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.

The market for imaging agents is highly competitive. Major competitors in our Global Medical Imaging segment include, among others:

- for contrast imaging agents: GE Healthcare, a division of General Electric Company, Bracco Imaging S.p.A., Bayer AG and Guerbet Group;
- for delivery systems: Nemoto & Co, Ltd.;
- for CMDS: Bayer AG and Bracco Imaging S.p.A.;
- for radiopharmaceutical generators sold in the U.S.: Lantheus Medical Imaging, Inc.;
- for radiopharmaceutical generators sold in Europe: GE Healthcare, IBA Group, and POLATOM; and
- for radiopharmaceutical SPECT "cold" kits: Lantheus Medical Imaging, Inc., GE Healthcare, Bracco Imaging S.p.A. and IBA Group.

Unlike some of our competition, we offer a full line of CMDS and radiopharmaceutical products. Our broad product portfolio allows us to be a complete source for most imaging agent needs.

Our current or future products could be rendered obsolete or uneconomical as a result of the competition described above and the factors described in "Intellectual Property" included within this Item 1. Business, as well as any of the risk factors described in Item 1A. Risk Factors included within this Annual Report on Form 10-K. Our failure to compete effectively could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Intellectual Property

We own or license a number of patents in the U.S. and other countries covering certain products and have also developed brand names and trademarks for other products. Generally, our Brands business relies upon patent protection to ensure market exclusivity for the life of the patent. We consider the overall protection of our patents, trademarks and license rights to be of material value and act to protect these rights from infringement. However, our business is not materially dependent upon any single patent, trademark or license or any group of patents, trademarks or licenses.

The majority of an innovative product's commercial value is usually realized during the period in which the product has market exclusivity. In the branded pharmaceutical industry, an innovator product's market exclusivity is generally determined by two forms of intellectual property: patent rights held by the innovator company and any regulatory forms of exclusivity to which the innovator is entitled. In the U.S. and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there often are very substantial and rapid declines in the branded product's sales. The rate of this decline varies by country and by therapeutic category; however, following patent expiration, branded products often continue to have some market viability based upon the goodwill of the product name, which typically benefits from trademark protection or is based on the difficulties associated with replicating the product formulation or bioavailability.

Patents are a key determinant of market exclusivity for most branded pharmaceuticals. Patents provide the innovator with the right to exclude others from practicing an invention related to the product. Patents may cover, among other things, the active ingredient(s), various uses of a drug product, pharmaceutical formulations, drug delivery mechanisms, and processes for (or intermediates useful in) the manufacture of products. Protection for individual products extends for varying periods in accordance with the expiration dates of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent, its scope of coverage and the availability of meaningful legal remedies in the country.

Many developed countries provide certain non-patent incentives for the development of pharmaceuticals. For example, the U.S., European Union ("E.U.") and Japan each provide for a minimum period of time after the approval of certain new drugs during which the regulatory agency may not rely upon the innovator's data to approve a competitor's generic copy. Regulatory exclusivity is also available in certain markets as incentives for research on new indications, orphan drugs (drugs that demonstrate promise for the diagnosis or treatment of rare diseases or conditions) and medicines that may be useful in treating pediatric patients. Regulatory exclusivity is independent of any patent rights and can be particularly important when a drug lacks broad patent protection. However, most regulatory forms of exclusivity do not prevent a competitor from gaining regulatory approval prior to the expiration of regulatory exclusivity on the basis of the competitor's own safety and efficacy data on its drug, even when that drug is identical to that marketed by the innovator.

We estimate the likely market exclusivity period for each of our branded products on a case-by-case basis. It is not possible to predict with certainty the length of market exclusivity for any of our branded products because of the complex interaction between patent and regulatory forms of exclusivity, the relative success or lack thereof by potential competitors' experience in product development and inherent uncertainties concerning patent litigation. There can be no assurance that a particular product will enjoy market exclusivity for the full period of time that we currently estimate or that the exclusivity will be limited to the estimate.

In addition to patents and regulatory forms of exclusivity, we also market products with trademarks. Trademarks have no effect on market exclusivity for a product, but are considered to have marketing value. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registrations of such trademarks are for fixed terms and subject to renewal as provided by the laws of the particular country.

Research and Development

We devote significant resources to the research and development of products and proprietary drug delivery technologies. We incurred R&D expenses of $165.7 million, $144.1 million and $141.5 million in fiscal 2013, 2012 and 2011, respectively. We expect to continue to invest in R&D activities, as well as enter into license agreements to

supplement our internal R&D initiatives. We intend to focus our R&D investments in the Specialty Pharmaceuticals segment, specifically investments to support our Brands business, where we believe there is the greatest opportunity for growth and profitability. Our low-risk, high productivity R&D approach will remain a key contributor to this growth. We currently expect our R&D investments to be in the range of 6% to 8% of annualized net sales. As noted in "Our Business and Product Strategies" included within this Item 1. Business, we market our products to pain specialists, anesthesiologists, neurologists and other physician specialists. In targeting future R&D spending, we focus on new product innovations that can be sold to these physician specialists.

The focus of our R&D within each of our businesses is noted below:

- Brands. Our R&D strategy focuses on branded product development in the area of pain, other central nervous system areas, such as spasticity, and adjacent areas.
- Generics and API. R&D within our Generics business is focused on developing Abbreviated New Drug Application ("ANDA") products that incorporate DEA-controlled substances and difficult to replicate formulations. Our API R&D is focused on process improvements to our core products, which is focused on increasing manufacturing yields to reduce our costs. We also selectively add API products to our portfolio where we believe we have created a unique, cost-effective and competitive manufacturing process. While we patent some of these API process improvements, many more are kept as trade secrets.
- Global Imaging. Our R&D efforts in our Global Medical Imaging segment are primarily focused on driving efficiency throughout CMDS. In our Nuclear Imaging business, our efforts relate to expanding our portfolio of radioisotopes and better utilizing existing capacity.

Key Areas of Study

Our R&D group is comprised of a number of highly experienced, trained and skilled individuals with nearly 25% holding Ph.D. degrees, who have developed expertise in a number of platform technologies, including:

- formulation of oral solids in novel ways to mimic patented delivery systems;
- formulation of parenteral products to provide sustained blood levels of select small molecules;
- linker technology to attach small molecules to radioisotopes; and
- abuse-deterrent characteristics for oral solids in both immediate-release as well as extended-release to limit the abuse and misuse of controlled substances.

While many of these programs are in pre-clinical development, we anticipate that some of these will form the basis of novel products in the future. However, there is no guarantee that any of the studies underway will lead to the development of a product or whether or when such product will be further developed, launched and become commercially viable.

Select Products in Development

We are presently developing a number of branded and generic products, some of which utilize novel drug-delivery systems, through a combination of internal and collaborative programs. As of September 27, 2013, we had two NDAs and five ANDAs awaiting review in the U.S. Our pipeline portfolio contains various products and product candidates that are reformulations of existing molecules for the treatment of pain and adjacent areas. The following are our most promising pipeline products:

- Xartemis XR. Xartemis XR is a controlled-release, long-acting oral formulation of oxycodone hydrochloride and acetaminophen that we are pursuing an indication for treatment of moderate to severe acute pain. Xartemis XR was formulated as a low-dose product to fulfill an unmet clinical need in the market with potentially abuse-deterrent characteristics. The formulation uses the patented Depomed, Inc. ("Depomed") Acuform™ drug-delivery technology, which we licensed in 2009. In July 2013, the FDA accepted our Xartemis XR NDA, filed as MNK-795, and granted it priority review. This acceptance marks a major milestone for us and is further evidence of our ability to advance our pipeline in both branded and generic products. In November 2013, in response to additional data we submitted, the FDA extended their review of the Xartemis XR NDA by three months. If approved, we anticipate launching Xartemis XR during the first half of fiscal 2014.
- MNK-155. MNK-155 is a controlled-release, long-acting oral formulation of hydrocodone and acetaminophen that we are pursuing an indication for treatment of moderate to severe acute pain. MNK-155 was formulated as a low-dose product to fulfill an unmet clinical need in the market with potentially abuse-deterrent characteristics. The formulation uses the patented Depomed Acuform drug-delivery technology. 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.
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Pennsaid 2%. Pennsaid 2% is a new 2% formulation of diclofenac topical solution which we anticipate will be indicated for the treatment of pain associated with osteoarthritis of the knee, and an extension of our Pennsaid franchise. This new formulation was studied using a twice-daily administration and is dispensed for topical usage by a new metered dose pump bottle. The NDA for Pennsaid 2%, originally filed as MNK-395, was submitted in June 2012 and, after repeating a pharmacokinetic study and submitting the results to the FDA, the application was accepted for filing in August 2013. If approved, we expect to launch this product in the second half of fiscal 2014.

- Intrathecal Product Development. Our acquisition of CNS Therapeutics in October 2012 provided us approved concentrations of Gablofen and a R&D pipeline that included an additional presentation and concentration of Gablofen, including the pre-filled syringes that were approved in January 2013. The R&D pipeline also included several investigational pain products, in various stages of development, which could provide an alternative to products that are only available today through compounding pharmacies. Additionally, this R&D pipeline may present opportunities for development of products that may be eligible to receive orphan drug designation from the FDA.
- Methylphenidate ER 18 mg. Methylphenidate ER, a generic version of the branded Concerta, is for the treatment of ADHD. In February 2013, we submitted a supplement to our approved ANDA to include the 18 mg dosage strength. The FDA has accepted this supplement and granted it priority review. If approved, we expect to launch this product in the second half of fiscal 2014. We would then have all four dosage strengths available on the market, as we currently offer the 27 mg, 36 mg and 54 mg dosage strengths.

Regulatory Matters

Quality Assurance Requirements

The FDA enforces regulations to ensure that the methods used in, and the facilities and controls used for, the manufacture, processing, packaging and holding of drugs and medical devices conform to current good manufacturing practice ("cGMP"). The cGMP regulations that the FDA enforces are comprehensive and cover all aspects of manufacturing operations, from receipt of raw materials to finished product distribution, and are designed to ensure that the finished products meet all the required identity, strength, quality and purity characteristics. The cGMP regulations for devices, called the Quality System Regulations, 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 U.S. Federal Food, Drug and Cosmetic Act ("the FFDCA"). Other regulatory authorities have their own cGMP rules. Ensuring 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, packaging, 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 practice ("GLP") or good clinical practice ("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 API 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 could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The FDA also conducts periodic inspections of drug and device facilities to assess their cGMP status. If the FDA were to find serious cGMP non-compliance during such an inspection, it could take regulatory actions that could materially adversely affect our business, results of operations, financial condition and cash flows. Additionally, imported API and other components needed to manufacture products could be rejected by U.S. Customs and Border Protection, usually after conferring with the FDA. In the case of domestic facilities, the FDA could initiate product seizures 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.

United States

In general, drug manufacturers operate in a highly regulated environment. In the U.S., we must comply with laws, regulations, guidance documents and standards promulgated by the FDA, the Department of Health and Human Services ("DHHS"), the DEA, the Environmental Protection Agency ("EPA"), the NRC, the Customs Service and

state boards of pharmacy.

The FDA's authority to regulate the safety and efficacy of pharmaceuticals comes from the FFDCA. In addition to reviewing NDAs, for branded drugs, and ANDAs, for generic drugs, the FDA has the authority to ensure that pharmaceuticals introduced into interstate commerce are neither "adulterated" nor "misbranded." Adulterated means that the product may cause or has caused injury to patients when used as intended because it fails to comply with current cGMP. Misbranded means that the labels of, or promotional materials for, the product contain false or misleading information. Failure to comply with applicable FDA and other federal and state regulations could result in product recalls or seizures, partial or complete suspension of manufacturing or distribution, refusal to approve pending NDAs or ANDAs, monetary fines, civil penalties or criminal prosecution.

In order to market and sell a new prescription drug product in the U.S., a drug manufacturer must file with the FDA a NDA that shows the safety and effectiveness of (a) a new chemical entity that serves as the API, known as a 505(b)(1) NDA; or (b) a product that has significant differences from an already approved one, known as a 505(b)(2) NDA. Alternatively, in order to market and sell a generic version of an already approved drug product, a drug manufacturer must file an ANDA that shows that the generic version is "therapeutically equivalent," or behaves almost the same when taken by a patient to the branded drug product and, therefore, is substitutable.

For all pharmaceuticals sold in the U.S., the FDA also regulates sales and marketing to ensure that drug product claims made by manufacturers are neither false nor misleading. Manufacturers are required to file copies of all product-specific promotional materials to the FDA's Office of Prescription Drug Promotion prior to their first use by sales representatives. In general, such advertising does not require FDA prior approval. Failure to implement a robust internal company review process and comply with FDA regulations regarding advertising and promotion increases the risk of enforcement action by either the FDA or the U.S. Department of Justice.

For both NDAs and ANDAs, the manufacture, marketing and selling of certain drug products may be limited by quota grants for controlled substances by the DEA. Refer to "Drug Enforcement Administration" within this Item 1. Business for further information.

NDA Process. The path leading to FDA approval of a NDA for a new chemical entity begins when the drug product is merely a chemical formulation in the laboratory. In general, the process involves the following steps:

- Completion of formulation, laboratory and animal testing in accordance with GLP that fully characterizes the drug product from a pre-clinical perspective and provides preliminary evidence that the drug product is safe to test in human beings;
- Filing with the FDA an Investigational New Drug Application that will permit the conduct of clinical trials (testing in human beings under adequate and well-controlled conditions);
- Designing and conducting clinical trials to show the safety and efficacy of the drug product in accordance with GCP;
- Submitting the NDA for FDA review, which provides a complete characterization of the drug product;
- Satisfactory completion of FDA pre-approval inspections regarding the conduct of the clinical trials and the manufacturing processes at the designated facility in accordance with cGMP;
- If applicable, satisfactory completion of a FDA Advisory Committee meeting in which the Agency requests help from outside experts in evaluating the NDA;
- Final FDA approval of the full prescribing information, labeling and packaging of the drug product; and
- Ongoing monitoring and reporting of adverse events related to the drug product, implementation of a REMS program, if applicable, and conduct of any required Phase IV studies.

Clinical trials are typically conducted in four sequential phases, although they may overlap. The four phases are as follows:

- Phase I trials are typically small (less than 100 healthy volunteers) and are designed to determine the toxicity and maximum safe dose of the drug product.
- Phase II trials usually involve 100 to 300 participants and are designed to determine whether the drug product produces any clinically significant effects in patients with the intended disease or condition. If the results of these trials show promise, then a larger Phase III trial may be conducted.
- Phase III trials are often multi-institution studies that involve a large number of participants and are designed to show efficacy. Phase III (and some Phase II) trials are designed to be pivotal, or confirmatory trials. The goal of a pivotal trial is to establish the safety and efficacy of a drug product by eliminating biases and increasing statistical power.
- In some cases, the FDA requires Phase IV trials, which are usually performed after the NDA has been approved. Such post-marketing surveillance is intended to obtain more information about the risks of harm, benefits and optimal use of the drug product by observing the results of the drug product in a large number of patients.

A drug manufacturer may conduct clinical trials either in the U.S. or outside the U.S., but in all cases must comply with GCP, which includes (a) a legally effective informed consent process when enrolling participants; (b) an independent review by an Institutional Review Board to minimize and manage the risks of harm to participants; and (c) ongoing monitoring and reporting of adverse events related to the drug product.

In addition, a drug manufacturer may decide to conduct a clinical trial of a drug product on pediatric patients in order to obtain a form of marketing exclusivity as permitted under the Best Pharmaceuticals for Children Act ("BPCA"). Alternatively, the FDA may require a drug manufacturer, using its authority under the Pediatric Research Equity Act, to conduct a pediatric clinical trial. The goal of conducting pediatric clinical trials is to gather data on how drug products should best be administered to this patient population.

The path leading to FDA approval of a NDA for a drug product that has significant differences from an already approved one is somewhat shorter. The FDA requires a drug manufacturer to submit data from either already published reports or newly conducted studies that show the safety and efficacy of those differences. Significant differences include different dosage strengths or route of administration.

Under the U.S. Prescription Drug User Fee Act, the FDA has the authority to collect fees from drug manufacturers who submit NDAs for review and approval. These user fees help the FDA fund the drug approval process. For fiscal 2014, the user fee rate has been set at $2,169,100 for a 505(b)(1) NDA and $1,084,550 for a NDA not requiring clinical data, generally a 505(b)(2) NDA. We expense these fees as they are incurred. The average review time for a NDA is approximately six months for priority review and ten months for standard review.

ANDA Process. The path leading to FDA approval of an ANDA is much different from that of a NDA. By statute, the FDA waives the requirement for a drug manufacturer to complete pre-clinical studies and clinical trials and instead focuses on data from bioequivalence studies. Bioequivalence studies generally involve comparing the absorption rate and concentration levels of a generic drug in the human body to that of the branded drug or Reference Listed Drug ("RLD"). In the event that the generic drug behaves in the same manner in the human body as the RLD, the two drug products are considered bioequivalent. The FDA considers a generic drug therapeutically equivalent, and therefore substitutable, if it also contains the same active ingredients, dosage form, route of administration and strength.

In August 2013, it was reported that the average review time for an ANDA is about 35 months. In 2010, U.S. Congress passed into law the Generic Drug User Fee Act to address the FDA's backlog, which at the time was over 2,000 ANDAs. This legislation granted the FDA authority to collect, for the first time, user fees from generic drug manufacturers who submit ANDAs for review and approval, and the fees collected will help the FDA fund the drug approval process. For fiscal 2014, the user fee rate is set at $63,860 for an ANDA and $31,930 for a prior approval supplement to an ANDA. The FDA also will collect from generic drug manufacturers a separate one-time Drug Master File fee and separate annual manufacturing facility fees for API and finished drug products. These fees are expensed as incurred. The FDA anticipates that the approval process timeframe will not begin to improve until fiscal 2015.

Aside from the backlog described above, the timing of FDA approval of ANDAs depends on other factors, including whether an ANDA holder has challenged any listed patents to the RLD and whether the RLD is entitled to one or more periods of marketing exclusivity under the FFDCA (such as pediatric exclusivity under the BPCA). In general, the FDA will not approve (but will continue to review) an ANDA in which the RLD holder has sued, within 45 days of receiving notice of the ANDA filing, the ANDA holder for patent infringement until either the litigation has been resolved or 30 months has elapsed, whichever is later.

Patent and Non-Patent Exclusivity Periods. A sponsor of a 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 a previous 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 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 RLD of the bases upon which the patents are challenged, and the holder of the RLD does not sue the later applicant for patent infringement within 45 days of receipt of notice. If an infringement suit is filed, the FDA may not approve the later application until the earliest of: (a) 30 months after receipt of the notice by the holder of the NDA for the RLD; (b) entry of an appellate court judgment holding the patent invalid, unenforceable or not infringed; (c) such time as the court may order; or (d) the expiration of the patent.

One of the key motivators for challenging patents is the 180-day market exclusivity period ("generic exclusivity") granted to the developer of a generic version of a product that is the first to make a Paragraph IV certification and that prevails in litigation with the manufacturer of the branded product over the applicable patent(s) or is not sued. For a variety of reasons, there are situations in which a company may not be able to take advantage of an award of generic exclusivity. The determination of when generic exclusivity begins and ends is very complicated.

The holder of the NDA for the RLD may also 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. Generally, if the RLD is a new chemical entity, the FDA may not accept for filing any application that references the innovator's NDA for five years from the approval of the innovator's NDA. However, this five-year period is shortened to four years where a filer's ANDA includes a Paragraph IV certification. In other cases, where the innovator has provided certain clinical study information, the FDA may accept for filing, but may not approve, an application that references the innovator's NDA for a period of three years from the approval of the innovator's NDA.

Certain additional periods of exclusivity may be available if the RLD is indicated for use in a rare disease or condition or is studied for pediatric indications.

Risk Evaluation and Mitigation Strategies. For certain drug products or classes, such as transmucosal immediate-release fentanyl products and extended-release and long-acting opioids, the FDA has the authority to require the manufacturer to provide a REMS that is intended to ensure that the benefits of a drug product (or class of drug products) outweigh the risks of harm. The FDA may require that a REMS include elements to ensure safe use to mitigate a specific serious risk of harm, such as requiring that prescriber have particular training or experience or that the drug product is dispensed in certain healthcare settings. The FDA has the authority to impose civil penalties on or take other enforcement action against any drug manufacturer who fails to properly implement an approved REMS program. Separately, a drug manufacturer cannot use an approved REMS program to delay generic competition.

In December 2011, the FDA approved a single, class-wide REMS program for transmucosal immediate-release fentanyl ("TIRF") products (called "the TIRF REMS Access Program") in order to ease the burden on the healthcare system. TIRF products are opioids used to manage pain in adults with cancer who routinely take other opioid pain medicines around-the-clock. We were part of the original industry working group that collaborated to develop and implement the TIRF REMS Access Program. The goals of this program are to ensure patient access to important medications and mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors by: (a) prescribing and dispensing only to appropriate patients, including use only in opioid-tolerant patients; (b) preventing inappropriate conversion between fentanyl products; (c) preventing accidental exposure to children and others for whom such products were not prescribed; and (d) educating prescribers, pharmacists and patients on the potential for misuse, abuse, addiction and overdose. This program started in March 2012 and requires manufacturers, distributors, prescribers, dispensers and patients to enroll in a real-time database that maintains a closed-distribution system.

In February 2009, the FDA requested that drug manufacturers help develop a single, shared REMS for extended-release and long-acting opioid products that contain fentanyl, hydromorphone, methadone, morphine, oxycodone and oxymorphone. In April 2009, the FDA announced that the "REMS would be intended to ensure that the benefits of these drugs continue to outweigh the risks associated with: (1) use of high doses of long-acting opioids and extended-release opioid products in non-opioid-tolerant and inappropriately selected individuals; (2) abuse; (3) misuse; and (4) overdose, both accidental and intentional." We were part of the original industry working group that collaborated to develop and implement this REMS program. Upon FDA approval of Exalgo in March 2010, we implemented the product-specific REMS program that was developed internally while continuing to collaborate on the class-wide REMS program. In July 2012, the FDA approved a class-wide REMS program (called "the Extended-Release and Long-Acting Opioid Analgesics REMS") that affected more than 30 extended-release and long-acting opioid analgesics (both branded and generic products). This REMS program requires drug manufacturers to make available training on appropriate prescribing practices for healthcare professionals who prescribe these opioid analgesics and to distribute educational materials on their safe use to prescribers and patients.

As part of our ongoing commitment to the responsible prescribing, dispensing and safe use of prescription opioids beyond the FDA's REMS requirements, we launched the C.A.R.E.S. Alliance in September 2010. For further discussion on the C.A.R.E.S. Alliance, refer to "Our Business and Product Strategies" within this Item 1. Business.

Drug Enforcement Administration. The DEA is the federal agency responsible for domestic enforcement of the Controlled Substances Act of 1970 ("CSA"). The CSA classifies drugs and other substances based on identified potential for abuse. Schedule I controlled substances, such as heroin and LSD, have a high abuse potential and have no currently accepted medical use; thus, they cannot be lawfully marketed or sold. Opioids, such as oxycodone, oxymorphone, morphine, fentanyl and hydrocodone, are either Schedule II or III controlled substances. Consequently, the manufacture, storage, distribution and sale of these substances are highly regulated.

The DEA regulates the availability of API, products under development and marketed drug products that are Schedule II or III by setting annual quotas. Every year, we must apply to the DEA for manufacturing quota to manufacture API and procurement quota to manufacture finished dosage products. Given that the DEA has discretion to grant or deny our manufacturing and procurement quota requests, the quota the DEA grants may be insufficient to meet our

commercial and R&D needs. To date in calendar 2013, manufacturing and procurement quotas granted by the DEA have been sufficient to meet our sales and inventory requirements on most products. During calendar 2012, the initial hydrocodone manufacturing and procurement quota grants we received from the DEA were below the amounts requested and were therefore insufficient to meet customer demand. While we were granted additional quota, these shortfalls did result in lost sales of hydrocodone products, the amount of which was not significant. Future delay or refusal by the DEA to grant, in whole or in part, our quota requests could delay or result in stopping the manufacture of our marketed drug products, new product launches or the conduct of bioequivalence studies and clinical trials.

In October 2013, the FDA announced its recommendation that the DEA reschedule hydrocodone combination products (such as Vicodin® (registered trademark of AbbVie Inc.) and our developmental product MNK-155) from Schedule III to Schedule II, thereby increasing regulatory controls on these drug products. The FDA expects to issue its formal recommendation to the DHHS in December 2013. This recommendation will begin a process that will lead to a final decision by the DEA on the scheduling of these products. At this time, it is too early to determine the degree of impact the hydrocodone rescheduling, if adopted, will have on our business.

DEA regulations make it extremely difficult for a manufacturer in the U.S. to import finished dosage forms of controlled substances manufactured outside the U.S. These rules reflect a broader enforcement approach by the DEA to regulate the manufacture, distribution and dispensing of legally produced controlled substances. Accordingly, drug manufacturers who market and sell finished dosage forms of controlled substances in the U.S. typically manufacture or have them manufactured in the U.S.

The DEA also requires drug manufacturers to design and implement a system that identifies suspicious orders of controlled substances, such as those of unusual size, those that deviate substantially from a normal pattern and those of unusual frequency, prior to completion of the sale. A compliant suspicious order monitoring ("SOM") system includes well-defined due diligence, "know your customer" efforts and order monitoring.

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 competitive position, business, financial condition, results of operations 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 lead to 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 all necessary registrations, and we believe all registrants operate in conformity with applicable registration requirements, under controlled substance laws.

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. The federal and 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, which could have material adverse consequences for the pharmaceutical industry as a whole and, consequently, also for us. However, we believe we have provided for our best estimate of potential refunds based on current information available.

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 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 pressure on the prices of prescription drugs in the Medicare program.

In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, "the Healthcare Reform Act") provides for major changes to the U.S. healthcare system, which may transform the delivery and payment for healthcare services in the U.S. While some provisions of the Healthcare Reform Act have already taken effect, most of the provisions to expand access to healthcare coverage will not be implemented until 2014 and beyond. The combination of these measures, which include the elimination of lifetime caps and no rescission of policies or denial of coverage due to preexisting conditions, could expand health insurance coverage by an estimated 32 million people in the U.S., improving patients' ability to obtain and maintain health insurance.

Since much of the implementation is yet to take place, 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. We intend to monitor closely

the implementation of the Healthcare Reform Act and related legislative and regulatory developments. The overall impact of the Healthcare Reform Act 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 for new formulations and the expansion of 340B pricing to new entities.

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, including the U.S. Anti-Kickback Statute and similar state statutes, the U.S. Federal Sunshine Law and other parts of the Healthcare Reform Act, the False Claims Act and the Health Insurance Portability and Accountability Act of 1996. Violations of these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs. These laws apply to hospitals, physicians and other potential purchasers of our products and are potentially applicable to us as both a manufacturer and a supplier of products reimbursed by federal healthcare programs. In addition, some states in the U.S. have enacted compliance and reporting requirements aimed at drug manufacturers.

We are also subject to the Foreign Corrupt Practices Act of 1977 and similar worldwide anti-bribery laws in non-U.S. jurisdictions which generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside of the U.S. are with governmental entities and are therefore subject to such anti-bribery laws. Our policies mandate compliance with these anti-bribery laws; however, we operate in many parts of the world that have experienced governmental corruption to some degree and, in certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not protect us from reckless or criminal acts committed by our employees or agents.

Compliance Programs

In order to systematically and comprehensively mitigate the risks of non-compliance with regulatory requirements described within this Item 1. Business, we have developed what we believe to be a robust compliance program based on the April 2003 Office of the Inspector General ("OIG") Compliance Program Guidance for Pharmaceutical Manufacturers, the U.S. Federal Sentencing Guidelines, the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, the Code of Ethics of the Advanced Medical Technology Association, the United Kingdom ("U.K.") Anti-Bribery guidance, and other relevant government guidances and national or regional industry codes of behavior. We conduct ongoing compliance training programs for all employees and maintain a 24-hour ethics and compliance reporting hotline.

As part of our compliance program, we have implemented internal cross-functional processes to review and approve all product-specific promotional materials, presentations and external communications to address the risk of misbranding or mislabeling our products through our promotional efforts. For example, we have established programs to monitor promotional speaker activities and field sales representatives, which includes a "ride along" program for field sales representatives similar to those included in recent Corporate Integrity Agreements from the OIG in order to obtain first-hand observations of how these approved materials are used. We have also implemented a comprehensive controlled substances compliance program, including anti-diversion efforts that go beyond the DEA's SOM requirements and we regularly assist federal, state and local law enforcement and prosecutors in the U.S. by providing information and testimony on our products and placebos for use by the DEA and other law enforcement agencies in investigations and at trial. As part of this program, we also work with some of our customers to help develop and implement what we believe are best practices for SOM and other anti-diversion activities.

We believe our compliance program design also addresses our FDA, healthcare anti-kickback and anti-fraud, and anti-bribery-related activities.

Outside the United States

Outside the U.S., we must comply with laws, guidelines and standards promulgated by other regulatory authorities that regulate the development, testing, manufacturing, marketing and selling of pharmaceuticals, including, but not limited to, Health Canada, the Medicines and Healthcare Products Regulatory Agency in the U.K., the Irish Medicines

Board, the European Medicines Agency and member states of the E.U., the State Food and Drug Administration in China, the Therapeutic Goods Administration in Australia, the New Zealand Medicines and Medical Devices Safety Authority, the Ministry of Health and Welfare in Japan, the European Pharmacopoeia of the Council of Europe and the International Conference on Harmonization. Although international harmonization efforts continue, many laws, guidelines and standards differ by region or country.

We currently market our products in Canada, in various countries in the E.U., and in the Latin American, Middle Eastern, African and Asia-Pacific regions. The approval requirements and process vary by country, and the time required to obtain marketing authorization may vary from that required for FDA approval. Certain drug products and variations in drug product lines also must meet country-specific and other local regulatory requirements. The following discussion highlights some of the differences in the approval process in other regions or countries outside the U.S.

European Union. Marketing authorizations are obtained either pursuant to a centralized or decentralized procedure. The centralized procedure, which provides for a single marketing authorization valid for all E.U. member states, is mandatory for the approval of certain drug products and is optional for novel drug products that are in the interest of patient health. Under the centralized procedure, a single marketing authorization application is submitted for review to the European Medicines Agency, which makes a recommendation on the application to the European Commission, who determines whether or not to approve the application. The decentralized procedure provides for concurrent mutual recognition of national approval decisions, and is available for products that are not subject to the centralized procedure.

The E.U. has also adopted directives and other laws that govern the labeling, marketing, advertising, supply, distribution and drug safety monitoring and reporting of drug products. Such directives set regulatory standards throughout the E.U. and permit member states to supplement such standards with additional requirements.

European governments also regulate drug prices through the control of national healthcare systems that fund a large part of such costs to patients. Many regulate the pricing of a new drug product at launch through direct price controls or reference pricing and, recently, some have also imposed additional cost-containment measures on drug products. Such differences in national pricing regimes may create price differentials between E.U. member states. Many European governments also advocate generic substitution by requiring or permitting prescribers or pharmacists to substitute a different company's generic version of a brand drug product that was prescribed, and patients are unlikely to take a drug product that is not reimbursed by their government.

Japan. The Pharmaceutical and Medical Devices Agency ("PMDA") is responsible for reviewing marketing authorizations of drug products. The PMDA may require bridging studies (a clinical trial with a smaller sub-population than the original clinical trials) to demonstrate that clinical trial data obtained in trials conducted outside of Japan are applicable to Japanese patients. After completing a comprehensive review, the PMDA reports its findings to the Ministry of Health, Labour and Welfare, which either approves or denies the application.

Japan's national health insurance system maintains a Drug Price List that specifies which drug products are eligible for reimbursement and the Ministry of Health, Labour and Welfare sets pricing for such drug products. In general, the Japanese government introduces a round of price cuts every other year and mandates price reductions for specific drug products. However, new drug products that are judged innovative or useful, indicated for pediatric use, or target orphan diseases may be eligible for premium prices. Similar to other countries, the Japanese government also advocates the prescribing and use of generic drugs, where available.

Emerging Markets. Many emerging markets continue to evolve their regulatory review and oversight processes. At present, such countries typically require prior regulatory approval or marketing authorization from large, developed markets (such as the U.S.) before they will initiate or complete their review. Some countries also require the applicant to conduct local clinical trials as a condition of marketing authorization. Many emerging markets continue to implement measures to control drug product prices, such as implementing direct price controls or advocating the prescribing and use of generic drugs.

Environmental

Our operations, like those of other pharmaceutical companies, involve the use of substances regulated under environmental laws, primarily in manufacturing processes and, as such, we are subject to numerous federal, state, local and non-U.S. environmental protection and health and safety laws and regulations. We cannot assure you that we have been or will be in full compliance with environmental, health and safety laws and regulations at all times. Certain environmental laws assess strict (i.e., can be imposed regardless of fault) and joint and several liability on current or previous owners of real property and current or previous owners or operators of facilities for the costs of investigation, removal or remediation of hazardous substances or materials at such properties or at properties at which parties have disposed of hazardous substances. We have, from time to time, received notification from the EPA and from state environmental agencies in the U.S. that conditions at a number of sites where the disposal of hazardous substances requires investigation, cleanup and other possible remedial actions. These agencies may require that we reimburse the government for costs incurred at these sites or otherwise pay for the cost of investigation and cleanup of these sites

including compensation for damage to natural resources. We have projects underway at a number of current and former manufacturing facilities to investigate and remediate environmental contamination resulting from past operations, as further described in Item 3. Legal Proceedings and Note 18 to Notes to Consolidated and Combined Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Environmental laws are complex, change frequently and generally have become more stringent over time. We believe that our operations currently comply in all material respects with applicable environmental laws and regulations, and have planned for future capital and operating expenditures to comply with these laws and to address liabilities arising from past or future releases of, or exposures to, hazardous substances. However, we cannot assure you that our costs of complying with current or future environmental protection, health and safety laws and regulations will not exceed our estimates or have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Further, we cannot assure you that we will not be subject to additional environmental claims for personal injury or cleanup in the future based on our past, present or future business activities. While it is not feasible to predict the outcome of all pending environmental matters, it is reasonably possible that there will be a need for future provisions for environmental costs that, in management's opinion, are not likely to have a material adverse effect on our financial condition, but could be material to the results of operations in any one accounting period.

Certain radiological licenses at certain manufacturing sites owned by us require the establishment of decommissioning programs which will require remediation in accordance with regulatory requirements upon cessation of operations at these sites.

Raw Materials

We contract with various third-party manufacturers and suppliers to provide us with raw materials used in our products, finished goods and certain services. If, for any reason, we are unable to obtain sufficient quantities of any of the raw materials or components required for our products, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The active ingredients in the majority of our current pharmaceutical products and products in development, including oxycodone, oxymorphone, morphine, fentanyl, methylphenidate 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 and the DEA limits both the availability of these active ingredients and the production of these products. As discussed in "Regulatory Matters" within this Item 1. Business, we must annually apply to the DEA for procurement and production quotas in order to obtain and produce these substances. The DEA has complete discretion to adjust these quotas from time to time during the calendar year and, as a result, our procurement and production quotas may not be sufficient to meet commercial demand or to conduct bioequivalence studies and clinical trials. Any delay or refusal by the DEA in granting, in whole or in part, our quota requests for controlled substances could delay or result in the stoppage of the manufacture of our pharmaceutical products, our clinical trials or product launches and could require us to allocate product among our customers.

Our radiopharmaceutical product offering includes "hot" radioisotopes including Mo-99, a critical ingredient of our Ultra-Technekow DTE Tc-99m generators. Mo-99 is produced in nuclear research reactors utilizing HEU or LEU targets. These targets, either tubular or flat and of varying sizes, are fabricated from HEU or LEU and, in either case, aluminum. The targets are placed in or near the core of the nuclear reactor where fission reactions occur resulting in the production of Mo-99 and other isotopes. This process, which takes approximately six days, is known as target irradiation. There are currently eight reactors around the world producing the global supply of Mo-99. We have agreements to obtain Mo-99 from three of these reactors and we rely predominantly on two of these reactors for our Mo-99 supply. These reactors are subject to scheduled and unscheduled shutdowns which can have a significant impact on the amount of Mo-99 available for processing. Mo-99 produced at these reactors is then finished at one of five processing sites located throughout the world, including our processing facility located in the Netherlands. At the processing facility, the targets are dissolved and chemically separated. In this process, the Mo-99 is isolated as a radiochemical. We transport finished Mo-99 from our processing facility in the Netherlands to our facility in Maryland Heights, Missouri, where it, together with Mo-99 received from other third-party processors, is loaded into our Tc-99m generators. Mo-99 has a 66 hour half-life and degrades into, among other things, Tc-99m, which has a half-life of only six hours. The radiopharmacies or hospitals prepare dosages from the Tc-99m generators for use in SPECT imaging medical procedures.

In November 2012, the High Flux Reactor ("HFR") in the Netherlands, one of two primary reactors we utilize, experienced an unscheduled shutdown. We were able to receive increased target irradiations at the two other reactors and purchased additional Mo-99 from other sources to continue meeting customer orders; however, the additional Mo-99 we procured from alternative sources came at a higher than normal cost. The HFR resumed production in June 2013.

In October 2013, the HFR experienced another unscheduled shutdown. In addition, our own Mo-99 processing facility in the Netherlands also experienced a shutdown. Until these facilities resume normal production, we expect to fulfill

customer orders through procurement of Mo-99 from alternative sources at higher than historical costs. Ongoing increased raw material and manufacturing costs will limit our ability to return the Global Medical Imaging segment to historical operating margins.

Sales, Marketing and Customers

Sales and Marketing

We market our branded, generic and CMDS products to physicians, pharmacists, pharmacy buyers, radiologists and radiology technicians. We distribute these products to major drug wholesalers, retail pharmacy chains, hospital networks and governmental agencies. In addition, we contract with GPOs and managed care organizations to improve access to our products. We sell and distribute API directly or through distributors to other pharmaceutical companies. In the U.S., we market and distribute our nuclear imaging products to radiopharmacies which, in turn, supply hospitals and standalone imaging centers with patient-customized doses. Outside the U.S., we market and distribute our nuclear imaging products to hospitals.

