory limits on deferrals and contributions, and also provides for a company match on the first six percent of deferrals to the extent not provided for under the Savings and Investment Plan. Payment occurs as elected, either in lump sum or in installments.

#### *Directors Deferred Compensation Plan*

Also in December 2007, the Board adopted the Endo Pharmaceuticals Holdings Inc. Directors Deferred Compensation Plan (now known as the Endo Health Solutions Inc. Directors Deferred Compensation Plan), effective January 1, 2008. The purpose of the Plan is to promote the interests of the Company and the stockholders of the Company by providing non-employee Directors the opportunity to defer up to 100% of meeting fees, retainer fees, and restricted stock units, with payout to occur as elected either in lump sum or installments.

### **NOTE 17. NET (LOSS) INCOME PER SHARE**

The following is a reconciliation of the numerator and denominator of basic and diluted net (loss) income per share (in thousands, except per share data):

	2012	2011	2010
<b>Numerator:</b>			
Net (loss) income attributable to Endo Health Solutions Inc. common stockholders .....	\$ (740,337)	\$ 187,613	\$ 259,006
<b>Denominator:</b>			
For basic per share data—weighted average shares .....	115,719	116,706	116,164
Dilutive effect of common stock equivalents .....	—	2,306	1,202
Dilutive effect of 1.75% Convertible Senior Subordinated Notes and warrants ...	—	2,166	585
For diluted per share data—weighted average shares.....	115,719	121,178	117,951
Basic net (loss) income per share attributable to Endo Health Solutions Inc.....	<u>\$ (6.40)</u>	<u>\$ 1.61</u>	<u>\$ 2.23</u>
Diluted net (loss) income per share attributable to Endo Health Solutions Inc.....	<u>\$ (6.40)</u>	<u>\$ 1.55</u>	<u>\$ 2.20</u>

Basic net (loss) income per share is computed based on the weighted average number of common shares outstanding during the period. Diluted income per common share is computed based on the weighted average number of common shares outstanding and, if there is net income during the period, the dilutive impact of common stock equivalents outstanding during the period. Common stock equivalents are measured under the treasury stock method.

The 1.75% Convertible Senior Subordinated Notes due April 15, 2015 (the Convertible Notes) are only included in the dilutive net income per share calculation using the treasury stock method during periods in which the average market price of our common stock was above the applicable conversion price of the Convertible Notes, or \$29.20 per share and the impact would not be anti-dilutive. In these periods, under the treasury stock method, we calculated the number of shares issuable under the terms of these notes based on the average market price of the stock during the period, and included that number in the total diluted shares outstanding for the period.

We have entered into convertible note hedge and warrant agreements that, in combination, have the economic effect of reducing the dilutive impact of the Convertible Notes. However, we separately analyze the impact of the convertible note hedge and the warrant agreements on diluted weighted average shares outstanding. As a result, the purchases of the convertible note hedges are excluded because their impact would be anti-dilutive. The treasury stock method is applied when the warrants are in-the-money with the proceeds from the exercise of the warrant used to repurchase shares based on the average stock price in the calculation of diluted weighted average shares. Until the warrants are in-the-money, they have no impact to the diluted weighted average share calculation.

The total number of shares that could potentially be included if the warrants were exercised is approximately 13.0 million at December 31, 2012.

The following reconciliation shows the maximum potential dilution of shares currently excluded from the calculation of diluted net (loss) income per share per share for the years ended December 31 (in thousands):

	2012	2011	2010
Weighted average shares excluded:			
1.75% Convertible senior subordinated notes due 2015 and warrants(1).....	25,993	23,827	25,408
Employee stock-based awards .....	4,991	2,043	2,721
	<u>30,984</u>	<u>25,870</u>	<u>28,129</u>

(1) Amounts represent the incremental potential total dilution that could occur if our Convertible Notes and warrants were converted to shares of our common stock.

#### NOTE 18. COST OF REVENUES

The components of Cost of revenues for the years ended December 31 (in thousands) were as follows:

	2012	2011	2010
Cost of net pharmaceutical product sales .....	\$ 971,570	\$ 823,455	\$ 451,096
Cost of device revenues .....	162,918	124,217	—
Cost of service and other revenues .....	126,605	117,536	53,661
Total cost of revenues .....	<u>\$ 1,261,093</u>	<u>\$ 1,065,208</u>	<u>\$ 504,757</u>

#### NOTE 19. DEBT

The components of our total indebtedness at December 31, (in thousands), were as follows:

	2012	2011
1.75% Convertible Senior Subordinated Notes due 2015 .....	\$ 379,500	\$ 379,500
Unamortized discount on 1.75% Convertible Senior Subordinated Notes due 2015 .....	(58,168)	(80,278)
1.75% Convertible Senior Subordinated Notes due 2015, net .....	<u>\$ 321,332</u>	<u>\$ 299,222</u>
7.00% Senior Notes due 2019 .....	\$ 500,000	\$ 500,000
7.00% Senior Notes due 2020 .....	\$ 400,000	\$ 400,000
Unamortized initial purchaser's discount .....	(3,101)	(3,382)
7.00% Senior Notes due 2020, net .....	<u>\$ 396,899</u>	<u>\$ 396,618</u>
7.25% Senior Notes due 2022 .....	\$ 400,000	\$ 400,000
3.25% AMS Convertible Notes due 2036 .....	\$ 795	\$ 841
4.00% AMS Convertible Notes due 2041 .....	\$ 111	\$ 131
Term Loan A Facility Due 2016 .....	\$ 1,387,500	\$ 1,471,875
Term Loan B Facility Due 2018 .....	\$ 160,550	\$ 438,250
Other long-term debt .....	\$ 4,758	\$ 5,657
Total long-term debt, net .....	<u>\$ 3,171,945</u>	<u>\$ 3,512,594</u>
Less current portion .....	<u>\$ 133,998</u>	<u>\$ 88,265</u>
Total long-term debt, less current portion, net .....	<u>\$ 3,037,947</u>	<u>\$ 3,424,329</u>

#### Credit Facility

On November 30, 2010, we established a \$400 million, five-year senior secured term loan facility (the Term Loan Facility), and a \$500 million, five-year senior secured revolving credit facility (the 2010 Revolving Credit Facility and, together with the Term Loan Facility, the 2010 Credit Facility) with JP Morgan Chase Bank, Royal Bank of Canada, and certain other lenders. The 2010 Credit Facility was established primarily to finance our acquisition of Qualitest Pharmaceuticals and was available for working capital, general corporate purposes and letters of credit. The agreement governing the 2010 Credit Facility (the 2010 Credit Agreement) also permitted up to \$200 million of additional revolving or term loan commitments from one or more of the existing lenders or other

lenders with the consent of the JP Morgan Chase Bank (the administrative agent) without the need for consent from any of the existing lenders under the 2010 Credit Facility.

The obligations of the Company under the 2010 Credit Facility were guaranteed by certain of the Company's domestic subsidiaries and were secured by substantially all of the assets of the Company and the subsidiary guarantors. The 2010 Credit Facility contained certain usual and customary covenants, including, but not limited to covenants to maintain maximum leverage and minimum interest coverage ratios. Borrowings under the 2010 Credit Facility bore interest at an amount equal to a rate calculated based on the type of borrowing and the Company's Leverage Ratio. For term loans and revolving loans (other than Swing Line Loans), the Company had been permitted to elect to pay interest based on an adjusted LIBOR rate plus between 2.00% and 2.75% or an Alternate Base Rate (as defined in the 2010 Credit Agreement) plus between 1.00% and 1.75%. The Company had also paid a commitment fee of between 35 to 50 basis points, payable quarterly, on the average daily unused amount of the Revolving Credit Facility.

Financing costs of \$16.5 million paid to establish the 2010 Credit Facility were deferred and were being amortized to interest expense over the life of the 2010 Credit Facility. Financing costs associated with prior credit facilities not yet amortized as of November 30, 2010 totaled approximately \$3.2 million on November 30, 2010. In accordance with the applicable accounting guidance for debt modifications, upon the termination of the prior credit facilities, approximately \$0.3 million of this amount was written off in proportion to decreased lending capacity provided by certain individual loan syndicates with a corresponding charge to earnings. The remaining \$2.9 million was deferred to be amortized over the life of the 2010 Credit Facility.

On June 17, 2011, we terminated the 2010 Credit Facility. Concurrent with the termination of the 2010 Credit Facility, we established a \$1,500 million, five-year senior secured term loan facility (the Term Loan A Facility), a \$700 million, seven-year senior secured term loan facility (the Term Loan B Facility, and, together with the Term Loan A Facility, the Term Loan Facilities), and a \$500 million, five-year senior secured revolving credit facility (the 2011 Revolving Credit Facility and, together with the Term Loan Facilities, the 2011 Credit Facility) with Morgan Stanley Senior Funding, Inc., as administrative agent, Bank of America, N.A., as Syndication Agent, and certain other lenders. The 2011 Credit Facility was established primarily to finance our acquisition of AMS, Inc. and is available for working capital, general corporate purposes and lines of credit. The agreement governing the 2011 Credit Facility (the 2011 Credit Agreement) also permits up to \$500 million of additional revolving or term loan commitments from one or more of the existing lenders or other lenders with the consent of Morgan Stanley Senior Funding, Inc. (the administrative agent) without the need for consent from any of the existing lenders under the 2011 Credit Facility.

The obligations of the Company under the 2011 Credit Facility are guaranteed by certain of the Company's domestic subsidiaries and are secured by substantially all of the assets of the Company and the subsidiary guarantors. The 2011 Credit Facility contains certain usual and customary covenants, including, but not limited to covenants to maintain maximum leverage and minimum interest coverage ratios. Borrowings under the 2011 Credit Facility bear interest at an amount equal to a rate calculated based on the type of borrowing and the Company's Leverage Ratio. For term A loans and revolving loans (other than Swing Line Loans), the Company is permitted to elect to pay interest based on an adjusted LIBOR rate plus between 1.75% and 2.50% or an Alternate Base Rate (as defined in the 2011 Credit Agreement) plus between 0.75% and 1.50%. For term B loans, the Company may elect to pay interest based on an adjusted LIBOR rate plus 3.00% or an Alternate Base Rate plus 2.00%. The Company will pay a commitment fee of between 37.5 to 50 basis points, payable quarterly, on the average daily unused amount of the Revolving Credit Facility.

Financing costs of \$56.2 million paid to establish the 2011 Credit Facility, including \$43.4 million paid to investment bankers that also helped structure the AMS, Inc. acquisition, as well as financing costs of \$6.2 million associated with prior credit facilities, were deferred and are being amortized to interest expense over the life of the 2011 Credit Facility. Approximately \$8.5 million of the deferred financing costs associated with prior credit facilities was written off at this time in accordance with the applicable accounting guidance for debt modifications and extinguishments and was included in the Consolidated Statements of Operations as a Net loss on extinguishment of debt.

In February 2012, we made a prepayment of \$205.0 million on our Term Loan B Facility. We made additional prepayments of \$33.0 million and \$39.7 million in July 2012 and September 2012, respectively. In accordance with the applicable accounting guidance for debt modifications and extinguishments, approximately \$7.2 million of the remaining unamortized financing costs was written off in connection with our 2012 prepayments. This amount was included in the Consolidated Statements of Operations as a Net loss on extinguishment of debt.

