Mallinckrodt plc
Form 10-K
December 13, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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FORM 10-K

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x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended September 27, 2013

or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number : 001-35803

_____

Mallinckrodt public limited company
(Exact name of registrant as specified in its charter)

_____

Ireland	98-1088325
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
Damastown, Mulhuddart Dublin 15, Ireland	
(Address of principal executive offices) (Zip Code)	

Telephone: +353 1 880-8180
(Registrant's telephone number, including area code)

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

Title of each class	Name of each exchange on which registered
Ordinary shares, par value $0.20 per share	New York Stock Exchange
Preferred share purchase rights	New York Stock Exchange

Securities registered pursuant to section 12(g) of the Act: None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 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 Section 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 Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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. o

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

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

As of March 29, 2013, the registrant's ordinary shares were not publicly traded.

The number of shares of the registrant's common stock outstanding as of December 6, 2013 was 58,002,372.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement for its annual meeting of shareholders, to be filed with the Securities and Exchange Commission within 120 days after September 27, 2013, are incorporated by reference into Part III of this report.

MALLINCKRODT PLC
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Presentation of Information

Unless the context requires otherwise, references to "Mallinckrodt plc," "Mallinckrodt," "we," "us," "our" and "the Company" refer to Mallinckrodt plc, an Irish public limited company, and its consolidated subsidiaries for periods subsequent to its separation from Covidien plc on June 28, 2013. For periods prior to June 28, 2013, these terms refer to the combined historical business and operations of Covidien plc's Pharmaceuticals business as it was historically managed as part of Covidien plc. Unless the context requires otherwise, references to "Covidien" refer to Covidien plc, an Irish public limited company, and its consolidated subsidiaries, which is Mallinckrodt's former parent company. References in this Annual Report on Form 10-K to the "Separation" refer to the legal separation and transfer of Covidien's Pharmaceuticals business to Mallinckrodt plc through a dividend distribution to Covidien shareholders on June 28, 2013. References to "dollars" or "$" refer to United States dollars.

Trademarks and Trade Names

Mallinckrodt owns or has rights to use trademarks and trade names that it uses in conjunction with the operation of its business. One of the more important trademarks that it owns or has rights to use that appears in this Annual Report on Form 10-K is "Mallinckrodt," which is a registered trademark or the subject of pending trademark applications in the United States and other jurisdictions. Solely for convenience, the Company only uses the ™ or ® symbols the first time any trademark or trade name is mentioned. Such references are not intended to indicate in any way that the Company will not assert, to the fullest extent permitted under applicable law, its rights to its trademarks and trade names. Each trademark or trade name of any other company appearing in this Annual Report on Form 10-K is, to the Company's knowledge, owned by such other company.

Forward-Looking Statements

The Company has made forward-looking statements in this Annual Report on Form 10-K that are based on management's beliefs and assumptions and on information currently available to management. Forward-looking statements include, but are not limited to, information concerning the Company's possible or assumed future results of operations, business strategies, financing plans, competitive position, potential growth opportunities, potential operating performance improvements, the effects of competition and the effects of future legislation or regulations. Forward-looking statements include all statements that are not historical facts and can be identified by the use of forward-looking terminology such as the words "believe," "expect," "plan," "intend," "project," "anticipate," "estimate," "predict," "potential," "continue," "may," "should" or the negative of these terms or similar expressions. Forward-looking statements involve risks, uncertainties and assumptions. Actual results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any forward-looking statements.

The risk factors included in Item 1A. of this Annual Report on Form 10-K could cause the Company's results to differ materially from those expressed in forward-looking statements. There may be other risks and uncertainties that the Company is unable to predict at this time or that the Company currently does not expect to have a material adverse effect on its business.

These forward-looking statements are made as of the filing date of this Annual Report on Form 10-K. The Company expressly disclaims any obligation to update these forward-looking statements other than as required by law.

PART I

Item 1. Business.

Overview

We are a global company that develops, manufactures, markets and distributes both branded and generic specialty pharmaceuticals, active pharmaceutical ingredients ("API") and diagnostic imaging agents. Our products are found in almost every hospital, standalone diagnostic imaging center or pharmacy in the United States ("U.S.") and we have a commercial presence in approximately 70 countries. We believe our extensive commercial reach and formulation expertise, coupled with our ability to navigate the highly regulated and technical nature of our business, have created compelling competitive advantages that we anticipate will sustain future revenue growth.