We often negotiate with parties that enter into supply contracts for the benefit of their member facilities, including GPOs, integrated delivery networks, large and medium size retail pharmacy chains, nuclear pharmacy chains, wholesalers and, solely outside the U.S., with governments through a tender process.
For further information on our sales and marketing strategies, refer to "Our Businesses and Product Strategies" included within this Item 1. Business.

Customers
Net sales to distributors that accounted for more than 10% of our total net sales in fiscal 2013, 2012 and 2011 were as follows:

	Fiscal Year					
	2013		2012		2011	
Cardinal Health, Inc.	18	%	19	%	19	%
McKesson Corporation	15	%	14	%	13	%
Amerisource Bergen Corporation	9	%	9	%	10	%

No other customer accounted for 10% or more of our net sales in the past three fiscal years.

Manufacturing and Distribution
We presently have ten manufacturing sites, including seven located in the U.S., as well as sites in Canada, Ireland and the Netherlands, which handle production, assembly, quality assurance testing, packaging and sterilization of our products. We estimate that our manufacturing production by region in fiscal 2013 (as measured by cost of production) was as follows:

U.S.	79	%
Europe	13	%
Canada	8	%

We maintain distribution centers in 17 countries. In addition, in certain countries outside the U.S. we utilize third-party distribution centers. Products generally are delivered to these distribution centers from our manufacturing facilities and then subsequently delivered to the customer. In some instances, product, such as nuclear medicine, is delivered directly from our manufacturing facility to the customer. We contract with a wide range of transport providers to deliver our products by road, rail, sea and air.

Backlog
At September 27, 2013, the backlog of firm orders was less than 1% of net sales. We anticipate that substantially all of the backlog as of September 27, 2013 will be shipped during fiscal 2014.

Seasonality
There are no significant seasonal aspects to our business; however, DEA quotas are allocated in each calendar year to companies and may impact our sales until the DEA grants additional quotas, if any. Impacts from quota limitations are most commonly experienced during the third and fourth calendar quarters, which represent our fourth and first fiscal quarters, respectively.

Employees
At September 27, 2013, we had approximately 5,500 employees, approximately 4,100 of which are based in the U.S. Certain of these employees are represented by unions or work councils. We believe that we generally have a good relationship with our employees, and with the unions and work councils that represent certain employees.

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Executive Officers

Set forth below are the names, ages as of December 1, 2013, and current positions of our executive officers.

Name	Age	Title
Mark Trudeau	52	President, Chief Executive Officer and Director
Matthew Harbaugh	43	Senior Vice President and Chief Financial Officer
Peter Edwards	52	Senior Vice President and General Counsel
Hugh O'Neill	50	Senior Vice President and President of Specialty Pharmaceuticals
Stephen Merrick	53	Senior Vice President and President, Commercial Operations, International
Gary Phillips	47	Senior Vice President and Chief Strategy Officer
Mario Saltarelli	53	Senior Vice President and Chief Science Officer
Ian Watkins	51	Senior Vice President and Chief Human Resources Officer
Meredith Fischer	60	Senior Vice President, Communications and Public Affairs

Set forth below is a brief description of the position and business experience of each of our executive officers.

Mark Trudeau is our President and Chief Executive Officer, and also serves on our board of directors. Mr. Trudeau joined the Pharmaceuticals segment of Covidien in February 2012 as a Senior Vice President and President of its Pharmaceuticals business. Mr. Trudeau previously worked for Bayer HealthCare Pharmaceuticals LLC USA, the U.S. healthcare business of Bayer AG, where he served as Chief Executive Officer, and simultaneously served as President of Bayer HealthCare Pharmaceuticals, the U.S. organization of Bayer's global pharmaceuticals business. In addition, Mr. Trudeau served as Interim President of the global specialty medicine business unit from January to August 2010. Prior to joining Bayer in 2009, Mr. Trudeau headed the Immunoscience Division at Bristol-Myers Squibb. During his ten-plus years at Bristol-Myers Squibb, he served in multiple senior roles, including President of the Asia/Pacific region, President and General Manager of Canada and General Manager/Managing Director in the U.K. Mr. Trudeau was also with Abbott Laboratories, serving in a variety of executive positions, from 1988 to 1998. Mr. Trudeau holds a Bachelor's degree in chemical engineering and a M.B.A., both from the University of Michigan.

Matthew Harbaugh is our Senior Vice President and Chief Financial Officer. Mr. Harbaugh previously served as Vice President, Finance of Covidien's Pharmaceuticals business, a position he held since July 2008. He also served as Interim President of Covidien's Pharmaceuticals business from November 2010 to January 2012. Mr. Harbaugh joined Covidien's Pharmaceuticals business in August 2007 as its Vice President and Controller, Global Finance for the Global Medical Imaging business. Mr. Harbaugh was a Lead Finance Executive with Cerberus Capital Management, L.P. from April 2007 until August 2007. Mr. Harbaugh worked for Monsanto from 1997 to 2007 serving in senior U.S. roles in treasury, investor relations, financial planning and analysis and strategy, in addition to two international assignments in Canada and Argentina.

Peter Edwards is our Senior Vice President and General Counsel. Mr. Edwards joined Covidien's Pharmaceuticals business in May 2010 as Vice President and General Counsel. Mr. Edwards previously worked for the Solvay Group in Brussels, Belgium, where he served as Executive Vice President and General Counsel for the global pharmaceuticals business from June 2007 until April 2010.

Hugh O'Neill is our Senior Vice President and President of Specialty Pharmaceuticals. Prior to joining Mallinckrodt in September 2013, Mr. O'Neill worked at Sanofi-Aventis for ten years where he held various commercial leadership positions including Vice President of Commercial Excellence from June 2012 to July 2013, General Manager, President of Sanofi-Aventis Canada from June 2009 to May 2012, Vice President Market Access and Business Development from 2006 to 2009. Mr. O'Neill joined Sanofi in 2003 as its Vice President, United States Managed Markets. Mr. O'Neill previously served in a variety of positions of increasing responsibility for Sandoz Pharmaceuticals, Forest Laboratories, Novartis Pharmaceuticals and Pfizer.

Stephen Merrick is our Senior Vice President and President of Commercial Operations, International. Mr. Merrick joined Covidien's Pharmaceuticals business in February 2013 as Vice President and President of Commercial Operations, International. Mr. Merrick was employed by Bristol-Myers Squibb Company, where he served as Vice President, Strategic Projects - Intercontinental Region from September 2012 until February 2013, President and

General Manager - Brazil from December 2009 until September 2012 and as Vice President - Distributor Markets and Geographic Optimization from November 2007 until December 2009.

Gary Phillips is our Senior Vice President and Chief Strategy Officer and joined Mallinckrodt in October 2013. Most recently, Dr. Phillips had served as head of Global Health and Healthcare Industries for the World Economic Forum in Geneva, Switzerland from January 2012 to September 2013. Prior to that, Dr. Phillips served as President of Reckitt Benckiser Pharmaceuticals North America from 2011 to 2012, as Head, Portfolio Strategy, Business Intelligence and Innovation at Merck Serono from 2008 to 2011, and as President of US Pharmaceuticals and Surgical and Bausch & Lomb from 2002 to 2008. Dr. Phillips has also held positions of leadership at Novartis Pharmaceuticals, Wyeth-Ayerst and Gensia Pharmaceuticals.

Mario Saltarelli is our Senior Vice President and Chief Science Officer. Prior to joining Mallinckrodt in October 2013, Dr. Saltarelli had served as Senior Vice President, R&D at Shire plc since September 2012 and as its Senior Vice President Clinical Development and Medical Affairs from January 2011 to September 2012. From 2004 to 2011, Dr. Saltarelli served as Divisional Vice President of Abbott Laboratories. From 1997 to 2004, he held positions of responsibility at Pfizer, and, prior to that, academic posts in the Department of Neurology at the Emory University School of Medicine in Atlanta.

Ian Watkins is our Senior Vice President and Chief Human Resources Officer. Mr. Watkins joined Covidien's Pharmaceuticals business in September 2012 as the Chief Human Resources Officer. Mr. Watkins served as Vice President, Global Human Resources at Synthes, Inc. from June 2007 to September 2012, which was recently acquired by Johnson & Johnson. Mr. Watkins served as Senior Vice President, Human Resources from 2003 to 2006 for Andrx Corporation, which is now part of Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.).

Meredith Fischer is our Senior Vice President, Communications and Public Affairs. Ms. Fischer joined Covidien's Pharmaceuticals business in February 2013 as Vice President, Communications and Public Affairs. Ms. Fischer was employed by Bayer Corporation from December 2001 until February 2013, where she served as Vice President of Communications and Public Policy for Bayer HealthCare and Bayer HealthCare Pharmaceuticals, North America. In that role, Ms. Fischer supported Bayer HealthCare's U.S. pharmaceutical and animal health divisions and the company's global medical care and consumer care businesses.

Available Information

Our website address is www.mallinckrodt.com. We are not including the information contained on our website as part of, or incorporating it by reference into, this filing. We make available to the public on our website, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after such material is electronically filed with, or furnished to, the U.S. Securities and Exchange Commission ("SEC"). Our reports filed with, or furnished to, the SEC may be read and copied at the SEC's Public Reference Room at 100 F Street, N.E. Washington, DC 20549. Investors may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. These filings are also available on the SEC's website at www.sec.gov.

Item 1A. Risk Factors.

You should carefully consider the risks described below in addition to all other information provided to you in this Annual Report on Form 10-K. Our competitive position, business, financial condition, results of operations and cash flows could be affected by the factors set forth below, any one of which could cause our actual results to vary materially from recent results or from our anticipated future results. The risks and uncertainties described below are those that we currently believe may materially affect our company.

Risks Related to Our Business

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. The following discussion highlights some of these risks and others are discussed elsewhere in this Annual Report on Form 10-K. These and other risks could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The DEA regulates the availability of controlled substances that are API, drug products under development and marketed drug products. At times, the procurement and manufacturing quotas granted by the DEA may be insufficient to meet our commercial and R&D needs.

The U.S. DEA is the federal agency responsible for domestic enforcement of the CSA. The CSA classifies drugs and other substances based on identified potential for abuse. Schedule I controlled substances, such as heroin and LSD, have a high abuse potential and have no currently accepted medical use; thus, they cannot be lawfully marketed or

sold. Schedule II or III controlled substances include molecules such as oxycodone, oxymorphone, morphine, fentanyl, hydrocodone and methylphenidate.

The manufacture, storage, distribution and sale of these controlled substances are permitted, but highly regulated. The DEA regulates the availability of API, products under development and marketed drug products that are Schedule II or III by setting annual quotas. Every year, we must apply to the DEA for manufacturing quota to manufacture API and procurement quota to manufacture finished dosage products. Given that the DEA has discretion to grant or deny our manufacturing and procurement quota requests, the quota the DEA grants may be insufficient to meet our commercial and R&D needs. To date in calendar 2013, manufacturing and procurement quotas granted by the DEA have been sufficient to meet our sales and inventory requirements on most products. During calendar 2012, the initial hydrocodone manufacturing and procurement quota grants we received from the DEA were below the amounts requested and were therefore insufficient to meet customer demand. While we were granted additional quota, these shortfalls did result in lost sales of hydrocodone products, the amount of which was not significant. Future delay or refusal by the DEA to grant, in whole or in part, our quota requests could delay or result in stopping the manufacture of our marketed drug products, new product launches or the conduct of bioequivalence studies and clinical trials. Such delay or refusal also could require us to allocate marketed drug products among our customers. These factors, along with any delay or refusal by the DEA to provide customers who purchase API from us with sufficient quota, could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The manufacture of our products is highly exacting and complex, and our business could suffer if we, or our suppliers, encounter manufacturing or supply problems.

The manufacture of our products is highly exacting and complex, due in part to strict regulatory and manufacturing requirements. Problems may arise during manufacturing for a variety of reasons including equipment malfunction, failure to follow specific protocols and procedures, defective raw materials and environmental factors. If a batch of finished product fails to meet quality standards during a production run, then that entire batch of product may have to be discarded. These problems could lead to backorders, increased costs (including contractual damages for failure to meet supply requirements), lost revenue, damage to customer relationships, time and expense spent investigating, correcting and preventing the root causes and, depending on the root causes, similar losses with respect to other products. In fiscal 2012, we experienced disruptions in supplying products to our customers due to a number of factors, including mechanical, capacity and packaging quality control issues and the implementation of a new production planning system at our Hobart, New York manufacturing facility. These issues resulted in higher than usual backorders and obligations to pay contractual damages for failure to meet supply requirements. During fiscal 2012, our Generics business incurred approximately $13 million of expenses for such contractual damages, a substantial portion of which was attributable to the issues experienced at this facility. We did not experience material expenses in fiscal 2013 related to manufacturing problems. In the event that manufacturing problems are not discovered before the product is released to the market, we also could incur product recall and product liability costs. If we incur a product recall or product liability costs involving one of our products, such product could receive reduced market acceptance and thus reduced product demand and could harm our reputation and our ability to market our products in the future. Significant manufacturing problems could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The global supply of fission-produced Mo-99 is limited. Our inability to obtain and/or to timely transport Mo-99 to our Tc-99m generator production facilities could prevent us from delivering our Ultra-Technekow DTE Tc-99m generators to our customers in the required quantities, within the required timeframe, or at all, which could result in order cancellations and decreased revenues or increased costs if we procure supply from other sources.

Mo-99 is a critical ingredient of our Tc-99m generators. Mo-99 is produced in nuclear research reactors utilizing HEU or LEU targets. These targets, either tubular or flat and of varying sizes, are fabricated from HEU or LEU and, in either case, aluminum. The targets are placed in or near the core of the nuclear reactor where fission reactions occur resulting in the production of Mo-99 and other isotopes. This process, which takes approximately six days, is known as target irradiation. There are currently eight reactors around the world producing the global supply of Mo-99. We

have agreements to obtain Mo-99 from three of these reactors and we rely predominantly on two of these reactors for our Mo-99 supply. These reactors are subject to scheduled and unscheduled shutdowns which can have a significant impact on the amount of Mo-99 available for processing. Mo-99 produced at these reactors is then finished at one of five processing sites located throughout the world, including our processing facility located in the Netherlands. At the processing facility, the targets are dissolved and chemically separated. In this process, the Mo-99 is isolated as a radiochemical. Once finished, Mo-99 must be transported to generator facilities where it is loaded into our Tc-99m generators that are sold, in the U.S., principally to nuclear radiopharmacies as well as hospitals and, in Europe and other markets, principally to hospitals, where single unit doses are then prepared. Mo-99 has a 66-hour half-life and decays primarily into Tc-99m, which has a half-life of only six hours. The radiopharmacies or hospitals prepare dosages from the Tc-99m generators for use in SPECT imaging medical procedures. Given the product's radioactive decay, if we encounter delays in transporting Mo-99 to our generator facilities, or if the generator facilities experience delays in loading Mo-99, we may be limited in the amount of Ultra-Technekow DTE generators that we could manufacture, distribute and sell, which could have a material adverse effect on our competitive position, business, financial condition, results of operation and cash flows.

In November 2012, the HFR in the Netherlands, one of two primary reactors we utilize, experienced an unscheduled shutdown. We were able to receive increased target irradiations at the two other reactors and purchased additional Mo-99 from other sources to continue meeting customer orders; however, the additional Mo-99 we procured from alternative sources came at a higher than normal cost. The reactor resumed production in June 2013.
In October 2013, the HFR experienced another unscheduled shutdown. In addition, our own Mo-99 processing facility in the Netherlands also experienced a shutdown. Until these facilities resume normal production, we expect to fulfill customer orders through procurement of Mo-99 from alternative sources at higher than historical costs.
Future unplanned shutdowns of nuclear reactors that we use to irradiate targets could impact the amount of available Mo-99, which could result in global shortages, continued increased raw material costs and decreased sales. While we are pursuing additional sources of Mo-99 from potential producers around the world to augment our current supply, it is not certain whether these possible additional sources of Mo-99 will produce commercial quantities of Mo-99 for our business, or that these suppliers, together with our current suppliers, will be able to deliver a sufficient quantity of Mo-99 to meet our needs. Ongoing increased raw material and manufacturing costs will limit our ability to return the Global Medical Imaging segment to historical operating margins.

In response to the U.S. National Security Administration's Global Threat Initiative, we are in the process of converting our Mo-99 production operation in the Netherlands from HEU targets to LEU targets. There can be no assurance that we will be successful in completing this conversion.
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. However, there is no assurance that we will be successful in completing the conversion. If we are successful in converting to LEU targets, we expect that the manufacturing costs will be higher than those incurred while utilizing HEU targets, which may negatively impact the profitability of our Global Medical Imaging segment.

Our customer concentration may materially 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. Sales to two of our distributors that supply our products to many end user customers, Cardinal Health, Inc. and McKesson Corporation, each accounted for 10% or more of our total net sales in each of the past three fiscal years. Additionally, AmerisourceBergen Corporation accounted for 10% of our total net sales in fiscal 2011. If we were to lose the business of these distributors, or if these distributors were to experience difficulty in paying us on a timely basis, this could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Cost-containment efforts of our customers, purchasing groups, third-party payors and governmental organizations could materially adversely affect our net sales and results of operations.
In an effort to reduce cost, many existing and potential customers for our products within the U.S. have become members of GPOs and integrated delivery networks ("IDNs"). GPOs and IDNs negotiate pricing arrangements with healthcare product manufacturers and distributors and offer the negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple manufacturers with the intention of driving down pricing. Due to the highly competitive nature of the GPO and IDN contracting processes, there is no assurance that we will be able to obtain or maintain contracts with major GPOs and IDNs across our product portfolio. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our products, thereby reducing our profitability. While having a contract with a GPO or IDN for a given product can facilitate sales to members of that GPO or IDN,

having a contract is no assurance that sales volume of those products will be maintained. GPOs and IDNs increasingly are awarding contracts to multiple suppliers for the same product category. Even when we are the sole contracted supplier of a GPO or IDN for a certain product, members of the GPO or IDN generally are free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause upon 60 to 90 days prior notice. Accordingly, although we have contracts with many major GPOs and IDNs, the members of such groups may choose to purchase from our competitors, which could result in a decline in our net sales and results of operations.

Distributors of our products are negotiating terms of sale more aggressively in an effort to increase their profitability. Failure to negotiate distribution arrangements having advantageous pricing and other terms of sale could cause us to lose market share to our competitors and could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. Outside the U.S., we have experienced pricing pressure due to the concentration of purchasing power in centralized governmental healthcare authorities and increased efforts by such authorities to lower healthcare costs. We frequently are required to engage in competitive bidding for the sale of our products to governmental purchasing agents. Our failure to offer acceptable prices to these customers could materially adversely affect our net sales and results of operations in these markets.

We may be unable to successfully develop or commercialize new products or adapt to a changing technology and diagnostic treatment landscape and, as a result, our results of operations may suffer.

Our future results of operations will depend to a significant extent upon our ability to successfully develop and commercialize new products in a timely manner. There are numerous difficulties in developing and commercializing new products, including:

- developing, testing and manufacturing products in compliance with regulatory and quality standards in a timely manner;
- receiving requisite regulatory approvals for such products in a timely manner, or at all;
- the availability, on commercially reasonable terms, of raw materials, including API and other key ingredients;
- developing and commercializing a new product is time-consuming, costly and subject to numerous factors, including legal actions brought by our competitors, that may delay or prevent the development and commercialization of new products;
- unanticipated costs;
- payment of prescription drug user fees to the FDA to defray the costs of review and approval of marketing applications for branded and generic drugs;
- experiencing delays as a result of limited resources at the FDA or other regulatory authorities;
- changing review and approval policies and standards at the FDA or other regulatory authorities;
- potential delay in the commercializing of generic products by up to 30 months resulting from the listing of patents with the FDA; and
- effective execution of the planned launch in a manner that is consistent with anticipated costs.

As a result of these and other difficulties, products currently in development by us may or may not receive timely regulatory approvals, or approvals at all, as to one or more dosage strengths. This risk particularly exists with respect to the development of proprietary products due to the uncertainties, higher costs and length of time associated with R&D of such products and the inherent unproven market acceptance of such products. In addition, we face heightened risks in connection with our development of extended-release products because of the technical complexities and evolving regulatory and quality requirements related to such products. Moreover, the FDA regulates the facilities, processes and procedures used to manufacture and market pharmaceutical 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 cGMP regulations enforced by the FDA. Compliance with cGMP regulations requires the dedication of substantial resources and requires significant expenditures. The FDA periodically inspects both our facilities and procedures to ensure compliance. The FDA 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 is required by the FDA to curtail or cease operations, or otherwise becomes inoperable, obtaining the required FDA authorization to manufacture at the same or a different manufacturing site could result in production delays, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. With respect to generic products for which we are the first developer to have its application accepted for filing by the FDA, and which filing includes a certification that the applicable patent(s) are invalid, unenforceable and/or not infringed (known as a "Paragraph IV certification"), our ability to obtain and realize the full benefits of 180-days of

market exclusivity is dependent upon a number of factors, including, for example, being the first to file, the status of any litigation that might be brought against us as a result of our filing or our not meeting regulatory, manufacturing or quality requirements or standards. If any of our products are not timely approved, or if we are unable to obtain and realize the full benefits of the 180-day market exclusivity period for our products, or if our products cannot be successfully manufactured or timely commercialized, our results of operations could be materially adversely affected. In addition, we cannot guarantee that any investment we make in developing products will be recouped, even if we are successful in commercializing those products.

Also, new products, including contrast agents, are being developed and existing products are being refined in the field of diagnostic imaging. Our own diagnostic imaging agents compete not only with other similarly administrated imaging agents, but also with imaging agents employed in different and often competing diagnostic modalities. New imaging agents in a given diagnostic modality may be developed that provide benefits superior to the then-dominant agent in that modality, resulting in commercial displacement. Similarly, changing perceptions about comparative efficacy and safety, including, among other things, with respect to comparative radiation exposure, and changing availability of supply may favor one agent over another or one modality over another.

We may be unable to protect our intellectual property rights or we may be subject to claims that we infringe on the intellectual property rights of others.

We rely on a combination of patents, trademarks, trade secrets, market exclusivity gained from the regulatory approval process and other intellectual property to support our business strategy. However, our efforts to protect our intellectual property rights may not be sufficient. If we do not obtain sufficient protection for our intellectual property, or if we are unable to effectively enforce our intellectual property rights, our competitiveness could be impaired, which would limit our growth and future revenue.

Our pending patent applications may not result in the issuance of patents, or the patents issued to or licensed by us in the past or in the future may be challenged or circumvented by competitors. Existing patents may be found to be invalid or insufficiently broad to preclude our competitors from using methods or making or selling products similar or identical to those covered by our patents and patent applications. Regulatory agencies may refuse to grant us the market exclusivity that we were anticipating, or may unexpectedly grant market exclusivity rights to other parties. In addition, our ability to obtain and enforce intellectual property rights is limited by the unique laws of each country. In some countries it may be particularly difficult to adequately obtain or enforce intellectual property rights, which could make it easier for competitors to capture market share in such countries by utilizing technologies and product features that are similar or identical to those developed or licensed by us. Competitors also may harm our sales by designing products that mirror the capabilities of our products or technology without infringing our patents. Competitors may diminish the value of our trade secrets by reverse engineering or by independent invention. Additionally, current or former employees may improperly disclose such trade secrets to competitors or other third parties. We may not become aware of any such improper disclosure, and, in the event we do become aware, we may not have an adequate remedy available to us.

We operate in an industry characterized by extensive patent litigation, and we may from time to time be a party to such litigation. In Tyco Healthcare Group LP, et al. v. Mutual Pharmaceutical Company, Inc., we filed a patent infringement suit in the U.S. District Court for the District of New Jersey against Mutual Pharmaceutical Co., Inc., et al. (collectively, "Mutual") on March 20, 2007 pursuant to procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984, after Mutual submitted an ANDA to the FDA seeking to sell a generic version of our 7.5 mg Restoril sleep aid product. Mutual also filed antitrust and unfair competition counterclaims. The patents at issue have since expired or been found invalid. On January 18, 2013, the trial court issued an opinion and order granting our motion for summary judgment regarding Mutual's antitrust and unfair competition counterclaims. On May 1, 2013, Mutual appealed this decision to the U.S. Court of Appeals for the Federal Circuit.

The pursuit of or defense against patent infringement, such as the case discussed above, is costly and time-consuming and we may not know the outcomes of such litigation for protracted periods of time. We may be unsuccessful in our efforts to enforce our patent or other intellectual property rights. In addition, patent litigation can result in significant damage awards, including the possibility of treble damages and injunctions. Additionally, we could be forced to stop manufacturing and selling certain products, or we may need to enter into license agreements that require us to make significant royalty or up-front payments in order to continue selling the affected products. Given the nature of our industry, we are likely to face additional claims of patent infringement in the future. A successful claim of patent or other intellectual property infringement against us could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We face significant competition and may not be able to compete effectively.

The industries in which we operate are highly competitive. Competition takes many forms, such as price reductions on products that are comparable to our own, development, acquisition or in-licensing of new products that may be more cost-effective than or have performance superior to our products, and the introduction of generic versions when our proprietary products lose their patent protection or market exclusivity. For further discussion on the competitive nature of our business, as well as intellectual property rights and market exclusivity, refer to Item 1. Business included within this Annual Report on Form 10-K. Our current or future products could be rendered obsolete or uneconomical as a result of this competition. Our failure to compete effectively could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Any acquisitions of technologies, products and businesses may be difficult to integrate, could materially adversely affect our relationships with key customers and/or could result in significant impairment charges.

We regularly review potential acquisitions of technologies, products and businesses complementary to our business. Acquisitions typically entail many risks and could result in difficulties in integrating operations, personnel, technologies and products. If we are not able to successfully integrate our acquisitions, we may not obtain the advantages and synergies that the acquisitions were intended to create, which may have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. Moreover, the due diligence that we conduct in conjunction with an acquisition may not sufficiently discover risks and contingent liabilities associated with the acquisition target and, consequently, we may consummate an acquisition for which the risks and contingent liabilities are greater than were projected. In addition, in connection with acquisitions, we could experience disruption in our business, technology and information systems, and our customer or employee base, including diversion of management's attention from our continuing operations. There is also a risk that key employees of companies that we acquire or key employees necessary to successfully commercialize technologies and products that we acquire may seek employment elsewhere, including with our competitors. Furthermore, there may be overlap between our products or customers and the companies which we acquire that may create conflicts in relationships or other commitments detrimental to the integrated businesses. Additionally, the time between our expenditures to acquire new products, technologies or businesses and the subsequent generation of revenues from those acquired products, technologies or businesses (or the timing of revenue recognition related to licensing agreements and/or strategic collaborations) could cause fluctuations in our financial performance from period to period. Finally, if we are unable to successfully integrate products, technologies, businesses or personnel that we acquire, we could incur significant impairment charges or other adverse financial consequences.

We may incur product liability losses and other litigation liability.

We are or may be involved in various legal proceedings and certain government inquiries and investigations, including, but not limited to, patent infringement, product liability, antitrust matters, breach of contract, Medicare and Medicaid reimbursements claims, or compliance with laws relating to marketing and sales or controlled substance distribution practices, including those relating to the establishment of SOM programs. Such proceedings, inquiries and investigations may involve claims for, or the possibility of fines and penalties involving substantial amounts of money or other relief, including but not limited to civil or criminal fines and penalties and exclusion from participation in various government healthcare-related programs. If any of these legal proceedings, inquiries or investigations were to result in an adverse outcome, the impact could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

With respect to product liability and clinical trial risks, in the ordinary course of business we are subject to liability claims and lawsuits, including potential class actions, alleging that our marketed products or products in development have caused, or could cause, serious adverse events or other injury. Any such claim brought against us, with or without merit, could be costly to defend and could result in an increase in our insurance premiums. We retain liability for the first $2.5 million per claim and purchase, through a combination of primary and umbrella/excess liability policies, $150 million of coverage beyond the retained liabilities. We believe this coverage level is adequate to meet our current business exposure. However, some claims brought against us might not be covered by our insurance policies. Moreover, where the claim is covered by our insurance, if our insurance coverage is inadequate, we would have to pay the amount of any settlement or judgment that is in excess of our policy limits. We may not be able to obtain insurance on terms acceptable to us or at all since insurance varies in cost and can be difficult to obtain. Our failure to maintain adequate insurance coverage or successfully defend against product liability claims could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The implementation of healthcare reform in the U.S. may materially adversely affect us.

In March 2010, the Healthcare Reform Act was enacted into law in the U.S. The Healthcare Reform Act contains a number of provisions that affect coverage and reimbursement of drug products and the medical imaging procedures in

which our drug products are used. For example, the Healthcare Reform Act includes a provision that imposes a $28 billion fee on the branded pharmaceutical industry over nine years, starting in 2011, and a $2.8 billion annual fee on the branded pharmaceutical industry thereafter. To the extent that the market share of our Brands business grows, the portion of this fee that we will be obligated to pay will increase.

There can be no assurance that the Healthcare Reform Act as currently enacted, and when fully implemented, will not materially adversely affect our competitive position, business, financial condition, results of operations and cash flows, nor can we predict with certainty how federal or state legislative or administrative changes relating to healthcare will affect our business.

Sales of our products are affected by the reimbursement practices of a small number of large public and private insurers. In addition, reimbursement criteria and the use of tender systems outside the U.S. could reduce prices for our products or reduce our market opportunities.

Sales of our products depend, in part, on the extent to which the costs of our products are reimbursed by governmental health administration authorities, private health coverage insurers and other third-party payors. Our potential customers' ability to obtain appropriate reimbursement for products and services from these third-party payors affects the selection of products they purchase and the prices they are willing to pay. In addition, demand for new products may be limited unless we obtain reimbursement approval from governmental and private third-party payors prior to introduction. Reimbursement criteria, which vary by country, are becoming increasingly stringent and require management expertise and significant attention to obtain and maintain qualification for reimbursement.

In addition, a number of markets in which we operate have implemented or may implement tender systems in an effort to lower prices. Under such tender systems, manufacturers submit bids which establish prices for products. The company that wins the tender receives preferential reimbursement for a period of time. Accordingly, the tender system often results in companies underbidding one another by proposing low pricing in order to win the tender. Certain other countries may consider implementation of a tender system. Even if a tender system is ultimately not implemented, the anticipation of such could result in price reductions. Failing to win tenders, or the implementation of similar systems in other markets leading to price declines, could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Our reporting and payment obligations under the Medicare and Medicaid rebate programs, and other governmental purchasing and rebate programs, are complex. Any determination of failure to comply with these obligations or those relating to healthcare fraud and abuse laws could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The regulations regarding reporting and payment obligations with respect to Medicare and Medicaid reimbursement programs, and rebates and other governmental programs, are complex. Because our processes for these calculations and the judgments used in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material adjustments to amounts previously paid.

Any governmental agencies that have commenced, or may commence, an investigation of Mallinckrodt relating to the sales, marketing, pricing, quality or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal healthcare programs including Medicare and Medicaid. Some of the applicable laws may 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, and even in the absence of any such ambiguity, a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. For example, from time to time states attorneys general have brought cases against us that allege generally that we and numerous other pharmaceuticals companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid, resulting in overpayment by state Medicaid programs for those drugs, and generally seek monetary damages and attorneys' fees. For example, we are named as a defendant in State of Utah v. Actavis US, Inc., et al., filed May 8, 2008, which is pending in the Third Judicial Circuit of Salt Lake County, Utah. While we intend to contest this case and explore other options as appropriate, any such penalties or sanctions that we might receive in this or other actions could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Changes in laws and regulations may materially adversely affect us.

The development, manufacture, marketing, sale, promotion, and distribution of our products are subject to comprehensive government regulation. Changes in laws and regulations could affect us in various ways. For example,

both the federal and state governments have given increased attention to the public health issue of opioid abuse, overdose and diversion. At the federal level, the White House Office of National Drug Control Policy continues to coordinate efforts between the FDA, DEA and other agencies to address this problem. In January 2013, the FDA released draft guidance on incorporating abuse-deterrent characteristics into extended-release opioids. When the FDA finds that a new formulation has abuse-deterrent characteristics, the agency has the authority to require that generics also have abuse-deterrent characteristics. One of our ANDAs that is currently under review in the U.S. refers to a NDA that did not have abuse-deterrent characteristics. From a compliance standpoint, the DEA continues to increase its efforts to hold manufacturers, distributors and pharmacies accountable through various enforcement actions as well as the implementation of compliance practices for controlled substances, including SOM activities for Schedule II opioids. In addition, many state legislatures continue to consider various bills intended to reduce opioid abuse, overdose and diversion, for example by establishing prescription drug monitoring programs, mandating prescriber education and prohibiting the substitution of generic versions of opioids that lack abuse-deterrent characteristics for branded products that have them. Future legislation and regulation in the markets that we serve

could affect access to healthcare products and services, increase rebates, reduce prices or the rate of price increases for healthcare products and services, change healthcare delivery systems, create new fees and obligations for the pharmaceutical industry, or require additional reporting and disclosure. These and other changes in laws and regulations could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

In October 2013, the FDA announced its recommendation that the DEA reschedule hydrocodone combination products (such as Vicodin and our developmental product MNK-155) from Schedule III to Schedule II, thereby increasing regulatory controls on these drug products. The FDA expects to issue its formal recommendation to the DHHS in December 2013. This recommendation will begin a process that will lead to a final decision by the DEA on the scheduling of these products. At this time, it is too early to determine the degree of impact the hydrocodone rescheduling, if adopted, will have on our business.

Global economic conditions could harm us.

Over the course of the last few years, global market and economic conditions have been unprecedented and challenging, with tighter credit conditions and recession in most major economies. Continued concerns about the systemic impact of potential long-term and wide-spread recession (including concerns that certain European countries may default on payments due on their national debt), energy costs, geopolitical issues and the availability and cost of credit have contributed to increased market volatility and diminished growth expectations for developed and developing economies.

As a result of these market conditions, the cost and availability of credit may be adversely affected. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide credit to businesses and consumers. These factors have resulted in a decrease in spending by businesses and consumers alike. Continued turbulence in the U.S. and international markets and economies and prolonged declines in consumer spending may materially adversely affect our liquidity and financial condition as well as our share price.

Our global operations expose us to risks and challenges associated with conducting business internationally.

We operate globally with offices or activities in Europe, Africa, Asia, South America, Australia and North America. We face several risks inherent in conducting business internationally, including compliance with international and U.S. laws and regulations that apply to our international operations. These laws and regulations include data privacy requirements, labor relations laws, tax laws, anti-competition regulations, import and trade restrictions, export requirements, U.S. laws such as the Foreign Corrupt Practices Act of 1977 and local laws which also prohibit corrupt payments to governmental officials or certain payments or remunerations to customers. Given the high level of complexity of these laws, there is a risk that some provisions may be violated, for example inadvertently or through fraudulent or negligent behavior of individual employees, our failure to comply with certain formal documentation requirements or otherwise. Violations of these laws and regulations could result in fines or criminal sanctions against us, our officers or our employees, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, our business and our results of operations. Our success depends, in part, on our ability to anticipate and prevent or mitigate these risks and manage difficulties as they arise.

In addition to the foregoing, engaging in international business inherently involves a number of other difficulties and risks, including:

- longer payment cycles in countries like Spain and Italy and difficulties in enforcing agreements and collecting receivables through certain non-U.S. legal systems;
- political and economic instability, including, most notably, the risks and uncertainty associated with the current concerns regarding the stability of the Eurozone and the related possibility of sovereign defaults in countries such as Spain and Italy, and the possibility that such a default or the exit of one or more member countries from the Eurozone

or from the E.U. entirely may lead to difficulties for other members of the E.U.;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and trade barriers; and
- failure to successfully implement our new non-U.S. operating structure, and difficulties and costs of staffing and managing non-U.S. operations.

These or other factors or any combination of them may have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Currency exchange rate fluctuations could materially adversely affect our business and results of operations.
We do business and generate sales in numerous countries outside the U.S. As such, currency exchange rate fluctuations may affect the costs that we incur in such international operations. Some of our operating expenses are incurred in non-U.S. dollar currencies. The appreciation of non-U.S. dollar currencies relative to the U.S. dollar in those countries where we have operations could increase our costs and could harm our results of operations and financial condition. We also have significant intercompany financing arrangements that may result in gains and losses in our results of operations. In an effort to mitigate the impact of currency exchange rate effects we may hedge certain of these intercompany transactions; however, our hedging strategies may not fully offset gains and losses recognized in our results of operations. In addition, we report our operating results in U.S. dollars, so the appreciation of the U.S. dollar relative to such other currencies could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Our operations expose us to the risk of material health, safety and environmental liabilities, litigation and violations.
We are subject to numerous federal, state, local and non-U.S. environmental protection and health and safety laws and regulations governing, among other things:

- the generation, storage, use and transportation of hazardous materials;
- emissions or discharges of substances into the environment;
- investigation and remediation of hazardous substances or materials at various sites;
- chemical constituents in products and end-of-life disposal, mandatory recycling and take-back programs; and
- the health and safety of our employees.

We may not have been, or we may not at all times be, in full compliance with environmental and health and safety laws and regulations. In the event a regulatory authority concludes that we are not in full compliance with these laws, we could be fined, criminally charged or otherwise sanctioned. Environmental laws are becoming more stringent, including outside the U.S., resulting in increased costs and compliance burdens.
Certain environmental laws assess liability on current or previous owners of real property and current or previous owners or operators of facilities for the costs of investigation, removal or remediation of hazardous substances or materials at such properties or at properties at which parties have disposed of hazardous substances. Liability for investigative, removal and remedial costs under certain federal and state laws is retroactive, strict (i.e., can be imposed regardless of fault) and joint and several. In addition to cleanup actions brought by governmental authorities, private parties could bring personal injury or other claims due to the presence of, or exposure to, hazardous substances.
Certain radiological licenses at certain manufacturing sites owned by us require the establishment of decommissioning programs which will require remediation in accordance with regulatory requirements upon cessation of operations at such sites. We have received notification from the EPA and similar state environmental agencies that conditions at a number of sites where the disposal of hazardous substances requires investigation, cleanup and other possible remedial action. These agencies may require that we reimburse the government for its costs incurred at these sites or otherwise pay for the costs of investigation and cleanup of these sites, including by providing compensation for natural resource damage claims arising from such sites.
In the ordinary course of our business planning process, we take into account our known environmental matters as we plan for our future capital and operating expenditures requirements. The ultimate cost of site cleanup and timing of future cash outflows is difficult to predict, given the uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations, and alternative cleanup methods. We concluded that, as of September 27, 2013, it was probable that we would incur remedial costs in the range of $46.4 million to $81.5 million. We also concluded that, as of September 27, 2013, the best estimate within this range was $46.4 million. For further information on our environmental obligations, refer to Item 3. Legal Proceedings and Note 18 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. Based upon information known to date, we believe our current capital and operating plans are adequate for costs associated with the investigation, cleanup and potential remedial action for our

known environmental matters.