In September 2011 and December 2011, we made prepayments of \$135.0 million and \$125.0 million, respectively, on our Term Loan B Facility. In accordance with the applicable accounting guidance for debt modifications and extinguishments, approximately \$3.4 million of the remaining unamortized financing costs was written off in connection with our 2011 prepayments and included in the Consolidated Statements of Operations as a Net loss on extinguishment of debt. Pursuant to our rights under the 2011 Credit Agreement, we elected to apply a portion of the September 2011 prepayment against all remaining contractual payments such that we had no remaining principal payment obligations until the maturity of the Term Loan B Facility on June 17, 2018.

During the years ended December 31, 2012, 2011 and 2010, we recognized \$57.8 million, \$51.3 million and \$5.4 million, respectively, of interest expense related to our Credit Facilities.

**7.00% Senior Notes Due 2019**

On June 8, 2011, we issued \$500 million in aggregate principal amount of 7.00% Notes due 2019 (the 2019 Notes) at an issue price of par. The 2019 Notes were issued in a private offering for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The 2019 Notes are senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain of the Company's domestic subsidiaries. Interest on the 2019 Notes is payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2012. The 2019 Notes will mature on July 15, 2019, subject to earlier repurchase or redemption in accordance with the terms of the Indenture incorporated by reference herein. We received proceeds of approximately \$485.9 million from the issuance, net of certain costs of the offering, including \$9.9 million of costs paid to investment bankers that also helped structure the AMS, Inc. acquisition.

On or after July 15, 2015, the Company may on any one or more occasions redeem all or a part of the 2019 Notes, at the redemption prices (expressed as percentages of principal amount) set forth below, plus accrued and unpaid interest and additional interest, if any, if redeemed during the twelve-month period beginning on July 15 of the years indicated below:

<u>Payment Dates (between indicated dates)</u>	<u>Redemption Percentage</u>
From July 15, 2015 to and including July 14, 2016 .....	103.500%
From July 15, 2016 to and including July 14, 2017 .....	101.750%
From July 15, 2017 and thereafter.....	100.000%

In addition, at any time prior to July 15, 2015, Endo may on any one or more occasions redeem all or a part of the 2019 Notes at a specified redemption price set forth in the Indenture, plus accrued and unpaid interest and additional interest, if any.

At any time prior to July 15, 2014, the Company may redeem up to 35% of the aggregate principal amount of the 2019 Notes at a specified redemption price set forth in the Indenture, plus accrued and unpaid interest and additional interest, if any, with the net cash proceeds of an equity offering subject to certain provisions. If the Company experiences certain change of control events, it must offer to repurchase the 2019 Notes at 101% of their principal amount, plus accrued and unpaid interest and additional interest, if any.

The Indenture contains covenants that, among other things, restrict the Company's ability and the ability of its restricted subsidiaries to incur certain additional indebtedness and issue preferred stock, make restricted payments, sell certain assets, agree to any restrictions on the ability of restricted subsidiaries to make payments to the Company, create certain liens, merge, consolidate, or sell substantially all of the Company's assets, or enter into certain transactions with affiliates. These covenants are subject to a number of important exceptions and qualifications, including the fall away or revision of certain of these covenants upon the 2019 Notes receiving investment grade credit ratings.

During the years ended December 31, 2012 and 2011, we recognized \$36.4 million and \$20.4 million, respectively, of interest expense related to our 2019 Notes.

**7.00% Senior Notes Due 2020**

In November 2010, we issued \$400 million in aggregate principal amount of 7.00% Senior Notes due 2020 (the 2020 Notes) at an issue price of 99.105%. The 2020 Notes were issued in a private offering for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The 2020 Notes are senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain of the Company's domestic subsidiaries. Interest on the 2020 Notes is payable semiannually in arrears on June 15 and December 15 of each year, beginning on June 15, 2011. The 2020 Notes will mature on December 15, 2020, subject to earlier repurchase or redemption in accordance with the terms of the Indenture incorporated by reference herein. We received proceeds of approximately \$386.6 million from the issuance, net of the initial purchaser's discount and certain other costs of the offering.

On or after December 15, 2015, the Company may on any one or more occasions redeem all or a part of the 2020 Notes, at the redemption prices (expressed as percentages of principal amount) set forth below, plus accrued and unpaid interest and additional interest, if any, if redeemed during the twelve-month period beginning on December 15 of the years indicated below:

<b><u>Payment Dates (between indicated dates)</u></b>	<b><u>Redemption Percentage</u></b>
From December 15, 2015 to and including December 14, 2016.....	103.500%
From December 15, 2016 to and including December 14, 2017.....	102.333%
From December 15, 2017 to and including December 14, 2018.....	101.167%
From December 15, 2018 and thereafter .....	100.000%

In addition, at any time prior to December 15, 2013, the Company may redeem up to 35% of the aggregate principal amount of the 2020 Notes at a specified redemption price set forth in the Indenture, plus accrued and unpaid interest and additional interest, if any, with the net cash proceeds of an equity offering subject to certain provisions. If the Company experiences certain change of control events, it must offer to repurchase the 2020 Notes at 101% of their principal amount, plus accrued and unpaid interest and additional interest, if any.

The Indenture contains covenants that, among other things, restrict the Company's ability and the ability of its restricted subsidiaries to incur certain additional indebtedness and issue preferred stock, make restricted payments, sell certain assets, agree to any restrictions on the ability of restricted subsidiaries to make payments to the Company, create certain liens, merge, consolidate, or sell substantially all of the Company's assets, or enter into certain transactions with affiliates. These covenants are subject to a number of important exceptions and qualifications, including the fall away or revision of certain of these covenants upon the 2020 Notes receiving investment grade credit ratings.

During the years ended December 31, 2012, 2011 and 2010, we recognized \$29.0 million, \$29.3 million and \$3.1 million, respectively, of interest expense related to our 2020 Notes.

#### ***7.25% Senior Notes Due 2022***

On June 8, 2011, we issued \$400 million in aggregate principal amount of 7.25% Senior Notes due 2022 (the 2022 Notes) at an issue price of par. The 2022 Notes were issued in a private offering for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The 2022 Notes are senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain of the Company's domestic subsidiaries. Interest on the 2022 Notes is payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2012. The 2022 Notes will mature on January 15, 2022, subject to earlier repurchase or redemption in accordance with the terms of the Indenture incorporated by reference herein. We received proceeds of approximately \$388.7 million from the issuance, net of certain costs of the offering, including \$7.9 million of costs paid to investment bankers that also helped structure the AMS, Inc. acquisition.

On or after July 15, 2016, the Company may on any one or more occasions redeem all or a part of the 2022 Notes, at the redemption prices (expressed as percentages of principal amount) set forth below, plus accrued and unpaid interest and additional interest, if any, if redeemed during the twelve-month period beginning on July 15 of the years indicated below:

<b><u>Payment Dates (between indicated dates)</u></b>	<b><u>Redemption Percentage</u></b>
From July 15, 2016 to and including July 14, 2017 .....	103.625%
From July 15, 2017 to and including July 14, 2018 .....	102.417%
From July 15, 2018 to and including July 14, 2019 .....	101.208%
From July 15, 2019 and thereafter .....	100.000%

In addition, at any time prior to July 15, 2016, Endo may on any one or more occasions redeem all or a part of the 2022 notes at a specified redemption price set forth in the Indenture, plus accrued and unpaid interest and additional interest, if any.

At any time prior to July 15, 2014, the Company may redeem up to 35% of the aggregate principal amount of the 2022 Notes at a specified redemption price set forth in the Indenture, plus accrued and unpaid interest and additional interest, if any, with the net cash proceeds of an equity offering subject to certain provisions. If the Company experiences certain change of control events, it must offer to repurchase the 2022 Notes at 101% of their principal amount, plus accrued and unpaid interest and additional interest, if any.

The Indenture contains covenants that, among other things, restrict the Company's ability and the ability of its restricted subsidiaries to incur certain additional indebtedness and issue preferred stock, make restricted payments, sell certain assets, agree to any restrictions on the ability of restricted subsidiaries to make payments to the Company, create certain liens, merge, consolidate, or

sell substantially all of the Company's assets, or enter into certain transactions with affiliates. These covenants are subject to a number of important exceptions and qualifications, including the fall away or revision of certain of these covenants upon the 2022 Notes receiving investment grade credit ratings.

During the years ended December 31, 2012 and 2011, we recognized \$29.8 million and \$16.8 million, respectively, of interest expense related to our 2022 Notes.

### ***2011 Exchange Offer***

On October 14, 2011, the Company filed a Form S-4 Registration Statement with the Securities and Exchange Commission. On October 31, 2011, it filed a prospectus pursuant to Rule 424(b)(3). Pursuant to both filings, the Company offered to exchange the 2019 Notes, 2020 Notes and 2022 Notes for a like principal amount of new notes having identical terms that have been registered under the Securities Act of 1933, as amended. On November 30, 2011, all of the 2019 Notes, 2020 Notes and 2022 Notes had been properly tendered in the exchange offer and not withdrawn.

### ***1.75% Convertible Senior Subordinated Notes Due 2015***

In April 2008, we issued \$379.5 million in aggregate principal amount of 1.75% Convertible Senior Subordinated Notes due April 15, 2015 (the Convertible Notes) in a private offering for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended.

We received proceeds of approximately \$370.7 million from the issuance, net of the initial purchaser's discount and certain other costs of the offering. Interest is payable semiannually in arrears on each April 15 and October 15 with the first interest payment being made on October 15, 2008. The Convertible Notes will mature on April 15, 2015, unless earlier converted or repurchased by us.

Holders of the Convertible Notes may convert their notes based on a conversion rate of 34.2466 shares of our common stock per \$1,000 principal amount of notes (the equivalent of \$29.20 per share), subject to adjustment upon certain events, only under the following circumstances as described in the indenture for the Convertible Notes: (1) during specified periods, if the price of our common stock reaches specified thresholds; (2) if the trading price of the Convertible Notes is below a specified threshold; (3) at any time after October 15, 2014; or (4) upon the occurrence of certain corporate transactions. We will be permitted to deliver cash, shares of Endo common stock or a combination of cash and shares, at our election, to satisfy any future conversions of the Convertible Notes. It is our current intention to settle the principal amount of any conversion consideration in cash.

Concurrently with the issuance of the Convertible Notes, we entered into a privately negotiated convertible note hedge transaction with affiliates of the initial purchasers. Pursuant to the hedge transaction we purchased common stock call options intended to reduce the potential dilution to our common stock upon conversion of the Convertible Notes by effectively increasing the initial conversion price of the Convertible Notes to \$40.00 per share, representing a 61.1% conversion premium over the closing price of our common stock on April 9, 2008 of \$24.85 per share. The call options allow us to purchase up to approximately 13.0 million shares of our common stock at an initial strike price of \$29.20 per share. The call options expires on April 15, 2015 and must be net-share settled. The cost of the call option was approximately \$107.6 million. In addition, we sold warrants to affiliates of certain of the initial purchasers whereby they have the option to purchase up to approximately 13.0 million shares of our common stock at an initial strike price of \$40.00 per share. The warrants expire on various dates from July 14, 2015 through October 6, 2015 and must be net-share settled. We received approximately \$50.4 million in cash proceeds from the sale of these warrants. The warrant transaction could have a dilutive effect on our net income per share to the extent that the price of our common stock exceeds the strike price of the warrants at exercise.