We conduct our business in the following two segments:

- Specialty Pharmaceuticals produces and markets branded and generic pharmaceuticals and API, comprised of medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients; and
- Global Medical Imaging develops, manufactures and markets contrast media and delivery systems ("CMDS") and radiopharmaceuticals (nuclear medicine).

For further information on our products and segments, refer to "Our Businesses and Product Strategies" within this Item 1. Business.

History and Development

Our Specialty Pharmaceuticals segment can trace its development from the founding of G. Mallinckrodt & Co. in 1867 (predecessor of today's API business). We expanded from the controlled substance API business into controlled substance generics in the mid-1990s to become the 12th largest U.S. generic pharmaceuticals business in 2012, as measured by prescription volume. We started our Brands product portfolio in 2001 and, by 2010, we had more than doubled our branded pharmaceuticals sales force and shifted our focus to pain management. We have since developed the business and are now providing physicians and patients with a comprehensive suite of pain management products, including our EXALGO® (hydromorphone HCl) ("Exalgo") Extended-Release tablets. Most recently, in October 2012, we acquired CNS Therapeutics, Inc. ("CNS Therapeutics"), a specialty pharmaceutical company focused on developing and commercializing intrathecal products for site-specific administration to the central nervous system to treat neurological disorders and intractable chronic pain.

Our Global Medical Imaging segment traces its start from a series of innovations by Mallinckrodt and its predecessors, including the introduction of barium in 1916 and of iodeikon as the first contrast agent for gall bladder imaging in 1920. Since then, we have expanded our CMDS business, including products for computed tomography ("CT") imaging and magnetic resonance imaging ("MRI"). We entered the nuclear imaging business in 1966 with our Ultra-Technekow™ DTE technetium generators, and have subsequently expanded this product line with "cold" kits and other radioisotopes. In 2008, we launched a generic version of Cardiolite® Kit for the Preparation of Technetium Tc99m Sestamibi for Injection, a leading branded cardiac imaging agent and registered trademark of Lantheus Medical Imaging, Inc., which allowed us to fundamentally change the competitive dynamics for technetium generators.

In 2010, we divested our nuclear radiopharmacies in the U.S., which allowed us to focus on our molybdenum-99 ("Mo-99") supply. Also, in 2010, we divested our Specialty Chemicals business (formerly known as Mallinckrodt Baker) to better focus our businesses on our pharmaceutical products.

Mallinckrodt plc was incorporated in Ireland on January 9, 2013 for the purpose of holding the Pharmaceuticals business of Covidien plc ("Covidien"). On June 28, 2013, Covidien shareholders of record received one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien held as of the record date, June 19, 2013, and the Pharmaceuticals business of Covidien was transferred to Mallinckrodt plc, thereby completing our legal separation from Covidien ("the Separation"). On July 1, 2013, we began regular way trading on the New York Stock Exchange under the ticker symbol "MNK."

Our principal executive offices are located at Damastown, Mulhuddart, Dublin 15, Ireland. Our telephone number at this location is +353 (1) 880-8180. Our U.S. headquarters is located at 675 James S. McDonnell Boulevard, Hazelwood, Missouri 63042. Our telephone number at this location is (314) 654-2000.

Our Competitive Strengths

We believe we have the following strengths:

- Expertise in the acquisition and importation of highly regulated raw materials, and strong regulatory relationships. We have expertise in the acquisition and importation of highly regulated raw materials, such as opioids, other controlled substances and radioisotopes. For example, in calendar 2012, we believe we received almost 40% of the U.S. Drug Enforcement Administration's ("DEA") total annual quota for controlled substances that we manufacture. In calendar 2012, our Generics business had an approximate 30% market share of DEA Schedules II and III opioid, oral solid doses, based on IMS Health data. The acquisition of certain raw materials and the processing of them into finished products requires a close collaboration with a wide variety of regulatory authorities including the DEA, U.S. Food and Drug Administration ("FDA"), U.S. Nuclear Regulatory Commission ("NRC"), European Medicines Agency and Irish Medicines Board, among many others. We have a long history of working closely with regulatory agencies to ensure ongoing, reliable access to these highly regulated materials.
- Specialized chemistry, development and formulation expertise which supports a product pipeline. We have specialized chemistry expertise in the formulation of new drug combinations and reformulation of existing drugs into a wide range of products, such as tablets, capsules, oral liquids, injectable and intrathecal products. In late 2009, we completed a significant upgrade to our formulation pilot plant in Webster Groves, Missouri. This expansion greatly enhanced our pharmaceutical formulation capability, which has resulted in a significant increase in both branded and generic formulations that have been approved by the FDA, or that are in various stages of pre-clinical development, clinical development or regulatory review.
- A broad portfolio of generic products and controlled substance API for pain and a pipeline of branded pharmaceutical pain products. Our Generics and API businesses have a strong position in the controlled substance generics market. We believe our Generics and API businesses offer the broadest product line of opioid and other controlled substances available (primarily DEA Schedules II and III), and we focus in a number of therapeutic areas with high barriers to entry, limited competition and long product life-cycles. Our strong market position is a result of the following:
  - Formulation and manufacturing expertise in controlled substances and complex generics;
  - Our commitment to investment in our research and development ("R&D") infrastructure and capabilities has resulted in a pipeline of generic and branded controlled substances, many of which are long-acting or hard to formulate products, which are under development or pending approval by the FDA. For example, in the fourth quarter of fiscal 2013, the FDA accepted for filing and granted priority review to our New Drug Application ("NDA") for the drug filed as MNK-795, which the FDA has granted conditional approval for the brand name XARTEMIS™ XR (oxycodone HCl and acetaminophen) Extended-Release Tablets ("Xartemis XR"). In the fourth quarter of fiscal 2013, the FDA accepted for filing our NDA for the drug filed as MNK-395, which the FDA has granted conditional approval for the brand name PENNSAID® (diclofenac sodium topical solution) 2% w/w ("Pennsaid 2%"). In addition, on December 28, 2012, we became the first company to receive approval from the FDA to manufacture and market in the U.S. a generic version of CONCERTA® (methylphenidate HCl) Extended-release Tablets (a registered trademark of Alza Corporation) ("Concerta"), a branded pharmaceutical for the treatment of attention deficit hyperactivity disorder ("ADHD").
  - Our strong position in controlled substance API and vertical integration from opioid raw materials to finished dosage forms; and
  - U.S. importation restrictions of controlled substance API and finished products.
- Solid market position in diagnostic imaging agents. We believe that we are one of the top three participants globally in nuclear radiopharmaceutical products. We are one of only two manufacturers of technetium-99m ("Tc-99m") generators (marketed under the brand name Ultra-Technekow DTE) in North America, one of only three in Europe and the only one on either continent that has its own Mo-99 processing facility, which provides cost and raw material supply advantages. In CMDS, we offer a fully integrated line of contrast media, pre-filled syringes and proprietary power injectors. Our leading contrast media product, Optiray™ (Ioversol Injection) ("Optiray"), has been on the market for over 25 years and is differentiated in part by being offered in pre-filled syringes that fit our proprietary power

injectors, which enhances clinician safety and reduces risks in medication management.