While we have planned for future capital and operating expenditures to comply with environmental laws, our costs of complying with current or future environmental protection and health and safety laws and regulations, or our liabilities arising from past or future releases of, or exposures to, hazardous substances may exceed our estimates or could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. We may also be subject to additional environmental claims for personal injury or cost recovery actions for remediation of facilities in the future based on our past, present or future business activities.

If we are unable to retain our key personnel, 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, regulatory and commercial personnel. The loss of key scientific, technical, regulatory and commercial personnel, or the failure to recruit additional key scientific, technical, regulatory and commercial personnel, could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. There is intense competition for qualified personnel in the areas of our activities, and we may not be able to continue to attract and retain the qualified personnel necessary for the development of our business.

Our business depends on the continued effectiveness and availability of our information technology infrastructure, and failures of this infrastructure could harm our operations.
To remain competitive in our industry, we must employ information technologies to support manufacturing processes, quality processes, distribution, R&D and regulatory applications that capture, manage and analyze, in compliance with applicable regulatory requirements, the large streams of data generated in our clinical trials. We rely extensively on technology to allow concurrent work sharing around the world. As with all information technology, our systems are vulnerable to potential damage or interruptions from fires, blackouts, telecommunications failures and other unexpected events, as well as physical and electronic break-ins, sabotage, piracy or intentional acts of vandalism. Given the extensive reliance of our business on technology, any substantial disruption or resulting loss of data that is not avoided or corrected by our backup measures could harm our business, operations and financial condition.

We may not achieve some or all of the expected benefits of our restructuring activities and our restructuring activities may adversely affect our business.
From time to time, we initiate restructuring programs as we continue to realign our cost structure due to the changing nature of our business and look for opportunities to achieve operating efficiencies that will reduce costs. We may not be able to obtain the cost savings and benefits that were initially anticipated when we launched our restructuring programs. Additionally, as a result of our restructuring activities we may experience a loss of continuity, loss of accumulated knowledge and/or inefficiency during transitional periods. Reorganizations and restructurings can require a significant amount of management and other employees' time and focus, which may divert attention from operating and growing our business. If we fail to achieve some or all of the expected benefits of our restructuring activities, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Risks Related to the Separation
The following discussion highlights some of the risks we face as a result of the Separation. These and other risks could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We have not operated as an independent company for a significant period of time, and our historical financial information is not necessarily representative of the results that we would have achieved had we been an independent, publicly-traded company for the entirety of the periods presented, and may not be an accurate indicator of our future results of operations.
Historical information about Mallinckrodt for periods prior to the Separation reflects the results of the Pharmaceuticals business of Covidien, as operated by and integrated with Covidien, and is derived from the consolidated financial statements and accounting records of Covidien. Accordingly, this historical financial information does not necessarily reflect the financial condition, results of operations or cash flows that we would have achieved as an independent, publicly-traded company during the entirety of the periods presented or those that we will achieve in the future for various factors, including those described below.
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Our business had historically been operated by Covidien as part of its broader corporate organization, rather than as an independent company, particularly in relation to our non-U.S. locations. Covidien or one of its affiliates performed various corporate functions for us, such as accounting, information technology and finance. Covidien will continue to provide some of these functions to us for a period of time pursuant to a transition services agreement. Our historical financial results for periods prior to the Separation include allocations of corporate expenses from Covidien for such functions and are likely to be less than the expenses we will incur operating as an independent, publicly-traded company.

We expect to incur additional expenses as a result of being an independent, publicly-traded company including, among other things, directors and officers liability insurance, director fees, reporting fees with the SEC, New York Stock Exchange listing fees, transfer agent fees, increased auditing and legal fees. These expenses may be significant and may negatively impact our results of operations as compared to periods prior to the Separation.

- Our financial results for periods prior to the Separation include costs incurred to separate Mallinckrodt from Covidien, which primarily related to legal, accounting, tax and other professional fees. We continue to incur separation related costs as a result of our transition services agreement with Covidien, as well as other transitional costs, such as costs to implement our own information and accounting systems. Our future separation related costs may fluctuate based on the nature and timing of our separation activities.
- We will need to make significant investments to replicate or outsource from other providers certain facilities, systems, infrastructure and personnel that were formerly available to us through Covidien. The initiatives to develop our independent operational and administrative infrastructure will be costly to implement, and we may not be able to operate our business efficiently or at comparable costs, which may cause our profitability to decline.
- Prior to the Separation, our working capital and capital for our general corporate purposes had been provided as part of the corporate-wide cash management policies of Covidien. In the future, we may need to obtain additional financing from lenders, through public offerings or private placements of debt or equity securities, strategic relationships or other arrangements.
- The cost of debt or equity capital for our business may be significantly different than that of Covidien.
- Prior to the Separation, we were able to use Covidien's purchasing power in procuring various goods and services and had shared economies of scope and scale in vendor relationships. As a standalone company, we may be unable to obtain goods and services at the prices and terms obtained prior to the Separation, which could decrease our overall profitability.

Other significant changes may occur in our cost structure, management, financing and business operations as a result of operating as a company separate from Covidien. Additional information about the past financial performance of our business and the basis of presentation of the historical combined financial statements is included elsewhere in this Annual Report on Form 10-K.

- As we build our information technology infrastructure and transition our data to our own systems, we could incur substantial additional costs and experience temporary business interruptions.
- We continue to install and implement information technology infrastructure to support our critical business functions, particularly in relation to areas outside the U.S., including systems relating to accounting and reporting, manufacturing process control, customer service, inventory control and distribution. We may incur temporary interruptions in business operations if we cannot transition effectively from Covidien's existing transactional and operational systems and data centers and the transition services that support these functions as we replace these systems. We may not be successful in effectively and efficiently implementing our new systems and transitioning our data, and we may incur substantially higher costs for implementation than currently anticipated. Our failure to avoid operational interruptions as we implement the new systems and replace Covidien's information technology services, or our failure to implement the new systems and replace Covidien's services effectively and efficiently, could disrupt our business and could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

- If we are unable to satisfy our reporting requirements or our internal control over financial reporting is not effective, our business, financial condition or results of operations could be materially adversely affected.
- Prior to the Separation, our financial results were included within the consolidated results of Covidien, and our reporting of internal control systems were appropriate for those of subsidiaries of a public company. Prior to the effectiveness of our registration statement on Form 10, we were not directly subject to reporting and other requirements of the Securities Exchange Act of 1934, as amended ("the Exchange Act") and Section 404 of the Sarbanes-Oxley Act of 2002 ("the Sarbanes-Oxley Act").
- As an independent, publicly-traded company, we are now subject to the reporting requirements of the Exchange Act and the Sarbanes-Oxley Act, as well as other reporting requirements. The Exchange Act requires that we file annual, quarterly and current reports about our business and financial condition. The Sarbanes-Oxley Act requires our

management to report on its assessment of the effectiveness of our internal control over financial reporting, and our independent auditors will be required to issue an opinion on their audit of our internal control over financial reporting. Our management report on internal controls and our auditors' report are not contained in this report due to a transition period established under SEC rules for newly public companies. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require demands on our management and administrative and operational resources, including accounting and information technology resources. To comply with these requirements we are upgrading our systems, including computer hardware infrastructure, implementing additional financial and management controls, reporting systems and procedures and have hired additional accounting, finance and information technology staff. If we are unable to upgrade our financial and management controls, reporting systems, information technology and procedures in a timely and effective fashion, our ability to comply with our financial reporting requirements and other rules that apply

to reporting companies could be impaired. Any failure to meet our reporting requirements or achieve and maintain effective internal controls could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We may have received more favorable or less favorable terms from unaffiliated third parties than the terms we received in our agreements with Covidien.

We entered into agreements with Covidien in connection with the Separation, including a separation and distribution agreement, a transition services agreement, a tax matters agreement and an employee matters agreement. Since such agreements were negotiated in the context of the Separation, the terms of such agreements may be more favorable or less favorable than the terms that would have resulted from arm's-length negotiations between unaffiliated third parties.

Covidien may fail to perform under various transaction agreements that were executed as part of the Separation, or we may fail to have necessary systems and services in place when certain of the transaction agreements expire.

In connection with the Separation, we entered into various agreements with Covidien, including a separation and distribution agreement, a tax matters agreement, an employee matters agreement and a transition services agreement. For further information on these agreements, refer to Exhibits 2.1, 10.1, 10.2 and 10.3, respectively, of our Current Report on Form 8-K filed with the SEC on July 1, 2013. Certain of these agreements provide for the performance of services by each company for the benefit of the other for a period of time after the Separation. We will rely on Covidien to satisfy its performance and payment obligations under these agreements. If Covidien is unable to satisfy its obligations under these agreements, including its indemnification obligations, we could incur operational difficulties or losses. If we do not have in place our own systems and services, or if we do not have agreements with other providers of these services when the transaction or long-term agreements terminate, we may not be able to operate our business effectively and our profitability may decline. We continue the process of creating our own, or engaging third parties to provide, systems and services to replace many of the systems and services Covidien provided to us prior to the Separation, and is continuing to provide us pursuant to these agreements. These systems and services may be more expensive or less efficient than the systems and services Covidien is providing during the transition period.

Potential indemnification liabilities to Covidien pursuant to the separation and distribution agreement could materially adversely affect us.

The separation and distribution agreement with Covidien provided for, among other things, the principal corporate transactions required to effect the Separation, certain conditions to the distribution and provisions governing the relationship between us and Covidien following the Separation. The separation and distribution agreement was filed with the SEC as Exhibit 2.1 to our Current Report on Form 8-K on July 1, 2013. Among other things, the separation and distribution agreement will provide for indemnification obligations principally designed to place financial responsibility for the obligations and liabilities of our business with us and financial responsibility for the obligations and liabilities of Covidien's remaining business with Covidien, among other indemnities. If we are required to indemnify Covidien under the circumstances set forth in the separation and distribution agreement, we may be subject to substantial liabilities. These potential indemnification obligations could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We may not achieve some or all of the expected benefits of the Separation, and the Separation may materially adversely affect our business.

We may not be able to achieve the full strategic and financial benefits expected to result from the Separation, or such benefits may be delayed or not occur at all. The Separation was expected to provide the following benefits, among others: (i) our ability to focus on our own strategic and operational plans and capital structure; (ii) an appropriate capital structure for Mallinckrodt; (iii) a distinct investment identity allowing investors to evaluate the merits,

performance and future prospects of us separately from Covidien; and (iv) more effective share-based compensation and currency for acquisitions.

We may not achieve these and other anticipated benefits for a variety of reasons, including, among others: (a) the Separation required significant amounts of management's time and effort, which may have diverted management's attention from operating and growing our business; (b) as an independent, publicly-traded company, we may be more susceptible to market fluctuations and other adverse events than if it were still a part of Covidien; (c) our business is less diversified than Covidien's business prior to the Separation; and (d) the continuing actions required to separate Covidien's and our respective businesses could disrupt our operations. If we fail to achieve some or all of the benefits expected to result from the Separation, or if such benefits are delayed, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Risks Related to Our Indebtedness

We have significant indebtedness, which could impact our ability to pay dividends and have a negative impact on our financing options and liquidity position.

As of September 27, 2013, we had $919.8 million of total debt. We may also incur additional indebtedness in the future. Our indebtedness may impose restrictions on us that could have material adverse consequences by:

- limiting our ability to obtain additional financing in the future for working capital, capital expenditures and acquisitions;
- limiting our ability to refinance our indebtedness on terms acceptable to us or at all;
- imposing restrictive covenants on our operations;
- requiring us to dedicate a significant portion of our cash flows from operations to paying the principal of and interest on our indebtedness, thereby reducing funds available for other corporate purposes; and
- making us more vulnerable to economic downturns and limiting our ability to withstand competitive pressures.

In connection with the Separation, we incurred a significant amount of debt for which Covidien retained a significant portion of the cash proceeds. As a result, the amount of leverage in our business has significantly increased. This has increased the riskiness of our business and of an investment in our ordinary shares.

Our ability to meet expense and debt service obligations will depend on our future performance, which will be affected by financial, business, economic and other factors, including government regulation, product development, intellectual property matters and pressure from competitors. If we do not generate enough cash to pay our debt service obligations, we may be required to refinance all or part of our existing debt, sell our assets, incur additional debt or issue equity. These actions may adversely impact the market price of our ordinary shares.

Our credit facility bears interest at variable rates and credit spreads. If interest rates or credit spreads increase, variable rate debt will create higher debt service requirements, which could adversely affect our cash flow if we were to have borrowings outstanding under this facility.

The agreements governing our revolving credit facility and senior notes contain various covenants that impose restrictions on us that may affect our ability to operate our business.

The agreements governing our revolving credit facility and senior notes contain various affirmative and negative covenants that restrict our ability to create liens, incur additional indebtedness, enter into sale and lease-back transactions, and merge or consolidate with any other person or sell or convey certain of our assets to any one person, among other things. In addition, some of our debt agreements contain financial covenants that require us to maintain certain financial ratios and minimum performance levels. Our ability to comply with these provisions may be affected by events beyond our control. Failure to comply with these covenants could result in an event of default, which, if not cured or waived, could accelerate our repayment obligations.

Challenges in the commercial and credit environment may materially adversely affect our ability to issue debt on acceptable terms and our future access to capital.

Our ability to issue debt or enter into other financing arrangements on acceptable terms could be materially adversely affected if there is a material decline in the demand for our products or in the solvency of our customers or suppliers, or if other significantly unfavorable changes in economic conditions occur. In addition, volatility in the world financial markets could increase borrowing costs or affect our ability to access the capital markets, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We may need additional financing in the future to meet our capital needs or to make acquisitions, and such financing may not be available on favorable or acceptable terms, and may be dilutive to existing shareholders.

We may need to seek additional financing for general corporate purposes. For example, we may need to increase our investment in R&D activities or need funds to make acquisitions. We may be unable to obtain any desired additional financing on terms that are favorable or acceptable to us. Depending on market conditions, adequate funds may not be available to us on acceptable terms and we may be unable to fund our expansion, successfully develop or enhance products, or respond to competitive pressures, any of which could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. If we raise additional funds through the issuance of equity securities, our shareholders will experience dilution of their ownership interest.

Risks Related to Tax Matters

If the distribution fails to qualify as a tax-free transaction for U.S. federal income tax purposes, then Mallinckrodt and Mallinckrodt's shareholders could be subject to significant tax liability or tax indemnity obligations.

Covidien received a U.S. Internal Revenue Service ("IRS") ruling substantially to the effect that, for U.S. federal income tax purposes, (i) certain transactions effected in connection with the Separation qualified as transactions under Sections 355 and 368(a) of the U.S. Internal Revenue Code ("the Code"), and (ii) the distribution of Mallinckrodt shares qualified as a transaction under Sections 355 and 368(a)(1)(D) of the Code. In addition to obtaining the IRS ruling, Covidien received a tax opinion from Skadden, Arps, Slate, Meagher & Flom LLP, which relied on the effectiveness of the IRS ruling, substantially to the effect that, for U.S. federal income tax purposes, the distribution and certain transactions entered into in connection with the distribution qualified as transactions under Sections 355 and 368(a) of the Code.

The IRS ruling and tax opinion rely on certain facts and assumptions, certain representations from Covidien and us regarding the past and future conduct of our respective businesses and other matters, and certain undertakings made by Covidien and us. Notwithstanding the IRS ruling and tax opinion, the IRS could determine on audit that the distribution should be treated as a taxable transaction if it determines that any of these facts, assumptions, representations or undertakings is not correct or has been violated, or that the distribution should be taxable for other reasons, including as a result of a significant change in stock or asset ownership after the distribution, or if the IRS were to disagree with the conclusions of the tax opinion that are not covered by the IRS ruling. If the distribution is ultimately determined to be taxable, the distribution could be treated as a taxable dividend to shareholders of Mallinckrodt, who acquired their shares through distribution to Covidien shareholders at the Separation date, for U.S. federal income tax purposes, and they could incur significant U.S. federal income tax liability. In addition, Covidien or we could incur significant U.S. federal income tax liabilities or tax indemnification obligations, whether under applicable law or the tax matters agreement ("the Tax Matters Agreement") that we entered into with Covidien, if it is ultimately determined that certain related transactions undertaken in anticipation of the distribution are taxable.

We could have significant tax liabilities under the Tax Matters Agreement with Covidien for periods during which our subsidiaries and operations were those of Covidien and of Tyco International Ltd.

Our tax returns are subject to examination by various tax authorities, including the IRS. The IRS is examining our U.S. federal income tax returns for periods during which certain of our subsidiaries and operations were those of Covidien. In addition, the IRS continues to examine the U.S. federal income tax returns of Tyco International Ltd. ("Tyco International") for periods during which certain of our subsidiaries and operations were those of Tyco International. Our potential liability under the Tax Matters Agreement with Covidien for any taxes related to periods prior to the Separation (after taking into account certain tax benefits realized by us), including those which are subject to the provisions of the tax sharing agreement by and among Covidien, Tyco International and TE Connectivity Ltd. ("the Tyco Tax Sharing Agreement"), is anticipated to be approximately $175 million, which excludes associated tax benefits from such payments, and will be subject to an overall limitation of $200 million, net of any benefits. For further information on the Tax Matters Agreement, refer to our Current Report on Form 8-K filed with the SEC on July 1, 2013.

The resolution of the matters arising during periods in which certain of our subsidiaries and operations were subsidiaries and operations of Covidien will be subject to the provisions of the Tax Matters Agreement. Under this agreement, Covidien will have the right to administer, control and settle, in its sole and absolute discretion, all tax audits that do not relate solely to non-U.S. taxes for periods prior to the Separation that are not covered by the Tyco Tax Sharing Agreement. The outcome of any such examination, and any associated litigation which might arise, is uncertain and could result in a significant increase in our liability for taxes arising during these periods, subject to the overall $200 million limitation described above. The timing and outcome of such examination or litigation is highly uncertain and could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. Under the Tax Matters Agreement, Covidien will agree to provide to us information it receives related to examinations of tax matters for which we may be liable but we will not otherwise be permitted to control or participate in the settlement or defense of such examinations.

The resolution of the matters arising during periods in which certain of our subsidiaries and operations were subsidiaries and operations of Tyco International will be subject to the provisions of the Tax Matters Agreement and the Tyco Tax Sharing Agreement. Under the Tyco Tax Sharing Agreement, Covidien, Tyco International and TE Connectivity Ltd. are responsible for 42%, 27% and 31%, respectively, of U.S. income tax liabilities prior to the 2007 separation of Covidien, Tyco International and TE Connectivity Ltd. We are not a party to the Tyco Tax Sharing Agreement. Under the Tax Matters Agreement we will, however, be liable for certain taxes relating to our subsidiaries and operations arising during periods governed by the Tyco Tax Sharing Agreement. Although we will be liable to Covidien for certain taxes arising during periods governed by the Tyco Tax Sharing Agreement, we will not be liable to Tyco International or TE Connectivity Ltd. under the Tyco Tax Sharing Agreement, nor will we share in the receivable that Covidien has from Tyco International or TE Connectivity Ltd. In addition, Covidien will retain all reimbursements from Tyco International or TE Connectivity Ltd. pursuant to the Tyco Tax Sharing Agreement, including reimbursements for taxes that are borne by us pursuant to the Tax Matters Agreement.
Under the Tyco Tax Sharing Agreement, Tyco International has the right to administer, control and settle all U.S. income tax audits for periods prior to the separation from Tyco International. In connection with such examinations, tax authorities, including the IRS, have proposed tax adjustments. Tyco International has appealed certain of the proposed tax adjustments and all but one of the matters associated with the proposed tax adjustments has been resolved. With respect to the remaining unresolved matter, Tyco International is contesting the adjustments through litigation. The outcome of any such litigation is uncertain and could result in a significant increase in our liability for taxes arising during these periods, subject to the overall $200 million limitation described above. While we believe that the amounts recorded as income taxes payable related to these adjustments are adequate, the timing and outcome of such litigation is highly uncertain and could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. Under the Tax Matters Agreement, Covidien has agreed to provide to us information it receives from Tyco International related to examinations of tax matters for which we may be liable that are governed by the Tyco Tax Sharing Agreement.

Examination and audits by tax authorities, including the IRS, could result in additional tax payments.
We provide reserves for potential payments of tax to various tax authorities related to uncertain tax positions. It is Covidien's intention to vigorously defend our prior tax returns. However, the calculation of our tax liabilities involves the application of complex tax regulations to our global operations in many jurisdictions. Therefore, any dispute with a tax authority may result in a payment that is materially different from our current estimate of the tax liabilities associated with these returns. If payment of these amounts ultimately proves to be less than the recorded amounts, the reversal of the reserves generally would result in tax benefits being recognized in the period when we determine the reserves are no longer necessary. If our estimate of tax liabilities proves to be less than the amount for which we are ultimately liable, we would incur additional charges to expense and such charges could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We may not be able to maintain a competitive worldwide effective corporate tax rate.
We cannot give any assurance as to what our effective tax rate will be in the future, because of, among other things, uncertainty regarding the tax policies of the jurisdictions where we operate. Our actual effective tax rate may vary from our expectation and that variance may be material. Additionally, the tax laws of Ireland and other jurisdictions could change in the future, and such changes could cause a material change in our effective tax rate.

Risks Related to Our Jurisdiction of Incorporation
Legislative action in the U.S. could materially adversely affect us.
Legislative action may be taken by the U.S. Congress which, if ultimately enacted, could limit the availability of tax benefits or deductions that we currently claim, override tax treaties upon which we rely or otherwise affect the taxes that the U.S. imposes on our worldwide operations. Such changes could materially adversely affect our effective tax rate and/or require us to take further action, at potentially significant expense, to seek to preserve our effective tax

rate. In addition, if proposals were enacted that had the effect of limiting our ability as an Irish company to take advantage of tax treaties with the U.S., we could incur additional tax expense or otherwise incur business detriment.

Irish law differs from the laws in effect in the U.S. and may afford less protection to holders of our securities.
It may not be possible to enforce court judgments obtained in the U.S. against us in Ireland based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liabilities provisions of the U.S. federal or state securities laws or hear actions against us or those persons based on those laws. We have been advised the U.S. currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland.
A judgment obtained against us will be enforced by the courts of Ireland if the following general requirements are met: (i) U.S. courts must have had jurisdiction in relation to the particular defendant according to Irish conflict of law rules (the submission to jurisdiction by the defendant would satisfy this rule) and (ii) the judgment must be final and conclusive and the decree must be final and unalterable in the court which pronounces it. A judgment can be final and conclusive even if it is subject to appeal or even if an appeal is pending. Where however the effect of lodging an appeal under the applicable law is to stay execution of the judgment, it is possible that in the meantime the judgment may not be actionable in Ireland. It remains to be determined whether final judgment given in default of appearance is final and conclusive. However, Irish courts may refuse to enforce a judgment of the U.S. courts which meets the above requirements for one of the following reasons: (i) if the judgment is not for a definite sum of money; (ii) if the judgment was obtained by fraud; (iii) the enforcement of the judgment in Ireland would be contrary to natural or constitutional justice; (iv) the judgment is contrary to Irish public policy or involves certain U.S. laws which will not be enforced in Ireland; or (v) jurisdiction cannot be obtained by the Irish courts over the judgment debtors in the enforcement proceedings by personal service in Ireland or outside Ireland under Order 11 of the Ireland Superior Courts Rules.
As an Irish company, we are governed by the Irish Companies Acts, which differ in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of our securities may have more difficulty protecting their interests than would holders of securities of a corporation incorporated in a jurisdiction of the U.S.

Irish law imposes restrictions on certain aspects of capital management.
Irish law allows our shareholders to pre-authorize shares to be issued by our board of directors without further shareholder approval for up to a maximum of five years. Our current authorization will therefore lapse approximately five years after the date of the Separation, June 28, 2013, unless renewed by shareholders, and we cannot guarantee that such renewal will always be approved. Additionally, subject to specified exceptions, including the opt-out that is included in our articles of association, Irish law grants statutory pre-emptive rights to existing shareholders to subscribe for new issuances of shares for cash. This opt-out also expires approximately five years after the Separation, unless renewed by further shareholder approval, and we cannot guarantee that such renewal of the opt-out from pre-emptive rights will always be approved. We cannot assure you that these Irish legal restrictions will not interfere with our capital management.

Risks Related to Our Ordinary Shares
Our share price may fluctuate significantly.
The market price of our ordinary shares may fluctuate significantly due to a number of factors, some of which may be beyond our control, including:
- actual or anticipated fluctuations in our results of operations;
- changes in earnings estimated by securities analysts or our ability to meet those estimates;

- the operating and share price performance of comparable companies;
- actual or anticipated sales of our ordinary shares;
- changes to the regulatory and legal environment in which we operate; and
- U.S. and worldwide economic conditions.

In addition, when the market price of a company's ordinary shares drops significantly, shareholders often institute securities class action lawsuits against the company. A lawsuit against us could cause us to incur substantial costs and could divert the time and attention of our management and other resources.
Furthermore, we cannot guarantee that an active trading market for our ordinary shares will continue to exist.

A number of our ordinary shares are eligible for future sale, which may cause our share price to decline.
We have approximately 58.0 million of our ordinary shares outstanding as of December 6, 2013. These shares are tradable without restriction or further registration under the U.S. Securities Act of 1933, as amended ("the Securities Act"), unless the shares are owned by one of our "affiliates," as that term is defined in Rule 405 under the Securities Act. Any sales of substantial amounts of our ordinary shares in the public market, or the perception that such sales might occur, may cause the market price of our ordinary shares to decline. Those sales also might make it more difficult for us to sell equity and equity-related securities in the future at a time and at a price that we consider appropriate.

Your percentage of ownership in Mallinckrodt may be diluted.
Your percentage ownership in Mallinckrodt may be diluted because of equity issuances for acquisitions, capital market transactions or otherwise, including equity awards granted to our directors, officers and employees. Such issuances may have a dilutive effect on our earnings per share, which could materially adversely affect the market price of our ordinary shares. In addition, our articles of association entitle our board of directors, without shareholder approval, to cause us to issue preferred shares with such terms as the board of directors may determine. Preferred shares may be preferred as to dividends, rights on a winding up or voting in such manner as our board of directors may resolve. The preferred shares may also be redeemable at the option of the holder of the preferred shares or at the option of us, and may be convertible into or exchangeable for shares of any other class or classes of our shares, depending on the terms of such preferred shares. The terms of one or more classes or series of preferred shares could dilute the voting power or reduce the value of our ordinary shares. For example, we could grant the holders of preferred shares the right to elect some number of our board of directors in all events or on the happening of specified events or the right to veto specified transactions. Similarly, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred shares could affect the residual value of our ordinary shares.
Pursuant to a rights agreement entered into at the Separation, we issued one preferred share purchase right (collectively, "the Rights") for each outstanding ordinary share to shareholders of record on July 9, 2013. The Rights will not be exercisable until ten days after the public announcement that a person or group has become an "acquiring person" by obtaining beneficial ownership of 10% or more of the outstanding ordinary shares of Mallinckrodt. The Rights will expire on June 28, 2014. In the event the Rights are exercised, this may dilute the percentage of ownership of our other shareholders.

Certain provisions in our articles of association, among other things, could prevent or delay an acquisition of us, which could decrease the trading price of our ordinary shares.
Our articles of association contain provisions that could have the effect of deterring coercive takeover practices, inadequate takeover bids and unsolicited offers. These provisions include, amongst others:

- provisions of our articles of association which allow our board of directors to adopt a shareholder rights plan (commonly known as a "poison pill") upon such terms and conditions as the board of directors deems expedient and in the best interests of our company;
- a provision of our articles of association which generally prohibits us from engaging in a business combination with an interested shareholder for a period of three years following the date the person became an interested shareholder, subject to certain exceptions;
- rules regarding how shareholders may present proposals or nominate directors for election at shareholder meetings;
- the right of our board of directors to issue preferred shares without shareholder approval in certain circumstances, subject to applicable law; and

- the ability of our board of directors to fill vacancies on our board of directors in certain circumstances.

We believe these provisions will provide some protection to our shareholders from coercive or otherwise unfair takeover tactics. These provisions are not intended to make us immune from takeovers. However, these provisions will apply even if the offer may be considered beneficial by some shareholders and could delay or prevent an acquisition that our board of directors determines is in the best interests of our company and its shareholders. These provisions may also prevent or discourage attempts to remove and replace incumbent directors.

In addition, several mandatory provisions of Irish law could prevent or delay an acquisition of us. For example, Irish law does not permit shareholders of an Irish public limited company to take action by written consent with less than unanimous consent. We also will be subject to various provisions of Irish law relating to mandatory bids, voluntary bids, requirements to make a cash offer and minimum price requirements, as well as substantial acquisition rules and rules requiring the disclosure of interests in our ordinary shares in certain circumstances. Also, Irish companies, including us, may only alter their memorandum of association and articles of association with the approval of the holders of at least 75% of the company's shares present and voting in person or by proxy at a general meeting of the company.

The agreements that we entered into with Covidien in connection with the Separation generally required Covidien's consent to any assignment by us of our rights and obligations under the agreements. The consent and termination rights set forth in these agreements might discourage, delay or prevent a change of control that shareholders may consider favorable.

Moreover, an acquisition or further issuance of our ordinary shares after the separation could trigger the application of Section 355(e) of the Code, even if the distribution and certain related transactions undertaken in connection therewith otherwise qualify for tax-free treatment. Under Section 355(e) of the Code, we or Covidien could incur tax upon certain transactions undertaken in anticipation of the distribution if 50% or more, by vote or value, of our ordinary shares or Covidien ordinary shares are acquired or issued as part of a plan or series of related transactions that include the separation. The process for determining whether an acquisition or issuance triggering these provisions has occurred is complex, inherently factual and subject to interpretation. Any acquisitions or issuances of our ordinary shares or Covidien ordinary shares within two years after the distribution are presumed to be part of such a plan, although we or Covidien, as applicable, may be able to rebut that presumption. Moreover, under the Tax Matters Agreement that we entered into with Covidien, we will be restricted from engaging in certain transactions within two years of the distribution which potentially could trigger application of Section 355(e) of the Code. During such period, these restrictions may limit the ability that we, or a potential acquirer of us, have to pursue certain strategic transactions that might increase the value of our ordinary shares.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our offices in the U.S. are located in a facility in Hazelwood, Missouri, which we own. As of September 27, 2013, we owned a total of 12 facilities in four countries. Our owned facilities consist of approximately 2.9 million square feet, and our leased facilities consist of approximately 0.6 million square feet. We presently have ten manufacturing sites, six of which are used by our Global Medical Imaging segment, three of which are used by our Specialty Pharmaceuticals segment and one of which is shared by both segments. We have a manufacturing site in each of Canada, Ireland and the Netherlands and seven manufacturing sites in the U.S. We believe all of these facilities are well-maintained and suitable for the operations conducted in them.

Item 3. Legal Proceedings.

We are subject to various legal proceedings and claims, including patent infringement claims, product liability matters, environmental matters, employment disputes, contractual disputes and other commercial disputes, including those described below. We believe that these legal proceedings and claims likely will be resolved over an extended period of time. Although it is not feasible to predict the outcome of these matters, we believe that their ultimate

resolution will not have a material adverse effect on our financial condition, results of operations and cash flows.

Governmental Proceedings

On November 30, 2011 and October 22, 2012, we received subpoenas from the United States ("U.S.") Drug Enforcement Administration requesting production of documents relating to our suspicious order monitoring programs. We are complying as required by the terms of the subpoenas. While it is not possible at this time to determine with certainty the outcome of these proceedings, we believe that the ultimate resolution will not have a material adverse effect on our financial condition, results of operations and cash flows.

Patent/Antitrust Litigation

Tyco Healthcare Group LP, et al. v. Mutual Pharmaceutical Company, Inc. We filed a patent infringement suit in the U.S. District Court for the District of New Jersey against Mutual Pharmaceutical Co., Inc., et al. (collectively, "Mutual") on March 20, 2007 pursuant to procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984, after Mutual submitted an Abbreviated New Drug Application to the U.S. Food and Drug Administration ("FDA") seeking to sell a generic version of our 7.5 mg Restoril sleep aid product. Mutual also filed antitrust and unfair competition counterclaims. The patents at issue have since expired or been found invalid. On January 18, 2013, the trial court issued an opinion and order granting our motion for summary judgment regarding Mutual's antitrust and unfair competition counterclaims. On May 1, 2013, Mutual appealed this decision to the U.S. Court of Appeals for the Federal Circuit. While it is not possible at this time to determine with certainty the ultimate outcome of the counterclaims, we believe that the final resolution of the claims will not have a material adverse effect on our financial condition, results of operations and cash flows.

Pricing Litigation

From time to time, states attorneys general have brought cases against us that allege generally that we and numerous other pharmaceuticals companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid, resulting in overpayment by state Medicaid programs for those drugs, and generally seek monetary damages and attorneys' fees. For example, we are named as a defendant in State of Utah v. Actavis US, Inc., et al. filed May 8, 2008, which is pending in the Third Judicial Circuit of Salt Lake County, Utah. We intend to contest this case and to explore other options as appropriate. While it is not possible at this time to determine with certainty the outcome of the case, we believe that the ultimate resolution will not have a material adverse effect on our financial condition, results of operations and cash flows.

Environmental Remediation and Litigation Proceedings

We are involved in various stages of investigation and cleanup related to environmental remediation matters at a number of sites, including those described below. The ultimate cost of site cleanup and timing of future cash outlays is difficult to predict, given the uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations and alternative cleanup methods. We concluded that, as of September 27, 2013, it was probable that we would incur remedial costs in the range of $46.4 million to $81.5 million. We also concluded that, as of September 27, 2013, the best estimate within this range was $46.4 million, of which $6.9 million was included in accrued and other current liabilities and the remainder was included in environmental liabilities on the consolidated balance sheet at September 27, 2013.

Crab Orchard National Wildlife Refuge Superfund Site, near Marion, Illinois. We are a successor in interest to International Minerals and Chemicals Corporation ("IMC"). Between 1967 and 1982, IMC leased portions of the Additional and Uncharacterized Sites ("AUS") Operable Unit at the Crab Orchard Superfund Site ("the Site") from the government and manufactured various explosives for use in mining and other operations. In March 2002, the Department of Justice, the U.S. Department of the Interior and the EPA (together, "the Government Agencies") issued a special notice letter to General Dynamics Ordnance and Tactical Systems, Inc. ("General Dynamics"), one of the other potentially responsible parties ("PRPs") at the Site, to compel General Dynamics to perform the remedial investigation and feasibility study ("RI/FS") for the AUS Operable Unit. General Dynamics negotiated an Administrative Order on Consent with the Government Agencies to conduct an extensive RI/FS at the Site under the direction of the U.S. Fish and Wildlife Service. General Dynamics asserted in August 2004 that we are jointly and severally liable, along with approximately eight other lessees and operators at the AUS Operable Unit, for alleged contamination of soils and groundwater resulting from historic operations, and has threatened to file a contribution claim against us and other parties for recovery of its costs incurred in connection with the RI/FS activities being conducted at the AUS Operable Unit. We and other PRPs who received demand letters from General Dynamics have explored settlement alternatives, but have not reached settlement to date. We and other PRPs are awaiting completion of the RI/FS by General Dynamics before the initiation of formal PRP negotiations to address resolution of these

alleged claims. While it is not possible at this time to determine with certainty the ultimate outcome of this case, we believe that the final resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on our financial condition, results of operations and cash flows.

Mallinckrodt Veterinary, Inc., Millsboro, Delaware. We previously operated a plant in Millsboro, Delaware ("the Millsboro Site") that manufactured various animal healthcare products. In 2005, the Delaware Department of Natural Resources and Environmental Control found trichloroethylene ("TCE") in the Millsboro public water supply at levels that exceeded the federal drinking water standards. Further investigation to identify the TCE plume in the ground water indicated that the plume has extended to property owned by a third party near the Millsboro Site. We, and other former owners, assumed responsibility for the Millsboro Site cleanup under the Alternative Superfund Program administered by the EPA. We and other PRPs entered into an Administrative Order on Consent with the EPA on May 10, 2010, which was subsequently amended in November 2010 and January 2011, to investigate the potential source of TCE contamination and to evaluate options to abate, mitigate or eliminate the release or threat of release of hazardous substances at the Millsboro Site. We, along with the other parties, continue to conduct the studies and prepare remediation

plans in accordance with the amended Administrative Order on Consent. While it is not possible at this time to determine with certainty the ultimate outcome of this matter, we believe that the final resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on our financial condition, results of operations and cash flows.

Coldwater Creek, Saint Louis County, Missouri. We are one of several companies named as defendants in six tort complaints (McClurg, et al. v. Mallinckrodt, Inc., et al., filed February 28, 2012; Adams, et al. v. Mallinckrodt, Inc., et al., filed April 10, 2012; Steinmann, et al. v. Mallinckrodt, Inc., et al., filed October 23, 2012; Schneider, et al. v. Mallinckrodt, Inc., et al., filed April 19, 2013; Vorce v. Mallinckrodt, Inc., et al., filed June 18, 2013; and Lange, et al. v. Mallinckrodt, Inc., et al., filed July 31, 2013) with numerous plaintiffs pending in the U.S. District Court for the Eastern District of Missouri. These cases allege personal injury for alleged exposure to radiological substances present in Coldwater Creek in Missouri. Plaintiffs lived in various locations in Saint Louis County, Missouri near Coldwater Creek. Radiological residues which may have been present in the creek have been remediated by the U.S. Army Corps of Engineers. We believe that we have meritorious defenses to these complaints and are vigorously defending against them. We are unable to estimate a range of reasonably possible losses for the following reasons: (i) the proceedings are in early stages; (ii) we have not received and reviewed complete information regarding the plaintiffs and their medical conditions; and (iii) there are significant factual issues to be resolved. While it is not possible at this time to determine with certainty the ultimate outcome of these cases, we believe that the final resolution of all known claims will not have a material adverse effect on our financial condition, results of operations and cash flows.