As discussed in Note 17. Net (Loss) Income Per Share, in periods in which our common stock price exceeds the conversion price of the Convertible Notes or the strike price of the warrants, we include the effects of the additional shares that may be issued in our diluted net income per share calculation using the treasury stock method.

The carrying values of the debt and equity components of our Convertible Notes are as follows (in thousands):

	December 31, 2012	December 31, 2011
Principal amount of Convertible Notes.....	\$ 379,500	\$ 379,500
Unamortized discount related to the debt component(1).....	(58,168)	(80,278)
Net carrying amount of the debt component.....	<u>\$ 321,332</u>	<u>\$ 299,222</u>
Carrying amount of the equity component .....	<u>\$ 142,199</u>	<u>\$ 142,199</u>

(1) Represents the unamortized portion of the original purchaser's discount and certain other costs of the offering as well as the unamortized portion of the discount created from the separation of the debt portion of our Convertible Notes from the equity portion. This discount will be amortized to interest expense over the term of the Convertible Notes.

For the year ended December 31, 2012, we recognized \$28.8 million of interest expense related to our Convertible Notes, of which \$6.6 million related to the contractual interest payments and \$22.2 million related to the amortization of the debt discount and certain other costs of the offering. For the year ended December 31, 2011, we recognized \$26.9 million of interest expense related to our Convertible Notes, of which \$6.6 million related to the contractual interest payments and \$20.3 million related to the amortization of the debt discount and certain other costs of the offering. For the year ended December 31, 2010, we recognized \$28.0 million of interest expense related to our Convertible Notes, of which \$9.3 million related to the contractual interest payments and \$18.6 million related to the amortization of the debt discount and certain other costs of the offering.

### **3.25% Convertible AMS Notes Due 2036 and 4.00% Convertible AMS Notes Due 2041**

As a result of our acquisition of AMS, Inc., the Company assumed AMS, Inc.'s 3.25% Convertible Notes due 2036 (the 2036 Notes) and 4.00% Convertible Notes due 2041 (the 2041 Notes and, together with the 2036 Notes, the AMS Notes). In accordance with the indentures governing the AMS Notes, the AMS Notes were immediately convertible upon the closing of Endo's acquisition of AMS, Inc. From the AMS, Inc. Acquisition Date until the make whole premium on the 2036 Notes expired on August 9, 2011, we paid \$95.7 million to redeem \$61.4 million of the 2036 Notes at a stated premium of 1.5571. From the AMS, Inc. Acquisition Date until the make whole premium on the 2041 Notes expired on August 1, 2011, we paid \$423.4 million to redeem \$249.9 million of the 2041 Notes at a stated premium of 1.6940. Our obligation remaining related to the AMS Notes is less than \$1.0 million at December 31, 2012, excluding accrued interest.

### **Maturities**

Maturities on long-term debt for each of the next 5 years as of December 31, 2012 are as follows (in thousands):

	December 31, 2012
2013.....	\$ 133,092
2014.....	\$ 151,347
2015.....	\$ 568,029
2016.....	\$ 919,252
2017.....	\$ 37

Maturities on long-term debt, and respective interest payments, primarily represent obligations of Endo Health Solutions Inc.

## **NOTE 20. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES**

We are exposed to certain risks relating to our ongoing business operations. With our June 2011 acquisition of AMS, Inc., we began using derivative instruments to mitigate a portion of our exposure to volatility in foreign currency exchange rates. Foreign currency exchange forward contracts are used to manage the currency risk associated with forecasted sales to and receivables from certain subsidiaries, denominated in their local currencies. We hedge only exposures in the ordinary course of business. We account for our derivative instruments at fair value, which is determined based on quoted prices for similar contracts.

We account for certain of our derivative instruments under hedge accounting provided we meet designation, documentary and analytic requirements. Hedge accounting creates the potential for a Consolidated Statement of Operations match between the changes in fair value of derivatives and the changes in the cost of the associated underlying transactions, in this case translation gain or loss. The effective portion of the change in the fair value of these foreign currency exchange contracts is reported in Accumulated other comprehensive loss, a component of stockholders' equity, and is recognized as an adjustment to Other income, net, in the same period



the related expenses are recognized in earnings. Ineffectiveness would occur when changes in the market value of the hedged transactions are not completely offset by changes in the market value of the derivatives. The ineffective portion of contracts designated for hedge accounting, the gain or loss from changes in the fair value of contracts not designated for hedge accounting and contracts where hedge accounting is discontinued when it is determined the underlying transaction is not going to occur, are recognized currently in the Consolidated Statements of Operations. Amounts due from counterparties (unrealized hedge gains) or due to counterparties (unrealized hedge losses) are included in Prepaid expenses and other current assets or other accrued expenses, respectively. Cash receipts or payments related to our derivatives are classified in the Consolidated Statements of Cash Flows as cash flows from operating activities, consistent with the related items being hedged, unless the derivative is not designated or does not qualify for hedge accounting, in which case the receipts or payments are classified in cash flows from investing activities.

At December 31, 2012, we have foreign currency exchange forward contracts outstanding which are designated as cash flow accounting hedges of currency fluctuations for a portion of our forecasted sales to certain subsidiaries, denominated in euros, British pounds, Canadian dollars and Australian dollars. These derivative instruments have remaining terms between one and twelve months. The notional amount of these foreign currency exchange forward contracts in U.S. dollars was \$31.8 million at December 31, 2012 and \$46.8 million at December 31, 2011.

We have also entered into foreign currency exchange forward contracts to manage a portion of our exposure to foreign exchange rate fluctuations on certain inter-company receivables denominated in euros, British pounds, Canadian dollars and Australian dollars. These contracts are not designated as accounting hedges and the associated underlying transactions are expected to occur within the next month. There were no such contracts outstanding at December 31, 2012. The notional amount of these contracts was \$10.8 million at December 31, 2011.

At December 31, 2012, the fair value of derivatives designated for hedge accounting of \$0.6 million was included in Accrued expenses in the Consolidated Balance Sheets. At December 31, 2011, \$1.5 million of the fair value of derivatives designated for hedge accounting was included in Prepaid expenses and other current assets and \$0.1 million was included in Accrued expenses in the Consolidated Balance Sheets.

At December 31, 2012, \$0.6 million of the existing net loss from contracts designated for hedge accounting, which is included in Accumulated other comprehensive loss, is expected to be reclassified into earnings within the next twelve months.

During the years ended December 31, 2012 and 2011, a loss of \$0.5 million and a gain of \$2.0 million, respectively, were recognized in Other income, net in the Consolidated Statements of Operations from contracts not designated for hedge accounting.

## **NOTE 21. SUPPLEMENTAL GUARANTOR INFORMATION**

In connection with the 2019 Notes, 2020 Notes and 2022 Notes, we have included this supplemental guarantor disclosure in accordance with Rule 3-10 of Regulation S-X. The 2019 Notes, 2020 Notes, and 2022 Notes are fully and unconditionally guaranteed, jointly and severally, on a senior unsecured basis by the following nineteen subsidiaries (together, the Guarantor Subsidiaries):

- Endo Pharmaceuticals Inc.
- Endo Pharmaceuticals Valera Inc.
- American Medical Systems Holdings, Inc.
- AMS Research Corporation
- AMS Sales Corporation
- Generics International (US Midco), Inc.
- Generics International (US), Inc.
- Generics Bidco II, LLC
- Wood Park Properties LLC
- Quartz Specialty Pharmaceuticals, LLC
- Endo Pharmaceuticals Solutions Inc.
- Ledgemont Royalty Sub LLC
- American Medical Systems, Inc.
- Laserscope
- Generics International (US Parent), Inc.
- Generics International (US Holdco), Inc.
- Generics Bidco I, LLC
- Moores Mill Properties LLC
- Vintage Pharmaceuticals, LLC

Each of the Guarantor Subsidiaries is 100 percent owned by us.

The following supplemental consolidating financial information presents the Consolidated Balance Sheets as of December 31, 2012 and 2011, the Consolidated Statements of Operations for the years ended December 31, 2012, 2011 and 2010, the Consolidated Statements of Comprehensive (Loss) Income for the years ended December 31, 2012, 2011 and 2010 and the Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010, for the Guarantor Subsidiaries as a group, and separately for our non-Guarantor Subsidiaries as a group.

The Consolidating Financial Statements are presented using the equity method of accounting for investments in 100% owned subsidiaries. Under the equity method, the investments in subsidiaries are recorded at cost and adjusted for our share of the subsidiaries' cumulative results of operations, capital contributions, distributions and other equity changes. The elimination entries principally eliminate investments in subsidiaries and intercompany balances and transactions. The financial information in this footnote should be read in conjunction with the Consolidated Financial Statements presented and other notes related thereto contained in this Annual Report on Form 10-K for the year ended December 31, 2012.

Subsequent to the issuance of the 2011 financial statements, the Company determined that a revision was required to correct the classification of intercompany cash transfers between Endo Pharmaceuticals Holdings, Inc. (n/k/a Endo Health Solutions Inc.) and Guarantor and Non-Guarantor Subsidiaries totaling \$85.1 million as of December 31, 2011. As a result, adjustments have been made from what was previously reported in the Consolidating Statement of Operations as of December 31, 2011. These adjustments to the 2011 Consolidating Statement of Operations resulted in a decrease to Endo Health Solution Inc.'s Dividend income from subsidiaries of \$85.1 million and a corresponding decrease in Endo Health Solution Inc.'s Income before income tax. Additionally, there was an increase of \$85.1 million in Endo Health Solutions Inc.'s Equity from earnings (loss) in subsidiaries. Each of these adjustments was offset in the Eliminations column on the Consolidating Statement of Operations. These adjustments had no effect on the total Consolidated net income or Net income attributable to Endo Health Solutions Inc. for the year ended December 31, 2011 and the change did not impact the Consolidating Balance Sheet or Consolidating Statement of Cash Flows.