- Distinctive high-quality manufacturing and distribution skills with vertical integration where there are competitive advantages. Our manufacturing and supply chain capabilities enable highly efficient controlled substance tableting, packaging and distribution. Our investments include one of the world's largest DEA Schedule C-II vault storage capacities for raw materials, intermediates and finished dosages. In our Global Medical Imaging segment, we have the capability to process Mo-99 for use in our Ultra-Technekow DTE generators and to manufacture cyclotron-derived isotopes such as thallium-201, indium-111, gallium-67, germanium-68 and iodine-123. In addition, we produce the large-volume terminally sterilized pre-filled plastic syringes that fit into our power injectors. Where appropriate, we have also pursued selective vertical integration initiatives to ensure our manufacturing and supply chain benefit from cost and productivity efficiencies, such as using several of our API products to provide the raw materials for some of our generic products.
- Global commercial reach. Our Global Medical Imaging segment operates throughout the world and its direct and indirect marketing and selling capabilities are tailored to business and geographic needs. We have unique capabilities in complex markets that are not easy to enter, navigate or operate in, and there are very few companies that have the experience and expertise in manufacturing, regulatory and distribution to effectively manage controlled substances on a global scale. Our Global Medical Imaging segment has a commercial presence in approximately 70 countries that has positioned us for growth in select markets.
- Strong management team with extensive industry experience. We benefit from having a management team with extensive experience in small, medium and large life sciences firms. Mark Trudeau, our President and Chief Executive Officer, has more than 29 years of experience in the pharmaceuticals industry. Prior to joining Covidien's Pharmaceuticals business in January 2012, Mr. Trudeau served as Chief Executive Officer of Bayer Healthcare LLC USA, the U.S. healthcare business of Bayer AG, and as President of Bayer HealthCare Pharmaceuticals U.S. Region. Mr. Trudeau also served on the Board of the Pharmaceutical Researchers and Manufacturers of America, the National Pharmaceutical Council and as a Trustee of the HealthCare Institute of New Jersey. Matthew Harbaugh, our Senior Vice President and Chief Financial Officer, joined Covidien's Pharmaceuticals business in 2007 and has over 20 years of financial experience, mostly in the life sciences field. Additional members of the senior management team include Peter Edwards, our Senior Vice President and General Counsel; Hugh O'Neill, our Senior Vice President and President of Specialty Pharmaceuticals; Steve Merrick, our Senior Vice President and President, Commercial Operations, International; Gary Phillips, our Senior Vice President and Chief Strategy Officer; Mario Saltarelli, our Senior Vice President and Chief Science Officer; Ian Watkins, our Senior Vice President and Chief Human Resources Officer; and Meredith Fischer, our Senior Vice President, Communications and Public Affairs; all of whom have industry experience.

While we have set forth our competitive strengths above, our business involves numerous risks and uncertainties which may prevent us from executing our strategies. These risks include, among others, risks relating to: DEA regulation of the availability of controlled substances that are API, drug products under development and marketed drug products; the highly exacting and complex nature of our manufacturing processes; the limited global supply of fission-produced Mo-99 for use in our Ultra-Technekow DTE generators; our customer concentration; cost-containment efforts of our customers, purchasing groups, third-party payors and governmental organizations; developing or commercializing new products or adapting to a changing technology and diagnostic treatment landscape; protecting our intellectual property rights or being subject to claims that we infringe on the intellectual property rights of others; and significant competition. For a more complete description of the risks associated with our business, see Item 1A. Risk Factors included within this Annual Report on Form 10-K.

Our Businesses and Product Strategies

We manage our business in two reportable segments: Specialty Pharmaceuticals and Global Medical Imaging. Management measures and evaluates our operating segments based on segment net sales and operating income. Information regarding the product portfolios and business strategies of these segments is included in the following discussion. Financial information regarding each of our reportable segments, as well as other geographical

information, is included in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and in Note 21 of Notes to Consolidated and Combined Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Specialty Pharmaceuticals

Our Specialty Pharmaceuticals segment has two major components (1) Brands, which we believe will continue to be a growth area for our business, and (2) Generics and API, which we expect will continue to grow and generate significant cash.

Our Brands business markets branded pain drugs, including Exalgo, to physicians. In addition, we have an organic pipeline of branded pain products that are either in clinical trials or awaiting approval from the FDA. We also provide generic drugs, including a variety of product formulations containing hydrocodone, oxycodone, methylphenidate and several other controlled substances. We have a pipeline of controlled substance generic products either in development or awaiting approval from the FDA. Our API business provides bulk API products, including opioids and acetaminophen, to a wide variety of pharmaceutical companies, many of which are direct competitors of our Brands and Generics businesses. In addition, we use our API for internal manufacturing of our finished dosage products. In fiscal 2013, our Specialty Pharmaceuticals segment accounted for 56.5% of net sales from our operating segments. We expect this segment will represent a larger percentage of our net sales over the long term.

We are committed to responsible prescribing, dispensing, use and storage of opioid analgesics to avoid misuse, abuse, addiction, diversion and overdose. In 2010, we started the Collaborating & Acting Responsibly to Ensure Safety Alliance ("the C.A.R.E.S. Alliance"), which offers free non-branded tools and materials to patients, pharmacists and physicians to foster the safe use of opioid pain medications. The C.A.R.E.S. Alliance sponsors drug take back programs among other initiatives. In addition to educational efforts, we work closely with our major distributors to monitor suspicious controlled substance orders and take active steps to limit potential diversion.