Products Liability Litigation

Beginning with lawsuits brought in July 1976, we are also named as a defendant in personal injury lawsuits based on alleged exposure to asbestos-containing materials. A majority of the cases involve product liability claims based principally on allegations of past distribution of products containing asbestos. A limited number of the cases allege premises liability based on claims that individuals were exposed to asbestos while on our property. Each case typically names dozens of corporate defendants in addition to us. The complaints generally seek monetary damages for personal injury or bodily injury resulting from alleged exposure to products containing asbestos. Our involvement in asbestos cases has been limited because we did not mine or produce asbestos. Furthermore, in our experience, a large percentage of these claims have never been substantiated and have been dismissed by the courts. We have not suffered an adverse verdict in a trial court proceeding related to asbestos claims and intend to continue to defend these lawsuits. When appropriate, we settle claims; however, amounts paid to settle and defend all asbestos claims have been immaterial. As of September 27, 2013, there were approximately 11,500 asbestos-related cases pending against us. We estimate pending asbestos claims and claims that were incurred but not reported and related insurance recoveries.

We estimate our liability for pending and future claims based on claims experience over the past five years and covers claims either currently filed or expected to be filed over the next seven years. We believe that we have adequate amounts recorded related to these matters. While it is not possible at this time to determine with certainty the ultimate outcome of these asbestos-related proceedings, we believe that the final outcome of all known and anticipated future claims, after taking into account amounts already accrued, along with recoveries from insurance, will not have a material adverse effect on our financial condition, results of operations and cash flows.

Other Matters

We are a defendant in a number of other pending legal proceedings related to present and former operations, acquisitions and dispositions. We do not expect the outcome of these proceedings, either individually or in the aggregate, to have a material adverse effect on our financial condition, results of operations and cash flows.

Item 4. Mine Safety Disclosures.

Not applicable.

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PART II

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

Market Information

On July 1, 2013, our ordinary shares began regular way trading on the New York Stock Exchange ("NYSE") under the ticker symbol "MNK." For the three months ended September 27, 2013, the high and low closing sales prices for our ordinary shares were, on a per share basis, $47.16 and $41.51, respectively.

Prior to July 1, 2013, our ordinary shares were traded on a "when-issued" basis. The high and low closing sales prices for the period June 17, 2013 to June 28, 2013 were, on a per share basis, $45.43 and $42.94, respectively.

There were approximately 3,529 shareholders of record of our ordinary shares as of December 6, 2013.

Dividends and Issuer Purchase of Equity Securities

Under Irish law, we can only pay dividends and repurchase shares out of distributable reserves. Upon completion of the Separation, we did not have any distributable reserves. On July 22, 2013, we filed a petition with the High Court of Ireland seeking the court's confirmation of a reduction of our share premium so that it can be treated as distributable for the purposes of Irish law. On September 9, 2013, the High Court of Ireland approved this petition and, upon approval, our share premium is treated as distributable reserves and our share premium balance was reclassified into additional paid-in capital. We did not declare or pay any dividends and we do not intend to pay dividends in the foreseeable future. Since our Separation, we have repurchased 483 shares at an average market price of $43.33. We have not and do not currently intend to initiate a comprehensive share repurchase program in the foreseeable future.

Performance Graph

The following performance graph and related information shall not be deemed "soliciting material" or to be "filed" with the United States Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the changes, for the period indicated, in the cumulative total value of $100 hypothetically invested in each of (a) Mallinckrodt ordinary shares, (b) the Russell 1000 index and (c) the NYSE Pharmaceutical Index. This graph covers the period from June 17, 2013, the first day our ordinary shares began "when-issued" trading on the NYSE, through September 27, 2013.

Comparison of Cumulative Total Return*

Among Mallinckrodt plc, the Russell 1000 Index and NYSE Pharmaceutical Index

*$100.00 invested on June 17, 2013 in shares or index.

Performance Graph Data

	Mallinckrodt	Russell 1000 Index	NYSE Pharmaceutical Index
June 17, 2013	$100.00	$100.00	$ 100.00
June 28, 2013	100.96	98.07	96.14
July 26, 2013	100.11	103.44	101.11
August 30, 2013	97.00	100.12	97.40
September 27, 2013	96.82	104.02	100.18

The share price performance included in this graph is not necessarily indicative of future share price performance.

Information regarding securities authorized for issuance under equity compensation plans will be included in our definitive proxy statement for our annual general meeting of shareholders, which will be filed with the United States Securities and Exchange Commission within 120 days after September 27, 2013.

Item 6. Selected Financial Data.

The following table sets forth selected financial data as of and for the fiscal years ended September 27, 2013, September 28, 2012, September 30, 2011, September 24, 2010 and September 25, 2009. This selected financial data reflects the consolidated position of Mallinckrodt plc and its consolidated subsidiaries (collectively, "Mallinckrodt") as an independent, publicly-traded company for periods on or after its legal separation from Covidien plc ("Covidien") on June 28, 2013. Selected financial data for periods prior to June 28, 2013 reflect the combined historical business and operations of Covidien's Pharmaceuticals business as it was historically managed as part of Covidien.

The consolidated and combined statement of income data for fiscal 2013, the combined statement of income data for fiscal 2012 and 2011, the consolidated balance sheet data as of September 27, 2013 and the combined balance sheet data as of September 28, 2012 were derived from our consolidated and combined financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K. The combined statement of income data for fiscal 2010 and the combined balance sheet data as of September 30, 2011 were derived from our audited combined financial statements that are not included in this Annual Report on Form 10-K. The combined statement of income data for fiscal 2009 and the combined balance sheet data as of September 24, 2010 and September 25, 2009 were derived from our unaudited combined financial statements that are not included in this Annual Report on Form 10-K. This selected financial information should be read in conjunction with our consolidated and combined financial statements and accompanying notes and Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations. Our historical results for periods prior to June 28, 2013 are not necessarily indicative of the results of operations or financial condition that would have been obtained had we operated as an independent, publicly-traded company for the entirety of the periods presented, nor are they necessarily indicative of our future performance as an independent, publicly-traded company.

(in millions, except per share data)	Fiscal Year [1]				
	2013	2012	2011	2010	2009 (unaudited)
Consolidated and Combined Statement of Income Data:					
Net sales [2]	$2,204.5	$ 2,056.2	$ 2,021.8	$2,047.6	$ 2,429.5
Gross profit	1,024.9	964.8	914.9	932.4	1,296.3
Research and development expenses [3]	165.7	144.1	141.5	119.1	155.2
Operating income [4] [5]	144.8	235.2	240.7	240.4	508.5
Income from continuing operations before income taxes	126.4	236.1	243.2	243.2	512.0
Income from continuing operations	57.8	141.3	157.0	145.9	315.5
Share Data [6]:					
Basic income from continuing operations per share	$1.00	$ 2.45	$ 2.72	$2.53	$ 5.47
Diluted income from continuing operations per share	1.00	2.45	2.72	2.53	5.47
Cash dividends per ordinary share	—	—	—	—	—
	September 27, 2013	September 28, 2012	September 30, 2011	September 24, 2010 (unaudited)	September 25, 2009(unaudited)
Consolidated and Combined Balance Sheet Data:					
Total assets	$3,556.6	$ 2,898.9	$ 2,832.2	$2,892.6	$ 3,167.4

Long-term debt	918.3	8.9	10.4	11.6	13.6
Shareholders' equity	1,255.6	1,891.9	1,788.7	1,835.9	2,016.4

(1) Fiscal 2011 included 53 weeks. All other fiscal years presented include 52 weeks.

(2) Fiscal 2009 includes $354.5 million of sales of oxycodone hydrocodone extended-release tablets, which were sold under a license agreement that began in the fourth quarter of fiscal 2008 and ended in the second quarter of fiscal 2009.

(3) Fiscal 2013 includes a $5.0 million charge related to milestone payments related to the acceptance of our Xartemis XR NDA for filing with the FDA. Fiscal 2009 includes a $35.3 million charge related to upfront fees and milestone payments related to a product acquisition and licensing agreements.

(4) Fiscal 2013 and 2012 include costs related to the build-out of our corporate infrastructure of $70.6 million and $10.7 million, respectively. Fiscal 2013, 2012 and 2011 include separation related costs of $74.2 million, $25.5 million and $2.9 million, respectively. Fiscal 2013, 2012, 2011, 2010 and 2009 include restructuring charges, net, of $33.2 million, $11.2 million, $8.4 million, $11.5 million and $26.7 million, respectively. Fiscal 2010 and 2009 include product liability charges of $31.3 million and $27.8 million, respectively. Fiscal 2009 also includes a $71.2 million charge for the estimated additional cost to remediate environmental matters at a site located in Orrington, Maine, the liability for which was retained by Covidien pursuant to the separation and distribution agreement.

(5) Fiscal 2013, 2012, 2011, 2010 and 2009 include expense allocations from Covidien of $39.6 million, $49.2 million, $56.3 million, $60.8 million and $60.6 million, respectively, which relate to finance, legal, information technology, human resources, communications, employee benefits and incentives, insurance and share-based compensation. Effective with the legal separation from Covidien on June 28, 2013, we have assumed responsibility for all of these functions and related costs and anticipate our costs as an independent, publicly-traded company will be higher than those allocated to us from Covidien.

(6) The computation of basic and diluted earnings per share assumes that the number of shares outstanding for periods prior to June 28, 2013 was equal to the number of ordinary shares of Mallinckrodt outstanding on June 28, 2013, immediately following the distribution of one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated and combined financial statements and the accompanying notes included in this Annual Report on Form 10-K. The following discussion may contain forward-looking statements that reflect our plans, estimates and beliefs and involve risks, uncertainties and assumptions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to these differences include those discussed in Item 1A. Risk Factors and "Forward-Looking Statements" included within this Annual Report on Form 10-K.

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 business and products, refer to Item 1. Business included within this Annual Report on Form 10-K.

Significant Events

Separation from Covidien

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 its 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 consolidated and combined financial statements reflect the consolidated financial position of Mallinckrodt plc and its subsidiaries as an independent publicly-traded company for periods subsequent to June 28, 2013, and as a combined reporting entity of Covidien, including operations relating to Covidien's Pharmaceuticals business, for periods prior to June 28, 2013. Our results for periods prior to June 28, 2013, including the nine months ended June 28, 2013 that is included with our fiscal 2013 results, may not be indicative of our future performance and do not necessarily reflect the results of operations, financial position and cash flows that would have been had we operated as an independent, publicly-traded company for the entirety of the periods presented, including as a result of changes in our capitalization in connection with the Separation. The combined financial statements for periods prior to June 28, 2013 include expense allocations related to finance, legal, information technology, human resources, communications, employee benefits and incentives, insurance and share-based compensation. The amounts allocated were $39.6 million, $49.2 million and $56.3 million in fiscal 2013, 2012 and 2011, respectively. Management considers the bases on which the expenses have been allocated to reasonably reflect the utilization of services provided to, or the benefit received by, us during the periods presented; however, the allocations may not reflect the expense we would have incurred as an independent, publicly-traded company. These allocations have not recurred following the completion of the Separation on June 28, 2013, as we have been performing these functions using our own resources or purchased services, certain of which are being provided by Covidien during a transitional period pursuant to a transition services

agreement dated June 28, 2013, between us and Covidien, particularly in relation to areas outside the U.S. The terms and prices on which such services are rendered may not be as favorable as those allocated to us by Covidien. We also may incur additional costs associated with being an independent, publicly-traded company. These additional anticipated costs are not reflected in our historical combined financial statements for periods prior to June 28, 2013.

Acquisitions

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, for total consideration of $95.0 million. The total consideration was comprised of an upfront cash payment of $88.1 million (net of cash acquired) and the fair value of contingent consideration of $6.9 million. This contingent consideration, which could potentially total a maximum of $9.0 million, is primarily based on whether the U.S. Food and Drug Administration ("FDA") approves another concentration of Gablofen (baclofen injection) on or before December 31, 2016. Gablofen injections are indicated for use in the management of severe spasticity of cerebal or spinal origin in patients age four years and above. The acquisition of CNS Therapeutics expanded our branded pharmaceuticals portfolio and supports our strategy of leveraging our therapeutic expertise and core capabilities in manufacturing, regulatory and commercialization to serve patients. The consolidated and combined income statement for fiscal 2013 included $29.2 million of net sales of intrathecal products added to our portfolio with this acquisition.

In August 2012, we paid $13.2 million under an agreement to acquire all of the rights to Roxicodone® from Xanodyne Pharmaceuticals, Inc., which was capitalized as an intangible asset. Roxicodone is an immediate-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain where the use of an opioid analgesic is appropriate. Roxicodone is the Reference Listed Drug for one of our generic products and is important to our product pipeline. Net sales of Roxicodone during fiscal 2013 were $8.4 million. There are no ongoing royalty payments under this agreement.

Divestitures

During fiscal 2011, we sold the rights to market TussiCaps, which are hydrocodone bitartrate and chlorpheniramine maleate extended-release capsules for use as a cough suppressant, for an upfront cash payment of $11.5 million. As a result of this transaction, we recorded a $11.1 million gain. The purchaser also may be obligated to make contingent payments to us of up to $11.5 million from December 31, 2011 through September 30, 2015, payable in equal quarterly installments until such time as a new competitive generic product is introduced into the market. In addition, we would receive a $1.0 million contingent payment if certain sales targets are achieved over the same time period. We received contingent payments of $2.9 million during both fiscal 2013 and 2012.

Royalty and Milestone Payments

We are required to pay royalties and milestone payments for various product acquisitions and license agreements we have entered into with third parties. For Exalgo (hydromorphone HCl) extended-release tablets ("Exalgo"), a pain management drug we acquired the rights to distribute and market in fiscal 2009, we are obligated to make additional payments based on the successful completion of specified development and regulatory milestones. Additionally, we are required to pay royalties on sales of the product. During fiscal 2013, 2012 and 2011, we paid royalties of $24.0 million, $16.1 million and $5.5 million, respectively. No milestone payments were made in any of the periods presented.

Also in fiscal 2009, we entered into a licensing agreement to utilize Depomed's Acuform gastric retentive drug delivery technology for the exclusive development of four products. This agreement may obligate us to make development milestone payments, and we are required to pay royalties on sales of products developed under this agreement. During fiscal 2013, we made a $5.0 million milestone payment upon the acceptance for filing by the FDA of our Xartemis XR (oxycodone and acetaminophen) Extended-Release Tablets ("Xartemis XR") New Drug Application ("NDA"). During fiscal 2012, an insignificant amount of milestone payments were expensed as incurred since regulatory approval had not been received. No milestone payments were made in fiscal 2011. No royalty payments have been made under this agreement.

We also entered into a license agreement which granted us rights to market and distribute Pennsaid (diclofenac sodium topical solution) 1.5% w/w ("Pennsaid") and MNK-395, an investigational product candidate that is a formulation of diclofenac sodium topical solution which we anticipate will be indicated for the treatment of pain

associated with osteoarthritis of the knee. We are responsible for all future development activities and expenses under this agreement, are required to pay royalties on sales of the products and may also be required to make additional payments based upon the successful completion of specified regulatory and sales milestones. No milestone payments were made during fiscal 2013, 2012 or 2011. During fiscal 2013 and 2012, we paid royalties of $3.9 million and $7.5 million. The amount of royalties paid in fiscal 2011 was insignificant.

Nuclear Imaging

In November 2012, the High Flux Reactor ("HFR") in the Netherlands, one of two primary reactors we utilize to irradiate targets as part of our Molybdenum 99 ("Mo-99") processing operation experienced an unscheduled shutdown. Mo-99 is a key raw material in our Ultra-Technekow DTE technetium generators that are sold by our Global Medical Imaging segment. We were able to receive increased target irradiations at two other reactors and purchased additional Mo-99 from other sources to continue meeting customer orders; however, the additional Mo-99 we procured from alternative sources came at a higher than normal cost. The reactor resumed production in June 2013. In October 2013, the HFR experienced another unscheduled shutdown. In addition, our own Mo-99 processing facility in the Netherlands also experienced a shutdown. Until these facilities resume normal production, we expect to fulfill customer orders through procurement of Mo-99 from alternative sources at higher than historical costs. Ongoing increased raw material and manufacturing costs will limit our ability to return the Global Medical Imaging segment to historical operating margins.

Business Factors Influencing the Results of Operations

New Products

On December 28, 2012, we received approval from the FDA to manufacture Methylphenidate HCl extended-release tablets USP (CII) ("Methylphenidate ER"), a generic version of the branded Concerta, a registered trademark of Alza Corporation, for the treatment of attention deficit hyperactivity disorder in 27 mg, 36 mg and 54 mg dosages. We held a 180-day exclusivity period for each of the 27 mg, 36 mg and 54 mg dosage strengths, which began upon the commercial launch of each dosage strength. We launched the 27 mg dosage strength upon FDA approval during the first quarter of fiscal 2013 and launched the 36 mg and 54 mg dosage strengths during the second quarter of fiscal 2013. In February 2013, we submitted a supplement to our approved Abbreviated New Drug Application ("ANDA") for an 18 mg dosage strength, which the FDA has accepted and granted priority review. Net sales of Methylphenidate ER were $148.3 million in fiscal 2013; however, we expect that sales of these products may subsequently decline in fiscal 2014 due to a number of factors, including expiration of the exclusivity periods. In July 2013, a competitor received FDA approval to manufacture all strengths of Methylphenidate ER and has entered the marketplace. As our exclusivity has expired, other competitors may also enter the market for Methylphenidate ER.

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 has the right, pursuant to agreements with us, to sell a generic version of Exalgo; however, their entrance to the market is dependent upon receiving FDA marketing approval. 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.

Net sales of Methylphenidate ER and Exalgo were $274.4 million, $91.9 million and $41.2 million in fiscal 2013, 2012, and 2011, respectively.

Restructuring Initiatives

We continue to look for opportunities to improve our cost structure and achieve operating excellence and efficiencies. Our initiatives prior to the Separation have primarily been part of Covidien's 2011 restructuring program, which also applied to its Pharmaceutical business. We launched an initiative that closed a manufacturing facility in Chesterfield, United Kingdom ("U.K."). The manufacturing facility produced API products and we transferred these processes to another manufacturing site, creating operating and logistic efficiencies. In addition, we announced a comprehensive initiative to renovate, upgrade and modernize key manufacturing operations at our Saint Louis, Missouri

manufacturing facility. We began to realize benefits from these initiatives in fiscal 2012.

Following the Separation, we continue to realign our cost structure due to the changing nature of our business and look for opportunities to achieve operating efficiencies. As such, in August 2013 our board of directors approved a restructuring program in the amount of $100 million to $125 million that is expected to occur over a three year period. We expect to recover the charges of each restructuring action taken within two years.

During fiscal 2013, 2012 and 2011, we incurred restructuring and related charges, net, of $35.8 million, $19.2 million and $10.0 million, respectively, which included accelerated depreciation costs of $2.6 million, $8.0 million and $1.6 million, respectively. The restructuring charges incurred during all of these periods primarily related to severance and employee benefit costs across both of our segments.

Research and Development Investment

We expect to continue to invest in research and development ("R&D") activities, as well as enter into license agreements to supplement our internal R&D initiatives. We intend to focus our R&D investments in the specialty pharmaceuticals area, specifically investments to support our Brands business, where we believe there is the greatest opportunity for growth and profitability. We currently expect our R&D investments to be in the range of 6% to 8% of annualized net sales.

Specialty Pharmaceuticals. We devote significant R&D resources for our branded products. A number of our branded products are protected by patents and have enjoyed market exclusivity. Our R&D strategy focuses on branded product development in the area of pain, other central nervous system areas, such as spasticity, and adjacent areas. We are presently developing a number of branded products, some of which utilize novel drug-delivery systems, through a combination of internal and collaborative programs. As of September 27, 2013, we had two NDAs under review in the U.S. In July 2013, the FDA accepted our MNK-795 NDA and granted it priority review. The FDA has granted conditional approval of the brand name Xartemis XR for the MNK-795 NDA. In November 2013, in response to additional data we submitted, the FDA extended their review of the Xartemis XR NDA by three months. We anticipate, if approved, Xartemis XR will be launched during the first half of fiscal 2014. Our NDA for MNK-395 was submitted in June 2012 and, after repeating a pharmacokinetic study and submitting the results to the FDA, the application was accepted for filing in August 2013. The FDA has granted conditional approval of the name Pennsaid 2% for the MNK-395 NDA. If approved, we expect to launch this product in the second half of fiscal 2014. 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.

We are presently developing a number of generic products through a combination of internal and collaborative programs. From a product development perspective, we are focused on controlled substances with difficult-to-replicate pharmacokinetic profiles. In addition, we are focused on process improvements to increase yields and reduce costs. As of September 27, 2013, we had five ANDAs on file with the FDA. This includes a supplement, filed in February 2013, to our approved ANDA for the 18 mg dosage strength of Methylphenidate ER. The FDA has accepted this supplement and granted it priority review. If accepted, we will have all four dosage strengths available on the market, as we currently offer the 27 mg, 36 mg and 54 mg dosage strengths.

Global Medical Imaging. Our R&D efforts in our Global Medical Imaging segment are focused on driving efficiency throughout CMDS. In our Nuclear Imaging business, we are expanding our portfolio of radioisotopes and better utilizing existing capacity.

Results of Operations

Fiscal Year Ended September 27, 2013 Compared with Fiscal Year Ended September 28, 2012

Net Sales

Net sales by geographic area are as follows (dollars in millions):

	Fiscal Year			
	2013	2012	Percentage Change	
U.S.	$1,518.7	$1,350.2	12.5	%
Europe, Middle East and Africa	404.3	411.0	(1.6	)
Other	281.5	295.0	(4.6	)
Net sales	$2,204.5	$2,056.2	7.2	

Net sales in fiscal 2013 increased $148.3 million, or 7.2%, to $2,204.5 million, compared with $2,056.2 million in fiscal 2012. This increase was primarily driven by increased sales within our Specialty Pharmaceuticals segment resulting from the launch of Methylphenidate ER, increased sales of Exalgo and the addition of Gablofen to our

product portfolio in early fiscal 2013. These increases were partially offset by decreased sales in both our CMDS and Nuclear Imaging businesses. For further information on changes in our net sales, refer to "Business Segment Results" within this Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Operating Income

Gross profit. Gross profit for fiscal 2013 increased $60.1 million, or 6.2%, to $1,024.9 million, compared with $964.8 million in fiscal 2012. The increase in gross profit primarily resulted from higher net sales in the current year period, in addition to a favorable product mix from increased sales of our higher margin pharmaceutical products. These factors were offset by increased manufacturing and raw material costs, primarily attributable to the unscheduled shutdown of the HFR that supplies us with Mo-99. Gross profit margin was 46.5% during fiscal 2013, compared with 46.9% during fiscal 2012.

Selling, general and administrative expenses. Selling, general and administrative expenses for fiscal 2013 were $609.9 million, compared with $551.7 million for fiscal 2012, an increase of $58.2 million, or 10.5%. The increase primarily resulted from $70.6 million of costs in the current year period related to the build-out of our corporate infrastructure, compared with $10.7 million in the prior year period. Selling, general and administrative expenses were 27.7% of net sales for fiscal 2013 and 26.8% of net sales for fiscal 2012. Selling, general and administrative expenses include allocations from Covidien of $39.6 million and $49.2 million in fiscal 2013 and 2012, respectively, for general corporate expenses. These expenses are generally consistent with functions we have developed in our corporate build-out and ceased following the completion of the Separation on June 28, 2013. Fiscal 2013 included minimal launch expenses related to Xartemis XR and Pennsaid 2%. Beginning in the first half of fiscal 2014, we expect expenses in our Brands business to increase in anticipation of our launch of these products.

Research and development expenses. R&D expenses increased $21.6 million, or 15.0%, to $165.7 million in fiscal 2013, compared with $144.1 million in fiscal 2012. The increase in R&D expenses is primarily attributable to increased development activities related to our MNK-155, Pennsaid 2% and intrathecal products. The increase in R&D also reflects a $5.0 million milestone payment related to acceptance of the Xartemis XR NDA for priority review by the FDA. As a percentage of our net sales, R&D expenses were 7.5% and 7.0% in fiscal 2013 and 2012, respectively.

Separation costs. During fiscal 2013 and 2012, we incurred separation costs of $74.2 million and $25.5 million, respectively, primarily related to legal, accounting, tax and other professional fees. Separation costs were higher in the current year period as we approached and completed the Separation on June 28, 2013. We expect to continue to incur costs related to the Separation as a result of our transition services agreement with Covidien, our costs to implement information and accounting systems, share-based compensation related to the conversion of Covidien awards to Mallinckrodt awards, and other transitional costs; however, these costs are not expected to recur at similar levels in future periods.

Restructuring and related charges, net. During fiscal 2013, we recorded $35.8 million of restructuring and related charges, net, of which $2.6 million related to accelerated depreciation and was included in cost of sales. The remaining $33.2 million primarily related to severance and employee benefits costs incurred across both our segments. During fiscal 2012, we recorded restructuring and related charges, net of $19.2 million, of which $8.0 million related to accelerated depreciation and was included in cost of sales. The remaining $11.2 million primarily related to severance and employee benefits costs incurred in the Global Medical Imaging segment.

Gain on divestitures. During both fiscal 2013 and 2012, we recorded gains of $2.9 million related to the sale of the rights to market TussiCaps extended-release capsules in fiscal 2011.

Non-Operating Items

Interest expense and interest income. During fiscal 2013, net interest expense was $19.2 million. Net interest expense is primarily attributable to our $900 million issuance of senior unsecured notes in April 2013. Interest expense during fiscal 2013 includes $1.1 million non-cash interest expense.

Other income, net. During fiscal 2013 and 2012, we recorded other income, net of $0.8 million and $1.0 million, respectively, which represents miscellaneous items, including gains and losses on intercompany financing foreign currency transactions and related hedging instruments.

Provision for income taxes. Income tax expense was $68.6 million and $94.8 million on income from continuing operations before income taxes of $126.4 million and $236.1 million for fiscal 2013 and 2012, respectively. Our

effective tax rate was 54.3% compared with 40.2% for fiscal 2013 and 2012, respectively. Our effective tax rate for fiscal 2013 was impacted by only receiving a $4.2 million tax benefit on $74.2 million of separation costs due to the tax-free status of the Separation, $13.3 million of expense associated with uncertain tax positions, and an $11.6 million benefit associated with intercompany debt transferred to the Company at the Separation. Our effective tax rate for fiscal 2012 was impacted by only receiving $1.8 million of tax benefit on $25.5 million of separation costs due to the tax-free status of the Separation and recognizing $2.3 million of expense associated with uncertain tax positions.

Income (loss) from discontinued operations, net of income taxes. We recorded a $1.0 million gain and $6.7 million loss on discontinued operations, net of income taxes, during fiscal 2013 and 2012, respectively. These amounts relate to indemnification obligations to the purchaser of our Specialty Chemicals business (formerly known as Mallinckrodt Baker), which was sold during fiscal 2010.

Fiscal Year Ended September 28, 2012 Compared with Fiscal Year Ended September 30, 2011

Net Sales

Net sales by geographic area are as follows (dollars in millions):

	Fiscal Year			
	2012	2011	Percentage Change	
U.S.	$1,350.2	$1,293.8	4.4	%
Europe, Middle East and Africa	411.0	419.7	(2.1	)
Other	295.0	308.3	(4.3	)
Net sales	$2,056.2	$2,021.8	1.7	

Net sales in fiscal 2012 increased $34.4 million, or 1.7%, to $2,056.2 million, compared with $2,021.8 million in fiscal 2011. This increase was primarily driven by a $50.7 million increase in sales of Exalgo within our Specialty Pharmaceuticals segment, partially offset by a $22.7 million decrease in sales of our Optiray contrast product within our Global Medical Imaging segment. For further information on changes in our net sales, refer to "Business Segment Results" within this Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Operating Income

Gross profit. Gross profit for fiscal 2012 increased $49.9 million, or 5.5%, to $964.8 million, compared with $914.9 million in fiscal 2011. The increase in gross profit was primarily a result of overall higher net sales. Gross margin was 46.9% in fiscal 2012, compared with 45.3% in fiscal 2011. The increase in gross margin was primarily attributable to a more favorable product mix resulting from increased sales of our higher margin branded pharmaceutical products.

Selling, general and administrative expenses. Selling, general and administrative expenses for fiscal 2012 were $551.7 million, compared with $532.5 million for fiscal 2011, an increase of $19.2 million, or 3.6%. The increase in selling, general and administrative expenses primarily resulted from higher legal and benefit costs. Selling, general and administrative expenses were 26.8% of net sales for fiscal 2012, compared with 26.3% of net sales for fiscal 2011.

Research and development expenses. R&D expenses increased $2.6 million, or 1.8%, to $144.1 million in fiscal 2012, compared with $141.5 million in fiscal 2011. The increase in R&D expenses is primarily attributable to increased development activities related to our Xartemis XR and MNK-155 products, as well as higher salary and benefit costs. As a percentage of our net sales, R&D expenses were 7.0% in both fiscal 2012 and 2011.

Separation costs. During fiscal 2012 and 2011, we incurred separation costs of $25.5 million and $2.9 million, respectively, primarily related to tax, accounting and other professional fees.

Restructuring and related charges, net. During fiscal 2012, we recorded $19.2 million of restructuring and related charges, net, of which $8.0 million related to accelerated depreciation and was included in cost of sales. The accelerated depreciation resulted from the decision to shut down our plant in Chesterfield, U.K. The remaining $11.2 million primarily related to severance and employee benefits costs due to a reduction in work force. During fiscal 2011, we recorded restructuring and related charges, net of $10.0 million, of which $1.6 million related to accelerated depreciation and was included in cost of sales. The remaining $8.4 million primarily related to severance and employee benefit costs incurred within our Specialty Pharmaceuticals segment.

Gain on divestitures. During fiscal 2011, we recorded a $11.1 million gain related to the sale of the rights to market TussiCaps extended-release capsules. We recorded an additional $2.9 million gain related to this sale during fiscal 2012.

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Non-Operating Items

Interest expense and interest income. During fiscal 2012 and 2011, interest expense, net of interest income, was $0.1 million and $0.4 million, respectively.

Other income, net. During fiscal 2012 and 2011, we recorded other income, net, of $1.0 million and $2.9 million, respectively, which primarily represented royalty payments from a subsidiary of Covidien for use of certain of our trademarks and technology.

Provision for income taxes. Income tax expense was $94.8 million and $86.2 million on income from continuing operations before income taxes of $236.1 million and $243.2 million for fiscal 2012 and 2011, respectively. Our effective tax rate was 40.2% and 35.4% for fiscal 2012 and 2011, respectively. The increase in effective tax rate for fiscal 2012 resulted primarily from a decrease in earnings in lower-tax jurisdictions. The expiration of the U.S. R&D tax credit as of December 31, 2011 and the retroactive reenactment of the 2010 R&D tax credit during fiscal 2011 also contributed to the increase in the effective tax rate in fiscal 2012, as compared with fiscal 2011. Had the U.S. R&D tax credit been fully enacted during fiscal 2012, our effective tax rate would have been approximately 0.7% lower. In addition, in fiscal 2011, we reached a settlement with certain non-U.S. taxing authorities that favorably benefited our fiscal 2011 effective tax rate.

Loss from discontinued operations, net of income taxes. We recorded $6.7 million and $6.3 million losses on discontinued operations, net of income taxes, during fiscal 2012 and 2011, respectively. These losses related to indemnification obligations to the purchaser of our Specialty Chemicals business (formerly known as Mallinckrodt Baker), which was sold during fiscal 2010.

Business Segment Results

The businesses included within our Specialty Pharmaceuticals and our Global Medical Imaging segments are described below:

Specialty Pharmaceuticals

- Brands include branded pharmaceuticals for pain and spasticity.
- Generics and API produces generic pharmaceutical products (including those to treat attention deficit hyperactivity disorder and addiction), medicinal opioids, synthetic controlled substances and acetaminophen.

Global Medical Imaging

- Contrast Media and Delivery Systems develops, manufactures and markets contrast media for diagnostic imaging applications, and power injectors to allow delivery of contrast media.
- Nuclear Imaging manufactures and markets radioactive isotopes and associated pharmaceuticals used for the diagnosis and treatment of disease.

Management measures and evaluates our operating segments based on segment net sales and operating income. Management excludes corporate expenses, amortization of intangibles, restructuring and related charges, net and separation costs from segment operating income. In addition, management evaluates the operating results of the segments excluding revenues and expenses associated with sales of products to our former parent company, Covidien. Although these amounts are excluded from segment operating income, as applicable, they are included in reported consolidated and combined operating income and accordingly, are included in our discussion of our consolidated and combined results of operations.

Fiscal Year Ended September 27, 2013 Compared with Fiscal Year Ended September 28, 2012

Net Sales

Net sales by segment are shown in the following table (dollars in millions):

	Fiscal Year			
	2013	2012	Percentage Change	
Specialty Pharmaceuticals	$1,217.6	$1,005.2	21.1	%
Global Medical Imaging	935.7	996.8	(6.1	)
Net sales of operating segments	2,153.3	2,002.0	7.6	
Other [(1)]	51.2	54.2	(5.5	)
Net sales	$2,204.5	$2,056.2	7.2	

(1) Represents products that were sold to Covidien.

Specialty Pharmaceuticals. Net sales for fiscal 2013 increased $212.4 million, or 21.1%, to $1,217.6 million, compared with $1,005.2 million for fiscal 2012. The increase in net sales was primarily driven by $148.3 million of sales from the launch of Methylphenidate ER during fiscal 2013, a $34.2 million increase in net sales of Exalgo, which was aided by the launch of the 32mg dosage in August 2012, and $29.2 million in net sales of intrathecal products.

Net sales for Specialty Pharmaceuticals by geography are as follows (dollars in millions):

	Fiscal Year			
	2013	2012	Percentage Change	
U.S.	$1,097.9	$880.6	24.7	%
Europe, Middle East and Africa	104.1	108.7	(4.2	)
Other	15.6	15.9	(1.9	)
Net sales	$1,217.6	$1,005.2	21.1	

Net sales for Specialty Pharmaceuticals by key products are as follows (dollars in millions):

	Fiscal Year			
	2013	2012	Percentage Change	
Acetaminophen (API) products	$216.2	$217.7	(0.7	)%
Oxycodone (API) and oxycodone-containing tablets	139.0	144.1	(3.5	)
Hydrocodone (API) and hydrocodone-containing tablets	140.0	130.5	7.3	
Other controlled substances	112.0	111.7	0.3	
Methylphenidate ER	148.3	—	—	
Other	255.7	244.8	4.5	
Generics and API	1,011.2	848.8	19.1	
Exalgo	126.1	91.9	37.2	
Intrathecal products	29.2	—	—	
Other	51.1	64.5	(20.8	)
Brands	206.4	156.4	32.0	
Specialty Pharmaceuticals	$1,217.6	$1,005.2	21.1	

Global Medical Imaging. Net sales for fiscal 2013 decreased $61.1 million, or 6.1%, to $935.7 million compared with $996.8 million for fiscal 2012. Net sales of CMDS products decreased $43.9 million, and were negatively impacted by the effects of commoditization in mature markets, which we expect to continue into the future, and a renegotiated customer contract in the U.S. market. Net sales of nuclear products decreased $17.2 million, primarily due to additional sales opportunities during fiscal 2012 that resulted from challenges a competitor faced in supplying the market.

Net sales for Global Medical Imaging by geography are as follows (dollars in millions):

	Fiscal Year		
	2013	2012	Percentage Change
U.S.	$418.2	$466.8	(10.4)%
Europe, Middle East and Africa	300.2	302.3	(0.7)
Other	217.3	227.7	(4.6)
Net sales	$935.7	$996.8	(6.1)

Net sales for Global Medical Imaging by key products are as follows (dollars in millions):

	Fiscal Year		
	2013	2012	Percentage Change
Optiray	$318.5	$352.2	(9.6)%
Optimark	44.8	48.0	(6.7)
Other	134.8	141.8	(4.9)
Contrast Media and Delivery Systems	498.1	542.0	(8.1)
Ultra-Technekow DTE	188.8	202.5	(6.8)
Octreoscan	82.8	78.7	5.2
Other	166.0	173.6	(4.4)
Nuclear Imaging	437.6	454.8	(3.8)
Global Medical Imaging	$935.7	$996.8	(6.1)

Operating Income

Operating income by segment and as a percentage of segment net sales for fiscal 2013 and 2012 is shown in the following table (dollars in millions):

	Fiscal Year					
	2013			2012		
Specialty Pharmaceuticals	$311.7	25.6	%	$162.8	16.2	%
Global Medical Imaging	112.3	12.0		214.3	21.5	
Segment operating income	424.0	19.7		377.1	18.8	
Unallocated amounts:						
Corporate and allocated expenses	(133.8)			(69.9)		
Intangible asset amortization	(35.4)			(27.3)		
Restructuring and related charges, net [1]	(35.8)			(19.2)		
Separation costs	(74.2)			(25.5)		
Total operating income	$144.8			$235.2		

(1) Includes restructuring-related accelerated depreciation of $2.6 million and $8.0 million for fiscal 2013 and 2012, respectively.

Specialty Pharmaceuticals. Operating income for fiscal 2013 increased $148.9 million to $311.7 million, compared with $162.8 million for fiscal 2012. Our operating margin increased to 25.6% for fiscal 2013, compared with 16.2%

for fiscal 2012. The increase in operating income and margin was primarily due to increased sales of higher margin products, such as Methylphenidate ER and Exalgo, and favorable pricing.