**CONSOLIDATING BALANCE SHEET**

(In thousands)

December 31, 2012

	Endo Health Solutions Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
<b>ASSETS</b>					
<b>CURRENT ASSETS:</b>					
Cash and cash equivalents .....	\$ 512	\$ 499,932	\$ 47,472	\$ —	\$ 547,916
Accounts receivable, net .....	—	601,967	75,752	13,131	690,850
Inventories, net .....	—	354,150	23,774	(20,286)	357,638
Prepaid expenses and other current assets .....	—	12,675	8,591	6,484	27,750
Income taxes receivable .....	39,503	(35,708)	32,585	109	36,489
Deferred income taxes .....	—	296,027	11,906	658	308,591
Total current assets .....	40,015	1,729,043	200,080	96	1,969,234
INTERCOMPANY RECEIVABLES .....	2,039,648	8,233,831	193,673	(10,467,152)	—
MARKETABLE SECURITIES .....	—	1,746	—	—	1,746
PROPERTY, PLANT AND EQUIPMENT, NET .....	—	356,427	29,573	(332)	385,668
GOODWILL .....	—	1,798,493	215,858	—	2,014,351
OTHER INTANGIBLES, NET .....	—	2,020,942	78,031	—	2,098,973
INVESTMENT IN SUBSIDIARIES .....	5,162,874	313,978	—	(5,476,852)	—
OTHER ASSETS .....	65,727	27,766	24,122	(19,028)	98,587
<b>TOTAL ASSETS .....</b>	<b>\$ 7,308,264</b>	<b>\$ 14,482,226</b>	<b>\$ 741,337</b>	<b>\$ (15,963,268)</b>	<b>\$ 6,568,559</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>					
<b>CURRENT LIABILITIES:</b>					
Accounts payable .....	\$ 90	\$ 410,532	\$ 6,492	\$ (232)	\$ 416,882
Accrued expenses .....	31,981	1,096,261	42,708	(5)	1,170,945
Current portion of long-term debt .....	131,250	906	1,842	—	133,998
Acquisition-related contingent consideration .....	—	6,195	—	—	6,195
Total current liabilities .....	163,321	1,513,894	51,042	(237)	1,728,020
INTERCOMPANY PAYABLES .....	3,031,742	7,351,093	84,317	(10,467,152)	—
DEFERRED INCOME TAXES .....	5,314	512,118	(867)	—	516,565
ACQUISITION-RELATED CONTINGENT CONSIDERATION .....	—	2,729	—	—	2,729
LONG-TERM DEBT, LESS CURRENT PORTION, NET .....	3,035,031	—	2,916	—	3,037,947
OTHER LIABILITIES .....	—	159,319	9,800	(19,027)	150,092
<b>STOCKHOLDERS' EQUITY:</b>					
Preferred Stock .....	—	—	—	—	—
Common Stock .....	1,400	—	30,430	(30,430)	1,400
Additional paid-in capital .....	1,035,115	4,195,802	571,928	(4,767,730)	1,035,115
Retained earnings (deficit) .....	811,573	754,551	(70,203)	(684,348)	811,573
Accumulated other comprehensive (loss) income .....	(6,802)	(7,280)	1,624	5,656	(6,802)
Treasury stock .....	(768,430)	—	—	—	(768,430)
Total Endo Health Solutions Inc. stockholders' equity .....	1,072,856	4,943,073	533,779	(5,476,852)	1,072,856
Noncontrolling interests .....	—	—	60,350	—	60,350
Total stockholders' equity .....	1,072,856	4,943,073	594,129	(5,476,852)	1,133,206
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY .....</b>	<b>\$ 7,308,264</b>	<b>\$ 14,482,226</b>	<b>\$ 741,337</b>	<b>\$ (15,963,268)</b>	<b>\$ 6,568,559</b>

**CONSOLIDATING BALANCE SHEET**  
(In thousands)

December 31, 2011

	Endo Health Solutions Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
<b>ASSETS</b>					
<b>CURRENT ASSETS:</b>					
Cash and cash equivalents .....	\$ 48,318	\$ 455,756	\$ 43,546	\$ —	\$ 547,620
Accounts receivable, net .....	—	656,265	74,584	2,373	733,222
Inventories, net .....	—	248,128	19,918	(5,627)	262,419
Prepaid expenses and other current assets .....	—	19,274	7,004	3,454	29,732
Deferred income taxes .....	—	205,606	9,497	—	215,103
<b>Total current assets .....</b>	<b>48,318</b>	<b>1,585,029</b>	<b>154,549</b>	<b>200</b>	<b>1,788,096</b>
INTERCOMPANY RECEIVABLES .....	1,777,233	7,322,603	193,223	(9,293,059)	—
MARKETABLE SECURITIES .....	—	19,105	—	—	19,105
PROPERTY, PLANT AND EQUIPMENT, NET .....	—	268,572	29,469	(310)	297,731
GOODWILL .....	—	2,303,940	254,101	—	2,558,041
OTHER INTANGIBLES, NET .....	—	2,415,531	88,593	—	2,504,124
INVESTMENT IN SUBSIDIARIES .....	5,860,570	317,544	—	(6,178,114)	—
OTHER ASSETS .....	87,099	27,338	31,049	(20,000)	125,486
<b>TOTAL ASSETS .....</b>	<b>\$ 7,773,220</b>	<b>\$ 14,259,662</b>	<b>\$ 750,984</b>	<b>\$ (15,491,283)</b>	<b>\$ 7,292,583</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>					
<b>CURRENT LIABILITIES:</b>					
Accounts payable .....	\$ —	\$ 251,715	\$ 8,667	\$ 3	\$ 260,385
Accrued expenses .....	38,623	651,653	42,558	(3)	732,831
Current portion of long-term debt .....	84,376	972	2,917	—	88,265
Acquisition-related contingent consideration .....	—	4,925	—	—	4,925
Income taxes payable .....	(23,204)	71,900	(13,214)	(110)	35,372
<b>Total current liabilities .....</b>	<b>99,795</b>	<b>981,165</b>	<b>40,928</b>	<b>(110)</b>	<b>1,121,778</b>
INTERCOMPANY PAYABLES .....	2,267,572	6,978,697	46,790	(9,293,059)	—
DEFERRED INCOME TAXES .....	6,573	611,625	(521)	—	617,677
ACQUISITION-RELATED CONTINGENT CONSIDERATION .....	—	3,762	—	—	3,762
LONG-TERM DEBT, LESS CURRENT PORTION, NET .....	3,421,590	—	2,739	—	3,424,329
OTHER LIABILITIES .....	—	94,915	10,531	(20,000)	85,446
<b>STOCKHOLDERS' EQUITY:</b>					
Preferred Stock .....	—	—	—	—	—
Common Stock .....	1,383	—	30,430	(30,430)	1,383
Additional paid-in capital .....	952,325	4,198,625	574,218	(4,772,843)	952,325
Retained earnings (deficit) .....	1,551,910	1,398,613	(15,364)	(1,383,249)	1,551,910
Accumulated other comprehensive loss .....	(9,436)	(7,740)	(668)	8,408	(9,436)
Treasury stock .....	(518,492)	—	—	—	(518,492)
<b>Total Endo Health Solutions Inc. stockholders'     equity .....</b>	<b>1,977,690</b>	<b>5,589,498</b>	<b>588,616</b>	<b>(6,178,114)</b>	<b>1,977,690</b>
Noncontrolling interests .....	—	—	61,901	—	61,901
<b>Total stockholders' equity .....</b>	<b>1,977,690</b>	<b>5,589,498</b>	<b>650,517</b>	<b>(6,178,114)</b>	<b>2,039,591</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY .....</b>	<b>\$ 7,773,220</b>	<b>\$ 14,259,662</b>	<b>\$ 750,984</b>	<b>\$ (15,491,283)</b>	<b>\$ 7,292,583</b>

**CONSOLIDATING STATEMENT OF OPERATIONS**  
(In thousands)

Year Ended December 31, 2012

	Endo Health Solutions Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
TOTAL REVENUES.....	\$ —	\$ 2,769,215	\$ 355,752	\$ (97,604)	\$ 3,027,363
COSTS AND EXPENSES:					
Cost of revenues .....	—	1,131,412	221,554	(91,873)	1,261,093
Selling, general and administrative .....	—	813,805	85,109	(67)	898,847
Research and development .....	—	218,840	7,280	—	226,120
Patent litigation settlement, net .....	—	85,123	—	—	85,123
Litigation-related and other contingencies .....	—	316,425	—	—	316,425
Asset impairment charges.....	—	715,551	52,916	—	768,467
Acquisition-related and integration items, net.....	—	19,412	3,603	—	23,015
OPERATING LOSS.....	—	(531,353)	(14,710)	(5,664)	(551,727)
INTEREST EXPENSE, NET.....	45,699	137,096	39	—	182,834
NET LOSS ON EXTINGUISHMENT OF DEBT .....	7,215	—	—	—	7,215
OTHER (INCOME) EXPENSE, NET.....	—	(14,720)	5,645	8,882	(193)
LOSS BEFORE INCOME TAX.....	(52,914)	(653,729)	(20,394)	(14,546)	(741,583)
INCOME TAX.....	(18,581)	(13,233)	(17,871)	(3,877)	(53,562)
EQUITY FROM LOSS IN SUBSIDIARIES.....	(706,004)	(3,566)	—	709,570	—
CONSOLIDATED NET LOSS.....	(740,337)	(644,062)	(2,523)	698,901	(688,021)
Less: Net income attributable to noncontrolling interests.....	—	—	52,316	—	52,316
NET LOSS ATTRIBUTABLE TO ENDO HEALTH SOLUTIONS INC.....	<u>\$ (740,337)</u>	<u>\$ (644,062)</u>	<u>\$ (54,839)</u>	<u>\$ 698,901</u>	<u>\$ (740,337)</u>

**CONSOLIDATING STATEMENT OF OPERATIONS**  
(In thousands)

Year Ended December 31, 2011

	Endo Health Solutions Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
TOTAL REVENUES .....	\$ —	\$ 2,580,530	\$ 280,431	\$ (130,840)	\$ 2,730,121
COSTS AND EXPENSES:					
Cost of revenues .....	—	1,033,334	164,775	(132,901)	1,065,208
Selling, general and administrative .....	58	753,855	59,372	(14)	813,271
Research and development .....	—	182,333	(47)	—	182,286
Litigation-related and other contingencies .....	—	—	11,263	—	11,263
Asset impairment charges .....	—	116,089	—	—	116,089
Acquisition-related and integration items, net.....	(7,050)	39,734	954	—	33,638
OPERATING INCOME .....	6,992	455,185	44,114	2,075	508,366
INTEREST EXPENSE, NET .....	38,908	109,060	56	—	148,024
NET LOSS ON EXTINGUISHMENT OF DEBT .....	11,919	—	—	—	11,919
OTHER INCOME, NET .....	—	(2,812)	(580)	124	(3,268)
(LOSS) INCOME BEFORE INCOME TAX .....	(43,835)	348,937	44,638	1,951	351,691
INCOME TAX .....	(18,245)	129,673	(2,580)	778	109,626
EQUITY FROM INCOME IN SUBSIDIARIES .....	213,203	1,548	—	(214,751)	—
CONSOLIDATED NET INCOME .....	\$ 187,613	\$ 220,812	\$ 47,218	\$ (213,578)	\$ 242,065
Less: Net income attributable to noncontrolling interests .....	—	—	54,452	—	54,452
NET INCOME (LOSS) ATTRIBUTABLE TO ENDO HEALTH SOLUTIONS INC .....	\$ 187,613	\$ 220,812	\$ (7,234)	\$ (213,578)	\$ 187,613