Brands

We started our Brands product portfolio in 2001 with the acquisition of a suite of products, including RESTORIL™ (temazepan) capsules, which is indicated for the short-term treatment of insomnia, and TOFRANIL-PM™ (imipramine pamoate) capsules, which is indicated for the relief of symptoms of depression, from Novartis International AG. In 2010, we shifted our focus to pain management and launched several dosage strengths of our then newly acquired pain product, Exalgo. We subsequently gained approval for a 32 mg dosage strength of Exalgo in August 2012. In addition, our NDA for Pennsaid 2% was accepted for filing in August 2013. Our development pipeline contains two extended-release formulations of controlled substance analgesics, Xartemis XR and MNK-155. In the fourth quarter of fiscal 2013, our filing of Xartemis XR was accepted by the FDA and granted priority review. In November 2013, in response to additional data we submitted, the FDA extended their review of the Xartemis XR NDA by three months. MNK-155 has completed Phase III clinical trials and our NDA is expected to be filed with the FDA during the second half of fiscal 2014. These two development products are combination products formulated with potentially abuse-deterrent characteristics to address unmet needs in the acute pain market. Our long-term strategy is to advance these pipeline products and bring them to market to expand the size and profitability of our Brands business. Moreover, we plan to enhance our branded commercial infrastructure by building upon our controlled substance core and entering into attractive adjacencies in our U.S. markets while focusing on priority markets internationally, through product launches, co-promotions, line extensions and selective acquisitions, such as our acquisition of CNS Therapeutics in October 2012.

We promote our branded products directly to physicians (including pain specialists, anesthesiologists and orthopedic surgeons) with our own direct sales force of over 200 sales representatives. To support the product launch of Xartemis XR, we have entered into an agreement to increase our Brands sales force by 150 to 200 contracted sales representatives. We also use our Brands sales force to promote other Brands products. Our products are purchased by wholesalers and retail pharmacy chains, among others, and are eventually dispensed by prescription to patients. We also market our branded products directly to managed care organizations to gain access to drug formularies and allow patients access to these medications.

The following is a description of select products in our Brands product portfolio:

- Exalgo, which was acquired in June 2009, is the only long-acting, once-daily form of hydromorphone in the U.S. market. In August 2012, the FDA approved a 32 mg tablet of Exalgo, which further expanded the patient population

that Exalgo can effectively treat with a single daily dose. The 8 mg, 12 mg and 16 mg dosages of Exalgo were approved by the FDA in March 2010 for the treatment of chronic pain in opioid-tolerant patients requiring continuous around-the-clock opioid analgesia for an extended amount of time, and have shown significant prescription growth since launch in April 2010. Exalgo was granted marketing exclusivity in the U.S. as a prescription medicine through March 2013 and is protected by two Orange Book-listed patents for a method of treating moderate to severe pain. Beginning in November 2013 for the 8 mg, 12 mg and 16 mg dosages and May 2014 for the 32 mg dosage, a third party will have the right, pursuant to agreements with us, to sell a generic version of Exalgo, contingent upon their obtaining marketing approval from the FDA. We expect sales of Exalgo to decrease in fiscal 2014 (compared with $126.1 million in fiscal 2013) when the third party enters the market pursuant to these agreements. Additionally, our patents for the 8 mg, 12 mg and 16 mg dosages expire in July 2014.

- GABLOFEN® (baclofen injection), which was acquired in October 2012 with the acquisition of CNS Therapeutics, is indicated for use in management of severe spasticity of cerebral or spinal origin in patients age four years and above. Gablofen is offered in three concentrations in vials and, after FDA approval in January 2013, in pre-filled syringes. Pre-filled syringes were created to reduce preparation steps, helping to simplify the pump refill process for patients receiving ITB Therapy℠ (Intrathecal Baclofen Therapy). Gablofen is delivered to the patient via intrathecal administration (an injection into the sheath around the spinal cord). Along with the acquisition of CNS Therapeutics came a developmental pipeline of an additional presentation and concentration of Gablofen, as well as several investigational pain products for intrathecal administration.

Generics and API

We market our API products to other pharmaceutical companies around the world, many of which are competitors of our Brands and Generics businesses. Additionally, we use our API for internal manufacturing of our finished dosage products. We are among the largest manufacturers of bulk acetaminophen in the world and the only producer of acetaminophen outside of Asia. We manufacture controlled substances under DEA quota restrictions and in calendar 2012 we believe we received approximately 40% of the total DEA quota provided to the U.S. market for the controlled substances we manufacture. We believe that our strong market position in the API business and allocation of opioid raw materials from the DEA is a competitive advantage for our API business and, in turn, for our Generics and Brands businesses. The strategy for our API business is based on manufacturing large volumes of high-quality product and customized product offerings, responsive technical services and timely delivery to our customers.