Global Medical Imaging. Operating income for fiscal 2013 decreased $102.0 million to $112.3 million, compared with $214.3 million for fiscal 2012. Our operating margin decreased to 12.0% for fiscal 2013, compared with 21.5% for fiscal 2012. The decrease in operating income was attributable to lower net sales, discussed previously, increased manufacturing and raw material costs and the effects of a renegotiated customer contract in the U.S., partially offset by a decrease in selling, general and administrative expenses. Our operating margin was most significantly impacted by higher raw material costs from the unscheduled shutdown of the HFR that supplies us with Mo-99. Ongoing increased materials and manufacturing costs will limit our ability to return the Global Medical Imaging segment to historical operating margins on a long-term basis.

Corporate and allocated expenses. Corporate and allocated expenses were $133.8 million and $69.9 million for fiscal 2013 and 2012, respectively. The increase primarily resulted from $70.6 million of costs related to the build-out of our corporate infrastructure during the current year period compared with $10.7 million during the prior year period. In addition to corporate infrastructure build-out costs, we were allocated general corporate expenses of $39.6 million and $49.2 million during fiscal 2013 and 2012, respectively, for certain functions provided by Covidien. These allocations ceased in periods following the completion of the Separation on June 28, 2013.

Fiscal Year Ended September 28, 2012 Compared with Fiscal Year Ended September 30, 2011

Net Sales

Net sales by segment are shown in the following table (dollars in millions):

	Fiscal Year			
	2012	2011	Percentage Change	
Specialty Pharmaceuticals	$1,005.2	$909.4	10.5	%
Global Medical Imaging	996.8	1,060.0	(6.0	)
Net sales of operating segments	2,002.0	1,969.4	1.7	
Other [(1)]	54.2	52.4	3.4	
Net sales	$2,056.2	$2,021.8	1.7	

(1) Represents products that were sold to Covidien.

Specialty Pharmaceuticals. Net sales for fiscal 2012 increased $95.8 million, or 10.5%, to $1,005.2 million, compared with $909.4 million for fiscal 2011. The increase in net sales was primarily driven by increased sales of our Exalgo and Pennsaid branded products. This increase was partially offset by the impact of the extra selling week in fiscal 2011 and a decrease in net sales of oxycodone immediate-release tablets.

Net sales for Specialty Pharmaceuticals by geography are as follows (dollars in millions):

	Fiscal Year			
	2012	2011	Percentage Change	
U.S.	$880.6	$784.8	12.2	%
Europe, Middle East and Africa	108.7	93.4	16.4	
Other	15.9	31.2	(49.0	)
Net sales	$1,005.2	$909.4	10.5	

Net sales for Specialty Pharmaceuticals by key products are as follows (dollars in millions):

	Fiscal Year			
	2012	2011	Percentage Change	
Acetaminophen (API) products	$217.7	$222.2	(2.0	)%
Oxycodone (API) and oxycodone-containing tablets	144.1	154.1	(6.5	)
Hydrocodone (API) and hydrocodone-containing tablets	130.5	116.9	11.6	
Other controlled substances	111.7	107.9	3.5	
Other	244.8	223.6	9.5	
Generics and API	848.8	824.7	2.9	
Exalgo	91.9	41.2	123.1	
Other	64.5	43.5	48.3	
Brands	156.4	84.7	84.7	
Specialty Pharmaceuticals	$1,005.2	$909.4	10.5	

Global Medical Imaging. Net sales for fiscal 2012 decreased $63.2 million, or 6.0%, to $996.8 million compared with $1,060.0 million for fiscal 2011. This decrease was largely due to decreased net sales of CMDS, primarily resulting from lower net sales of Optiray due to the renegotiation of a customer contract in the U.S. market and discontinuance of a product, combined with unfavorable currency exchange rate fluctuations and other market-related challenges. In addition, fiscal 2012 net sales growth was negatively impacted by the extra selling week in fiscal 2011.

Net sales for Global Medical Imaging by geography are as follows (dollars in millions):

	Fiscal Year			
	2012	2011	Percentage Change	
U.S.	$466.8	$505.8	(7.7	)%
Europe, Middle East and Africa	302.3	326.3	(7.4	)
Other	227.7	227.9	(0.1	)
Net sales	$996.8	$1,060.0	(6.0	)

Net sales for Global Medical Imaging by key products are as follows (dollars in millions):

	Fiscal Year			
	2012	2011	Percentage Change	
Optiray	$352.2	$374.9	(6.1	)%
Optimark	48.0	50.3	(4.6	)
Other	141.8	170.3	(16.7	)
Contrast Media and Delivery Systems	542.0	595.5	(9.0	)
Ultra-Technekow DTE	202.5	200.3	1.1	
Octreoscan	78.7	76.9	2.3	
Other	173.6	187.3	(7.3	)
Nuclear Imaging	454.8	464.5	(2.1	)
Global Medical Imaging	$996.8	$1,060.0	(6.0	)

Operating Income

Operating income by segment and as a percentage of segment net sales for fiscal 2012 and 2011 is shown in the following table (dollars in millions):

	Fiscal Year					
	2012			2011		
Specialty Pharmaceuticals	$162.8	16.2	%	$121.5	13.4	%
Global Medical Imaging	214.3	21.5		232.4	21.9	
Segment operating income	377.1	18.8		353.9	18.0	
Unallocated amounts:						
Corporate and allocated expenses	(69.9)			(73.3)		
Intangible asset amortization	(27.3)			(27.0)		
Restructuring and related charges, net [(1)]	(19.2)			(10.0)		
Separation costs	(25.5)			(2.9)		
Total operating income	$235.2			$240.7		

(1) Includes restructuring-related accelerated depreciation of $8.0 million and $1.6 million for fiscal 2012 and 2011, respectively.

Specialty Pharmaceuticals. Operating income for fiscal 2012 increased $41.3 million to $162.8 million, compared with $121.5 million for fiscal 2011. Our operating margin increased to 16.2% for fiscal 2012, compared with 13.4% for fiscal 2011. The increase in operating income and margin was primarily due to favorable product mix resulting from increased net sales of our higher margin branded products.

Global Medical Imaging. Operating income for fiscal 2012 decreased $18.1 million to $214.3 million, compared with $232.4 million for fiscal 2011. Our operating margin decreased to 21.5% for fiscal 2012, compared with 21.9% for fiscal 2011. The decrease in operating income and margin was primarily due to lower pricing and volume from renegotiated contracts with certain customer groups, which resulted in a switch to a dual source contract from a single source contract.

Corporate and allocated expenses. Corporate and allocated expenses were $69.9 million and $73.3 million for fiscal 2012 and 2011, respectively. These amounts include allocations of $49.2 million and $56.3 million during fiscal 2012 and 2011, respectively, for certain functions provided by Covidien. Excluding the $7.1 million decrease in the amount of allocated expenses, the remaining $3.7 million increase in corporate expenses in fiscal 2012, compared with fiscal 2011, primarily resulted from $10.7 million of costs incurred to build-out our corporate infrastructure, partially offset by lower environmental and asbestos-related costs.

Liquidity and Capital Resources

Significant factors driving our liquidity position include cash flows generated from operating activities, financing transactions, capital expenditures and cash paid in connection with acquisitions and license agreements. Historically, we have typically generated, and expect to continue to generate, positive cash flow from operations. Through June 28, 2013, as part of Covidien, our cash was swept regularly by Covidien at its discretion. Covidien also funded our operating and investing activities as needed prior to the Separation. The cash and cash equivalents held by Covidien at the corporate level were not specifically identifiable or otherwise allocable to us and, as such, were not reflected on the combined balance sheets for dates prior to June 28, 2013. Cash flows related to financing activities prior to the Separation reflect changes in Covidien's investments in us. Transfers of cash to and from Covidien were reflected as a component of parent company investment within parent company equity on our combined balance sheets through June 28, 2013. Our cash flows for periods prior to June 28, 2013, may not be indicative of our future performance and do not necessarily represent the cash flows that would have been generated had we operated as an independent, publicly-traded company for the entirety of the periods presented.

Effective June 28, 2013, we are no longer participating in cash management and funding arrangements with Covidien and our ability to fund our capital needs is impacted by our ongoing ability to generate cash from operations and access to capital markets. We believe that our future cash from operations, borrowing capacity under our revolving credit facility and access to capital markets will provide adequate resources to fund our working capital needs, capital expenditures and strategic investments.

In fiscal 2014, we expect our total capital expenditures to be in the range of $140 million to $160 million. While we intend to fund these capital expenditures with cash generated from operations, we also have $250 million of borrowing capacity under a revolving credit facility. At September 27, 2013, we had capital expenditure commitments of $6.9 million.

A summary of our cash flows from operating, investing and financing activities is provided in the following table (dollars in millions):

	Fiscal Year		
	2013	2012	2011
Net cash provided by (used in):			
Operating activities	$135.9	$255.8	$370.2
Investing activities	(234.7)	(152.2)	(112.6)
Financing activities	373.0	(103.6)	(257.6)
Effect of currency exchange rate changes on cash and cash equivalents	1.3	—	—
Net increase in cash and cash equivalents	$275.5	$—	$—

Operating Activities

Net cash provided by operating activities of $135.9 million for fiscal 2013 was primarily attributable to income from continuing operations, as adjusted for non-cash items, partially offset by a $79.0 million outflow from net investment in working capital. The working capital outflow was primarily driven by a $181.2 million increase in accounts receivable and a $16.0 million outflow in other working capital accounts, partially offset by a $60.7 million increase in income taxes payable, which was substantially settled through parent company investment, a $27.7 million decrease in inventory and a $22.6 million increase in accrued and other liabilities. The increase in accounts receivable was primarily attributable to the fact that $95.6 million of accounts receivable in certain jurisdictions outside the U.S. were retained by Covidien through parent company investment, which is included within the financing section of the consolidated and combined statement of cash flows.

Net cash provided by operating activities of $255.8 million for fiscal 2012 was primarily attributable to income from continuing operations, as adjusted for depreciation and amortization, partially offset by a $25.4 million outflow from net investments in working capital. The working capital outflow was primarily driven by a $62.8 million increase in inventory and a $38.7 million decrease in accrued and other liabilities, partially offset by a $79.4 million increase in income taxes payable, the latter of which was recorded in parent company investment. A build-up of inventory in advance of a planned plant closure contributed to the increase in inventory, while environmental payments contributed to the decrease in accrued and other liabilities.

Net cash provided by operating activities of $370.2 million in fiscal 2011 was primarily attributable to income from continuing operations, as adjusted for depreciation and amortization, deferred income taxes and an increase in working capital of $58.1 million. The increase in working capital was primarily driven by a $36.0 million increase in income taxes payable, which was recorded in parent company investment.

Investing Activities

Net cash used in investing activities increased $82.5 million to $234.7 million for fiscal 2013, compared with $152.2 million for fiscal 2012. This increase primarily resulted from an $88.1 million payment made during fiscal 2013 to acquire CNS Therapeutics and a $3.7 million increase in capital expenditures. These increases were partially offset by a $13.2 million payment in fiscal 2012 to acquire rights to Roxicodone.

Net cash used in investing activities increased $39.6 million to $152.2 million in fiscal 2012, compared with $112.6 million in fiscal 2011. This increase primarily resulted from a $23.8 million increase in capital expenditures and a $13.2 million payment made in fiscal 2012 to acquire rights to Roxicodone.

Financing Activities

Net cash provided by financing activities was $373.0 million for fiscal 2013, compared with net cash used in financing activities of $103.6 million for fiscal 2012. The $476.6 million increase in cash provided by financing activities resulted from the receipt of $886.1 million of cash proceeds from the issuance of debt, net of debt financing costs, partially offset by a $411.9 million increase in net transfers to Covidien. This increase was attributable to remitting the net proceeds from the issuance of debt partially offset by the initial cash capitalization, funding of higher

capital expenditures and funding of the CNS Therapeutics acquisition.

Net cash used in financing activities decreased $154.0 million to $103.6 million in fiscal 2012, compared with $257.6 million in fiscal 2011. This resulted from a decrease in net transfers to Covidien. Net transfers to Covidien were lower in fiscal 2012 due to a decrease in operating cash flow and an increase in capital expenditures.

Inflation

Inflationary pressures have had an adverse effect on us through higher raw material and fuel costs, primarily in our Global Medical Imaging segment as noted previously. We have entered into commodity swap contracts in the past to mitigate the impact of rising prices and may do so in the future. If these contracts are not effective or we are not able to achieve price increases on our products, we may continue to be impacted by these increased costs.

Foreign Currency

Certain net sales and costs of our international operations are denominated in the local currency of the respective countries. As such, profits from these subsidiaries may be impacted by fluctuations in the value of these local currencies relative to the U.S. dollar. We also have significant intercompany financing arrangements that may result in gains and losses in our results of operations. In an effort to mitigate the impact of currency exchange rate effects we may hedge certain operational and intercompany transactions; however, our hedging strategies may not fully offset gains and losses recognized in our results of operations.

Concentration of Credit and Other Risks

Financial instruments that potentially subject us to concentrations of credit risk primarily consist of accounts receivable. We generally do not require collateral from customers. A portion of our accounts receivable outside the U.S. includes sales to government-owned or supported healthcare systems in several countries, which are subject to payment delays. Payment is dependent upon the financial stability and creditworthiness of those countries' national economies. Deteriorating credit and economic conditions in parts of Western Europe, particularly in Spain and Italy, may continue to increase the average length of time it takes us to collect our accounts receivables in certain regions within these countries.

We routinely evaluate all government receivables for potential collection risks associated with the availability of government funding and reimbursement practices. We have not incurred any significant losses on government receivables; however, if the financial condition of customers or the countries' healthcare systems continue to deteriorate such that their ability to make payments is uncertain, additional allowances may be required in future periods.

For further information on these and other concentration risks, refer to Note 20 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.

Debt and Capitalization

At September 27, 2013, total debt was $919.8 million compared with total debt at September 28, 2012 of $10.2 million, both of which were directly incurred with third parties as Covidien's debt had not been allocated to us in historical periods.

In March 2013, Mallinckrodt International Finance S.A. ("MIFSA") entered into a $250 million five-year senior unsecured revolving credit facility that matures in June 2018 ("the Credit Facility"). Borrowings under the Credit Facility will initially bear interest at LIBOR plus 1.50% per annum (subject to adjustment pursuant to a ratings-based pricing grid). The Credit Facility contains a $150 million letter of credit sublimit. The Credit Facility is subject to an initial annual facility fee of 0.25%, which is also subject to adjustment pursuant to a ratings-based pricing grid, and the fee applied to outstanding letters of credit is based on the interest rate applied to borrowings. The Credit Facility agreement contains customary affirmative and negative covenants, including a financial maintenance covenant that limits our ratio of debt to earnings before interest, income taxes, depreciation and amortization, as adjusted for certain items, and another financial maintenance covenant that requires our ratio of earnings before interest, income taxes, depreciation and amortization, as adjusted for certain items, to interest expense to exceed certain thresholds. Other nonfinancial covenants restrict, among other things, our ability to create liens, the ability of non-guarantor subsidiaries to incur additional indebtedness and our ability to merge or consolidate with any other person or sell or convey certain

of our assets to any one person. MIFSA was not permitted to draw upon the Credit Facility until certain conditions were met, including completion of the Separation and Mallinckrodt plc's guaranty of MIFSA's obligations under the Credit Facility. These conditions were satisfied as of June 28, 2013; however, there were no borrowings or letters of credit outstanding under the Credit Facility as of September 27, 2013.

In April 2013, MIFSA issued $300 million aggregate principal amount of 3.50% senior unsecured notes due April 2018 and $600 million aggregate principal amount of 4.75% senior unsecured notes due April 2023 (collectively, "the Notes"). Mallinckrodt plc has fully and unconditionally guaranteed the Notes on an unsecured and unsubordinated basis as of the completion of the Separation. The Notes are subject to an indenture which contains covenants limiting the ability of MIFSA, its restricted subsidiaries (as defined in the Notes) and Mallinckrodt plc, as guarantor, to incur certain liens or enter into sale and lease-back transactions. It also restricts Mallinckrodt plc and MIFSA's ability to merge or consolidate with any other person or sell or convey all or substantially all of their assets to any one person. MIFSA may redeem all of the Notes at any time, and some of the Notes from time to time, at a redemption price equal to the principal amount of the Notes redeemed plus a make-whole premium. MIFSA will pay interest on the Notes semiannually in arrears on April 15 and October 15 of each year, commencing on October 15, 2013. The net proceeds to MIFSA from the issuance and sale of the Notes was $889.3 million, the majority of which was retained by Covidien per the terms of the separation and distribution agreement entered into with Covidien on June 28, 2013 ("the Separation and Distribution Agreement"). The Notes were issued and sold in a private placement; however, MIFSA is required to register the Notes with the U.S. Securities and Exchange Commission ("SEC") within one year of the issuance of the Notes.

Debt Covenants

As of September 27, 2013, we were, and expect to remain, in compliance with the provisions and covenants associated with our Credit Agreement, the Notes and our other debt agreements.

Capitalization

The cash capitalization at June 28, 2013 was subject to adjustment to compensate either Mallinckrodt or Covidien, as applicable, to the extent that the aggregate of our cash, indebtedness and specified working capital accounts as of the distribution date, as well as capital expenditures made with respect to our business during fiscal 2013 through the distribution date, deviated from a target. The adjustment payment would only be payable if the amount of the adjustment payment exceeded $20 million (in which case the entire amount would be paid). Upon final calculation, no adjustment payment was required by either us or Covidien.

Dividends

We currently do not anticipate paying any cash dividends for the foreseeable future, as we intend to retain any earnings to finance R&D, acquisitions and the operation and expansion of our business. The recommendation, declaration and payment of any dividends in the future by us will be subject to the sole discretion of our board of directors and will depend upon many factors, including our financial condition, earnings, capital requirements of our operating subsidiaries, covenants associated with certain of our debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by our board of directors. Moreover, if we determine to pay any dividends in the future, there can be no assurance that we will continue to pay such dividends.

Commitments and Contingencies

Contractual Obligations

The following table summarizes our contractual obligations as of September 27, 2013 (in millions):

	Payments Due By Period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Long-term debt obligations [1]	$1,270.8	$40.7	$81.2	$381.2	$767.7
Capital lease obligations [1]	3.4	1.5	1.9	—	—
Operating lease obligations	66.7	19.3	23.7	13.5	10.2
Purchase obligations [2]	120.9	74.9	46.0	—	—
Total contractual obligations	$1,461.8	$136.4	$152.8	$394.7	$777.9

(1) Interest on debt and capital lease obligations are projected for future periods using interest rates in effect as of September 27, 2013. Certain of these projected interest payments may differ in the future based on changes in market interest rates.

(2) Purchase obligations consist of commitments for purchases of goods and services made in the normal course of business to meet operational and capital requirements.

The preceding table does not include other liabilities of $472.4 million, primarily consisting of obligations under our pension and postretirement benefit plans, unrecognized tax benefits for uncertain tax positions and related accrued interest and penalties, environmental liabilities and asset retirement obligations, because the timing of their future cash outflow is uncertain. The most significant of these liabilities are discussed below.

Income taxes payable is included within other income tax liabilities on the consolidated and combined balances sheets and, as of September 27, 2013, was $153.1 million. Payment of these liabilities is uncertain and, even if payments are determined to be necessary, they are subject to the timing of rulings by the Internal Revenue Service of tax positions we take. For further information on income tax related matters, refer to Note 7 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.

As of September 27, 2013, we had net unfunded pension and postretirement benefit obligations of $45.7 million and $53.2 million, respectively. While the timing and amounts of long-term funding requirements for pension and postretirement obligations are uncertain, we do not anticipate making material contributions to our pension and postretirement benefit plans during fiscal 2014.

We are involved in various stages of investigation and cleanup related to environmental remediation matters at a number of sites. These projects relate to a variety of activities, including decontamination and decommissioning of radioactive materials and removal of solvents, metals and other hazardous substances from soil and groundwater. The ultimate cost of cleanup and timing of future cash outlays is difficult to predict given uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations and alternative cleanup methods. As of September 27, 2013, we believe that it is probable that we will incur investigation and remedial costs of approximately $46.4 million, of which $6.9 million is included in accrued and other current liabilities on our consolidated balance sheet at September 27, 2013. Note 18 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 provides additional information regarding environmental matters, including asset retirement obligations.

Legal Proceedings

We are subject to various legal proceedings and claims, including patent infringement claims, product liability matters, environmental matters, employment disputes, contractual disputes and other commercial disputes, including those described in Item 3. Legal Proceedings of this Annual Report on Form 10-K. We believe that these legal proceedings and claims likely will be resolved over an extended period of time. Although it is not feasible to predict the outcome of these matters, management believes that their ultimate resolution will not have a material adverse effect on our financial condition, results of operations and cash flows.

Guarantees

In disposing of assets or businesses, we have historically provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to the assets, environmental risks involved in the sale of real estate, liability to investigate and remediate environmental contamination at waste disposal sites and manufacturing facilities, and unidentified tax liabilities related to periods prior to disposition. The Company assesses the probability of potential liabilities related to such representations, warranties and indemnities and adjusts potential liabilities as a result of changes in facts and circumstances. The Company has no reason to believe that these uncertainties would have a material adverse effect on its financial condition, results of operations and cash flows.

In connection with the sale of the Specialty Chemicals business (formerly known as Mallinckrodt Baker) in fiscal 2010, we agreed to indemnify the purchaser with respect to various matters, including certain environmental, health, safety, tax and other matters. The indemnification obligations relating to certain environmental, health and safety matters have a term of 17 years from the sale, while some of the other indemnification obligations have an indefinite term. The amount of the liability relating to all of these indemnification obligations included in other liabilities on our consolidated balance sheet at September 27, 2013 was $20.1 million, of which $17.2 million related to environmental, health and safety matters. The value of the environmental, health and safety indemnity was measured based on the

probability-weighted present value of the costs expected to be incurred to address environmental, health and safety claims made under the indemnity. The aggregate fair value of these indemnification obligations did not differ significantly from their aggregate carrying value at September 27, 2013. As of September 27, 2013, the maximum future payments we could be required to make under these indemnification obligations was $75.5 million. We were required to pay $30.0 million into an escrow account as collateral to the purchaser, of which $23.5 million remained in other assets on the consolidated balance sheet at September 27, 2013.

We have recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 18 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. In addition, we are liable for product performance; however, in the opinion of management, such obligations will not have a material adverse effect on our financial condition, results of operations and cash flows.

Off-Balance Sheet Arrangements

We are required to provide the U.S. Nuclear Regulatory Commission financial assurance demonstrating our ability to fund the decommissioning of our Maryland Heights, Missouri radiopharmaceuticals production facility upon closure, though we do not intend to close this facility. We have provided this financial assurance in the form of a $58.0 million surety bond.

In addition, as of September 27, 2013, we had a $21.1 million letter of credit to guarantee decommissioning costs associated with our Saint Louis, Missouri plant. As of September 27, 2013, we had various other letters of credit and guarantee and surety bonds totaling $38.1 million.

We exchanged title to $11.3 million of our plant assets in return for an equal amount of Industrial Revenue Bonds ("IRB") issued by Saint Louis County. We also simultaneously leased such assets back from Saint Louis County under a capital lease expiring December 2022, the terms of which provide us with the right of offset against the IRBs. The lease also provides an option for us to repurchase the assets at the end of the lease for nominal consideration. These transactions collectively result in a property tax abatement ten years from the date the property is placed in service. Due to right of offset, the capital lease obligation and IRB asset are recorded net in the consolidated and combined balance sheets. The Company expects that the right of offset will be applied to payments required under these arrangements.

In addition, the Separation and Distribution Agreement provides for cross-indemnities principally designed to place financial responsibility of the obligations and liabilities of our business with us and financial responsibility for the obligations and liabilities of Covidien's remaining business with Covidien, among other indemnities.

Critical Accounting Policies and Estimates

The consolidated and combined financial statements have been prepared in U.S. dollars and in accordance with accounting principles generally accepted in the U.S. ("GAAP"). The preparation of the consolidated and combined financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses. The following accounting policies are based on, among other things, judgments and assumptions made by management that include inherent risks and uncertainties. Management's estimates are based on the relevant information available at the end of each period.

Revenue Recognition

We recognize revenue for product sales when title and risk of loss have transferred from us to the buyer, which may be upon shipment or upon delivery to the customer site, based on contract terms or legal requirements in non-U.S. jurisdictions. We sell products direct to retail pharmacies and end user customers and through distributors who resell the products to retail pharmacies, institutions and end user customers. We establish contracts with wholesalers, chain stores, government agencies, institutions, managed care organizations and group purchasing organizations that provide for rebates, sales incentives, distribution service agreements ("DSAs") fees, fees for services and administration fees. Direct rebates and fees are paid based on direct customer's purchases from us, including DSA fees paid to wholesalers under our DSAs. Indirect rebates and fees are paid based on products purchased from a wholesaler under a contract with us. 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 enter into agreements with wholesalers at a contract price to offer our products 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.

When we recognize net sales, we simultaneously record an adjustment to revenue for estimated chargebacks, rebates, product returns and other sales deductions. These provisions are estimated based upon historical experience, estimated future trends, estimated customer inventory levels, current contracted sales terms with customers, level of utilization

of our products and other competitive factors. We adjust reserves for rebates and chargebacks, product returns and other sales deductions to reflect differences between estimated and actual experience. Such adjustments impact the amount of sales we recognize in the period of adjustment.

Sales return reserves for new products are estimated and primarily based on our historical sales return experience with similar products, such as those within the same product line or those within the same or similar therapeutic category. In limited circumstances, where the new product is not an extension of an existing product line or where we have no historical experience with products in a similar therapeutic category (such that we cannot reliably estimate expected returns), we would defer recognition of revenue until the right of return no longer exists or until we have developed sufficient historical experience to estimate sales returns. When establishing sales return reserves for new products, we also consider estimated levels of inventory in the distribution channel and projected demand. The following table reflects activity in our sales reserve accounts (dollars in millions):

	Rebates and Chargebacks	Product Returns	Other Sales Deductions	Total
Balance at September 24, 2010	$205.3	$32.5	$11.9	$249.7
Provisions	1,218.8	40.5	47.1	1,306.4
Payments or credits	(1,200.1)	(39.1)	(45.7)	(1,284.9)
Balance at September 30, 2011	224.0	33.9	13.3	271.2
Provisions	1,085.9	30.0	41.9	1,157.8
Payments or credits	(1,077.7)	(29.2)	(42.3)	(1,149.2)
Balance at September 28, 2012	232.2	34.7	12.9	279.8
Provisions	1,219.8	37.1	60.0	1,316.9
Payments or credits	(1,194.9)	(21.7)	(57.2)	(1,273.8)
Balance at September 27, 2013	$257.1	$50.1	$15.7	$322.9

Inventory

Inventories are recorded at the lower of cost or market value, primarily using the first-in, first-out convention. We reduce the carrying value of inventories for those items that are potentially excess, obsolete or slow-moving based on changes in customer demand, technology developments or other economic factors. If market conditions and actual demands are less favorable than projected, additional inventory write-downs may be required.

Goodwill and Other Intangible Assets

In performing goodwill assessments, management relies on a number of factors including operating results, business plans, economic projections, anticipated future cash flows, and transactions and market place data. There are inherent uncertainties related to these factors and judgment in applying them to the analysis of goodwill impairment. Since judgment is involved in performing goodwill valuation analyses, there is risk that the carrying value of our goodwill may be overstated or understated. We calculate our goodwill valuations using an income approach based on the present value of future cash flows of each reporting unit. This approach incorporates many assumptions including future growth rates, discount factors and income tax rates. Changes in economic and operating conditions impacting these assumptions could result in goodwill impairment in future periods.

We test goodwill during the fourth quarter of each year for impairment, or more frequently if certain indicators are present or changes in circumstances suggest that impairment may exist. We utilize a two-step approach. The first step requires a comparison of the carrying value of the reporting units to the fair value of these units. We estimate the fair value of our reporting units through internal analyses and valuation, using an income approach based on the present value of future cash flows. If the carrying value of a reporting unit exceeds its fair value, we will perform the second step of the goodwill impairment to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compares the implied fair value of a reporting unit's goodwill with its carrying value. To determine the implied fair value of goodwill, we allocate the fair value of a reporting unit to all of the assets and liabilities of that unit, including intangible assets, as if the reporting unit had been acquired in a business combination. Any excess of the value of a reporting unit over the amounts assigned to its assets and liabilities represents the implied fair value of goodwill. The results of our annual goodwill impairment test for fiscal 2013 showed that the fair value of each of our reporting units exceeded their respective carrying values.

Intangible assets include completed technology, licenses, trademarks and in-process research and development. We record intangible assets at cost and amortize finite-lived intangible assets using the straight-line method over five to thirty years. When a triggering event occurs, we evaluate potential impairment of finite-lived intangible assets by first comparing undiscounted cash flows associated with the asset to its carrying value. If the carrying value is greater than the undiscounted cash flows, the amount of potential impairment is measured by comparing the fair value of the assets with their carrying value. The fair value of the intangible asset is estimated using an income approach. If the fair value is less than the carrying value of the intangible asset, the amount recognized for impairment is equal to the difference between the carrying value of the asset and the present value of future cash flows. In the fourth quarter of each year, we test the indefinite-lived intangible assets for impairment by comparing the fair value of the assets, estimated using an income approach, with their carrying value and record an impairment when the carrying value exceeds the fair value. We

assess the remaining useful life and the recoverability of finite-lived intangible assets whenever events or circumstances indicate that the carrying value of an asset may not be recoverable.

Contingencies

We are involved, both as a plaintiff and a defendant, in various legal proceedings that arise in the ordinary course of business, including, without limitation, patent infringement, product liability and environmental matters, as further discussed in Item 3. Legal Proceedings included within this Annual Report on form 10-K. Accruals recorded for various contingencies, including legal proceedings, self-insurance and other claims, are based on judgment, the probability of losses and, where applicable, the consideration of opinions of internal and/or external legal counsel, internal and/or external technical consultants and actuarially determined estimates. When a range is established but a best estimate cannot be made, we record the minimum loss contingency amount. These estimates are often initially developed substantially earlier than the ultimate loss is known, and the estimates are reevaluated each accounting period as additional information becomes available. When we are initially unable to develop a best estimate of loss, we record the minimum amount of loss, which could be zero. As information becomes known, additional loss provision is recorded when either a best estimate can be made or the minimum loss amount is increased. When events result in an expectation of a more favorable outcome than previously expected, our best estimate is changed to a lower amount. We record receivables from third-party insurers up to the amount of the related liability when we have determined that existing insurance policies will provide reimbursement. In making this determination, we consider applicable deductibles, policy limits and the historical payment experience of the insurance carriers. Receivables are not netted against the related liabilities for financial statement presentation.

Pension and Postretirement Benefits

Our pension expense and obligations are developed from actuarial valuations. Two critical assumptions in determining pension expense and obligations are the discount rate and expected long-term return on plan assets. We evaluate these assumptions at least annually. Other assumptions reflect demographic factors such as retirement, mortality and turnover and are evaluated periodically and updated to reflect our actual experience. Actual results may differ from actuarial assumptions. The discount rate is used to calculate the present value of the expected future cash flows for benefit obligations under our pension plans. For our U.S. plans, we use a broad population of Moody's AA-rated corporate bonds to determine the discount rate assumption. All bonds are non-callable, denominated in U.S. dollars and have a minimum amount outstanding of $250 million. This population of bonds was used to generate a yield curve and associated spot rate curve, to discount the projected benefit payments for the U.S. plans. The discount rate is the single level rate that produces the same result as the spot rate curve. For our non-U.S. plans, the discount rate is generally determined by reviewing country- and region-specific government and corporate bond interest rates. A decrease in the discount rate increases the present value of pension benefit obligations and increases pension expense. A 50 basis point decrease in the discount rate would increase our present value of pension obligations by approximately $29.8 million.

We consider the current and expected asset allocations of our pension plans, as well as historical and expected long-term rates of return on those types of plan assets, in determining the expected long-term return on plan assets. In determining the expected return on pension plan assets, we consider the relative weighting of plan assets by class and individual asset class performance expectations as provided by external advisors in reaching our conclusions on appropriate assumptions. Our overall investment objective is to obtain a long-term return on plan assets that is consistent with the level of investment risk that is considered appropriate. Investment risks and returns are reviewed regularly against benchmarks to ensure objectives are being met. A 50 basis point decrease in the expected long-term return on plan assets would increase our annual pension expense by approximately $2.2 million.

Share-Based Compensation

Share-based compensation cost is measured at the grant or modification date based on the value of the award and is recognized as expense over the vesting period for awards expected to vest. Determining the fair value of share-based

awards at the grant date requires judgment, including estimating the expected term, expected stock price volatility, risk-free interest rate and expected dividends. Additionally, judgment is required in estimating the amount of share-based awards that are expected to be forfeited before vesting. The original estimate of the grant date fair value is not subsequently revised unless the awards are modified, but the estimate of expected forfeitures is revised throughout the vesting period and the cumulative share-based compensation cost recognized is adjusted accordingly. For more information about our share-based awards, refer to Note 14 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.

Income Taxes

In determining income for financial statement purposes, we must make certain estimates and judgments. These estimates and judgments affect the calculation of certain tax liabilities and the determination of the recoverability of certain of the deferred tax assets, which arise from temporary differences between the tax and financial statement recognition of revenue and expense.

Deferred tax assets are reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. In evaluating our ability to recover our deferred tax assets, we consider all available positive and negative evidence including our past operating results, the existence of cumulative losses in the most recent years and our forecast of future taxable income. In estimating future taxable income, we develop assumptions including the amount of future state, federal and international pre-tax operating income, the reversal of temporary differences, and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates we use to manage the underlying businesses.

We determine whether it is more likely than not that a tax position will be sustained upon examination. The tax benefit of any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the uncertainty. To the extent a full benefit is not realized on the uncertain tax position, an income tax liability is established. We adjust these liabilities as a result of changing facts and circumstances; however, due to the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the tax liabilities. A significant portion of our potential tax liabilities are recorded in non-current income taxes payable, which is included in other liabilities on our consolidated and combined balance sheets, as payment is not expected within one year.

The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax regulations in a multitude of jurisdictions across our global operations. Changes in tax laws and rates could affect recorded deferred tax assets and liabilities in the future. Management is not aware of any such changes, however, which would have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We believe that we will generate sufficient future taxable income in the appropriate jurisdictions to realize the tax benefits related to the net deferred tax assets on our consolidated and combined balance sheets. However, any reduction in future taxable income, including any future restructuring activities, may require that we record an additional valuation allowance against our deferred tax assets. An increase in the valuation allowance would result in additional income tax expense in such period and could have a significant impact on our future earnings. Our income tax expense recorded in the future may also be reduced to the extent of decreases in our valuation allowances.

Recently Issued Accounting Standards

Refer to Note 3 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 for a discussion regarding recently issued accounting standards and their estimated impact on our financial condition, results of operations and cash flows.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Our operations include activities in the U.S. and countries outside of the U.S. These operations expose us to a variety of market risks, including the effects of changes in interest rates and currency exchange rates. We monitor and manage these financial exposures as an integral part of our overall risk management program. We do not utilize derivative instruments for trading or speculative purposes.

Interest Rate Risk

As of September 27, 2013, our outstanding debt consisted primarily of our fixed-rate 3.50% and 4.75% senior unsecured notes due in April 2018 and April 2023, respectively, with a combined principal amount of $900 million. The carrying value of these notes was $898.1 million as of September 27, 2013. As these notes are fixed-rate debt,

they do not subject us to interest rate risk.

In addition, we maintain a $250 million five-year senior unsecured revolving credit facility with a variable interest rate equal to LIBOR plus a margin subject to adjustment pursuant to a ratings-based pricing grid. As a result, we will be exposed to fluctuations in interest rates to the extent of our borrowings under this facility. As of September 27, 2013, there were no outstanding borrowings under this credit facility.

Currency Risk

Certain net sales and costs of our international operations are denominated in the local currency of the respective countries. As such, profits from these subsidiaries may be impacted by fluctuations in the value of these local currencies relative to the U.S. dollar. We also have significant intercompany financing arrangements that may result in gains and losses in our results of operations. In an effort to mitigate the impact of currency exchange rate effects we may hedge certain operational and intercompany transactions; however, our hedging strategies may not fully offset gains and losses recognized in our results of operations.

The consolidated statement of income is significantly exposed to currency risk from intercompany financing arrangements, which primarily consist of intercompany debt and intercompany cash pooling, where the denominated currency of the transaction differs from the functional currency of one or more of our subsidiaries. We performed a sensitivity analysis for these arrangements as of September 27, 2013 that measures the potential unfavorable impact to income from continuing operations before income taxes from a hypothetical 10% adverse movement in foreign exchange rates relative to the U.S. dollar, with all other variables held constant. The aggregate potential unfavorable impact from a hypothetical 10% adverse change in foreign exchange rates was $34.2 million as of September 27, 2013. This hypothetical loss does not reflect any hypothetical benefits that would be derived from hedging activities, including cash holdings in similar foreign currencies, that we have historically utilized to mitigate our exposure to movements in foreign exchange rates.

The financial results of our non-U.S. operations are translated into U.S. dollars, further exposing us to currency exchange rate fluctuations. We have performed a sensitivity analysis as of September 27, 2013 that measures the change in the net financial position arising from a hypothetical 10% adverse movement in the exchange rates of the Euro, the British Pound and the Canadian Dollar, our most widely used foreign currencies, relative to the U.S. dollar, with all other variables held constant. The aggregate potential change in net financial position from a hypothetical 10% adverse change in the above currencies was $47.5 million as of September 27, 2013. The change in the net financial position associated with the translation of these currencies is generally recorded as an unrealized gain or loss on foreign currency translation within accumulated other comprehensive income in shareholders' equity of our consolidated and combined balance sheets.

Item 8. Financial Statements and Supplementary Data.