**CONSOLIDATING STATEMENT OF OPERATIONS**  
(In thousands)

Year Ended December 31, 2010

	Endo Health Solutions Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
TOTAL REVENUES.....	\$ —	\$ 1,633,328	\$ 102,144	\$ (19,243)	\$ 1,716,229
COSTS AND EXPENSES:					
Cost of revenues .....	—	470,339	53,661	(19,243)	504,757
Selling, general and administrative .....	61	530,143	17,401	—	547,605
Research and development .....	—	144,525	—	—	144,525
Asset impairment charges.....	—	35,000	—	—	35,000
Acquisition-related and integration items, net.....	(42,970)	46,635	15,311	—	18,976
OPERATING INCOME.....	42,909	406,686	15,771	—	465,366
INTEREST EXPENSE (INCOME), NET .....	23,953	22,681	(33)	—	46,601
OTHER INCOME, NET .....	—	(1,427)	(506)	—	(1,933)
INCOME BEFORE INCOME TAX.....	18,956	385,432	16,310	—	420,698
INCOME TAX.....	(7,985)	145,272	(3,609)	—	133,678
EQUITY FROM INCOME IN SUBSIDIARIES.....	232,065	—	—	(232,065)	—
CONSOLIDATED NET INCOME.....	\$ 259,006	\$ 240,160	\$ 19,919	\$ (232,065)	\$ 287,020
Less: Net income attributable to noncontrolling interests.....	—	—	28,014	—	28,014
NET INCOME (LOSS) ATTRIBUTABLE TO ENDO HEALTH SOLUTIONS INC.....	\$ 259,006	\$ 240,160	\$ (8,095)	\$ (232,065)	\$ 259,006



**CONSOLIDATING STATEMENT OF COMPREHENSIVE (LOSS) INCOME**  
**(In thousands)**

Year Ended December 31, 2012

	Endo Health Solutions Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
CONSOLIDATED NET LOSS.....	\$ (740,337)	\$ (644,062)	\$ (2,523)	\$ 698,901	\$ (688,021)
OTHER COMPREHENSIVE INCOME .....	2,634	460	2,292	(2,752)	2,634
CONSOLIDATED COMPREHENSIVE LOSS.....	(737,703)	(643,602)	(231)	696,149	(685,387)
Less: Comprehensive income attributable to noncontrolling interests .....	—	—	52,316	—	52,316
COMPREHENSIVE LOSS ATTRIBUTABLE TO ENDO HEALTH SOLUTIONS INC.....	<u>\$ (737,703)</u>	<u>\$ (643,602)</u>	<u>\$ (52,547)</u>	<u>\$ 696,149</u>	<u>\$ (737,703)</u>

**CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME (LOSS)**  
**(In thousands)**

Year Ended December 31, 2011

	Endo Health Solutions Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
CONSOLIDATED NET INCOME.....	\$ 187,613	\$ 220,812	\$ 47,218	\$ (213,578)	\$ 242,065
OTHER COMPREHENSIVE LOSS.....	(8,275)	(6,579)	(668)	7,247	(8,275)
CONSOLIDATED COMPREHENSIVE INCOME....	179,338	214,233	46,550	(206,331)	233,790
Less: Comprehensive income attributable to noncontrolling interests .....	—	—	54,452	—	54,452
COMPREHENSIVE INCOME (LOSS) ATTRIBUTABLE TO ENDO HEALTH SOLUTIONS INC.....	\$ 179,338	\$ 214,233	\$ (7,902)	\$ (206,331)	\$ 179,338

**CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME (LOSS)**  
**(In thousands)**

Year Ended December 31, 2010

	Endo Health Solutions Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
CONSOLIDATED NET INCOME.....	\$ 259,006	\$ 240,160	\$ 19,919	\$ (232,065)	\$ 287,020
OTHER COMPREHENSIVE INCOME .....	720	720	—	(720)	720
CONSOLIDATED COMPREHENSIVE INCOME....	259,726	240,880	19,919	(232,785)	287,740
Less: Comprehensive income attributable to noncontrolling interests .....	—	—	28,014	—	28,014
COMPREHENSIVE INCOME (LOSS) ATTRIBUTABLE TO ENDO HEALTH SOLUTIONS INC.....	<u>\$ 259,726</u>	<u>\$ 240,880</u>	<u>\$ (8,095)</u>	<u>\$ (232,785)</u>	<u>\$ 259,726</u>

**CONSOLIDATING STATEMENT OF CASH FLOWS**  
(In thousands)

Year Ended December 31, 2012

	Endo Health Solutions Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
<b>OPERATING ACTIVITIES:</b>					
Net cash provided by operating activities .....	\$ 43,094	\$ 649,475	\$ 41,310	\$ —	\$ 733,879
<b>INVESTING ACTIVITIES:</b>					
Purchases of property, plant and equipment .....	—	(84,621)	(15,197)	—	(99,818)
Proceeds from sale of property, plant and equipment .....	—	132	1,294	—	1,426
Acquisitions, net of cash acquired .....	—	—	(3,175)	—	(3,175)
Proceeds from investments .....	—	18,800	—	—	18,800
License fees .....	—	(5,000)	(700)	—	(5,700)
Net cash used in investing activities .....	—	(70,689)	(17,778)	—	(88,467)
<b>FINANCING ACTIVITIES:</b>					
Capital lease obligations repayments .....	—	(661)	(198)	—	(859)
Principal payments on Term Loans .....	(362,075)	—	—	—	(362,075)
Payment on AMS Convertible Notes .....	—	(66)	—	—	(66)
Principal payments on other indebtedness .....	—	—	(899)	—	(899)
Tax benefits of stock awards .....	—	4,949	—	—	4,949
Exercise of Endo Health Solutions Inc. stock options .....	19,358	—	—	—	19,358
Purchase of common stock .....	(256,000)	—	—	—	(256,000)
Issuance of common stock from treasury .....	6,062	—	—	—	6,062
Cash distributions to noncontrolling interests .....	—	—	(53,269)	—	(53,269)
Cash buy-out of noncontrolling interests, net of cash contributions .....	—	—	(2,748)	—	(2,748)
Intercompany activity .....	501,755	(538,832)	37,077	—	—
Net cash used in financing activities .....	(90,900)	(534,610)	(20,037)	—	(645,547)
Effect of foreign exchange rate .....	—	—	431	—	431
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS .....	(47,806)	44,176	3,926	—	296
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD .....	48,318	455,756	43,546	—	547,620
CASH AND CASH EQUIVALENTS, END OF PERIOD .....	<u>\$ 512</u>	<u>\$ 499,932</u>	<u>\$ 47,472</u>	<u>\$ —</u>	<u>\$ 547,916</u>

**CONSOLIDATING STATEMENT OF CASH FLOWS**  
(In thousands)

Year Ended December 31, 2011

	Endo Health Solutions Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
<b>OPERATING ACTIVITIES:</b>					
Net cash provided by operating activities .....	\$ 64,311	\$ 577,150	\$ 60,654	\$ —	\$ 702,115
<b>INVESTING ACTIVITIES:</b>					
Purchases of property, plant and equipment.....	—	(49,895)	(9,488)	—	(59,383)
Proceeds from sale of property, plant and equipment.....	—	345	1,281	—	1,626
Acquisitions, net of cash acquired.....	—	(2,341,143)	(52,254)	—	(2,393,397)
Proceeds from investments.....	—	85,025	—	—	85,025
Purchases of investments .....	—	(14,025)	—	—	(14,025)
Other investments.....	—	(4,628)	—	—	(4,628)
License fees .....	—	(2,300)	—	—	(2,300)
Proceeds from sale of business.....	—	—	12,990	—	12,990
Intercompany activity.....	—	(30,430)	—	30,430	—
Net cash used in investing activities.....	—	(2,357,051)	(47,471)	30,430	(2,374,092)
<b>FINANCING ACTIVITIES:</b>					
Capital lease obligations repayments .....	—	(1,212)	(232)	—	(1,444)
Proceeds from issuance of 2019 and 2022 Notes.....	900,000	—	—	—	900,000
Proceeds from issuance of Term Loans.....	2,200,000	—	—	—	2,200,000
Proceeds from other indebtedness.....	—	—	500	—	500
Principal payments on Term Loans.....	(689,876)	—	—	—	(689,876)
Payment on AMS Convertible Notes .....	—	(519,040)	—	—	(519,040)
Deferred financing fees .....	(82,504)	—	—	—	(82,504)
Payment for contingent consideration.....	—	—	(827)	—	(827)
Tax benefits of stock awards .....	—	6,145	(236)	—	5,909
Exercise of Endo Health Solutions Inc. stock options .....	28,954	—	—	—	28,954
Purchase of common stock.....	(34,702)	—	—	—	(34,702)
Cash distributions to noncontrolling interests.....	—	—	(53,997)	—	(53,997)
Cash buy-out of noncontrolling interests, net of cash contributions.....	—	—	(292)	—	(292)
Intercompany activity.....	(2,383,265)	2,345,595	68,100	(30,430)	—
Net cash (used in) provided by financing activities.....	(61,393)	1,831,488	13,016	(30,430)	1,752,681
Effect of foreign exchange rate .....	—	—	702	—	702
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS .....</b>	<b>2,918</b>	<b>51,587</b>	<b>26,901</b>	<b>—</b>	<b>81,406</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD .....</b>	<b>45,400</b>	<b>404,169</b>	<b>16,645</b>	<b>—</b>	<b>466,214</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD .....</b>	<b>\$ 48,318</b>	<b>\$ 455,756</b>	<b>\$ 43,546</b>	<b>\$ —</b>	<b>\$ 547,620</b>

**CONSOLIDATING STATEMENT OF CASH FLOWS**  
(In thousands)

Year Ended December 31, 2010

	Endo Health Solutions Inc.	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Eliminations	Consolidated Total
<b>OPERATING ACTIVITIES:</b>					
Net cash provided by operating activities .....	\$ 15,435	\$ 179,754	\$ 258,457	\$ —	\$ 453,646
<b>INVESTING ACTIVITIES:</b>					
Purchases of property, plant and equipment.....	—	(15,500)	(4,391)	—	(19,891)
Proceeds from sale of property, plant and equipment .....	—	356	—	—	356
Acquisitions, net of cash acquired.....	—	(896,966)	(208,074)	—	(1,105,040)
Proceeds from sales of trading securities .....	—	231,125	—	—	231,125
Other investments.....	—	(2,473)	—	—	(2,473)
License fees .....	—	(400)	—	—	(400)
Net cash used in investing activities.....	—	(683,858)	(212,465)	—	(896,323)
<b>FINANCING ACTIVITIES:</b>					
Capital lease obligations repayments .....	—	(313)	—	—	(313)
Proceeds from issuance of 2020 Notes .....	386,576	—	—	—	386,576
Proceeds from issuance of Term Loans.....	400,000	—	—	—	400,000
Proceeds from other indebtedness.....	—	1,696	—	—	1,696
Principal payments on HealthTronics, Inc. senior credit facility .....	—	(40,000)	—	—	(40,000)
Principal payments on Qualitest Pharmaceuticals debt .....	—	(406,758)	—	—	(406,758)
Principal payments on other indebtedness .....	—	(61,559)	—	—	(61,559)
Deferred financing fees .....	(13,563)	—	—	—	(13,563)
Tax benefits of stock awards .....	—	1,944	—	—	1,944
Exercise of Endo Health Solutions Inc. stock options .....	20,883	—	—	—	20,883
Purchase of common stock.....	(58,974)	—	—	—	(58,974)
Cash distributions to noncontrolling interests.....	—	—	(28,870)	—	(28,870)
Cash buy-out of noncontrolling interests, net of cash contributions.....	—	—	(633)	—	(633)
Intercompany activity.....	(747,543)	747,543	—	—	—
Net cash (used in) provided by financing activities.....	(12,621)	242,553	(29,503)	—	200,429
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS.....</b>	<b>2,814</b>	<b>(261,551)</b>	<b>16,489</b>	<b>—</b>	<b>(242,248)</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD .....</b>	<b>42,586</b>	<b>665,720</b>	<b>156</b>	<b>—</b>	<b>708,462</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD .....</b>	<b>\$ 45,400</b>	<b>\$ 404,169</b>	<b>\$ 16,645</b>	<b>\$ —</b>	<b>\$ 466,214</b>

**NOTE 22. SUBSEQUENT EVENTS*****Long-Term Incentive Compensation***

In early 2013, long-term incentive compensation in the form of stock options and restricted stock units were granted to employees. Stock options will generally vest over 4 years and expire 10 years from the date of the grant. Restricted stock units will vest over 4 years. The exercise price of the options granted was equal to the closing price on the dates of grant. The grant date fair value of the stock options and restricted stock units granted was approximately \$31.7 million.