We believe our Generics and API businesses represent the broadest available product line of opioid and other controlled substances (primarily DEA Schedules II and III). Our Generics and API businesses have a strong position in the controlled substance generics market with products, including hydrocodone, hydrocodone-containing tablets, oxycodone and oxycodone-containing tablets, all of which are significant products in the overall pain products industry, as well as methylphenidate and other controlled substance products. Historically, our primary competition has been other U.S. participants due to importation restrictions on controlled substance API and finished products. Our commitment to investment in our R&D infrastructure and capabilities has resulted in a pipeline of generic controlled substances, many of which are long-acting or hard to formulate products, which are under development or pending approval by the FDA. For example, we were the first company to receive FDA approval to manufacture and market a generic version of Concerta, a branded pharmaceutical for the treatment of ADHD.

We market our generic products principally to drug wholesalers, large- and medium-size retail pharmacy chains, food store chains with pharmacies, pharmaceutical benefit managers that have mail order pharmacies and hospital buying groups.

The following is a list of significant products and product families in our Generics and API product portfolio:

- acetaminophen (API) products (represent 10%, 11% and 11% of our total net sales in fiscal 2013, 2012 and 2011, respectively);
- hydrocodone (API) and hydrocodone-containing tablets;
- oxycodone (API) and oxycodone-containing tablets; and
- methylphenidate HCl extended-release tablets USP (CII) ("Methylphenidate ER"), our generic form of Concerta.

Global Medical Imaging

Our Global Medical Imaging segment develops, manufactures and markets products in two areas: CMDS, used in CT and MRI imaging, and Nuclear Imaging, which provides radiopharmaceuticals used in single photon emission computed tomography ("SPECT") imaging for myocardial perfusion cardiac imaging and bone scans. In fiscal 2013, our Global Medical Imaging segment accounted for 43.5% of net sales from our operating segments. We believe our Global Medical Imaging segment provides a platform for growth in select markets outside the U.S. and provides cash flow that we will use to fund growth in our Specialty Pharmaceuticals segment. Therefore, we are focused on driving

operating efficiencies in the Global Imaging segment to maximize operating margins and cash flow.

Contrast Media and Delivery Systems

Our contrast media include the brands Optiray for CT and Optimark™ for MRI, which are packaged in pre-filled syringes, vials and bottles. Our delivery systems include power injectors to allow delivery of contrast media into the patient, coordination of the timing of the injection with the CT or MRI scanner and delivery of the contrast media at a specific rate and volume. Our CMDS product strategy is based on differentiating our Optiray and Optimark brands with pre-filled syringes as opposed to vials or bulk containers that must be transferred to a syringe for injection. Pre-filled syringes offer a safer alternative to self-filled doses and offer risk reduction benefits that address The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations) and U.S. Pharmacopeia <797> guidelines. In addition, our pre-filled syringes are color coded and pre-labeled for easier medication management. Our delivery systems are marketed under the brand Optivantage™ Dual-Head ("Optivantage DH") for CT, Optistar™ for MRI and Illumena™ for cardiac catheterization laboratories. All of our injectors can accept both pre-filled syringes and our disposable syringes for use with saline and contrast media. We sell our CMDS products primarily to hospitals and imaging centers through group purchasing organizations ("GPOs").

The following are significant products in our CMDS product portfolio:

- Optiray (ioversol injection) is a low osmolar, lower viscosity and nonionic organically bound solution of iodine with a broad range of indications in CT imaging procedures, including peripheral and coronary arteriography, angiography and venography. Optiray is available in a Radio Frequency Identification ("RFID")-enabled Ultraject pre-filled syringe that, when combined with a RFID-enabled Optivantage DH CT Contrast Delivery System (a medical device used to synchronize the injection of contrast media with the CT scanner), provides a safer and more efficient method of delivering contrast media. Sales of our Optiray product represent 14%, 17% and 19% of our total net sales in fiscal 2013, 2012 and 2011, respectively. Optiray has been on the market for over 25 years. The high capital intensity in manufacturing API for Optiray products and our significant scale have contributed to the longevity of this product.
- Optimark (gadoversetamide injection) is a non-ionic extracellular Gadolinium-Based Contrast Agent ("GBCA") indicated for use with MRI in patients where abnormal vascularity of the brain or liver is suspected. It is the only GBCA approved by the FDA for administration by power injector and is available in pre-filled syringes to help reduce medication errors and improve patient safety.

