ENDO HEALTH SOLUTIONS INC.
Form 10-K
March 01, 2013
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

(Mark One)
x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the fiscal year ended December 31, 2012
Or
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the transition period from to
Commission file number: 001-15989

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

Delaware	13-4022871
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
1400 Atwater Drive, Malvern, Pennsylvania	19355
(Address of Principal Executive Offices)	(Zip Code)

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.	Yes x No o
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.	Yes o No x
Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.	Yes x No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every interactive data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months.	Yes x No o

x

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act

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

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

The aggregate market value of the voting common equity held by non-affiliates as of June 30, 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.

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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.

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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® 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®, Opana® ER, Voltaren® Gel, Percocet®, Frova®, Supprelin® LA, Vantas®, Valstar® and Fortesta® 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. 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).

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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® 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®, 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®, Opana® ER, Voltaren® Gel, Percocet®, Frova®, Supprelin® LA, Vantas®, Valstar® and Fortesta® 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 urogynocology. For a more detailed description of our development pipeline, see “Select Products in Development.”
Research and development expertise. Our research and development efforts are focused on the development of a balanced, diversified portfolio of innovative and clinically differentiated products. We are continuously seeking opportunities that deepen our

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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.

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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® 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®, the bladder oncology space with Valstar®, and the central precocious puberty therapeutic area with Supprelin® LA. With our early 2011 launch of Fortesta® Gel, which was approved by the FDA in December 2010 for the treatment of hypogonadism, we entered the testosterone replacement therapy (TRT) market. We anticipate increasing our presence in this market through our development product Aveed™. As a result of our acquisition of AMS, 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

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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