***Appointment of New President and Chief Executive Officer***

On February 25, 2013, the Company announced the appointment of Mr. Rajiv De Silva to the position of President and Chief Executive Officer of the Registrant, effective March 18, 2013, which will be the effective date of David P. Holveck's retirement. Mr. De Silva will also be appointed to the Board effective March 18, 2013, which is the effective date of Mr. Holveck's resignation from the Board. In connection with Mr. De Silva's appointment as President and Chief Executive Officer of the Company, he entered into an executive employment agreement, effective as of March 18, 2013.

**NOTE 23. QUARTERLY FINANCIAL DATA (UNAUDITED)**

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share data)			
<b>2012(1)</b>				
Total revenues.....	\$ 690,633	\$ 785,188	\$ 750,482	\$ 801,060
Gross profit.....	\$ 325,813	\$ 490,618	\$ 456,215	\$ 493,624
Operating (loss) income .....	\$ (61,078)	\$ 70,153	\$ 143,516	\$ (704,318)
Net (loss) income attributable to Endo Health Solutions Inc.....	\$ (87,345)	\$ 9,465	\$ 53,809	\$ (716,266)
Net (loss) income per share attributable to Endo Health Solutions Inc. (basic).....	\$ (0.75)	\$ 0.08	\$ 0.46	\$ (6.35)
Net (loss) income per share attributable to Endo Health Solutions Inc. (diluted).....	\$ (0.75)	\$ 0.08	\$ 0.45	\$ (6.35)
Weighted average shares (basic).....	117,052	116,992	116,022	112,811
Weighted average shares (diluted).....	117,052	121,080	119,579	112,811
<b>2011(2)</b>				
Total revenues.....	\$ 560,026	\$ 607,611	\$ 759,078	\$ 803,406
Gross profit.....	\$ 328,468	\$ 370,914	\$ 456,906	\$ 508,625
Operating income .....	\$ 120,879	\$ 134,315	\$ 140,154	\$ 113,018
Net income attributable to Endo Health Solutions Inc.....	\$ 55,787	\$ 54,583	\$ 40,649	\$ 36,594
Net income per share attributable to Endo Health Solutions Inc. (basic) .....	\$ 0.48	\$ 0.47	\$ 0.35	\$ 0.31
Net income per share attributable to Endo Health Solutions Inc. (diluted) ...	\$ 0.46	\$ 0.44	\$ 0.34	\$ 0.30
Weighted average shares (basic).....	116,354	116,663	116,816	116,992
Weighted average shares (diluted).....	120,761	122,686	120,847	120,418

- (1) Operating income for the year ended December 31, 2012 was impacted by (1) milestone payments to collaborative partners of \$45.8 million, \$5.7 million, \$5.3 million and \$3.9 million in the first, second, third and fourth quarters, respectively (2) acquisition-related and integration items, net of \$3.7 million, \$7.1 million, \$5.8 million and \$6.4 million during the first, second, third and fourth quarters, respectively (3) asset impairment charges of \$40.0 million, \$3.0 million, \$11.2 million and \$714.3 million during the first, second, third and fourth quarters, respectively (4) net inventory step-up of \$1.3 million and \$(0.4) million in the first and second quarters, respectively (5) amortization expense relating to intangible assets of \$53.5 million, \$58.7 million, \$58.9 million and \$56.8 million during the first, second, third and fourth quarters, respectively (6) certain integration costs and separation benefits incurred in connection with continued efforts to enhance the company's operations and other miscellaneous costs of \$11.6 million, \$3.8 million, \$11.6 million and \$20.1 million during the first, second, third and fourth quarters, respectively and (7) other charges related to litigation-related and other contingent matters totaling \$110.0 million, \$131.4 million, \$30.4 million and \$231.8 million during the first, second, third and fourth quarters, respectively.



(2) Operating income for the year ended December 31, 2011 was impacted by (1) milestone payments to collaborative partners of \$11.0 million, \$14.0 million, \$2.4 million and \$0.8 million in the first, second, third and fourth quarters, respectively (2) acquisition-related and integration items, net of \$6.1 million, \$17.6 million, \$5.8 million and \$4.1 million during the first, second, third and fourth quarters, respectively (3) asset impairment charges of \$22.7 million and \$93.4 million during the third and fourth quarters, respectively (4) net inventory step-up of \$13.8 million, \$3.0 million, \$23.9 million and \$8.7 million in the first, second, third and fourth quarters, respectively (5) amortization expense relating to intangible assets of \$37.4 million, \$40.6 million, \$59.0 million and \$54.6 million during the first, second, third and fourth quarters, respectively (6) certain integration costs and separation benefits incurred in connection with continued efforts to enhance the company's operations of \$3.5 million, \$0.5 million, \$13.6 million and \$4.2 million during the first, second, third and fourth quarters, respectively and (7) other charges related to litigation-related and other contingent matters totaling \$11.3 million during the fourth quarter.

Quarterly and year to date computations of per share amounts are made independently; therefore, the sum of the per share amounts for the quarters may not equal the per share amounts for the year.

## Exhibit Index

<u>Exhibit No.</u>	<u>Title</u>
3.1	Amended and Restated Certificate of Incorporation of Endo (incorporated herein by reference to Exhibit 3.1 of the Current Report on Form 8-K filed with the Commission on May 25, 2012)
3.2	Amended and Restated By-Laws Endo (incorporated herein by reference to Exhibit 3.2 of the Current Report on Form 8-K filed with the Commission on May 25, 2012)
10.6	Indenture by and between Endo Pharmaceuticals Holdings Inc. (n/k/a Endo Health Solutions Inc.) and The Bank of New York dated April 15, 2008 (incorporated herein by reference to Exhibit 4.1 of the Current Report on Form 8-K filed with the Commission on April 15, 2008)
10.7	Convertible Bond Hedge Transaction Confirmation entered into by and between Endo and Deutsche Bank AG, London Branch, dated April 9, 2008 (incorporated herein by reference to Exhibit 10.7 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.8	Issuer Warrant Transaction Confirmation entered into by and between Endo and Deutsche Bank AG, London Branch, dated April 9, 2008 (incorporated herein by reference to Exhibit 10.8 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.9	Issuer Share Repurchase Transaction Confirmation entered into by and between Endo and Deutsche Bank AG, London Branch, dated April 9, 2008 (incorporated herein by reference to Exhibit 10.9 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.10*	Sole and Exclusive License Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals Inc. (Endo Pharmaceuticals) and Hind HealthCare, Inc. (incorporated herein by reference to Exhibit 10.10 of the Registration Statement filed with the Commission on June 9, 2000)
10.11	Amended and Restated Executive Deferred Compensation Plan
10.12	Amended and Restated 401(k) Restoration Plan
10.13	Directors Deferred Compensation Plan
10.14*	Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd (incorporated herein by reference to Exhibit 10.14 of the Registration Statement filed with the Commission on June 9, 2000)
10.14.1*	First Amendment, dated April 24, 2007, to the Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc. (incorporated herein by reference to Exhibit 10.14.1 of the Current Report on Form 8-K dated April 30, 2007)
10.14.2*	Second Amendment, effective December 16, 2009, to the Supply and Manufacturing Agreement, dated as of November 23, 1998 and as amended as of April 24, 2007, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc. (incorporated herein by reference to Exhibit 10.14.2 of the Current Report on Form 8-K dated January 11, 2010)
10.14.3*	Third Amendment, effective November 1, 2010, to the Supply and Manufacturing Agreement, dated as of November 23, 1998 and as amended as of December 16, 2009, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc. (incorporated herein by reference to Exhibit 10.14.3 of the Form 10-Q for the Quarter ended September 30, 2010 filed with the Commission on November 2, 2010)
10.16*	Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16 of the Registration Statement filed with the Commission on June 9, 2000)
10.16.1*	First Amendment, effective July 1, 2000, to the Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16.1 of the Current Report on Form 8-K dated April 14, 2006)
10.16.2*	Second Amendment, dated April 10, 2006, to the Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16.2 of the Current Report on Form 8-K dated April 14, 2006)
10.16.3	Third Amendment, effective June 30, 2011, to the Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.118 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2011 filed with the Commission on October 31, 2011)