Nuclear Imaging

Our Nuclear Imaging business manufactures radioactive isotopes for the diagnosis and treatment of disease. Our nuclear radiopharmaceutical product offering includes both "hot" radioisotopes (primarily Tc-99m, used in approximately 82% of nuclear medicine imaging procedures) and "cold" kits (tagging agents that are paired with "hot" radioisotopes for diagnostic procedures). We have significant expertise in managing the highly regulated nature of the radioactive materials used to manufacture the isotope generators and the short half-life of isotopes, which precludes stockpiling and requires exacting execution along all aspects of the supply chain. We believe that our investment in Tc-99m generators in North America and Europe, our own Mo-99 processing facility and a very well-coordinated logistics network provides us with a competitive advantage. Our strategy for our Nuclear Imaging business is focused on bolstering the Tc-99m/Mo-99 supply chain through supplier diversification and our investments in generator manufacturing lines. We have entered into agreements to obtain Mo-99 from the Maria nuclear research reactor in Poland, the High Flux Reactor in the Netherlands and the BR2 reactor in Belgium, and are also able to purchase finished Mo-99 from other suppliers in the marketplace with whom we do not have long-term supply agreements. Going forward, we will continue to seek further diversification of our supplier base.

We intend to ultimately eliminate the use of high enriched uranium ("HEU") in favor of using low enriched uranium ("LEU"). We currently use HEU targets for the production of Mo-99. In 2004, the U.S. National Security Administration established its Global Threat Initiative to, as quickly as possible, identify, secure and remove or facilitate the disposition of vulnerable, high-risk nuclear and radiological materials around the world. Included as one of the stated initiatives is the conversion by research reactors and isotope production facilities to LEU from HEU. We are in the process of converting our Mo-99 production operation in the Netherlands to LEU targets. For a discussion of how Mo-99 is used in our business, refer to "Raw Materials" within this Item 1. Business and Item 1A. Risk

Factors. We primarily market our nuclear radiopharmaceutical products to nuclear radiopharmacies in the U.S. and to hospitals in Europe.

The following are significant products in our Nuclear Imaging product portfolio:

- Ultra-Technekow DTE is a dry-ship, top eluting Tc-99m radioisotope generator that provides an on-site isotope source of Tc-99m solution that is combined by a nuclear pharmacist with various "cold" kit targeting agents to prepare an individualized radiopharmaceutical dose. The prepared Tc-99m radiopharmaceutical is used in procedures using SPECT. SPECT radiopharmaceutical scans account for approximately 81% of all radiopharmaceutical scans and are used in a number of applications, including myocardial perfusion imaging and bone scans. Tc-99m is a decay product of Mo-99, the parent isotope contained in the Tc-99m generator. We are one of only a limited number of manufacturers of Tc-99m generators in North America and Europe, and the only one on either continent that has its own Mo-99 processing facility, which provides significant cost and raw material supply advantages.
- Octreoscan™ (kit for the preparation of indium In-111 pentetreotide) is a unique molecular imaging agent used for the localization of primary and metastatic neuroendocrine tumors bearing somatostatin receptors. The product was approved by the FDA in June 1994 and is sold primarily in the U.S. and Europe. There are three Orange Book-listed patents for the drug product and usage in detection of neuroendocrine tumors. The last patent expires in September 2017.

Industry Overview and Trends

We believe our businesses are well positioned in attractive markets based on a broadening of access to healthcare globally, increased demand for pharmaceutical products from emerging markets and the medical industry's continued focus on diagnostic imaging for the early diagnosis of diseases.

We expect that the specialty pharmaceuticals market in the U.S. will likely grow in the low-to-mid single digits in the near-term, with the most successful companies being focused on innovation. With respect to branded drugs, most disease areas are addressed by products of a small group of companies that can create extensions of existing brands. Pain management represents the largest therapeutic prescription market in the U.S., with pain medications accounting for approximately one out of every ten dispensed prescriptions in 2012. Pain management is a time-tested therapeutic area, and pain products have been available on the U.S. market since the 1920s.