INDEX TO FINANCIAL STATEMENTS

Consolidated and Combined Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Mallinckrodt plc:

We have audited the accompanying consolidated and combined balance sheets of Mallinckrodt plc and subsidiaries (the "Company") as of September 27, 2013 and September 28, 2012, and the related consolidated and combined statements of income, comprehensive income, changes in shareholders' equity, and cash flows for each of the three fiscal years in the period ended September 27, 2013. Our audits also included the financial statement schedule listed in the Index at Item 15. These consolidated and combined financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the consolidated and combined 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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 and combined financial statements present fairly, in all material respects, the financial position of Mallinckrodt plc and subsidiaries as of September 27, 2013 and September 28, 2012, and the results of their operations and their cash flows for each of the three fiscal years in the period ended September 27, 2013, 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 and combined financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 1 to the consolidated and combined financial statements, the Company’s combined financial statements for periods prior to June 28, 2013, including the nine months ended June 28, 2013 that is included within the Company’s fiscal 2013 results, may not be indicative of the Company’s future performance and do not necessarily reflect the results of operations, financial position and cash flows that would have been had it operated as an independent, publicly-traded company for the entirety of the periods presented.

/s/DELOITTE & TOUCHE LLP
St. Louis, Missouri
December 13, 2013

MALLINCKRODT PLC
CONSOLIDATED AND COMBINED STATEMENTS OF INCOME
(in millions, except per share data)

	Fiscal Year		
	2013	2012	2011
Net sales	$2,204.5	$2,056.2	$2,021.8
Cost of sales	1,179.6	1,091.4	1,106.9
Gross profit	1,024.9	964.8	914.9
Selling, general and administrative expenses	609.9	551.7	532.5
Research and development expenses	165.7	144.1	141.5
Separation costs	74.2	25.5	2.9
Restructuring charges, net	33.2	11.2	8.4
Gain on divestiture	(2.9)	(2.9)	(11.1)
Operating income	144.8	235.2	240.7
Interest expense	(19.5)	(0.5)	(0.6)
Interest income	0.3	0.4	0.2
Other income, net	0.8	1.0	2.9
Income from continuing operations before income taxes	126.4	236.1	243.2
Provision for income taxes	68.6	94.8	86.2
Income from continuing operations	57.8	141.3	157.0
Income (loss) from discontinued operations, net of income taxes	1.0	(6.7)	(6.3)
Net income	$58.8	$134.6	$150.7
Basic earnings (loss) per share (Note 8):			
Income from continuing operations	$1.00	$2.45	$2.72
Income (loss) from discontinued operations, net of income taxes	0.02	(0.12)	(0.11)
Net income	1.02	2.33	2.61
Basic weighted-average shares outstanding	57.7	57.7	57.7
Diluted earnings (loss) per share (Note 8):			
Income from continuing operations	$1.00	$2.45	$2.72
Income (loss) from discontinued operations, net of income taxes	0.02	(0.12)	(0.11)
Net income	1.02	2.33	2.61
Diluted weighted-average shares outstanding	57.8	57.7	57.7

See Notes to Consolidated and Combined Financial Statements.

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MALLINCKRODT PLC
CONSOLIDATED AND COMBINED STATEMENTS OF COMPREHENSIVE INCOME
(in millions)

	Fiscal Year		
	2013	2012	2011
Net income	$58.8	$134.6	$150.7
Other comprehensive income (loss), net of tax			
Currency translation adjustments	1.5	(2.9)	(0.5)
Unrecognized loss on derivatives, net of $-, $- and $- tax	(7.3)	—	—
Unrecognized gain (loss) on benefit plans, net of ($23.9), $4.6 and ($4.5) tax	34.2	(10.7)	12.4
Total other comprehensive income (loss), net of tax	28.4	(13.6)	11.9
Comprehensive income	$87.2	$121.0	$162.6

See Notes to Consolidated and Combined Financial Statements.

MALLINCKRODT PLC
CONSOLIDATED AND COMBINED BALANCE SHEETS
(in millions, except share data)

	September 27, 2013	September 28, 2012
Assets		
Current Assets:		
Cash and cash equivalents	$ 275.5	$ —
Accounts receivable, less allowance for doubtful accounts of $4.6 and $9.4	400.8	315.4
Inventories	403.1	435.3
Deferred income taxes	171.1	119.9
Prepaid expenses and other current assets	134.4	31.0
Total current assets	1,384.9	901.6
Property, plant and equipment, net	997.4	945.2
Goodwill	532.0	507.5
Intangible assets, net	422.1	365.6
Other assets	220.2	179.0
Total Assets	$ 3,556.6	$ 2,898.9
Liabilities and Shareholders' Equity		
Current Liabilities:		
Current maturities of long-term debt	$ 1.5	$ 1.3
Accounts payable	120.9	112.5
Accrued payroll and payroll-related costs	66.5	60.3
Accrued branded rebates	34.6	24.3
Accrued and other current liabilities	376.7	221.7
Total current liabilities	600.2	420.1
Long-term debt	918.3	8.9
Pension and postretirement benefits	108.0	189.6
Environmental liabilities	39.5	136.5
Deferred income taxes	310.1	73.7
Other income tax liabilities	153.1	19.4
Other liabilities	171.8	158.8
Total Liabilities	2,301.0	1,007.0
Commitments and contingencies (Note 18)		
Shareholders' Equity:		
Preferred shares, $0.20 par value, 500,000,000 authorized; none issued or outstanding	—	—
Ordinary shares, $0.20 par value, 500,000,000 authorized; 57,713,873 issued; 57,713,390 outstanding	11.5	—
Ordinary shares held in treasury at cost, 483	—	—
Additional paid-in capital	1,102.1	—
Retained earnings	33.5	—
Parent company investment	—	1,807.0
Accumulated other comprehensive income	108.5	84.9
Total Shareholders' Equity	1,255.6	1,891.9
Total Liabilities and Shareholders' Equity	$ 3,556.6	$ 2,898.9

See Notes to Consolidated and Combined Financial Statements.

MALLINCKRODT PLC
CONSOLIDATED AND COMBINED STATEMENTS OF CASH FLOWS
(in millions)

	Fiscal Year		
	2013	2012	2011
Cash Flows From Operating Activities:			
Net income	$58.8	$134.6	$150.7
(Income) loss from discontinued operations, net of income taxes	(1.0)	6.7	6.3
Income from continuing operations	57.8	141.3	157.0
Adjustments to reconcile net cash provided by operating activities:			
Depreciation and amortization	139.6	130.9	119.8
Share-based compensation	16.2	10.7	10.3
Deferred income taxes	(9.0)	9.0	36.4
Other non-cash items	10.3	(10.7)	(11.4)
Changes in assets and liabilities, net of the effects of acquisitions:			
Accounts receivable, net	(181.2)	(6.8)	0.7
Inventories	27.7	(62.8)	12.2
Accounts payable	7.2	(8.3)	4.6
Income taxes	60.7	79.4	36.0
Accrued and other liabilities	22.6	(38.7)	(3.5)
Other	(16.0)	11.8	8.1
Net cash provided by operating activities	135.9	255.8	370.2
Cash Flows From Investing Activities:			
Capital expenditures	(147.9)	(144.2)	(120.4)
Acquisition, net of cash acquired	(88.1)	—	—
Purchase of product rights	—	(13.2)	—
Other	1.3	5.2	7.8
Net cash (used in) investing activities	(234.7)	(152.2)	(112.6)
Cash Flows From Financing Activities:			
Issuance of external debt	898.1	—	—
Repayment of capital leases	(1.3)	(1.3)	(1.3)
Debt financing costs	(12.0)	—	—
Excess tax benefit from share-based compensation	3.4	1.7	1.8
Net transfers to parent	(515.9)	(104.0)	(258.1)
Proceeds from exercise of share options	0.6	—	—
Other	0.1	—	—
Net cash provided by (used in) financing activities	373.0	(103.6)	(257.6)
Effect of currency rate changes on cash	1.3	—	—
Net increase in cash and cash equivalents	275.5	—	—
Cash and cash equivalents at beginning of period	—	—	—
Cash and cash equivalents at end of period	$275.5	$—	$—
Supplemental Disclosures of Cash Flow Information:			
Cash paid for interest, net	$0.8	$0.6	$0.6
Cash paid for income taxes, net	15.0	4.9	11.6

See Notes to Consolidated and Combined Financial Statements.

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MALLINCKRODT PLC
CONSOLIDATED AND COMBINED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY
(in millions)

	Ordinary Shares		Additional Paid-In Capital	Retained Earnings	Contributed Surplus	Parent Company Investment	Accumulated Other Comprehensive Income	Total Shareholders' Equity
	Number	Par Value						
Balance at September 24, 2010	—	$—	$—	$—	$ —	$ 1,749.3	$ 86.6	$ 1,835.9
Net income	—	—	—	—	—	150.7	—	150.7
Currency translation adjustments	—	—	—	—	—	—	(0.5)	(0.5)
Minimum pension liability, net of tax	—	—	—	—	—	—	12.4	12.4
Net transfers to parent	—	—	—	—	—	(209.8)	—	(209.8)
Balance at September 30, 2011	—	—	—	—	—	1,690.2	98.5	1,788.7
Net income	—	—	—	—	—	134.6	—	134.6
Currency translation adjustments	—	—	—	—	—	—	(2.9)	(2.9)
Minimum pension liability, net of tax	—	—	—	—	—	—	(10.7)	(10.7)
Net transfers to parent	—	—	—	—	—	(17.8)	—	(17.8)
Balance at September 28, 2012	—	—	—	—	—	1,807.0	84.9	1,891.9
Net income	—	—	—	33.5	—	25.3	—	58.8
Currency translation adjustments	—	—	—	—	—	—	1.5	1.5
Change in derivatives, net of tax	—	—	—	—	—	—	(7.3)	(7.3)
Minimum pension liability, net of tax	—	—	—	—	—	—	34.2	34.2
Net transfers to parent	—	—	—	—	—	(515.9)	—	(515.9)
Separation related adjustments	—	—	—	—	—	(209.9)	(4.8)	(214.7)
Transfer of parent company investment to contributed surplus	—	—	—	—	1,106.5	(1,106.5)	—	—
Transfer of contributed surplus to distributable reserves	—	—	1,095.0	—	(1,095.0)	—	—	—
Share options exercised	—	—	0.6	—	—	—	—	0.6
Share-based compensation	—	—	6.5	—	—	—	—	6.5
Issuance of ordinary shares	57.7	11.5	—	—	(11.5)	—	—	—
Balance at September 27, 2013	57.7	$11.5	$1,102.1	$33.5	$ —	$—	$ 108.5	$ 1,255.6

See Notes to Consolidated and Combined Financial Statements.

MALLINCKRODT PLC
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS
(dollars in millions, expect share data and where indicated)

1. Background and Basis of Presentation

Background

Mallinckrodt plc, and its subsidiaries (collectively, "Mallinckrodt" or "the Company"), is a global company that develops, manufactures, markets and distributes both branded and generic specialty pharmaceuticals, active pharmaceutical ingredients ("API") and diagnostic imaging agents. These products are found in almost every hospital, standalone diagnostic imaging center or pharmacy in the United States ("U.S.") and the Company has a commercial presence in approximately 70 countries. The Company believes its extensive commercial reach and formulation expertise, coupled with its ability to navigate the highly regulated and technical nature of its business, have created compelling competitive advantages that it anticipates will sustain future revenue growth.

The Company conducts its 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).

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 its legal separation from Covidien ("the Separation"). On July 1, 2013, Mallinckrodt plc began regular way trading on the New York Stock Exchange under the ticker symbol "MNK."

Basis of Presentation

The accompanying consolidated and combined financial statements reflect the consolidated financial position of the Company as an independent, publicly-traded company for periods subsequent to June 28, 2013, and as a combined reporting entity of Covidien, including operations relating to Covidien's Pharmaceuticals business, for periods prior to June 28, 2013.

The consolidated and combined financial statements have been prepared in U.S. dollars and in accordance with accounting principles generally accepted in the U.S. ("GAAP"). The preparation of the consolidated and combined financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses. Actual results may differ from those estimates. The consolidated and combined financial statements include the accounts of the Company, its wholly-owned subsidiaries and entities in which they own or control more than fifty percent of the voting shares, or have the ability to control through similar rights. The results of entities disposed of are included in the consolidated and combined financial statements up to the date of disposal and, where appropriate, these operations have been reflected as discontinued operations. Divestitures of product lines not representing businesses have been reflected in operating income. All intercompany balances and transactions have been eliminated in consolidation and, in the opinion of management, all normal recurring adjustments necessary for a fair presentation have been included in the results reported.

Certain amounts from prior years have been reclassified to conform to the current year presentation. The presentation of rebate obligations for Brands products has been reclassified from a reduction to accounts receivable to accrued and other current liabilities in the consolidated and combined balance sheets.

The Company's combined financial statements for periods prior to June 28, 2013, including the nine months ended June 28, 2013 that is included within the Company's fiscal 2013 results, may not be indicative of its future performance and do not necessarily reflect the results of operations, financial position and cash flows that would have

been had it operated as an independent, publicly-traded company for the entirety of the periods presented, including as a result of changes in the Company's capitalization in connection with the Separation. The combined financial statements for periods prior to June 28, 2013 include expense allocations for certain functions provided by Covidien, including, but not limited to, general corporate expenses related to finance, legal, information technology, human resources, communications, employee benefits and incentives, insurance and share-based compensation. These expenses were allocated to the Company on the basis of direct usage when identifiable, with the remainder allocated on the basis of operating expenses, headcount or other measures. The amounts allocated were $39.6 million, $49.2 million and $56.3 million for fiscal 2013, 2012 and 2011, respectively, and were included within selling, general and administrative expenses. Management considers the bases on which the expenses have been allocated to reasonably reflect the utilization of services provided to, or the benefit received by, the Company during the periods presented; however, the allocations may not reflect the expense the Company would have incurred as an

independent, publicly-traded company. Actual costs that may have been incurred if the Company had been a standalone company would depend on a number of factors, including organizational structure, what functions were outsourced or performed by employees, and strategic decisions made in areas such as information technology and infrastructure. The Company is unable to determine what those costs would have been had the Company been independent during the applicable periods. Following the Separation, the Company has performed these functions using its own resources or purchased services, certain of which are being provided by Covidien during a transitional period pursuant to a transition services agreement dated June 28, 2013, between Mallinckrodt and Covidien, particularly in relation to areas outside the U.S. The terms and prices on which such services are rendered may not be as favorable as those that were allocated to the Company by Covidien. The Company also may incur additional costs associated with being an independent, publicly-traded company. These additional anticipated costs are not reflected in the historical combined financial statements for periods prior to June 28, 2013.

The combined balance sheets prior to June 28, 2013 include certain assets and liabilities that have historically been recorded at the Covidien corporate level but are specifically identifiable or otherwise allocable to the Company. The cash and cash equivalents held by Covidien at the corporate level were not specifically identifiable to the Company and, as such, were not allocated to the Company for periods prior to June 28, 2013. Covidien's debt and related interest expense were not allocated to the Company since the Company was not the legal obligor of such debt and Covidien's borrowings were not directly attributable to the Company's business. Debt incurred by the Company directly has been included in the combined financial statements. Intercompany transactions between the Company and Covidien, prior to the Separation, have been included in the combined financial statements and were considered to be effectively settled for cash at the time the transaction was recorded. The total net effect of the settlement of these intercompany transactions was reflected in the combined statements of cash flows as a financing activity and in the combined balance sheet as parent company investment.

Prior to June 28, 2013, Covidien's investment in the Pharmaceuticals business is shown as parent company investment in the combined financial statements. On June 28, 2013, Covidien completed a distribution of one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien. Upon completion of the Separation, the Company had 57,694,885 ordinary shares outstanding at a par value of $0.20 per share. After Separation adjustments were recorded, the remaining parent company investment balance, which included all earnings prior to the Separation, was transferred to contributed surplus.

Under Irish law, the Company can only pay dividends and repurchase shares out of distributable reserves, as discussed further in the Company's information statement filed with the U.S. Securities and Exchange Commission ("SEC") as Exhibit 99.2 to the Company's Current Report on Form 8-K filed on July 1, 2013. Upon completion of the Separation, the Company did not have any distributable reserves. On July 22, 2013, the Company filed a petition with the High Court of Ireland seeking the court's confirmation of a reduction of the Company's share premium so that it can be treated as distributable for the purposes of Irish law. On September 9, 2013, the High Court of Ireland approved this petition and the High Court's order and minutes were filed with the Registrar of Companies. Upon this filing, the Company's share premium is treated as distributable reserves and the share premium balance was reclassified into additional paid-in capital within the consolidated balance sheet. Net income subsequent to the Separation has been included in retained earnings and is included in distributable reserves.

Preferred Shares

Mallinckrodt is authorized to issue 500,000,000 preferred shares, par value of $0.20 per share, none of which were issued and outstanding at September 27, 2013. Rights as to dividends, return of capital, redemption, conversion, voting and otherwise with respect to these shares may be determined by Mallinckrodt's board of directors on or before the time of issuance. In the event of the liquidation of the Company, the holders of any preferred shares then outstanding would, if issued on such terms that they carry a preferential distribution entitlement on liquidation, be entitled to payment to them of the amount for which the preferred shares were subscribed and any unpaid dividends prior to any payment to the ordinary shareholders.

Preferred Share Purchase Rights

Pursuant to the rights agreement entered into on June 28, 2013 with Computershare Trust Company, N.A., as the Rights Agent ("the Rights Agreement"), the Company issued one preferred share purchase right (collectively, "the Rights") for each outstanding ordinary share of the Company to shareholders of record on July 9, 2013. The Rights will not be exercisable until ten days after the public announcement that a person or group has become an "Acquiring Person" by obtaining beneficial ownership of 10% or more of the outstanding ordinary shares of Mallinckrodt plc. The Rights will expire on June 28, 2014. The Rights Agreement and the Rights are discussed further in the Company's Form 8-A filed with the SEC on July 1, 2013.

Fiscal Year

The Company reports its results based on a "52-53 week" year ending on the last Friday of September. Fiscal 2013 and 2012 consisted of 52 weeks and ended on September 27, 2013 and September 28, 2012, respectively. Fiscal 2011 consisted of 53 weeks and ended on September 30, 2011. Unless otherwise indicated, fiscal 2013, 2012 and 2011 refer to the Company's fiscal years ended September 27, 2013, September 28, 2012 and September 30, 2011, respectively.

2. Summary of Significant Accounting Policies

Revenue Recognition

The Company recognizes revenue for product sales when title and risk of loss have transferred from the Company to the buyer, which may be upon shipment or upon delivery to the customer site, based on contract terms or legal requirements in non-U.S. jurisdictions. The Company sells products direct to retail pharmacies and end user customers and through distributors who resell the products to retail pharmacies, institutions and end user customers. Chargebacks and rebates represent credits that are provided to certain distributors and customers for either the difference between the Company's contracted price with a customer and the distributor's invoice price paid to the Company or for contractually agreed volume price discounts. When the Company recognizes net sales, it simultaneously records an adjustment to revenue for estimated chargebacks, rebates, product returns and other sales deductions. These provisions are estimated based upon historical experience, estimated future trends, estimated customer inventory levels, current contracted sales terms with customers, level of utilization of the Company's products and other competitive factors. The Company adjusts these reserves to reflect differences between estimated activity and actual experience. Such adjustments impact the amount of net sales recognized by the Company in the period of adjustment.

Taxes collected from customers relating to product sales and remitted to governmental authorities are accounted for on a net basis. Accordingly, such taxes are excluded from both net sales and expenses.

Shipping and Handling Costs

Shipping costs, which are costs incurred to physically move product from the Company's premises to the customer's premises, are classified as selling, general and administrative expenses. Handling costs, which are costs incurred to store, move and prepare product for shipment, are classified as cost of sales. Shipping costs included in selling, general and administrative expenses were $56.5 million, $59.1 million and $57.3 million in fiscal 2013, 2012 and 2011, respectively.

Research and Development

Internal research and development costs are expensed as incurred. Research and development expenses include salary and benefits, allocated overhead and occupancy costs, clinical trial and related clinical manufacturing costs, contract services and other costs.

Upfront and milestone payments made to third parties under license arrangements are expensed as incurred up to the point of regulatory approval of the product. Milestone payments made to third parties upon or subsequent to regulatory approval are capitalized as an intangible asset and amortized to cost of sales over the estimated useful life of the related product.

Advertising

Advertising costs are expensed when incurred. Advertising expense was $7.5 million, $8.8 million and $9.7 million in fiscal 2013, 2012 and 2011, respectively, and is included in selling, general and administrative expenses.

Currency Translation

For the Company's non-U.S. subsidiaries that transact in a functional currency other than U.S. dollars, assets and liabilities are translated into U.S. dollars using fiscal year-end exchange rates. Revenues and expenses are translated at the average exchange rates in effect during the related month. The net effect of these translation adjustments is shown in the consolidated and combined financial statements as a component of accumulated other comprehensive income. For subsidiaries operating in highly inflationary environments or where the functional currency is different from the local currency, non-monetary assets and liabilities are translated at the rate of exchange in effect on the date the assets and liabilities were acquired or assumed, while monetary assets and liabilities are translated at fiscal year-end exchange rates. Translation adjustments of these subsidiaries are included in net income. Gains and losses resulting from foreign currency transactions are included in net income. Foreign currency losses included within net income for fiscal 2013 and 2011 were $14.2 million and $4.3 million, respectively. The impact of foreign currency on net income in fiscal 2012 was immaterial.

Cash and Cash Equivalents

The Company classifies cash on hand and deposits in banks, including commercial paper, money market accounts and other investments it may hold from time to time, with an original maturity to the Company of three months or less, as cash and cash equivalents.

Accounts Receivable and Allowance for Doubtful Accounts

Trade accounts receivable are presented net of an allowance for doubtful accounts. The allowance for doubtful accounts reflects an estimate of losses inherent in the Company's accounts receivable portfolio determined on the basis of historical experience, specific allowances for known troubled accounts and other available evidence. Accounts receivable are written off when management determines they are uncollectible. Trade accounts receivable are also presented net of reserves related to chargebacks and non-branded rebates payable to customers for whom we have trade accounts receivable and the right of offset exists.

Inventories

Inventories are recorded at the lower of cost or market value, primarily using the first-in, first-out convention. The Company reduces the carrying value of inventories for those items that are potentially excess, obsolete or slow-moving based on changes in customer demand, technology developments or other economic factors.

Property, Plant and Equipment

Property, plant and equipment are stated at cost. Major renewals and improvements are capitalized, while routine maintenance and repairs are expensed as incurred. Depreciation for property, plant and equipment assets, other than land and construction in process, is based upon the following estimated useful lives, using the straight-line method:

Buildings	10	to	50 years
Leasehold improvements	2	to	14 years
Capitalized software	1	to	14 years
Machinery and equipment	3	to	20 years

The Company capitalizes certain computer software and development costs incurred in connection with developing or obtaining software for internal use.

Upon retirement or other disposal of property, plant and equipment, the cost and related amount of accumulated depreciation are eliminated from the asset and accumulated depreciation accounts, respectively. The difference, if any,

between the net asset value and the proceeds is included in net income.

The Company assesses the recoverability of assets using undiscounted cash flows whenever events or circumstances indicate that the carrying value of an asset may not be recoverable. If an asset is found to be impaired, the amount recognized for impairment is equal to the difference between the carrying value of the asset and the present value of future cash flows or other reasonable estimate of fair value.

Acquisitions

Amounts paid for acquisitions are allocated to the tangible assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. The Company then allocates the purchase price in excess of net tangible assets acquired to identifiable intangible assets, including purchased research and development. The fair value of identifiable intangible assets is based on detailed valuations. The Company allocates any excess purchase price over the fair value of the net tangible and intangible assets acquired to goodwill.

The Company's purchased research and development represents the estimated fair value as of the acquisition date of in-process projects that have not reached technological feasibility. The primary basis for determining technological feasibility of these projects is obtaining regulatory approval.

The value of in-process research and development ("IPR&D") is determined using the discounted cash flow method. In determining the value of IPR&D, the Company considers, among other factors, appraisals, the stage of completion of the projects, the technological feasibility of the projects, whether the projects have an alternative future use and the estimated residual cash flows that could be generated from the various projects and technologies over their respective projected economic lives. The discount rate used is determined at the time of acquisition and includes a rate of return which accounts for the time value of money, as well as risk factors that reflect the economic risk that the cash flows projected may not be realized.

The value attributable to IPR&D projects at the time of acquisition is capitalized as an indefinite-lived intangible asset and tested for impairment until the project is completed or abandoned. Upon completion of the project, the indefinite-lived intangible asset is then accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is abandoned, the indefinite-lived intangible asset is charged to expense. As of September 27, 2013, the Company had IPR&D of $18.6 million. As of September 28, 2012, the Company had no IPR&D.

Goodwill and Other Intangible Assets

Goodwill represents the excess of the purchase price of an acquired entity over the amounts assigned to assets and liabilities assumed in a business combination. The Company tests goodwill for impairment during the fourth quarter of each year, or more frequently if impairment indicators arise. The Company utilizes a two-step approach. The first step requires a comparison of the carrying value of the reporting units to the fair value of these units. The Company estimates the fair value of its reporting units through internal analyses and valuation, utilizing an income approach based on the present value of future cash flows. If the carrying value of a reporting unit exceeds its fair value, the Company will perform the second step of the goodwill impairment test to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compares the implied fair value of a reporting unit's goodwill with its carrying value. The implied fair value of goodwill is determined in the same manner that the amount of goodwill recognized in a business combination is determined. The Company allocates the fair value of a reporting unit to all of the assets and liabilities of that unit, including intangible assets, as if the reporting unit had been acquired in a business combination. Any excess of the value of a reporting unit over the amounts assigned to its assets and liabilities is the implied fair value of goodwill.

Intangible assets acquired in a business combination are recorded at fair value, while intangible assets acquired in other transactions are recorded at cost. Intangible assets with finite useful lives are subsequently amortized using the straight-line method over the following estimated useful lives of the assets:

Completed technology	5	to	25 years
License agreements	8	to	30 years
Trademarks			30 years

Amortization expense related to completed technology and certain other intangible assets is included in cost of sales, while amortization expense related to intangible assets that contribute to the Company's ability to sell, market and distribute products is included in selling, general and administrative expenses. When a triggering event occurs, we evaluate potential impairment of finite-lived intangible assets by first comparing undiscounted cash flows associated with the asset to its carrying value. If the carrying value is greater than the undiscounted cash flows, the amount of potential impairment is measured by comparing the fair value of the assets with their carrying value. The fair value of the intangible asset is estimated using an income approach. If the fair value is less than the carrying value of the intangible asset, the amount recognized for impairment is equal to the difference between the carrying value of the asset and the present value of future cash flows. The Company annually tests the indefinite-lived intangible assets for impairment by comparing the fair value of the assets, estimated using an income approach, with their carrying value and records an impairment when the carrying value exceeds the fair value. The Company assesses the remaining useful life and the recoverability of finite-lived intangible assets whenever events or circumstances indicate that the carrying value of an asset may not be recoverable. Indefinite-lived intangible assets are tested for impairment at least annually.

Contingencies

The Company is subject to various patent, product liability, government investigations, environmental liability and other legal proceedings in the ordinary course of business. The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. The Company discounts environmental liabilities using a risk-free rate of return when the obligation is fixed or reasonably determinable. The impact of the discount in the consolidated and combined balance sheets was not material in any period presented. Legal fees, other than those pertaining to environmental and asbestos matters, are expensed as incurred. Insurance recoveries related to potential claims are recognized up to the amount of the recorded liability when coverage is confirmed and the estimated recoveries are probable of payment. Assets and liabilities are not netted for financial statement presentation.

Asset Retirement Obligations

The Company establishes asset retirement obligations for certain assets at the time they are installed. The present value of an asset retirement obligation is recorded as a liability when incurred. The liability is subsequently adjusted in future periods as accretion expense is recorded or as revised estimates of the timing or amount of cash flows required to retire the asset are obtained. The corresponding asset retirement costs are capitalized as part of the carrying value of the related long-lived asset and depreciated over the asset's useful life. The Company's obligations to decommission two facilities upon a cessation of its radiological licensed operations are primarily included on the consolidated and combined balance sheets as other liabilities.

Share-Based Compensation

The Company recognizes the cost of employee services received in exchange for awards of equity instruments based on the grant-date fair value of those awards. That cost is recognized over the period during which an employee is required to provide service in exchange for the award, the requisite service period (generally the vesting period). For more information about our share-based awards, refer to Note 14.

Income Taxes

Income taxes for periods prior to the Separation were calculated on a separate tax return basis (inclusive of certain loss benefits), although the Company's operations had historically been included in Covidien's U.S. federal and state tax returns or the tax returns of non-U.S. jurisdictions. Accordingly, the income taxes presented for periods prior to June 28, 2013 do not necessarily reflect the results that would have occurred as an independent, publicly-traded company. With the exception of certain non-U.S. entities, the Company did not maintain taxes payable to or from Covidien and the Company was deemed to settle the annual current tax balances immediately with the legal tax-paying entities in the respective jurisdictions. These settlements were reflected as changes in parent company investment.

Deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been reflected in the consolidated and combined financial statements. Deferred tax assets and liabilities are determined based on the differences between the book and tax bases of assets and liabilities and operating loss carryforwards, using tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided to reduce net deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company determines whether it is more likely than not that a tax position will be sustained upon examination. The tax benefit of any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the uncertainty. To the extent a full benefit is not expected to be realized on the uncertain tax position, an income tax liability is established. Interest and penalties on income tax obligations, including uncertain tax positions, are included in the provision for income taxes. The calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations in a multitude of jurisdictions across the Company's global operations. Due to the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from current estimates

of the tax liabilities. If the Company's estimate of tax liabilities proves to be less than the ultimate assessment, an additional charge to expense would result. If payment of these amounts ultimately proves to be less than the recorded amounts, the reversal of the liabilities may result in income tax benefits being recognized in the period when it is determined that the liabilities are no longer necessary. A significant portion of these potential tax liabilities are recorded in other income tax liabilities on the consolidated and combined balance sheets as payment is not expected within one year.

Parent Company Investment

Parent company investment in the combined balance sheet as of September 28, 2012 represents Covidien's historical investment in the Company, the Company's accumulated net earnings after income taxes for periods prior to that date, and the net effect of transactions with and allocations from Covidien.

3. Recently Issued Accounting Standards

The Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2011-11 in December 2011, "Disclosures about Offsetting Assets and Liabilities," which was clarified in January 2013 by ASU 2013-01 "Clarifying the Scope of Disclosures about Offsetting Assets and Liabilities." This guidance provides new disclosure requirements about instruments and transactions eligible for offset in the statement of financial position, as well as instruments and transactions subject to an agreement similar to a netting agreement, to enable users of financial statements to understand the effects or potential effects of those arrangements on an entity's financial position. The guidance is effective for the Company in the first quarter of fiscal 2014. The Company is still assessing the impact of the pronouncement but does not expect it will have a material impact on its financial condition, results of operations and cash flows.

FASB issued ASU 2013-02, "Reporting Amounts Classified out of Accumulated Other Comprehensive Income," in February 2013. This guidance requires an entity to present, either on the face of the statement of income or separately in the notes to the financial statements, the effects on net income of significant amounts reclassified out of each component of accumulated other comprehensive income, if those amounts are required to be reclassified to net income in their entirety in the same reporting period. For other amounts not required to be reclassified to net income in their entirety, an entity is required to cross-reference to other disclosures that provide additional details about those amounts. The guidance is effective for the Company in the first quarter of fiscal 2014. The Company is still assessing the impact of the pronouncement but does not expect it will have a material impact on its financial condition, results of operations and cash flows.

FASB issued ASU 2013-04, "Obligations Resulting from Joint and Several Liability Arrangements for Which the Total Amount of the Obligation Is Fixed at the Reporting Date," in February 2013. This update provides guidance for the recognition, measurement and disclosure of obligations resulting from joint and several liability arrangements for which the total amount of the obligation is fixed at the reporting date, except for obligations addressed within existing guidance. An entity is required to measure those obligations as the sum of the amount the entity has agreed to pay on the basis of its arrangement among its co-obligors, and any additional amounts it expects to pay on behalf of its co-obligors. The guidance also requires the entity to disclose the nature and amount of those obligations. The guidance is effective for the Company in the first quarter of fiscal 2015. The Company is still assessing the impact of the pronouncement but does not expect it will have a material impact on its financial condition, results of operations and cash flows.

4. Discontinued Operations and Divestitures

Discontinued Operations

During fiscal 2010, the Specialty Chemicals business (formerly known as "Mallinckrodt Baker"), which was part of the Company's Specialty Pharmaceuticals segment, was sold because its products and customer bases were not aligned with the Company's long-term strategic objectives. This business met the discontinued operations criteria and, accordingly, was included in discontinued operations for all periods presented. During fiscal 2013, the Company recorded a gain of $1.0 million and in fiscal 2012 recorded a loss of $6.7 million. This gain and loss were primarily related to the indemnification obligations to the purchaser, which are discussed in Note 17. During fiscal 2011, the Company recorded a $6.3 million loss on the sale of Mallinckrodt Baker, primarily for pension settlements related to employees of this business.

Divestitures

During fiscal 2011, the Company sold the rights to market TussiCaps extended-release capsules, a cough suppressant, for an upfront cash payment of $11.5 million. As a result of this transaction, the Company recorded an $11.1 million gain. The purchaser also may be obligated to make contingent payments to the Company of up to $11.5 million from December 31, 2011 through September 30, 2015, payable in equal quarterly installments until such time as a new competitive generic product is introduced into the market. In addition, the Company would receive a $1.0 million contingent payment if certain sales targets are achieved over the same time period. The Company received $2.9 million of contingent payments during both fiscal 2013 and 2012.

During fiscal 2010, the Company sold its nuclear radiopharmacies in the U.S. In connection with this sale, the Company also entered into a supply agreement, under which the purchaser committed to annual purchase volumes through December 31, 2014.

5. Acquisitions and License Agreements

Business Acquisitions

CNS Therapeutics

On October 1, 2012, the Company's Specialty Pharmaceuticals segment acquired all the outstanding equity of CNS Therapeutics, Inc. ("CNS Therapeutics"), a specialty pharmaceuticals 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, for total consideration of $95.0 million. The total consideration was comprised of an upfront cash payment of $88.1 million (net of cash acquired of $3.6 million) and the fair value of contingent consideration of $6.9 million. This contingent consideration, which could potentially total a maximum of $9.0 million, is discussed further in Note 20. The acquisition of CNS Therapeutics expanded the Company's branded pharmaceuticals portfolio and supports the Company's strategy of leveraging its therapeutic expertise and core capabilities in manufacturing, regulatory and commercialization to serve patients. With the acquisition, the Company now offers products for use in the management of severe spasticity of cerebal or spinal origin with a research and development pipeline of an additional presentation and concentration of Gablofen, as well as other investigational pain products for intrathecal administration.

The following amounts represent the final allocation of the fair value of the identifiable assets acquired and liabilities assumed:

Current assets [1]	$13.3
Intangible assets	91.9
Goodwill (non-tax deductible) [2]	24.5
Total assets acquired	129.7
Current liabilities	4.0
Deferred tax liabilities, net (non-current)	27.1
Contingent consideration (non-current)	6.9
Total liabilities assumed	38.0
Net assets acquired	$91.7

(1) This amount includes $3.3 million of accounts receivable, which is also the gross contractual value. As of the acquisition date, the fair value of accounts receivable approximated carrying value.

(2) Goodwill relates to the Company's ability to exploit CNS Therapeutics' technologies.

The following reconciles the total consideration to net assets acquired:

Total consideration	$95.0
Plus: cash assumed in acquisition	3.6
Less: contingent consideration	(6.9)
Net assets acquired	$91.7

Intangible assets acquired consist of the following:

	Amount	Weighted-Average Amortization Period
Completed technology	$73.1	13 years
Trademark	0.2	3 years
In-process research and development	18.6	Non-Amortizable
	$91.9	

The in-process research and development projects primarily relate to certain investigational intrathecal pain products. As of the date of acquisition, these pain products were in various stages of development, with further development, testing, clinical trials and regulatory submission required in order to bring them to market. At the acquisition date, the total cost to complete these products was estimated to be approximately $18.0 million. The Company expects that regulatory approvals will occur between 2015 and 2018. The valuation of the in-process research and development was determined using, among other factors, appraisals primarily based on the discounted cash flow method. The cash flows were discounted at a 35% rate, which was considered commensurate with the risks and stages of development of the pain products. Future residual cash flows that could be generated from the products were determined based upon management's estimate of future revenue and expected profitability of the products. These projected cash flows were then discounted to their present values taking into account management's estimate of future expenses that would be necessary to bring the products to completion.

The consolidated and combined statement of income for fiscal 2013 contained $29.2 million of net sales of intrathecal products added to the Company's portfolio from the CNS Therapeutics acquisition. Acquisition and integration costs included in the periods presented were not material. The Company does not believe that the results of operations for the periods presented would have been materially different had the acquisition taken place at the beginning of the first period presented.

Product Acquisitions

Roxicodone

In August 2012, the Company's Specialty Pharmaceuticals segment paid $13.2 million under an agreement to acquire all of the rights to Xanodyne Pharmaceuticals, Inc.'s Roxicodone, which was capitalized as an intangible asset. Roxicodone is an immediate-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain where the use of an opioid analgesic is appropriate. Roxicodone is the Reference Listed Drug for one of the Company's generic products and is important to the Company's product pipeline. Sales of Roxicodone during fiscal 2013 were $8.4 million. There are no ongoing royalty payments under this agreement.

License Agreements

Exalgo

In 2009, the Company's Specialty Pharmaceuticals segment acquired the rights to market and distribute the pain management drug Exalgo in the U.S. Under the license agreement, the Company is obligated to make additional payments of up to $73.0 million based on the successful completion of specified development and regulatory milestones. Through fiscal 2013, $65.0 million of additional payments have been made, with $55.0 million being capitalized as an intangible asset. The amount capitalized related to the U.S. Food and Drug Administration's ("FDA") approval of the New Drug Application ("NDA") for the 8 mg, 12 mg and 16 mg tablet dosage forms of Exalgo. During fiscal 2012 the Company received FDA approval to market a 32 mg tablet dosage form. The Company is also required to pay royalties on sales of the product. During fiscal 2013, 2012 and 2011, the Company paid royalties of $24.0 million, $16.1 million and $5.5 million, respectively.