<u>Exhibit No.</u>	<u>Title</u>
10.16.4	Fourth Amendment, effective July 31, 2011, to the Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.119 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2011 filed with the Commission on October 31, 2011)
10.16.5	Fifth Amendment, effective August 31, 2011, to the Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.120 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2011 filed with the Commission on October 31, 2011)
10.17*	Supply Agreement, dated as of April 27, 2012, between Endo Pharmaceuticals and Noramco, Inc. (incorporated herein by reference to Exhibit 10.17 of the Quarterly Report on Form 10-Q for the Quarter Ended March 31, 2012 filed with the Commission on May 1, 2012)
10.19*	Master Services Agreement, dated as of May 18, 2010, by and between Endo Pharmaceuticals and UPS Supply Chain Solutions, Inc. (incorporated herein by reference to Exhibit 10.19 of the Current Report on Form 8-K dated May 20, 2010)
10.19.1*	Amendment No. 1 to the Master Services Agreement, between UPS Supply Chain Solutions, Inc. and Endo Pharmaceuticals, dated February 21, 2012 (incorporated herein by reference to Exhibit 10.19.1 of the Form 10-K for the year ended December 31, 2011 filed with the Commission on February 29, 2012)
10.21	Endo Health Solutions Inc. 2000 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.21 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.22	Endo Health Solutions Inc. 2010 Stock Incentive Plan (incorporated herein by reference to Exhibit A of the 2010 Definitive Proxy Statement filed with the Commission on April 29, 2010)
10.31*	License and Supply Agreement by and by and among Novartis, AG, Novartis Consumer Health, Inc. and Endo Pharmaceuticals dated as of March 4, 2008 (incorporated herein by reference to Exhibit 10.31 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.31.1*	Amendment No. 1 to the License and Supply Agreement by and by and among Novartis, AG, Novartis Consumer Health, Inc. and Endo Pharmaceuticals dated as of March 28, 2008 (incorporated herein by reference to Exhibit 10.31.1 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.31.2*	Amendment No. 2 to License and Supply Agreement, by and among Novartis AG, Novartis Consumer Health, Inc. and Endo Pharmaceuticals dated as of December 31, 2012
10.32*	Sales and Promotional Services Agreement, effective December 30, 2011, by and between Ventiv Commercial Services, LLC and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.32 of the Form 10-K for the year ended December 31, 2011 filed with the Commission on February 29, 2012)
10.32.1*	First Amendment, effective September 26, 2012, to the Sales and Promotional Services Agreement by and between Ventiv Commercial Services, LLC and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.32.1 of the Current Report on Form 8-K filed with the Commission on February 20, 2013)
10.34	Lease Agreement, dated as of May 5, 2000, by and between Endo Pharmaceuticals and Painters' Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34 of the Registration Statement filed with the Commission on June 9, 2000)
10.34.1	Amendment to Lease Agreement, dated as of November 6, 2006, by and between Endo Pharmaceuticals and Painters Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34.1 of the Form 10-Q for the quarter ended September 30, 2006 filed with the Commission on November 9, 2006)
10.35	Amended and Restated Employment Agreement, dated as of December 19, 2007, by and between Endo and Caroline B. Manogue (incorporated herein by reference to Exhibit 10.29 of the Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)
10.36	Employment Agreement between Endo Pharmaceuticals Holdings Inc. (n/k/a Endo Health Solutions Inc.) and Julie McHugh (incorporated herein by reference to Exhibit 10.2 of the Current Report on Form 8-K, dated March 12, 2010)
10.37	Endo Health Solutions Inc. 2004 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.37 of the Form 10-Q for the Quarter ended June 30, 2004 filed with the Commission on August 9, 2004)
10.38	Endo Health Solutions Inc. Amended and Restated 2007 Stock Incentive Plan (incorporated herein by reference to Exhibit B of the Definitive Proxy Statement on Schedule 14A filed with the Commission on April 29, 2009)

<u>Exhibit No.</u>	<u>Title</u>
10.39*	Master Development and Toll Manufacturing Agreement, dated as of May 3, 2001, by and between Novartis Consumer Health, Inc. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.39 of the Form 10-Q for the Quarter Ended June 30, 2001 filed with the Commission on August 14, 2001)
10.39.1*	First Amendment, effective February 1, 2003, to the Master Development and Toll Manufacturing Agreement between Endo Pharmaceuticals and Novartis Consumer Health, Inc. (incorporated herein by reference to Exhibit 10.39.1 of the Form 10-Q for the Quarter Ended June 30, 2005 filed with the Commission on August 8, 2005)
10.39.2*	Second Amendment, effective as of December 1, 2004, to the Master Development and Toll Manufacturing Agreement between Endo Pharmaceuticals and Novartis Consumer Health, Inc. (incorporated herein by reference to Exhibit 10.39.2 of the Form 10-Q for the Quarter Ended June 30, 2005 filed with the Commission on August 8, 2005)
10.39.3	Letter of termination of Master Development and Toll Manufacturing Agreement, dated February 23, 2011, between Endo Pharmaceuticals and Novartis Consumer Health, Inc. (incorporated herein by reference to Exhibit 10.39.3 of the Form 10-K for the year ended December 31, 2010 filed with the Commission on February 28, 2011)
10.39.4	Termination Agreement Relating to the Master Development and Toll Manufacturing Agreement, effective as of December 31, 2012, by and between Endo Pharmaceuticals and Novartis Consumer Health, Inc.
10.40	Lease Agreement between Painters' Crossing Three Associates, L.P. and Endo Pharmaceuticals dated January 19, 2007 (incorporated herein by reference to Exhibit 10.40 of the Annual Report on Form 10-K for the Year Ended December 31, 2006 filed with the Commission on March 1, 2007)
10.40.1	First Amendment to Lease Agreement, dated as of March 3, 2008 by and between Partners' Crossing Three Associates, L.P. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.40.1 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.41	Policy of Endo Relating to Insider Trading in Company Securities and Confidentiality of Information (incorporated herein by reference to Exhibit 10.41 of the Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2012 filed with the Commission on August 7, 2012)
10.42	Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K, dated May 8, 2009)
10.43	Employment Agreement between Endo and Alan G. Levin (incorporated herein by reference to Exhibit 10.2 of the Current Report on Form 8-K, dated May 8, 2009)
10.45	Lease Agreement, dated as of November 13, 2003, by and between Endo Pharmaceuticals and Painters' Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.45 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
10.45.1	Amendment to Lease Agreement, dated as of February 16, 2005, by and between Endo Pharmaceuticals and Painters' Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.45.1 of the Current Report on Form 8-K dated February 18, 2005)
10.45.2	Amendment to Lease Agreement, dated as of November 6, 2006, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.34.1 of the Form 10-Q for the quarter ended September 30, 2006 filed with the Commission on November 9, 2006)
10.48*	License and Co-Promotion Rights Agreement, dated as of July 14, 2004, by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.48 of the Current Report on Form 8-K dated July 19, 2004)
10.48.2*	Second Amendment, dated as of December 12, 2005, to the License Agreement by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.48.2 of the Current Report on Form 8-K dated December 29, 2005)
10.48.4	Third Amendment, dated as of July 23, 2007, to the License Agreement by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.48.4 of the Current Report on Form 8-K dated July 27, 2007)
10.48.5*	Fourth Amendment, dated as of February 19, 2008, to the License Agreement by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.48.5 of the Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)
10.48.6	Fifth Amendment, dated as of August 15, 2011, to the License Agreement by and between Endo Pharmaceuticals and Vernalis Development Limited, dated July 14, 2004 (incorporated herein by reference to Exhibit 10.123 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2011 filed with the Commission on October 31, 2011)

<u>Exhibit No.</u>	<u>Title</u>
10.50	Form of Stock Option Grant Agreement under the 2007 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.50 of the Form 10-K for the year ended December 31, 2008 filed with the Commission on March 2, 2009)
10.51	Form of Restricted Stock Unit Grant Agreement under the 2007 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.51 of the Form 10-K for the year ended December 31, 2008 filed with the Commission on March 2, 2009)
10.52	Agreement and Plan of Merger dated January 5, 2009, by and between Endo, BTB Purchaser, and Indevus Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated January 5, 2009)
10.52.1	Amendment, dated January 7, 2009 to the Agreement and Plan of Merger, by and between Endo, BTB Purchaser, and Indevus Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated January 7, 2009)
10.52.2	Amendment No. 2, dated February 4, 2009, to the Agreement and Plan of Merger, by and among Endo, BTB Purchaser Inc. and Indevus Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1 of the Current Report on Form 8-K dated February 6, 2009)
10.57	Amended and Restated License, Commercialization and Supply Agreement executed September 18, 2007 between Indevus and Esprit Pharma, Inc. (n/k/a Allergan USA, Inc.) (incorporated herein by reference to Exhibit 10.1 to the Indevus Current Report on Form 8-K dated September 21, 2007)
10.58	First Amendment to Amended and Restated License, Commercialization and Supply Agreement between Indevus Pharmaceuticals, Inc. and Allergan USA, Inc. dated as of January 9, 2009 (incorporated herein by reference to Exhibit 10.1 to the Indevus Current Report on Form 8-K, dated January 15, 2009)
10.59	Endo Health Solutions Inc. Endo Stock Award Agreement Under the 2010 Stock Incentive Plan
10.60	Endo Health Solutions Inc. 2010 Stock Incentive Plan Stock Option Agreement
10.61	Agreement and Plan of merger, dated as of December 11, 2006, by and among Indevus, Hayden Merger Sub, Inc. and Valera Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1 to the Indevus Current Report on Form 8-K, dated December 12, 2006)
10.80	Purchase and Sale Agreement by and between Ledgemont Royalty Sub LLC and Indevus dated August 26, 2008 (incorporated herein by reference to Exhibit 10.215 to the Indevus Form 10-K for the fiscal year ending September 30, 2008, filed with the Commission on December 11, 2008)
10.81	Note Purchase Agreement by and among Ledgemont Royalty Sub LLC, Indevus and the purchasers named therein dated August 26, 2008 (incorporated herein by reference to Exhibit 10.216 to the Indevus Form 10-K for the fiscal year ending September 30, 2008, filed with the Commission on December 11, 2008)
10.82	Indenture by and between Ledgemont Royalty Sub LLC and U.S. Bank National Association dated August 26, 2008 (incorporated herein by reference to Exhibit 10.217 to the Indevus Form 10-K for the fiscal year ending September 30, 2008, filed with the Commission on December 11, 2008)
10.83	Pledge and Security Agreement made by Indevus to U.S. Bank National Association, as Trustee, dated August 26, 2008 (incorporated herein by reference to Exhibit 10.218 to the Indevus Form 10-K for the fiscal year ending September 30, 2008, filed with the Commission on December 11, 2008)
10.90	Pledge and Security Agreement dated as of October 16, 2009 by and among Endo Pharmaceuticals Holdings Inc. (n/k/a Endo Health Solutions Inc.), the lenders named therein and JPMorgan Chase Bank, N.A., as administrative agent (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated October 22, 2009)
10.91	Agreement and Plan of Merger dated May 5, 2010, by and between Endo, HT Acquisition Corp., and HealthTronics, Inc. (incorporated herein by reference to Exhibit 2.1 of the Current Report on Form 8-K dated May 7, 2010)
10.94	Agreement and Plan of Merger, dated August 9, 2010, by and among Endo Pharmaceuticals Holdings Inc. (n/k/a Endo Health Solutions Inc.), West Acquisition Corp., and Penwest Pharmaceuticals Co. (incorporated herein by reference to Exhibit 2.1 of the Current Report on Form 8-K dated August 12, 2010)
10.96	Stock Purchase Agreement, dated September 28, 2010, by and among Endo Pharmaceuticals, Endo Pharmaceuticals Holdings Inc. (n/k/a Endo Health Solutions Inc.), Generics International (US Parent), Inc., and Apax Quartz (Cayman) L.P. (incorporated herein by reference to Exhibit 2.1 of the Current Report on Form 8-K dated September 30, 2010)
10.96.1	Amendment to Stock Purchase Agreement, effective October 17, 2012, by and among Endo Pharmaceuticals, Endo Health Solutions Inc., Generics International (US Parent), Inc., and Apax Quartz (Cayman) L.P. (incorporated herein by reference to Exhibit 10.144 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2012 filed with the Commission on November 5, 2012)