We believe our experience satisfying the regulatory requirements relating to raw materials for nuclear radiopharmaceuticals provides competitive advantages versus other potential competitors. Currently, imaging tends to be concentrated in developed markets due to its high capital-intensity requirements. However, there are opportunities for growth in emerging markets as governments build out their healthcare infrastructure.

Competition

Specialty Pharmaceuticals

Our Specialty Pharmaceuticals products compete with products manufactured by many other companies in highly competitive markets, primarily throughout the U.S. Our competitors vary depending upon therapeutic and product categories. Major competitors of our Specialty Pharmaceuticals segment include Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.), Endo Health Solutions Inc., Johnson & Johnson (including its Noramco, Inc. subsidiary), Johnson Matthey plc, Mylan Inc., Pfizer Inc., Purdue Pharma L.P. and Teva Pharmaceutical Industries Ltd., among others. Our secure sources of raw opioid material, vertically integrated manufacturing capabilities, broad offerings of API controlled substances and acetaminophen, comprehensive generic controlled substance product line and established relationships with retail pharmacies enable us to compete effectively with larger generics manufacturers. In addition, we believe that our experience with the FDA, DEA and Risk Evaluation and Mitigation Strategies ("REMS") provides us the knowledge to successfully operate in this highly competitive and highly regulated environment.

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. The ability to effectively compete in product development, acquisitions and in-licensing is important to our long-term growth strategy. 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, reliability of supply, reputation and access to technical information.

The highly competitive environment of our Brands business requires us to continually seek out technological innovations and to market our products effectively. Most new products that we introduce must compete with other products already on the market, as well as other products that are later developed by competitors. For our branded products, we may be granted market exclusivity through either the FDA, the U.S. Patent Office or similar agencies internationally. Regulatory exclusivity is granted by the FDA for new innovations, such as new clinical data, a new chemical entity or orphan drugs, and patents are issued for inventions, such as composition of matter or method of use. While patents offer a longer period of exclusivity, there are more bases to challenge that exclusivity than with regulatory exclusivity. Once market exclusivity expires on our branded products, competition will likely

intensify as generic forms of the product are launched. Manufacturers of generic pharmaceuticals typically invest far less in R&D than research-based pharmaceutical companies, causing generic versions to typically be significantly less expensive than the related branded products. The generic form may also 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, decreased sales volume or both. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our branded products offer not only medical benefits but also cost advantages, as compared with other forms of care.

In our Generics business, we face intense competition from other generic drug manufacturers, brand-name pharmaceutical companies through authorized generics, existing branded equivalents and manufacturers of therapeutically similar drugs. The competition varies depending on the specific product category and dosage strength, and we believe that our competitive advantages include our ability to introduce new generic versions of brand-name drug products, our formulation expertise and drug delivery technology, our access to controlled substance API, our quality and cost-effective production, our customer service and the breadth of our generic product line. Among the large generic controlled substance providers, we are the only generic manufacturer that has its own controlled substance API manufacturing capability, and we believe the vertical integration and production of our own API allows us to compete effectively against other pharmaceutical companies. New drugs and future developments in improved or advanced drug delivery technologies or other therapeutic techniques may provide therapeutic or cost advantages to competing products. The maintenance of profitable operations in generic pharmaceuticals depends, in part, on our ability to select, develop and timely launch new generic products and to manufacture such new products in a cost efficient, high-quality manner.

As a result of consolidation among wholesale distributors and rapid growth of large retail drug store chains, a small number of large wholesale distributors and retail drug store chains 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.

In our API business, we believe that our competitive advantages include our manufacturing capabilities in controlled substances that enable high-speed, high-volume tableting, packaging and distribution. Additionally, we believe we offer customers reliability of supply and broad-based technical customer service.

Global Medical Imaging

We compete primarily on the ability of our products to capture market share. While we believe that the number of procedures using contrast media will grow in emerging markets, due in part to increasing access to healthcare, we expect that our ability to compete with other providers of contrast media will be impacted by pricing pressures. We believe that our key product characteristics, such as proven efficacy, reliability and safety, coupled with our core competencies such as our efficient manufacturing processes and established distribution network, are important factors that distinguish us from our competitors.