Depomed

In 2009, the Company's Specialty Pharmaceuticals segment licensed worldwide rights to utilize Depomed, Inc.'s ("Depomed") Acuform gastric retentive drug delivery technology for the exclusive development of four products. Under this license agreement, the Company may be obligated to pay up to $64.0 million in development milestone payments. Through fiscal 2013, approximately $7.0 million of these payments have been made by the Company. The Company will also pay Depomed a royalty on sales of products developed under this license agreement. During fiscal 2013, subsequent to the FDA's acceptance of our NDA for MNK-795 in July 2013, a milestone payment of $5.0 million was made, for which the FDA granted conditional approval of the brand name Xartemis XR. During fiscal 2012, an insignificant amount of milestone payments were expensed as incurred since regulatory approval had not been received, and no milestone payments were made in fiscal 2011. In addition, no royalties have been paid through

fiscal 2013.

Pennsaid

In 2009, the Company's Specialty Pharmaceuticals segment entered into a licensing agreement which granted it rights to market and distribute Pennsaid and MNK-395, an investigational product candidate that is a formulation of diclofenac sodium topical solution which we anticipate will be indicated for the treatment of pain associated with osteoarthritis of the knee. The Company is responsible for all future development activities and expenses and may be required to make milestone payments of up to $120.0 million based upon the successful completion of specified regulatory and sales milestones. Through fiscal 2013, $15.0 million of these payments were made, all of which were capitalized as an intangible asset as the payment related to the fiscal 2010 FDA approval of the Pennsaid NDA. The Company is also required to pay royalties on sales of the products under this agreement. During fiscal 2013 and 2012, the Company paid royalties of $3.9 million and $7.5 million, respectively, with this product, and the amount of royalties paid in fiscal 2011 was insignificant.

6. Restructuring and Related Charges

During fiscal 2013, the Company launched a restructuring program designed to improve its cost structure ("the 2013 Mallinckrodt Program"). The 2013 Mallinckrodt Program includes actions across all segments, as well as within the corporate functions. The Company expects to incur charges of $100 million to $125 million under this program as the specific actions required to execute on these initiatives are identified and approved, most of which are expected to be incurred by the end of fiscal 2016. Restructuring actions associated with acquisitions made prior to the Separation are included within Other programs below.

Prior to Separation, Covidien initiated restructuring programs, which also applied to its Pharmaceutical business. These programs were substantially completed as of September 27, 2013.

Net restructuring and related charges by segment are as follows:

	Fiscal Year		
	2013	2012	2011
Specialty Pharmaceuticals	$16.4	$11.3	$6.5
Global Medical Imaging	16.4	7.9	3.8
Corporate	3.0	—	(0.3)
Restructuring and related charges, net	35.8	19.2	10.0
Less: accelerated depreciation	(2.6)	(8.0)	(1.6)
Restructuring charges, net	$33.2	$11.2	$8.4

Net restructuring and related charges are comprised of the following:

	Fiscal Year		
	2013	2012	2011
2013 Mallinckrodt Program	$14.9	$—	$—
Other programs	20.9	19.2	10.0
Total programs	35.8	19.2	10.0
Less: non-cash charges, including accelerated depreciation	(2.6)	(6.2)	(1.6)
Total charges expected to be settled in cash	$33.2	$13.0	$8.4

The following table summarizes cash activity for restructuring reserves, substantially all of which related to employee severance and benefits:

	2013 Mallinckrodt Program	Other Programs	Total
Balance at September 24, 2010	$—	$4.5	$4.5
Charges	—	9.6	9.6
Changes in estimate	—	(1.2)	(1.2)
Cash payments	—	(3.5)	(3.5)
Reclassifications [1]	—	(1.6)	(1.6)
Currency translation	—	(0.2)	(0.2)
Balance at September 30, 2011	—	7.6	7.6
Charges	—	12.8	12.8
Changes in estimate	—	0.2	0.2
Cash payments	—	(11.5)	(11.5)
Reclassifications [1]	—	(0.2)	(0.2)
Balance at September 28, 2012	—	8.9	8.9
Charges	14.9	20.9	35.8
Changes in estimate	—	(2.6)	(2.6)
Cash payments	—	(15.1)	(15.1)
Reclassifications [1]	—	(1.5)	(1.5)
Balance at September 27, 2013	$14.9	$10.6	$25.5

(1) Represents the reclassification of pension and other postretirement benefits from restructuring reserves to pension and postretirement obligations, and the transfer of certain restructuring liabilities in conjunction with the Separation.

Net restructuring and related charges, including associated asset impairments, incurred cumulative to date related to the 2013 Mallinckrodt Program are as follows:

Specialty Pharmaceuticals	$2.4
Global Medical Imaging	9.5
Corporate	3.0
	$14.9

Substantially all of the restructuring reserves are included in accrued and other current liabilities on the Company's consolidated and combined balance sheets.

7. Income Taxes

The U.S. and non-U.S. components of income from continuing operations before income taxes were as follows:

	2013	2012	2011
U.S.	$70.0	$174.6	$134.9
Non-U.S.	56.4	61.5	108.3
Total	$126.4	$236.1	$243.2

Significant components of income taxes related to continuing operations are as follows:

	2013	2012	2011
Current:			
U.S.:			
Federal	$45.7	$61.1	$19.2
State	9.2	7.2	2.4
Non-U.S.	22.7	17.5	28.2
Current income tax provision	77.6	85.8	49.8
Deferred:			
U.S.:			
Federal	(11.7)	5.3	37.8
State	(1.2)	2.4	4.3
Non-U.S.	3.9	1.3	(5.7)
Deferred income tax (benefit) provision	(9.0)	9.0	36.4
	$68.6	$94.8	$86.2

The reconciliation between U.S. federal income taxes at the statutory rate and the Company's provision for income taxes on continuing operations is as follows:

	2013	2012	2011
Notional U.S. federal income taxes at the statutory rate	$44.3	$82.6	$85.1
Adjustments to reconcile to income tax provision:			
U.S. state income tax provision, net	4.8	7.1	5.9
Rate difference between non-U.S. and U.S. jurisdictions [1] [2]	(2.2)	(3.5)	(16.8)
Domestic manufacturing deduction	(2.5)	(3.0)	—
Valuation allowances, nonrecurring	3.4	—	—
Adjustments to accrued income tax liabilities and uncertain tax positions [2]	8.6	1.2	(1.0)
Interest on accrued income tax liabilities and uncertain tax positions [2]	4.7	1.1	1.9
Withholding tax, net	0.3	0.4	3.8
Credits, principally research [3]	(6.2)	(0.8)	(4.1)
Permanently nondeductible and nontaxable items	12.0	8.1	8.4
Other	1.4	1.6	3.0
Provision for income taxes	$68.6	$94.8	$86.2

(1) Excludes non-deductible charges and other items which are broken out separately in the statutory rate reconciliation presented. Also includes the impact of certain valuation allowances.

(2) Includes impact of items relating to entities retained by Covidien in connection with the Separation.

(3) Due to the December 31, 2011 tax law expiration, fiscal 2012 includes U.S. Research Credits for only the three months ended December 31, 2011. During fiscal 2013, the legislation was extended, with a retroactive effective date of January 1, 2012. As such, fiscal 2013 includes approximately $2.3 million of credit related to the period January 1, 2012 through September 28, 2012.

As of September 27, 2013, September 28, 2012 and September 30, 2011, the amounts of unrecognized tax benefits for which the Company is legally and directly liable and would be required to remit cash if not sustained were $100.1 million, $13.4 million and $14.2 million, respectively. For periods prior to the Separation, the Company's operations had been included in tax returns filed by Covidien or certain of its subsidiaries not included in the Company's historical combined financial statements. As a result, some federal uncertain tax positions related to the Company's operations resulted in unrecognized tax benefits that are obligations of entities not included in the combined financial statements for periods prior to June 28, 2013. Because the activities that gave rise to these unrecognized tax benefits relate to the Company's operations, the impact of these items (presented in the table below) were charged to the

income tax provision through parent company investment, which was a component of parent company equity in the combined balance sheets.

The following table summarizes the activity related to the Company's unrecognized tax benefits, excluding interest:

	2013	2012	2011
Balance at beginning of fiscal year	$165.5	$168.4	$175.7
Unrecognized tax benefits retained by Covidien	(153.7)	—	—
Unrecognized tax benefits transferred from Covidien	84.2	—	—
Additions related to current year tax positions	3.5	1.3	2.2
Additions related to prior period tax positions	6.6	1.6	1.1
Reductions related to prior period tax positions	(4.3)	(1.9)	(3.9)
Settlements	(1.6)	(1.7)	(6.7)
Lapse of statute of limitations	(0.1)	(2.2)	—
Balance at end of fiscal year	100.1	165.5	168.4
Cash advance paid in connection with proposed settlements	—	(23.5)	(23.5)
Balance at end of fiscal year, net of cash advance	$100.1	$142.0	$144.9

During fiscal 2011, Covidien made a $35.1 million advance payment to the U.S. Internal Revenue Service ("IRS") in connection with the proposed settlement of certain tax matters. This payment was comprised of $23.5 million of tax and $11.6 million of interest. This amount was retained by Covidien in connection with the Separation. The Company expects to make an advance payment of $30.0 million in fiscal 2014, which is comprised of unrecognized tax benefits, other tax items unrelated to unrecognized tax benefits and associated interest. This amount has been recorded within accrued and other current liabilities as of September 27, 2013.

Unrecognized tax benefits, excluding interest, are reported in the following consolidated and combined balance sheet captions in the amount shown:

	September 27, 2013	September 28, 2012
Accrued and other current liabilities	$ 23.4	$ —
Other income tax liabilities	76.7	13.4
Parent company investment	—	152.1
	$ 100.1	$ 165.5

The changes in the balance sheet captions between periods in the above table reflects the transfer of the liabilities to the Company from Covidien with the Separation. Pursuant to the separation and distribution agreement ("the Separation and Distribution Agreement") and other agreements, certain assets and liabilities that were formerly associated with the Pharmaceuticals business of Covidien were retained by Covidien and, conversely, certain non-operating assets and liabilities were transferred to the Company. The amounts related to unrecognized tax benefits recorded within parent company investment at the Separation were retained by Covidien, and $84.2 million of liabilities related to unrecognized tax benefits, excluding interest, were transferred to the Company.

Included within total unrecognized tax benefits at September 27, 2013, September 28, 2012 and September 30, 2011, there were $96.3 million, $144.3 million and $144.8 million, respectively, of unrecognized tax benefits, which if favorably settled would benefit the effective tax rate. The remaining unrecognized tax benefits for each period would be offset by the write-off of related deferred and other tax assets, if recognized. During fiscal 2013, 2012 and 2011, the Company accrued additional interest of $2.4 million, $1.4 million and $3.8 million, respectively, with no additional penalties accrued during these periods. The total amount of accrued interest related to uncertain tax positions was $62.1 million, $33.9 million and $32.5 million, respectively, with no penalties accrued during these periods. Of the $33.9 million accrued as of September 28, 2012, $26.0 million was included within parent company investment on the combined balance sheet. This amount was retained by Covidien in connection with the Separation and $51.8 million of accrued interest related to unrecognized tax benefits was transferred to the Company. During fiscal 2013 $4.0 million in penalty accruals were transferred to the Company by Covidien in connection with the Separation.

It is reasonably possible that within the next twelve months, as a result of the resolution of various federal, state and foreign examinations and appeals and the expiration of various statutes of limitation, that the unrecognized tax benefits that would affect the effective tax rate will decrease by up to $22.6 million. The amount of interest and penalties that will affect the effective tax rate will decrease by up to $15.6 million.

Income taxes payable, including uncertain tax positions and related interest accruals, is reported in the following consolidated and combined balance sheet captions in the amounts shown. Non-current other income tax liabilities also includes anticipated refunds and other items not related to uncertain tax positions.

	September 27, 2013	September 28, 2012
Accrued and other current liabilities	$ 28.2	$ 2.6
Other income tax liabilities	153.1	19.4
	$ 181.3	$ 22.0

Covidien continues to be examined by various taxing authorities for periods the Company was included within the consolidated results of Covidien. The resolution of these tax matters could result in a significant change in the Company's unrecognized tax benefits; however, the Company does not expect that the total amount of unrecognized tax benefits will significantly change over the next twelve months. In connection with the Separation, the Company entered into a tax matters agreement ("the Tax Matters Agreement") with Covidien that generally governs Covidien's and Mallinckrodt's respective rights, responsibilities and obligations after the Separation with respect to certain taxes, including, but not limited to, ordinary course of business taxes. For further information on the Tax Matters Agreement, refer to Note 16.

As of September 27, 2013, tax years that remain subject to examination in the Company's major tax jurisdictions are as follows:

Jurisdiction	Earliest Open Year
U.S. - federal and state	1996
Ireland	2009
Netherlands	2013
Switzerland	2012

Deferred income taxes result from temporary differences between the amount of assets and liabilities recognized for financial reporting and tax purposes. The components of the net deferred tax (liability) asset at the end of each fiscal year were as follows:

	September 27, 2013	September 28, 2012
Deferred tax assets:		
Accrued liabilities and reserves	$ 53.8	$ 47.4
Inventories	30.5	36.4
Tax loss and credit carryforwards	53.6	1.2
Environmental liabilities	27.3	66.4
Rebate reserves	43.4	38.1
Indemnification reserves	8.2	14.9
Postretirement benefits	30.2	67.7
Federal and state benefit of uncertain tax positions and interest	47.1	5.7
Deferred intercompany interest	19.2	—
Other	30.8	13.9
	344.1	291.7
Deferred tax liabilities:		
Property, plant and equipment	(160.5)	(139.9)
Intangible assets	(113.1)	(89.1)
Investment in partnership	(173.6)	—
	(447.2)	(229.0)

Net deferred tax (liability) asset before valuation allowances	(103.1)	62.7
Valuation allowances	(30.0)	(15.3)
Net deferred tax (liability) asset	$ (133.1)	$ 47.4

Deferred taxes are reported in the following consolidated and combined balance sheet captions in the amounts shown:

	September 27, 2013	September 28, 2012
Deferred income taxes (current asset)	$ 171.1	$ 119.9
Other non-current assets	7.5	3.8
Accrued and other current liabilities	(1.6)	(2.6)
Deferred income taxes (non-current liability)	(310.1)	(73.7)
Net deferred tax (liability) asset	$ (133.1)	$ 47.4

The Company's current deferred tax asset increased from $119.9 million at September 28, 2012 to $171.1 million at September 27, 2013 primarily due to $16.5 million being transferred to the Company from Covidien in connection with the Separation, $19.2 million of deferred U.S. tax deduction on intercompany interest and $5.8 million related to the acquisition of CNS Therapeutics. Additionally, the Company's noncurrent deferred tax liability increased from $73.7 million at September 28, 2012 to $310.1 million at September 27, 2013, primarily due to $165.1 million being transferred to the Company from Covidien in connection with the Separation and $32.9 million related to the acquisition of CNS Therapeutics. The transfer from Covidien in connection with the Separation was predominately related to an indefinite-lived deferred tax liability of $173.6 million related to the Company’s wholly-owned U.S. operating partnership.

At September 27, 2013, the Company had approximately $13.6 million of net operating loss carryforwards in certain non-U.S. jurisdictions, of which $11.4 million have no expiration and the remaining $2.2 million will expire in future years through 2023. The Company had $23.2 million of U.S. federal and state net operating loss carryforwards and $5.4 million of U.S. federal capital loss carryforwards at September 27, 2013, which will expire during fiscal 2014 through 2033.

At September 27, 2013 the Company also had $11.4 million of tax credits available to reduce future income taxes payable, primarily in jurisdictions within the U.S., of which $0.6 million have no expiration and the remainder expire during fiscal 2014 through 2033.

The deferred tax asset valuation allowances of $30.0 million and $15.3 million at September 27, 2013 and September 28, 2012, respectively, relate principally to the uncertainty of the utilization of certain deferred tax assets, primarily non-US net operating losses, certain reserves in non-U.S. jurisdictions and realized and unrealized capital losses in the U.S. The Company believes that it will generate sufficient future taxable income to realize the tax benefits related to the remaining net deferred tax assets.

During fiscal 2013, 2012 and 2011, the Company provided for U.S. and non-U.S. income and withholding taxes in the amount of $0.2 million, $0.4 million and $3.8 million, respectively, on earnings that were or are intended to be repatriated. In general, the remaining earnings of the Company's subsidiaries are considered to be permanently reinvested. Income taxes are not provided on undistributed earnings of U.S. and non-U.S. subsidiaries that are either indefinitely reinvested or can be distributed on a tax-free basis. As of September 27, 2013, the cumulative amount of such undistributed earnings was approximately $1.0 billion. It is not practicable to determine the cumulative amount of tax liability that would arise if these earnings were remitted.

8. Earnings (Loss) per Share

Basic earnings (loss) per share is computed by dividing net income by the number of weighted-average shares outstanding during the period. Diluted earnings (loss) per share is computed using the weighted-average shares outstanding and, if dilutive, potential ordinary shares outstanding during the period. Potential ordinary shares represents the incremental ordinary shares issuable for restricted share units and share option exercises. The Company calculates the dilutive effect of outstanding restricted share units and share options on earnings (loss) per share by application of the treasury stock method.

The computations of basic and diluted earnings (loss) per share assumes that the number of shares outstanding for periods prior to June 28, 2013 was equal to the number of ordinary shares of Mallinckrodt outstanding on June 28,

2013, immediately following the distribution of one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien. The dilutive effect of the Company's share-based awards that were issued as a result of the conversion of Covidien share-based awards with the Separation, the initial equity awards granted to certain of the Company's executives on July 1, 2013 and any other Company grants made since the Separation have been included in the computation of diluted earnings per share for fiscal 2013, weighted appropriately for the portion of the period they were outstanding.

	2013	2012	2011
Weighted-average shares for basic earnings (loss) per share	57.7	57.7	57.7
Effect of share options and restricted shares	0.1	—	—
Weighted-average shares for diluted earnings (loss) per share	57.8	57.7	57.7

The computation of diluted earnings per share for fiscal 2013 excludes approximately 0.5 million of equity awards because the effect would have been anti-dilutive.

9. Inventories

Inventories are comprised of the following at the end of each period:

	September 27, 2013	September 28, 2012
Raw materials and supplies	$ 68.8	$ 74.1
Work in process	191.5	184.7
Finished goods	142.8	176.5
Inventories	$ 403.1	$ 435.3

10. Property, Plant and Equipment

The gross carrying amount and accumulated depreciation of property, plant and equipment at the end of each period was as follows:

	September 27, 2013	September 28, 2012
Land	$ 60.4	$ 60.0
Buildings	316.6	297.3
Capitalized software	76.4	59.9
Machinery and equipment	1,226.6	1,152.8
Construction in process	193.7	181.4
	1,873.7	1,751.4
Less: accumulated depreciation	(876.3)	(806.2)
Property, plant and equipment, net	$ 997.4	$ 945.2

The amounts above include property under capital leases of $17.8 million and $17.0 million at September 27, 2013 and September 28, 2012, respectively, consisting primarily of buildings. Accumulated amortization of capitalized lease assets was $15.8 million and $14.3 million at at the end of fiscal 2013 and 2012, respectively.

Depreciation expense, including amounts related to capitalized leased assets, was $104.2 million, $103.6 million and $92.8 million for fiscal 2013, 2012 and 2011, respectively. Depreciation expense includes depreciation on demonstration equipment of $3.6 million, $3.4 million and $3.9 million for fiscal 2013, 2012 and 2011, respectively. Demonstration equipment is included within other assets on the consolidated and combined balance sheets.

11. Goodwill and Intangible Assets

The changes in the carrying amount of goodwill by segment were as follows:

	Specialty Pharmaceuticals	Global Medical Imaging	Total
Goodwill at September 28, 2012	$ 287.8	$219.7	$507.5
Acquisitions	24.5	—	24.5
Goodwill at September 27, 2013	$ 312.3	$219.7	$532.0

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The gross carrying amount and accumulated amortization of intangible assets at the end of each period were as follows:

	September 27, 2013		September 28, 2012	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortizable:				
Completed technology	$449.2	$196.6	$376.1	$173.7
Licenses	191.1	79.3	191.1	67.1
Trademarks	7.9	3.8	7.7	3.5
Total	$648.2	$279.7	$574.9	$244.3
Non-Amortizable:				
Trademarks	$35.0		$35.0	
In-process research and development	18.6		—	
Total	$53.6		$35.0	

Intangible asset amortization expense was $35.4 million, $27.3 million and $27.0 million in fiscal 2013, 2012 and 2011, respectively. The estimated aggregate amortization expense on intangible assets owned by the Company is expected to be as follows:

Fiscal 2014	$35.4
Fiscal 2015	35.4
Fiscal 2016	35.3
Fiscal 2017	33.9
Fiscal 2018	25.2

12. Debt

Debt was comprised of the following at the end of each period:

	September 27, 2013	September 28, 2012
Current maturities of long-term debt:		
Capital lease obligation	$ 1.4	$ 1.3
Loan payable	0.1	—
Total current debt	1.5	1.3
Long-term debt:		
7.00% debentures due December 2013 (1)	—	5.8
3.50% notes due April 2018	299.9	—
9.50% debentures due May 2022 (2)	10.4	—
8.00% debentures due March 2023 (2)	8.0	—
4.75% notes due April 2023	598.2	—
Capital lease obligation	1.8	3.1
Total long-term debt	918.3	8.9
Total debt	$ 919.8	$ 10.2

(1) Under the terms of the Separation and Distribution Agreement, the 7.00% debentures due December 2013 were retained by Covidien.

(2) Under the terms of the Separation and Distribution Agreement, the 8.00% and 9.50% debentures due in March 2023 and May 2022, respectively, were transferred to the Company.

In November 2012, Mallinckrodt International Finance S.A. ("MIFSA") was formed as a 100% owned subsidiary of Covidien in connection with the Separation. MIFSA is a holding company established to own, directly or indirectly, substantially all of the operating subsidiaries of the Company, to issue debt securities and to perform treasury operations. At the time of the Separation, MIFSA became a 100% owned subsidiary of the Company.

In March 2013, MIFSA entered into a $250 million five-year senior unsecured revolving credit facility that matures in June 2018 ("the Credit Facility"). Borrowings under the Credit Facility will initially bear interest at LIBOR plus 1.50% per annum (subject to adjustment pursuant to a ratings-based pricing grid). The Credit Facility contains a $150 million letter of credit sublimit. The Credit Facility is subject to an initial annual facility fee of 0.25%, which is also subject to adjustment pursuant to a ratings-based pricing grid, and the fee applied to outstanding letters of credit is based on the interest rate applied to borrowings. The Credit Facility agreement contains customary affirmative and negative covenants, including a financial maintenance covenant that limits the Company's ratio of debt to earnings before interest, income taxes, depreciation and amortization, as adjusted for certain items, and another financial maintenance covenant that requires the Company's ratio of earnings before interest, income taxes, depreciation and amortization, as adjusted for certain items, to interest expense to exceed certain thresholds. Other nonfinancial covenants restrict, among other things, the Company's ability to create liens, the ability of the non-guarantor subsidiaries to incur additional indebtedness and the ability of the Company to merge or consolidate with any other person or sell or convey certain of its assets to any one person. MIFSA was not permitted to draw upon the Credit Facility until certain conditions were met, including completion of the Separation and Mallinckrodt plc's guaranty of MIFSA's obligations under the Credit Facility. These conditions were satisfied as of June 28, 2013; however, there were no borrowings or letters of credit outstanding under the Credit Facility at September 27, 2013.

In April 2013, MIFSA issued $300 million aggregate principal amount of 3.50% senior unsecured notes due April 2018 and $600 million aggregate principal amount of 4.75% senior unsecured notes due April 2023 (collectively, "the Notes"). Mallinckrodt plc has fully and unconditionally guaranteed the Notes on an unsecured and unsubordinated basis as of the completion of the Separation. The Notes are subject to an indenture which contains covenants limiting the ability of MIFSA, its restricted subsidiaries (as defined in the Notes) and Mallinckrodt plc, as guarantor, to incur certain liens or enter into sale and lease-back transactions. It also restricts Mallinckrodt plc and MIFSA's ability to merge or consolidate with any other person or sell or convey all or substantially all of their assets to any one person. MIFSA may redeem all of the Notes at any time, and some of the Notes from time to time, at a redemption price equal to the principal amount of the Notes redeemed plus a make-whole premium. MIFSA will pay interest on the Notes semiannually in arrears on April 15 and October 15 of each year, commencing on October 15, 2013. The net proceeds to MIFSA from the issuance and sale of the Notes was $889.3 million, the majority of which was retained by Covidien per the terms of the Separation and Distribution Agreement. The Notes were issued and sold in a private placement; however, MIFSA is required to register the Notes with the SEC within one year of the issuance of the Notes.

As of September 27, 2013, the Company was, and expects to remain, in compliance with the provisions and covenants associated with its Credit Agreement, the Notes and its other debt agreements.

The Company's capital lease obligation relates to a non-U.S. manufacturing facility. This lease expires in December 2015. The aggregate amounts of debt, including the capital lease obligation, maturing during the next five fiscal years are as follows:

Fiscal 2014	$1.5
Fiscal 2015	1.4
Fiscal 2016	0.4
Fiscal 2017	—
Fiscal 2018	300.0

13. Retirement Plans

Defined Benefit Plans

The Company sponsors a number of defined benefit retirement plans covering certain of its U.S. employees and non-U.S. employees. As of September 27, 2013, U.S. plans represented 73% of both the Company's total pension plan assets and projected benefit obligation. The Company generally does not provide postretirement benefits other than retirement plan benefits for its employees; however, certain of the Company's U.S. employees participate in postretirement benefit plans that provide medical benefits. These plans are unfunded.

During fiscal 2013, the Company incurred settlement charges of $6.8 million resulting from lump sum distributions to former employees. During fiscal 2011, the Company incurred settlement charges of $11.1 million resulting from the level of lump-sum payments paid out of one of its U.S. pension plans, a significant portion of which were driven by the divestiture of Mallinckrodt Baker.

The net periodic benefit cost (credit) for the Company's pension and postretirement benefit plans was as follows:

	Pension Benefits			Postretirement Benefits		
	Fiscal Year			Fiscal Year		
	2013	2012	2011	2013	2012	2011
Service cost	$5.0	$5.0	$6.2	$0.1	$0.1	$0.2
Interest cost	18.2	21.2	23.5	2.4	3.1	3.8
Expected return on plan assets	(29.6)	(24.5)	(25.3)	—	—	—
Amortization of net actuarial loss	12.3	11.7	11.8	0.3	0.2	0.5
Amortization of prior service cost	0.6	0.7	0.8	(9.1)	(9.2)	(9.0)
Plan settlements loss	6.8	(0.2)	11.1	—	—	—
Curtailments	—	—	1.9	—	—	(4.6)
Special termination benefits	—	—	0.1	—	—	—
Net periodic benefit cost (credit)	$13.3	$13.9	$30.1	$(6.3)	$(5.8)	$(9.1)

The following table represents the changes in benefit obligations, plan assets and the net amounts recognized on the consolidated and combined balance sheets for pension and postretirement benefit plans at the end of fiscal 2013 and 2012:

	Pension Benefits		Postretirement Benefits	
	2013	2012	2013	2012
Change in benefit obligation:				
Projected benefit obligations at beginning of year	$533.2	$491.1	$80.3	$80.1
Service cost	5.0	5.0	0.1	0.1
Interest cost	18.2	21.2	2.4	3.1
Employee contributions	0.3	0.3	—	—
Actuarial (gain) loss	(24.0)	53.3	(9.3)	2.8
Benefits and administrative expenses paid	(21.9)	(32.3)	(3.8)	(5.8)
Plan amendments	(9.0)	—	(16.5)	—
Plan settlements	(24.2)	(0.3)	—	—
Plan combinations	18.4	—	—	—
Curtailments	—	—	—	—
Currency translation	5.7	(5.1)	—	—
Projected benefit obligations at end of year	$501.7	$533.2	$53.2	$80.3
Change in plan assets:				
Fair value of plan assets at beginning of year	$432.0	$383.6	$—	$—
Actual return on plan assets	17.3	63.0	—	—
Employer contributions	44.4	23.4	3.8	5.8
Employee contributions	0.3	0.3	—	—
Benefits and administrative expenses paid	(21.9)	(32.3)	(3.8)	(5.8)
Plan settlements	(24.2)	(0.3)	—	—
Plan combinations	2.3	—	—	—
Currency translation	5.8	(5.7)	—	—
Fair value of plan assets at end of year	$456.0	$432.0	$—	$—
Funded status at end of year	$(45.7)	$(101.2)	$(53.2)	$(80.3)

	Pension Benefits		Postretirement Benefits	
	2013	2012	2013	2012
Amounts recognized on the consolidated and combined balance sheet:				
Non-current assets	$17.1	$17.7	$—	$—
Current liabilities	(3.1)	(2.2)	(4.9)	(7.4)
Non-current liabilities	(59.7)	(116.7)	(48.3)	(72.9)
Net amount recognized on the consolidated and combined balance sheet	$(45.7)	$(101.2)	$(53.2)	$(80.3)
Amounts recognized in accumulated other comprehensive income consist of:				
Net actuarial loss	$(102.9)	$(127.5)	$(2.4)	$(12.1)
Prior service credit (cost)	7.9	(1.8)	28.2	20.8
Net amount recognized in accumulated other comprehensive income	$(95.0)	$(129.3)	$25.8	$8.7

The estimated amounts that will be amortized from accumulated other comprehensive income into net periodic benefit cost (credit) in fiscal 2014 are as follows:

	Pension Benefits	Postretirement Benefits
Amortization of net actuarial loss	$(8.3)	$ —
Amortization of prior service cost	0.6	9.3

The accumulated benefit obligation for all pension plans at the end of fiscal 2013 and 2012 was $499.9 million and $527.6 million, respectively. Additional information related to pension plans is as follows:

	2013	2012
Pension plans with accumulated benefit obligations in excess of plan assets:		
Accumulated benefit obligation	$377.6	$414.3
Fair value of plan assets	316.2	295.4

The accumulated benefit obligation and fair value of plan assets for pension plans with projected benefit obligations in excess of plan assets do not significantly differ from the amounts in the table above since substantially all of the Company's pension plans are frozen.

Actuarial Assumptions

Weighted-average assumptions used each fiscal year to determine net periodic benefit cost for the Company's pension plans are as follows:

	U.S. Plans			Non-U.S. Plans		
	2013	2012	2011	2013	2012	2011
Discount rate	3.5%	4.4%	4.9%	4.0%	5.2%	4.7%
Expected return on plan assets	7.9%	7.5%	7.6%	3.5%	4.0%	4.0%
Rate of compensation increase	—	2.8%	2.8%	3.7%	3.7%	3.7%

Weighted-average assumptions used each fiscal year to determine benefits obligations for the Company's pension plans are as follows:

	U.S. Plans			Non-U.S. Plans		
	2013	2012	2011	2013	2012	2011

Discount rate	4.3	% 3.5	% 4.4	% 3.7	% 4.0	% 5.2	%
Rate of compensation increase	—	—	2.8	% 3.5	% 3.7	% 3.7	%

For the Company's U.S. plans, the discount rate is based on the market rate for a broad population of Moody's AA-rated corporate bonds over $250 million. For the Company's non-U.S. plans, the discount rate is generally determined by reviewing country and region specific government and corporate bond interest rates.

In determining the expected return on pension plan assets, the Company considers the relative weighting of plan assets by class and individual asset class performance expectations as provided by external advisors in reaching conclusions on appropriate assumptions. The investment strategy for the pension plans had been governed by Covidien for periods prior to the Separation. Covidien's overall investment objective is to obtain a long-term return on plan assets that is consistent with the level of investment risk that is considered appropriate. At this time, the Company's investment objectives are similar to Covidien's. Investment risks and returns are reviewed regularly against benchmarks to ensure objectives are being met.

The weighted-average discount rate used to determine net periodic benefit cost and obligations for the Company's postretirement benefit plans are as follows:

	2013		2012		2011	
Net periodic benefit cost	3.2	%	4.1	%	4.6	%
Benefit obligations	4.0	%	3.2	%	4.1	%

Healthcare cost trend assumptions for postretirement benefit plans are as follows:

	2013		2012	
Healthcare cost trend rate assumed for next fiscal year	7.3	%	7.5	%
Rate to which the cost trend rate is assumed to decline	4.5	%	4.5	%
Fiscal year the ultimate trend rate is achieved	2029		2029	

A one-percentage-point change in assumed healthcare cost trend rates would have the following effects:

	One-Percentage-Point Increase	One-Percentage-Point Decrease
Effect on total of service and interest cost	$ 0.1	$ (0.1)
Effect on postretirement benefit obligation	0.4	(0.3)

Plan Assets

The Company's U.S. pension plans have a target allocation of 42% equity securities and 58% debt securities. Various asset allocation strategies are in place for non-U.S. pension plans depending upon local law, status, funding level and duration of liabilities, and are 39% equity securities, 53% debt securities and 8% other (primarily cash) for our Japanese pension plan and 10% equity securities, 2% debt securities and 88% other (primarily insurance contracts) for our plan in the Netherlands.

Pension plans have the following weighted-average asset allocations at the end of each fiscal year:

	U.S. Plans				Non-U.S. Plans			
	2013		2012		2013		2012	
Equity securities	42	%	58	%	7	%	8	%
Debt securities	56		40		3		2	
Cash and cash equivalents	1		1		—		—	
Real estate and other	1		1		90		90	
Total	100	%	100	%	100	%	100	%

The following tables provide a summary of plan assets held by the Company's pension plans that are measured at fair value on a recurring basis at the end of fiscal 2013 and 2012:

		Basis of Fair Value Measurement		
	Fiscal 2013	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Equity Securities:				
U.S. small mid cap	$19.3	$19.3	$—	$ —
U.S. large cap	76.9	76.9	—	—
International	52.2	43.9	8.3	—
Debt securities:				
Diversified fixed income funds [1]	170.0	166.7	3.3	—
High yield bonds	11.7	11.7	—	—
Emerging market funds	7.9	7.9	—	—
Diversified/commingled funds	—	—	—	—
Insurance contracts	112.0	—	—	112.0
Other	6.0	3.1	2.9	—
Total	$456.0	$329.5	$14.5	$ 112.0

		Basis of Fair Value Measurement		
	Fiscal 2012	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Equity Securities:				
U.S. small mid cap	$24.0	$24.0	$—	$ —
U.S. large cap	101.2	101.2	—	—
International	66.8	57.2	9.6	—
Debt securities:				
Diversified fixed income funds [1]	97.4	97.4	—	—
High yield bonds	15.9	15.9	—	—
Emerging market funds	12.0	12.0	—	—
Diversified/commingled funds	2.2	—	2.2	—
Insurance contracts	105.1	—	—	105.1
Other	7.4	3.8	3.6	—
Total	$432.0	$311.5	$15.4	$ 105.1

(1) Diversified fixed income funds consist of U.S. Treasury bonds, mortgage-backed securities, corporate bonds, asset-backed securities and U.S. agency bonds.

Equity securities. Equity securities primarily consist of mutual funds with underlying investments in foreign equity and domestic equity markets. The fair value of these investments is based on net asset value of the units held in the

respective fund, which are determined by obtaining quoted prices on nationally recognized securities exchanges (level 1) or through net asset values provided by the fund administrators that can be corroborated by observable market data (level 2).

Debt securities. Debt securities are primarily invested in mutual funds with underlying fixed income investments in U.S. government and corporate debt, U.S. dollar denominated foreign government and corporate debt, asset-backed securities, mortgage-backed securities and U.S. agency bonds. The fair value of these investments is based on the net asset value of the units held in the respective fund which are determined by obtaining quoted prices on nationally recognized securities exchanges.

Diversified/commingled funds. Diversified/commingled funds held by the Company primarily consist of corporate debt securities and mutual funds invested in U.S. and non-U.S. equity securities. The fair value of these investments is determined using other inputs, such as net asset values provided by the fund administrators that can be corroborated by observable market data.

Insurance contracts. Insurance contracts held by the Company are issued primarily by Delta Lloyd, a well-known, highly rated insurance company. The fair value of these insurance contracts is based upon the present value of future cash flows under the terms of the contracts and therefore the fair value of these assets has been classified as level 3 within the fair value hierarchy. Significant assumptions used in determining the fair value of these contracts are the amount and timing of future cash flows and counterparty credit risk. The objective of the insurance contracts is to provide the Company with future cash flows that will match the estimated timing and amount of future pension benefit payments. Delta Lloyd's insurance subsidiaries have a Standard & Poor's credit rating of A.

Other. Other includes cash and cash equivalents invested in a money market mutual fund, the fair value of which is determined by obtaining quoted prices on nationally recognized securities exchanges (level 1). In addition, other includes real estate funds, the fair value of which is determined using other inputs, such as net asset values provided by the fund administrators that can be corroborated by observable market data (level 2).

The following table provides a summary of the changes in the fair value measurements that used significant unobservable inputs (level 3) for fiscal 2013 and 2012:

	Insurance Contracts
Balance at September 30, 2011	$97.8
Net unrealized gains	15.1
Net purchases, sales and issuances	(2.9)
Currency translation	(4.9)
Balance at September 28, 2012	105.1
Net unrealized gains	3.3
Net purchases, sales and issuances	(1.8)
Currency translation	5.4
Balance at September 27, 2013	$112.0

Mallinckrodt shares are not a direct investment of the Company's pension funds; however, the pension funds may indirectly include Mallinckrodt shares. The aggregate amount of the Mallinckrodt shares are not material relative to the total pension fund assets.

Contributions

The Company's funding policy is to make contributions in accordance with the laws and customs of the various countries in which the Company operates, as well as to make discretionary voluntary contributions from time to time. In fiscal 2013, the Company made $44.4 million in contributions to the Company's pension plans, including a $37.5 million voluntary contribution by Covidien prior to the Separation. The Company does not anticipate making material contributions to its defined benefit pension plans or its postretirement benefit plans during fiscal 2014.

Expected Future Benefit Payments

Benefit payments expected to be paid, reflecting future expected service as appropriate, are as follows:

	Pension Benefits	Postretirement Benefits
Fiscal 2014	$40.6	$ 4.9
Fiscal 2015	35.1	5.2
Fiscal 2016	34.0	4.9
Fiscal 2017	33.5	4.5
Fiscal 2018	33.0	4.2
Fiscal 2019 - 2023	152.9	17.4

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Defined Contribution Retirement Plans

The Company maintains one active tax-qualified 401(k) retirement plan in the U.S., which provides for an automatic Company contribution of three percent of an eligible employee's pay. The Company also makes a matching contribution generally equal to 50% of each employee's elective contribution to the plan up to six percent of the employee's eligible pay. Total 401(k) expense related to continuing operations was $22.7 million, $20.9 million and $19.3 million for fiscal 2013, 2012 and 2011, respectively.