<u>Exhibit No.</u>	<u>Title</u>
10.97	Lease Agreement dated May 19, 2008, by and between HealthTronics, Inc. and HEP-Davis Spring, L.P. (incorporated herein by reference to Exhibit 10.2 to HealthTronics' Current Report on Form 8-K filed with the Securities and Exchange Commission on June 20, 2008)
10.98	Second Amendment to Lease Agreement, dated as of August 20, 2009, between HEP-Davis Spring, L.P. as landlord and HealthTronics, Inc. as tenant (incorporated herein by reference to Exhibit 10.2 of HealthTronics' 10-Q filed with the Securities and Exchange Commission on November 6, 2009)
10.101	Indenture among the Company, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated November 23, 2010 (incorporated herein by reference to Exhibit 4.1 of the Current Report on Form 8-K filed with the Commission on November 24, 2010)
10.102	Form of 7.00% Senior Notes due 2020 dated November 23, 2010 (incorporated herein by reference to Exhibit 4.1 of the Current Report on Form 8-K filed with the Commission on November 24, 2010)
10.104	Agreement and Plan of Merger, among Endo Pharmaceuticals Holdings Inc. (n/k/a Endo Health Solutions Inc.), NIKA Merger Sub, Inc. and American Medical Systems Holdings, Inc., dated as of April 10, 2011 (incorporated herein by reference to Exhibit 2.1 of the Current Report on Form 8-K date April 15, 2011)
10.105	Commitment Letter to Endo Pharmaceutical Holdings, Inc. (n/k/a Endo Health Solutions Inc.), from Morgan Stanley Senior Funding, Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated and Bank of America, N.A., dated April 10, 2011 (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated April 15, 2011)
10.106	Form of Amended and Restated Performance Award Agreement under the 2007 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.106 of the Quarterly Report on Form 10-Q for the Quarter Ended March 31, 2011 filed with the Commission on April 29, 2011)
10.108	Credit Facility, among Endo Pharmaceuticals Holdings Inc. (n/k/a Endo Health Solutions Inc.), the lenders named therein, Morgan Stanley Senior Funding, Inc. and Bank of America, N.A., dated as of June 17, 2011 (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the Commission on June 20, 2011)
10.109	Indenture among the Company, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011 (incorporated herein by reference to Exhibit 4.1 of the Current Report on Form 8-K filed with the Commission on June 9, 2011)
10.110	Form of 7% Senior Notes due 2019 (included in Exhibit 10.110) (incorporated herein by reference to Exhibit 4.2 of the Current Report on Form 8-K filed with the Commission on June 9, 2011)
10.111	Indenture among the Company, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011 (incorporated herein by reference to Exhibit 4.3 of the Current Report on Form 8-K filed with the Commission on June 9, 2011)
10.112	Form of 7 <sup>1</sup> / <sub>4</sub> % Senior Notes due 2022 (included in Exhibit 10.112) (incorporated herein by reference to Exhibit 4.4 of the Current Report on Form 8-K filed with the Commission on June 9, 2011)
10.115	Endo Health Solutions Inc. Assumed Stock Incentive Plan
10.116	Endo Health Solutions Inc. Stock Option Agreement (Under the Endo Health Solutions Inc. Assumed Stock Incentive Plan)
10.117	Endo Health Solutions Inc. Stock Award Agreement (Under the Endo Health Solutions Inc. Assumed Stock Incentive Plan)
10.121	Executive Employment Agreement between Endo and David P. Holveck, dated as of October 27, 2011 (incorporated herein by reference to Exhibit 10.121 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2011 filed with the Commission on October 31, 2011)
10.122	Executive Employment Agreement between Endo and Ivan P. Gergel, dated as of October 27, 2011 (incorporated herein by reference to Exhibit 10.122 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2011 filed with the Commission on October 31, 2011)
10.123	Executive Employment Agreement between Endo and Rajiv De Silva, dated as of February 24, 2013 and effective as of March 18, 2013 (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the Commission on February 25, 2013)
10.124	Build to Suit Lease Agreement between Endo Pharmaceuticals and RT/TC Atwater LP (incorporated herein by reference to Exhibit 10.124 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2011 filed with the Commission on October 31, 2011)

<u>Exhibit No.</u>	<u>Title</u>
10.125	First Supplemental Indenture, among Penwest Pharmaceuticals Co. and Generics International (US), Inc., as guaranteeing subsidiaries, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated December 13, 2010, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated November 23, 2010 (incorporated herein by reference as Exhibit 4.2 to the Form S-4 filed with the Commission on October 14, 2011)
10.126	Second Supplemental Indenture, among Generics Bidco I, LLC, as guaranteeing subsidiary, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated December 21, 2010, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated November 23, 2010 (incorporated herein by reference as Exhibit 4.3 to the Form S-4 filed with the Commission on October 14, 2011)
10.127	Third Supplemental Indenture, among Ledgemont Royalty Sub LLC, as guaranteeing subsidiary, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated February 17, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated November 23, 2010 (incorporated herein by reference as Exhibit 4.4 to the Form S-4 filed with the Commission on October 14, 2011)
10.128	Fourth Supplemental Indenture, among Vintage Pharmaceuticals, LLC, as guaranteeing subsidiary, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated April 5, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated November 23, 2010 (incorporated herein by reference as Exhibit 4.5 to the Form S-4 filed with the Commission on October 14, 2011)
10.129	Fifth Supplemental Indenture, among American Medical Systems Holdings, Inc., American Medical Systems, Inc., AMS Research Corporation, AMS Sales Corporation and Laserscope, as guaranteeing subsidiaries, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 22, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated November 23, 2010 (incorporated herein by reference as Exhibit 4.6 to the Form S-4 filed with the Commission on October 14, 2011)
10.130	Sixth Supplemental Indenture, among American Medical Systems, Inc. and Laserscope, as successor guarantors, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated August 16, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated November 23, 2010 (incorporated herein by reference as Exhibit 4.7 to the Form S-4 filed with the Commission on October 14, 2011)
10.131	Seventh Supplemental Indenture, among Generics Bidco II, LLC, Generics International (US Holdco), Inc., Generics International (US Midco), Inc., Generics International (US Parent), Inc., Moores Mill Properties L.L.C., Quartz Specialty Pharmaceuticals, LLC and Wood Park Properties LLC, as guaranteeing subsidiaries, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated September 26, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated November 23, 2010 (incorporated herein by reference as Exhibit 4.8 to the Form S-4 filed with the Commission on October 14, 2011)
10.132	First Supplemental Indenture, among American Medical Systems Holdings, Inc., American Medical Systems, Inc., AMS Research Corporation, AMS Sales Corporation and Laserscope, as guaranteeing subsidiaries, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 17, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011 (incorporated herein by reference as Exhibit 4.11 to the Form S-4 filed with the Commission on October 14, 2011)
10.133	Second Supplemental Indenture, among American Medical Systems, Inc. and Laserscope, as successor guarantors, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated August 16, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011 (incorporated herein by reference as Exhibit 4.12 to the Form S-4 filed with the Commission on October 14, 2011)
10.134	Third Supplemental Indenture, among Generics Bidco II, LLC, Generics International (US Holdco), Inc., Generics International (US Midco), Inc., Generics International (US Parent), Inc., Moores Mill Properties L.L.C., Quartz Specialty Pharmaceuticals, LLC and Wood Park Properties LLC, as guaranteeing subsidiaries, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated September 26, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011 (incorporated herein by reference as Exhibit 4.13 to the Form S-4 filed with the Commission on October 14, 2011)
10.135	First Supplemental Indenture, among American Medical Systems Holdings, Inc., American Medical Systems, Inc., AMS Research Corporation, AMS Sales Corporation and Laserscope, as guaranteeing subsidiaries, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 17, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011 (incorporated herein by reference as Exhibit 4.16 to the Form S-4 filed with the Commission on October 14, 2011)



<u>Exhibit No.</u>	<u>Title</u>
10.136	Second Supplemental Indenture, among American Medical Systems, Inc. and Laserscope, as successor guarantors, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated August 16, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011 (incorporated herein by reference as Exhibit 4.17 to the Form S-4 filed with the Commission on October 14, 2011)
10.137	Third Supplemental Indenture, among Generics Bidco II, LLC, Generics International (US Holdco), Inc., Generics International (US Midco), Inc., Generics International (US Parent), Inc., Moores Mill Properties L.L.C., Quartz Specialty Pharmaceuticals, LLC and Wood Park Properties LLC, as guaranteeing subsidiaries, Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated September 26, 2011, to the Indenture among Endo, the guarantors named therein and Wells Fargo Bank, National Association, as trustee, dated June 8, 2011 (incorporated herein by reference as Exhibit 4.18 to the Form S-4 filed with the Commission on October 14, 2011)
10.138	Endo Health Solutions Inc. Employee Stock Purchase Plan (incorporated herein by reference to Exhibit A of the 2011 Definitive Proxy Statement filed with the Commission on April 29, 2011)
10.139*	Development, License and Supply Agreement, dated as of December 18, 2007, between Endo Pharmaceuticals and Grünenthal GMBH (incorporated herein by reference to Exhibit 10.139 of the Quarterly Report on Form 10-Q for the Quarter Ended March 31, 2012 filed with the Commission on May 1, 2012)
10.139.1*	First Amendment to Development, License and Supply Agreement, dated as of December 19, 2012, between Endo Pharmaceuticals and Grünenthal GMBH
10.140*	Settlement and License Agreement dated as of June 8, 2010 by and among Penwest Pharmaceuticals Co., Endo Pharmaceuticals and IMPAX Laboratories, Inc. (incorporated herein by reference to Exhibit 10.4 to the Penwest Pharmaceuticals Co. Form 10-Q for the quarterly period ended June 30, 2010, filed with the Commission on August 6, 2010)
10.141	Settlement and License Agreement, dated as of May 28, 2012, by and among Endo Pharmaceuticals, Teikoku Pharma USA, Inc. Teikoku Seiyaku Co., Ltd. and Watson Laboratories, Inc. (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the Commission on May 29, 2012)
10.142*	2008 Amended and Restated Packaging and Labeling Services Agreement, effective as of September 15, 2008, by and between Endo Pharmaceuticals and Sharp Corporation (incorporated herein by reference to Exhibit 10.142 of the Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2012 filed with the Commission on August 7, 2012)
10.142.1	First Amendment, effective as of December 1, 2010, to the 2008 Amended and Restated Packaging and Labeling Services Agreement by and between Endo Pharmaceuticals and Sharp Corporation (incorporated herein by reference to Exhibit 10.142.1 of the Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2012 filed with the Commission on August 7, 2012)
10.142.2*	Second Amendment, effective as of June 1, 2012, to the 2008 Amended and Restated Packaging and Labeling Services Agreement by and between Endo Pharmaceuticals and Sharp Corporation (incorporated herein by reference to Exhibit 10.142.2 of the Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2012 filed with the Commission on August 7, 2012)
10.143	Preferability letter regarding change in accounting policy related to Goodwill (incorporated herein by reference to Exhibit 10.143 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2012 filed with the Commission on November 5, 2012)
21	Subsidiaries of the Registrant
23	Consent of Independent Registered Public Accounting Firm
24	Power of Attorney
31.1	Certification of the President and Chief Executive Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of the President and Chief Executive Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the Chief Financial Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

**Exhibit**  
**No.**

**Title**

101 The following materials from Endo Health Solutions Inc.'s Annual Report on Form 10-K for the year ended December 31, 2012, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive (Loss) Income, (iv) the Consolidated Statements of Stockholders' Equity, (v) the Consolidated Statements of Cash Flows and (vi) the Notes to Consolidated Financial Statements.

\* Confidential portions of this exhibit (indicated by asterisks) have been redacted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