Deferred Compensation Plans

As discussed in Note 20, the Company maintains one active non-qualified deferred compensation plan in the U.S., which permits eligible employees to defer a portion of their compensation. Deferred compensation expense for each period presented was insignificant.

Rabbi Trusts and Other Investments

The Company maintains several rabbi trusts, the assets of which are used to pay retirement benefits. The rabbi trust assets are subject to the claims of the Company's creditors in the event of the Company's insolvency. Plan participants are general creditors of the Company with respect to these benefits. The trusts primarily hold life insurance policies and debt and equity securities, the value of which is included in other assets on the consolidated and combined balance sheets. Note 20 provides additional information regarding the debt and equity securities. The carrying value of the 135 life insurance contracts held by these trusts was $54.6 million and $37.8 million at September 27, 2013 and September 28, 2012, respectively. These contracts have a total death benefit of $143.1 million and $93.9 million at September 27, 2013 and September 28, 2012, respectively. However, there are outstanding loans against the policies amounting to $35.3 million and $16.9 million at September 27, 2013 and September 28, 2012, respectively.

The Company has insurance contracts which serve as collateral for certain of the Company's non-U.S. pension plan benefits, which totaled $13.1 million and $9.8 million at September 27, 2013 and September 28, 2012, respectively. These amounts were also included in other assets on the consolidated and combined balance sheets.

14. Share Plans

Total share-based compensation cost was $16.2 million, $11.1 million and $10.6 million for fiscal 2013, 2012 and 2011, respectively. These amounts are generally included within selling, general and administrative expenses in the consolidated and combined statements of income; however, the incremental fair value associated with the conversion of Covidien equity awards into Mallinckrodt equity awards discussed below is included in separation costs. The Company recognized a related tax benefit associated with this expense of $5.8 million, $3.8 million and $3.4 million in fiscal 2013, 2012 and 2011, respectively.

Incentive Equity Awards Converted from Covidien Awards

Prior to the Separation, all employee incentive equity awards were granted by Covidien. At the time of Separation, the restricted share units and share options granted to Mallinckrodt employees prior to June 28, 2013 where converted into restricted share units and share options, respectively, of Mallinckrodt, and all of the performance share awards granted to Mallinckrodt employees were converted to restricted share units of Mallinckrodt (collectively, "the Conversion"). Mallinckrodt incentive equity awards issued upon completion of the Conversion and the related weighted average grant date fair value is presented below:

	Awards	Weighted-Average Grant-Date Fair Value
Share options	2,399,822	$ 7.96
Restricted share units	575,213	38.97

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Share Options. A summary of the status of the Company's share option awards upon completion of the Conversion on June 28, 2013 is presented below:

	Shares Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at June 28, 2013	2,399,822	$35.94	8.0	$22.9
Exercisable at June 28, 2013	550,097	30.94	5.9	8.0

The Conversion resulted in a modification of the previously issued share option awards. The Company compared the aggregate fair value of the awards immediately before and immediately after the Separation. The fair value of the awards immediately after the Separation was higher than the awards immediately before, primarily due to the elimination of Covidien's dividend yield assumption and the Company's higher volatility as compared to Covidien. The incremental fair value for vested awards was recognized immediately within separation costs, as the incremental fair value is directly attributable to the Separation, and the incremental fair value for unvested awards will be recognized on a straight-line basis over the remaining vesting period of the applicable awards, also within separation costs.

The weighted-average assumptions used in the Black-Scholes pricing model for determining the fair value of the share option awards immediately before and immediately after the Separation were as follows:

	Pre-Separation	Post-Separation
Expected share price volatility	26 %	32 %
Risk-free interest rate	0.99 %	0.99 %
Expected annual dividend per share	1.65 %	—
Expected life of options (in years)	3.8	3.8
Fair value per option	$18.04	$16.51
Share option awards	1,745,258	2,399,822

Restricted share units. The Conversion resulted in a modification of the previously issued restricted share unit awards ("RSUs"). The Company compared the aggregate fair value of the awards immediately before and immediately after the Separation. The Conversion did not result in incremental fair value.

Performance share units. The Conversion resulted in a modification of the previously issued performance share unit awards. The Company compared the aggregate fair value of the awards immediately before and immediately after the Separation. The fair value of the awards was higher after the Conversion as the performance factor utilized to convert the award was higher than what had previously been estimated. The incremental fair value was recognized immediately within separation costs for the service period to date and the remaining incremental fair value will be recognized over the remaining vesting period within separation costs.

Stock Compensation Plans

Prior to the Separation, the Company adopted the 2013 Mallinckrodt Pharmaceuticals Stock and Incentive Plan ("the 2013 Plan"). The 2013 Plan provides for the award of share options, share appreciation rights, annual performance bonuses, long-term performance awards, restricted units, restricted shares, deferred share units, promissory shares and other share-based awards (collectively, "Awards"). The 2013 Plan provides for a maximum of 5.7 million common shares to be issued as Awards, subject to adjustment as provided under the terms of the 2013 Plan. As of September 27, 2013, all equity awards held by the Company's employees were either converted from Covidien equity awards at the Separation or granted under its 2013 Plan.

Share options. Share options are granted to purchase the Company's ordinary shares at prices that are equal to the fair market value of the shares on the date the share option is granted. Share options generally vest in equal annual installments over a period of four years and expire ten years after the date of grant. The grant-date fair value of share options, adjusted for estimated forfeitures, is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. Forfeitures are estimated based on historical experience.

Share option activity and information is as follows:

	Share Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at June 28, 2013	2,399,822	$ 35.94		
Granted	406,169	44.00		
Exercised	(17,332)	30.04		
Expired/Forfeited	(28,428)	36.85		
Outstanding at September 27, 2013	2,760,231	37.30	8.2	$17.3
Vested and unvested expected to vest as of September 27, 2013	2,394,431	37.27	8.2	15.1
Exercisable at September 27, 2013	536,405	31.04	5.7	6.7

As of September 27, 2013, there was $22.0 million of total unrecognized compensation cost related to unvested share option awards, which is expected to be recognized over a weighted-average period of 2.3 years.

The grant date fair value of share options has been estimated using the Black-Scholes pricing model. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. The expected volatility assumption is based on the historical and implied volatility of the Company's peer group with similar business models for periods after the Separation, and on Covidien's peer group with similar business models for periods prior to the Separation. The expected life assumption is based on the contractual and vesting term of the share option, employee exercise patterns and employee post-vesting termination behavior. The expected annual dividend per share is based on the Company's current intentions regarding payment of cash dividends, or Covidien's dividend rate on the date of grant. The risk-free interest rate is based on U.S. Treasury zero-coupon issues with a remaining term equal to the expected life assumed at the date of grant. The weighted-average assumptions used in the Black-Scholes pricing model for share options granted subsequent to the Separation are included within the discussion of modification expense above. As all stock option awards were granted immediately following the Separation, the valuation assumptions for the modification and subsequent award were consistent.

Subsequent to the Separation, the total intrinsic value of share options exercised and the related excess cash tax benefit was not significant.

Restricted share units. Recipients of RSUs have no voting rights and receive dividend equivalent units which vest upon the vesting of the related shares. RSUs generally vest in equal annual installments over a period of four years. Restrictions on RSUs lapse upon normal retirement, death or disability of the employee. The grant-date fair value of RSUs, adjusted for estimated forfeitures, is recognized as expense on a straight-line basis over the service period. The fair market value of RSUs granted after the Conversion is determined based on the market value of the Company's shares on the date of grant for periods after the Separation.

RSU activity is as follows:

	Shares	Weighted-Average Grant-Date Fair Value
Non-vested at June 28, 2013	575,213	$ 38.97
Granted	167,546	43.86
Vested	(1,656)	31.28
Forfeited	(16,834)	38.57
Non-vested at September 27, 2013	724,269	40.62

The total fair value of Mallinckrodt restricted share unit awards granted during fiscal 2013 following the Separation was $7.3 million. The total fair value of Mallinckrodt restricted share unit awards vested during fiscal 2013 following the Separation was $0.1 million. As of September 27, 2013, there was $18.2 million of total unrecognized compensation cost related to non-vested restricted share units granted. The cost is expected to be recognized over a weighted-average period of 2.4 years.

Employee Stock Purchase Plans

The Company adopted the Mallinckrodt Employee Stock Purchase Plan ("ESPP") effective October 1, 2013. Substantially all full-time employees of the Company's U.S. subsidiaries and employees of certain qualified non-U.S. subsidiaries are eligible to participate in this ESPP. Eligible employees authorize payroll deductions to be made for the purchase of shares. The Company matches a portion of the employee contribution by contributing an additional 15% (25% in fiscal 2014) of the employee's payroll deduction up to a $25,000 employee contribution. All shares purchased under the ESPP are purchased on the open market by a designated broker.

15. Accumulated Other Comprehensive Income

The components of accumulated other comprehensive income are as follows:

	Currency Translation	Unrecognized Loss on Derivatives	Unrecognized Gain (Loss) on Benefit Plans	Accumulated Other Comprehensive Income
Balance at September 24, 2010	$160.5	$—	$(73.9)	$ 86.6
Pre-tax change	(0.5)	—	16.9	16.4
Income tax provision	—	—	(4.5)	(4.5)
Balance at September 30, 2011	160.0	—	(61.5)	98.5
Pre-tax change	(2.9)	—	(15.3)	(18.2)
Income tax benefit	—	—	4.6	4.6
Balance at September 28, 2012	157.1	—	(72.2)	84.9
Pre-tax change	1.5	(7.3)	51.4	45.6
Income tax provision	—	—	(22.0)	(22.0)
Balance at September 27, 2013	$158.6	$(7.3)	$(42.8)	$ 108.5

16. Transactions with Former Parent Company

Prior to the completion of the Separation on June 28, 2013, the Company was part of Covidien and, as such, transactions between Covidien and the Company were considered related party transactions. As discussed in Note 1, these intercompany transactions are included in the combined financial statements and were considered to be effectively settled for cash at the time the transaction was recorded. The continuing relationship between Covidien and the Company is primarily governed through agreements entered into as part of the Separation. The Separation and Distribution Agreement, Tax Matters Agreement and a transition services agreement were filed with the SEC as Exhibits 2.1, 10.1 and 10.3, respectively, to the Company's Current Report on Form 8-K filed on July 1, 2013. The following discusses the related party transactions and those agreements.

Sales and Purchases

During fiscal 2013, 2012 and 2011, the Company sold inventory to Covidien in the amount of $51.2 million, $54.2 million and $52.4 million, respectively, which is included in net sales in the consolidated and combined statements of income. The Company also purchases inventories from Covidien. The Company recognized cost of sales from these inventory purchases of $38.4 million, $34.7 million and $41.1 million during fiscal 2013, 2012 and 2011, respectively.

Allocated Expenses

As discussed in Note 1, the combined financial statements for periods prior to June 28, 2013 include expense allocations for certain functions provided by Covidien, including, but not limited to, general corporate expenses related to finance, legal, information technology, human resources, communications, employee benefits and incentives, insurance and share-based compensation. These expenses were allocated to the Company on the basis of direct usage when identifiable, with the remainder allocated on the basis of operating expenses, headcount or other measures. The amounts allocated were $39.6 million, $49.2 million and $56.3 million for fiscal 2013, 2012 and 2011,

respectively, and are included within selling, general and administrative expenses.

Balance Sheet Impacts

Prior to the Separation, intercompany transactions between the Company and Covidien were considered to be effectively settled for cash at the time the transaction was recorded and were presented within parent company investment in the combined balance sheet. However, at the completion of the Separation on June 28, 2013, certain transactions remained unsettled and were reclassified from parent company investment and included within the assets and liabilities of the Company. The condensed consolidated balance sheet immediately following the Separation included $22.3 million of amounts due to the Company from Covidien and $61.9 million of amounts the Company owes Covidien. Subsequent to the Separation, Covidien made an additional cash contribution for the net difference in these amounts, which was recorded through shareholders' equity. In conjunction with this contribution, each party settled the amounts outstanding immediately following the Separation.

Subsequent to the Separation, the Company and Covidien maintain an ongoing relationship in which each party may provide services to the other party, including the distribution of goods. As a result of these relationships, the consolidated balance sheet as of September 27, 2013 includes $62.2 million of amounts due to the Company from Covidien, within prepaid expenses and other current assets, and $79.3 million of amounts the Company owes Covidien, included within accrued and other liabilities.

In connection with the Separation, the Company recorded separation related adjustments within parent company investment, which represent transfers of certain assets and liabilities with Covidien pursuant to the Separation and Distribution Agreement. The Company has used available information to develop its best estimates for certain assets and liabilities related to the Separation. In limited instances, final determination of the balances will be made in subsequent periods. Any adjustments, if necessary, are not expected to be material and will be recorded through shareholders' equity in subsequent periods when determined.

Separation and Distribution Agreement

On June 28, 2013, the Company entered into a Separation and Distribution Agreement and other agreements with Covidien to effect the Separation and provide a framework for the Company's relationships with Covidien after the Separation. These agreements govern the relationship between Mallinckrodt and Covidien subsequent to the Separation and provide for the assignment to Mallinckrodt of certain of Covidien's assets, liabilities and obligations attributable to periods prior to the Separation.

In general, each party to the Separation and Distribution Agreement assumed liability for all pending, threatened and unasserted legal matters related to its own business or its assumed or retained liabilities and will indemnify the other party for any liability to the extent arising out of, or resulting from, such assumed or retained legal matters.

The Separation and Distribution Agreement provided for the initial cash capitalization of Mallinckrodt in the amount of approximately $168 million at June 28, 2013. The Separation and Distribution Agreement also provided for an adjustment payment to compensate either Mallinckrodt or Covidien, as applicable, to the extent that the aggregate of the Company's cash, indebtedness and specified working capital accounts as of June 28, 2013 ("the Distribution Date"), as well as the capital expenditures made with respect to the Company's business during fiscal 2013 through the Distribution Date, deviated from a target. The target was calculated pursuant to a formula set forth in the Separation and Distribution Agreement, which assumed the Distribution Date would be June 28, 2013, that the Pharmaceuticals business was conducted in the ordinary course through that date and that the Company would have approximately $168 million of cash upon completion of the distribution. The Separation and Distribution Agreement also provided that an adjustment payment would only be payable if the amount of the adjustment payment exceeded $20 million (in which case the entire amount would be paid). Upon final calculation, no adjustment payment was required by either the Company or Covidien.

Tax Matters Agreement

In connection with the Separation, Mallinckrodt entered into the Tax Matters Agreement with Covidien that generally will govern Covidien's and Mallinckrodt's respective rights, responsibilities and obligations after the Separation with respect to certain taxes, including ordinary course of business taxes and taxes, if any, incurred as a result of any failure

of the distribution of Mallinckrodt shares to qualify as a tax-free distribution for U.S. federal income tax purposes within the meaning of Section 355 of the U.S. Internal Revenue Code, or other applicable tax law, or any failure of certain internal transactions undertaken in anticipation of the distribution to qualify for tax-free or tax-favored treatment under the applicable tax law. The Company expects, with certain exceptions, to be responsible for the payment of all taxes attributable to Mallinckrodt or its subsidiaries for taxable periods beginning on or after September 29, 2012. For periods prior to September 29, 2012, the Company is subject to a $200 million liability limitation, net of any benefits, as prescribed by the Tax Matters Agreement. To the extent that the Company's liability for such taxes, net of any tax benefits, does not exceed $200 million, it may be responsible for additional taxes attributable to periods prior to September 29, 2012, taxes related to the Separation and a percentage of any taxes arising from the Separation failing to qualify for tax-free or tax-favored treatment through no fault of Covidien or the Company. The Tax Matters Agreement also assigns rights and responsibilities for administrative matters, such as the filing of returns, payment of taxes due, retention of records, tax reporting practices and conduct of audits, examinations or similar proceedings. In addition, the Tax Matters Agreement provides for cooperation and information sharing with respect to tax matters.

The Tax Matters Agreement also contains restrictions on the Company's ability to take actions without Covidien's consent that could cause the Separation or certain internal transactions undertaken in anticipation of the Separation to fail to qualify as tax-free or tax-favored transactions under applicable tax law. These transactions include, but are not limited to, entering into, approving or allowing any transaction that results in a change in ownership of more than 35% of Mallinckrodt's shares; any merger, consolidation, scheme of arrangement, liquidation or partial liquidation, or any approval or allowance of such transaction with respect to certain of the Company's subsidiaries; the cessation or transfer of certain business activities; the sale, issuance or other disposition of any equity interest in certain of the Company's subsidiaries; a sale or other disposition of a substantial portion of the Company's assets or a substantial portion of the assets of certain of the Company's subsidiaries; extraordinary distributions by or to certain of the Company's subsidiaries; or engaging in certain internal transactions. These restrictions will all apply for the two-year period after the Separation and in some cases will apply for periods as long as five years following the Separation. Any taxes imposed on the other party attributable to certain post-distribution actions taken by or in respect of the responsible party or its shareholders that result in failure of the Separation or internal transactions to qualify as tax-free or tax-favored transactions are the responsibility of the party at fault, regardless of whether the actions occur more than two years after the distribution, or whether Covidien consents to such actions. Any actions of the Company or its shareholders that directly give rise to additional taxes are not subject to the $200 million threshold noted previously.

Transition Services Agreement

Mallinckrodt and Covidien entered into a transition services agreement in connection with the Separation pursuant to which Mallinckrodt and Covidien will provide each other, on an interim and transitional basis, various services including, but not limited to, treasury administration, information technology services, non-exclusive distribution and importation services for our products in certain countries outside the U.S., regulatory, general administrative services and other support services. The agreed-upon charges for such services are generally intended to allow the servicing party to recover all out-of-pocket costs and expenses, and include a predetermined profit margin.

17. Guarantees

In disposing of assets or businesses, the Company has historically provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to the assets, environmental risks involved in the sale of real estate, liability to investigate and remediate environmental contamination at waste disposal sites and manufacturing facilities, and unidentified tax liabilities related to periods prior to disposition. The Company assesses the probability of potential liabilities related to such representations, warranties and indemnities and adjusts potential liabilities as a result of changes in facts and circumstances. The Company has no reason to believe that these uncertainties would have a material adverse effect on its financial condition, results of operations and cash flows.

In connection with the sale of Mallinckrodt Baker in fiscal 2010, the Company agreed to indemnify the purchaser with respect to various matters, including certain environmental, health, safety, tax and other matters. The indemnification obligations relating to certain environmental, health and safety matters have a term of 17 years from the sale, while some of the other indemnification obligations have an indefinite term. The amount of the liability relating to all of these indemnification obligations included in other liabilities on the Company's consolidated and combined balance sheets at September 27, 2013 and September 28, 2012 was $20.1 million and $22.4 million, respectively, of which $17.2 million and $18.3 million, respectively, related to environmental, health and safety matters. The value of the environmental, health and safety indemnity was measured based on the probability-weighted present value of the costs expected to be incurred to address environmental, health and safety claims made under the indemnity. The aggregate fair value of these indemnification obligations did not differ significantly from their aggregate carrying value at September 27, 2013 and September 28, 2012. As of September 27, 2013, the maximum future payments the Company could be required to make under these indemnification obligations was $75.5 million. The Company was required to pay $30.0 million into an escrow account as collateral to the purchaser, of which $23.5 million and $24.5 million remained in other assets on the consolidated and combined balance sheets at September 27, 2013 and September 28,

2012, respectively.

The Company has recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 18. In addition, the Company is liable for product performance; however in the opinion of management, such obligations will not have a material adverse effect on its financial condition, results of operations and cash flows.

The Company is required to provide the U.S. Nuclear Regulatory Commission financial assurance demonstrating its ability to fund the decommissioning of its Maryland Heights, Missouri radiopharmaceuticals production facility upon closure, though the Company does not intend to close this facility. The Company has provided this financial assurance in the form of a $58.0 million surety bond.

In addition, as of September 27, 2013, the Company had a $21.1 million letter of credit to guarantee decommissioning costs associated with its Saint Louis, Missouri plant. As of September 27, 2013, the Company had various other letters of credit and guarantee and surety bonds totaling $38.1 million.
In addition, the Separation and Distribution Agreement provides for cross-indemnities principally designed to place financial responsibility of the obligations and liabilities of the Company's business with the Company and financial responsibility for the obligations and liabilities of Covidien's remaining business with Covidien, among other indemnities.

18. Commitments and Contingencies
The Company has purchase obligations related to commitments to purchase certain goods and services. At September 27, 2013, such obligations were as follows:

Fiscal 2014	$74.9
Fiscal 2015	23.7
Fiscal 2016	22.3
Fiscal 2017	—
Fiscal 2018	—

The Company is subject to various legal proceedings and claims, including patent infringement claims, product liability matters, environmental matters, employment disputes, contractual disputes and other commercial disputes, including those described below. The Company believes that these legal proceedings and claims likely will be resolved over an extended period of time. Although it is not feasible to predict the outcome of these matters, the Company is of the opinion that their ultimate resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

Governmental Proceedings
On January 7, 2009, the Company received a subpoena from the U.S. Attorney's Office for the Northern District of California requesting production of documents relating to the sales and marketing of its Tofranil-PM, Restoril and Magnacet products. In June 2013, the Company agreed to settlement terms in this proceeding providing for a cash payment by the Company of $3.5 million, which was consistent with the Company's previously established accrual.
On November 30, 2011 and October 22, 2012, the Company received subpoenas from the U.S. Drug Enforcement Administration requesting production of documents relating to its suspicious order monitoring programs. The Company is complying as required by the terms of the subpoenas. While it is not possible at this time to determine with certainty the outcome of these proceedings, the Company believes that the ultimate resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

Patent/Antitrust Litigation
Tyco Healthcare Group LP, et al. v. Mutual Pharmaceutical Company, Inc. The Company filed a patent infringement suit in the U.S. District Court for the District of New Jersey against Mutual Pharmaceutical Co., Inc., et al. (collectively, "Mutual") on March 20, 2007 pursuant to procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984, after Mutual submitted an Abbreviated New Drug Application to the FDA seeking to sell a generic version of the Company's 7.5 mg Restoril sleep aid product. Mutual also filed antitrust and unfair competition counterclaims. The patents at issue have since expired or been found invalid. On January 18, 2013, the trial court issued an opinion and order granting the Company's motion for summary judgment regarding Mutual's antitrust and unfair competition counterclaims. On May 1, 2013, Mutual appealed this decision to the U.S. Court of Appeals for the Federal Circuit. While it is not possible at this time to determine with certainty the ultimate outcome of the counterclaims, the Company believes that the final resolution of the claims will not have a material adverse effect on its financial condition, results of operations and cash flows.

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Pricing Litigation

Two cases were brought against the Company that allege generally that the Company and numerous other pharmaceuticals companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid, resulting in overpayment by state Medicaid programs for those drugs. These cases, brought by state Attorneys General in Utah and Louisiana, generally seek monetary damages and attorneys' fees. The Company is named as a defendant in State of Utah v. Actavis US, Inc., et al. filed May 8, 2008, which is pending in the Third Judicial Circuit of Salt Lake County, Utah. The Company was also named in State of Louisiana v. Abbott Laboratories Inc., et al. filed November 3, 2010, which was pending in the 19th Judicial District, Parish of East Baton Rouge, Louisiana. In May 2013, the Company agreed to terms of settlement with the Attorney General for the State of Louisiana resolving all claims in State of Louisiana v. Abbott Laboratories Inc., et al. The settlement did not have a material impact on the Company's consolidated and combined financial statements. The Utah case is pending and the Company intends to contest that case and to explore other options as appropriate. While it is not possible at this time to determine with certainty the outcome of the case, the Company believes that the ultimate resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

Environmental Remediation and Litigation Proceedings

The Company is involved in various stages of investigation and cleanup related to environmental remediation matters at a number of sites, including those described below. The ultimate cost of site cleanup and timing of future cash outlays is difficult to predict, given the uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations and alternative cleanup methods. The Company concluded that, as of September 27, 2013, it was probable that it would incur remedial costs in the range of $46.4 million to $81.5 million. The Company also concluded that, as of September 27, 2013, the best estimate within this range was $46.4 million, of which $6.9 million was included in accrued and other current liabilities and the remainder was included in environmental liabilities on the consolidated balance sheet at September 27, 2013.

Orrington, Maine. The Company was a successor to a company which owned and operated a chemical manufacturing facility in Orrington, Maine from 1967 until 1982. As such, the Company was responsible for the costs of completing an environmental site investigation required by the U.S. Environmental Protection Agency ("EPA") and the Maine Department of Environmental Protection. The Company estimated that, as of September 28, 2012, the cost to comply with the proposed remediation alternatives at this site ranged from $95.8 million to $170.3 million. At September 28, 2012, estimated future investigation and remediation costs of $95.8 million were accrued for this site.

In accordance with the Separation and Distribution Agreement, this liability was retained by Covidien, and, therefore, this liability was removed from environmental liabilities as of June 28, 2013, the date the Separation was completed. As the Company no longer manages this case, it will not continue to update its status for further developments. Further information and details on the history of the case can be found in the information statement filed with the SEC as Exhibit 99.2 to the Company's Current Report on Form 8-K filed on July 1, 2013.

Penobscot River and Bay. Since April 2000, the Company had been involved in the lawsuit, Maine People's Alliance and Natural Resources Defense Council, Inc. v. HoltraChem Manufacturing Company, LLC and Mallinckrodt US LLC, filed in the U.S. District Court for the District of Maine by the Natural Resources Defense Council and the Maine People's Alliance. Plaintiffs sought an injunction requiring the Company to conduct extensive studies of mercury contamination of the Penobscot River and Bay and options for remediating such contamination, and to perform appropriate remedial activities, if necessary.

In accordance with the Separation and Distribution Agreement, this liability was retained by Covidien, and, therefore, this liability was removed from environmental liabilities as of June 28, 2013, the date the Separation was completed. As the Company no longer manages this case, it will not continue to update its status for further developments. Further information and details on the history of this case can be found in the information statement filed with the SEC as Exhibit 99.2 to the Company's Current Report on Form 8-K filed on July 1, 2013.

Crab Orchard National Wildlife Refuge Superfund Site, near Marion, Illinois. The Company is a successor in interest to International Minerals and Chemicals Corporation ("IMC"). Between 1967 and 1982, IMC leased portions of the

Additional and Uncharacterized Sites ("AUS") Operable Unit at the Crab Orchard Superfund Site ("the Site") from the government and manufactured various explosives for use in mining and other operations. In March 2002, the Department of Justice, the U.S. Department of the Interior and the EPA (together, "the Government Agencies") issued a special notice letter to General Dynamics Ordnance and Tactical Systems, Inc. ("General Dynamics"), one of the other potentially responsible parties ("PRPs") at the Site, to compel General Dynamics to perform the remedial investigation and feasibility study ("RI/FS") for the AUS Operable Unit. General Dynamics negotiated an Administrative Order on Consent with the Government Agencies to conduct an extensive RI/FS at the Site under the direction of the U.S. Fish and Wildlife Service. General Dynamics asserted in August 2004 that the Company is jointly and severally liable, along with approximately eight other lessees and operators at the AUS Operable Unit, for alleged contamination of soils and groundwater resulting from historic operations, and has threatened to file a contribution claim against the Company and other parties for recovery of its costs incurred in connection with the RI/FS activities being conducted at the AUS Operable Unit. The Company and other PRPs

who received demand letters from General Dynamics have explored settlement alternatives, but have not reached settlement to date. The Company and other PRPs are awaiting completion of the RI/FS by General Dynamics before the initiation of formal PRP negotiations to address resolution of these alleged claims. While it is not possible at this time to determine with certainty the ultimate outcome of this case, the Company believes that the final resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on its financial condition, results of operations and cash flows.

Mallinckrodt Veterinary, Inc., Millsboro, Delaware. The Company previously operated a plant in Millsboro, Delaware ("the Millsboro Site") that manufactured various animal healthcare products. In 2005, the Delaware Department of Natural Resources and Environmental Control found trichloroethylene ("TCE") in the Millsboro public water supply at levels that exceeded the federal drinking water standards. Further investigation to identify the TCE plume in the ground water indicated that the plume has extended to property owned by a third party near the Millsboro Site. The Company, and other former owners, assumed responsibility for the Millsboro Site cleanup under the Alternative Superfund Program administered by the EPA. The Company and other PRPs entered into an Administrative Order on Consent with the EPA on May 10, 2010, which was subsequently amended in November 2010 and January 2011, to investigate the potential source of TCE contamination and to evaluate options to abate, mitigate or eliminate the release or threat of release of hazardous substances at the Millsboro Site. The Company, along with other parties, continues to conduct the studies and prepare remediation plans in accordance with the amended Administrative Order on Consent. While it is not possible at this time to determine with certainty the ultimate outcome of this matter, the Company believes that the final resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on its financial condition, results of operations and cash flows.

Coldwater Creek, Saint Louis County, Missouri. The Company is one of several companies named as defendants in six tort complaints (McClurg, et al. v. Mallinckrodt, Inc., et al., filed February 28, 2012; Adams, et al. v. Mallinckrodt, Inc., et al., filed April 10, 2012; Steinmann, et al. v. Mallinckrodt, Inc., et al., filed October 23, 2012; Schneider, et al. v. Mallinckrodt, Inc., et al., filed April 19, 2013; Vorce v. Mallinckrodt, Inc., et al., filed June 18, 2013; and Lange, et al. v. Mallinckrodt, Inc., et al., filed July 31, 2013) with numerous plaintiffs pending in the U.S. District Court for the Eastern District of Missouri. These cases allege personal injury for alleged exposure to radiological substances present in Coldwater Creek in Missouri. Plaintiffs lived in various locations in Saint Louis County, Missouri near Coldwater Creek. Radiological residues which may have been present in the creek have been remediated by the U.S. Army Corps of Engineers. The Company believes that it has meritorious defenses to these complaints and is vigorously defending against them. The Company is unable to estimate a range of reasonably possible losses for the following reasons: (i) the proceedings are in early stages; (ii) the Company has not received and reviewed complete information regarding the plaintiffs and their medical conditions; and (iii) there are significant factual issues to be resolved. While it is not possible at this time to determine with certainty the ultimate outcome of these cases, the Company believes that the final resolution of all known claims will not have a material adverse effect on its financial condition, results of operations and cash flows.

Products Liability Litigation

The Company is one of four manufacturers of Gadolinium-Based Contrast Agents, such as the Company's Optimark product, involved in litigation alleging that administration of these agents causes development of nephrogenic systemic fibrosis in a small number of patients with advanced renal impairment. In May 2013, the Company agreed to terms of settlement with the plaintiffs in all of its previously disclosed lawsuits involving its Optimark product. These settlements resolved cases that were included in federal multi-district litigation pending in the U.S. District Court for the Northern District of Ohio (In re Gadolinium-Based Contrast Agents Product Liability Litigation, which was established on February 27, 2008) and cases in various state courts. These settlements did not have a material impact on the Company's consolidated and combined financial statements.

Beginning with lawsuits brought in July 1976, the Company is also named as a defendant in personal injury lawsuits based on alleged exposure to asbestos-containing materials. A majority of the cases involve product liability claims based principally on allegations of past distribution of products containing asbestos. A limited number of the cases

allege premises liability based on claims that individuals were exposed to asbestos while on the Company's property. Each case typically names dozens of corporate defendants in addition to the Company. The complaints generally seek monetary damages for personal injury or bodily injury resulting from alleged exposure to products containing asbestos. The Company's involvement in asbestos cases has been limited because it did not mine or produce asbestos. Furthermore, in the Company's experience, a large percentage of these claims have never been substantiated and have been dismissed by the courts. The Company has not suffered an adverse verdict in a trial court proceeding related to asbestos claims and intends to continue to defend these lawsuits. When appropriate, the Company settles claims; however, amounts paid to settle and defend all asbestos claims have been immaterial. As of September 27, 2013, there were approximately 11,500 asbestos-related cases pending against the Company.

The Company estimates pending asbestos claims and claims that were incurred but not reported and related insurance recoveries, which are recorded on a gross basis in the consolidated and combined balance sheet. The Company's estimate of its liability for pending and future claims is based on claims experience over the past five years and covers claims either currently filed or expected to be filed over the next seven years. The Company believes that it has adequate amounts recorded related to these matters. While it is not possible at this time to determine with certainty the ultimate outcome of these asbestos-related proceedings, the Company believes that the final outcome of all known and anticipated future claims, after taking into account amounts already accrued, along with recoveries from insurance, will not have a material adverse effect on its financial condition, results of operations and cash flows.

Asset Retirement Obligations

The Company has recorded asset retirement obligations for the estimated future costs primarily associated with legal obligations to decommission facilities within the Global Medical Imaging segment, including the facilities located in the Netherlands and Maryland Heights, Missouri. Substantially all of these obligations are included in other liabilities on the consolidated and combined balance sheets. The following table provides a summary of the changes in the Company's asset retirement obligations for fiscal 2013 and 2012:

	2013	2012
Balance at beginning of period	$46.4	$45.9
Additions	0.4	—
Accretion expense	2.9	2.5
Payments	(0.2)	—
Currency translation	1.1	(2.0)
Balance at end of period	$50.6	$46.4

The Company believes that any potential payment of such estimated amounts will not have a material adverse effect on its financial condition, results of operations and cash flows.

Leases

The Company has facility, vehicle and equipment leases that expire at various dates. Rental expense under facility, vehicle and equipment operating leases related to continuing operations was $16.9 million, $15.5 million and $14.4 million for fiscal 2013, 2012 and 2011, respectively. The Company also has facility and equipment commitments under capital leases.

The following is a schedule of minimum lease payments for non-cancelable leases as of September 27, 2013:

	Operating Leases	Capital Leases
Fiscal 2014	$19.3	$1.5
Fiscal 2015	13.3	1.5
Fiscal 2016	10.4	0.4
Fiscal 2017	8.7	—
Fiscal 2018	4.8	—
Thereafter	10.2	—
Total minimum lease payments	$66.7	3.4
Less: interest portion of payments		(0.2)
Present value of minimum lease payments		$3.2

The Company exchanged title to $11.3 million of its plant assets in return for an equal amount of Industrial Revenue Bonds ("IRB") issued by the Saint Louis County. The Company also simultaneously leased such assets back from Saint Louis County under a capital lease expiring December 2022, the terms of which provide the Company with the right of offset against the IRBs. The lease also provides an option for the Company to repurchase the assets at the end

of the lease for nominal consideration. These transactions collectively result in a property tax abatement ten years from the date the property is placed in service. Due to right of offset, the capital lease obligation and IRB asset are recorded net in the consolidated and combined balance sheets and excluded from the above table. The Company expects that the right of offset will be applied to payments required under these arrangements.

Tax Matters

The income tax returns of the Company and its subsidiaries are periodically examined by various tax authorities. The resolution of these matters is subject to the conditions set forth in the Tax Matters Agreement between the Company and Covidien. Covidien has the right to administer, control and settle all U.S. income tax audits for periods prior to the Separation. While it is not possible at this time to determine with certainty the ultimate outcome of these matters, the Company believes that established liabilities are reasonable and that final resolution of these matters will not have a material adverse effect on its financial condition, results of operations and cash flows.

With respect to certain tax returns filed by predecessor affiliates of the Company and Covidien, the IRS has concluded its field examination for the years 1997 through 2000 and has proposed tax adjustments. Several of the proposed adjustments could also affect both Covidien's and the Company's income tax returns for years after 2000. Certain of the IRS's proposed adjustments have been appealed, and all but one of the matters associated with the proposed tax adjustments have been resolved. The unresolved proposed adjustment asserts that substantially all of the predecessor affiliates' intercompany debt originating during the years 1997 through 2000 should not be treated as debt for U.S. federal income tax purposes, and has disallowed interest deductions related to the intercompany debt and certain tax attribute adjustments recognized on the U.S. income tax returns. This matter is subject to the Company's $200 million limitation for periods prior to September 29, 2012, as prescribed in the Tax Matters Agreement. While it is not possible at this time to determine with certainty the ultimate outcome of this matter, the Company believes that it will not have a material adverse effect on its financial condition, results of operations and cash flows.

Other Matters

The Company is a defendant in a number of other pending legal proceedings relating to present and former operations, acquisitions and dispositions. The Company does not expect the outcome of these proceedings, either individually or in the aggregate, to have a material adverse effect on its financial condition, results of operations and cash flows.

19. Derivative Instruments

The Company is exposed to certain risks relating to its business operations. Prior to the Separation on June 28, 2013, the Company participated in the centralized hedging functions of Covidien to help mitigate risks related to foreign exchange exposure and certain commodity price exposures. Foreign currency option and forward contracts were used to manage the foreign exchange exposures of operations outside the U.S. Swap contracts on commodities were periodically entered into to manage the price risk associated with forecasted purchases of commodities used in the Company's manufacturing processes. The associated derivative assets and liabilities for these types of instruments were not included on the Company's combined balance sheet prior to June 28, 2013, since derivative activity was centrally managed by Covidien. In conjunction with the Separation, the Company assumed the foreign currency forward and option contacts directly related to its business and, as such, has recognized the fair value of the these derivatives in its consolidated balance sheet as of September 27, 2013. The commodity swap contracts were retained by Covidien. Changes in the fair value of the derivative financial instruments which related to the Company's business operations have been recognized in the Company's earnings unless specific hedge criteria are met. Covidien designated certain commodity swap contracts as cash flow hedges but did not designate the foreign currency forward and option contracts as hedging instruments.

Risks that relate to interest rate exposure were managed by using derivative instruments. In March 2013 and April 2013, MIFSA entered into forward interest rate lock contracts to hedge the risk of variability in the market interest rates prior to the issuance of the Notes in April 2013. These transactions have been reflected in the consolidated and combined financial statements for all periods, since the transactions were solely entered into in connection with the Separation and were not centrally managed by Covidien.

Foreign Exchange Exposure

The Company has foreign exchange exposure on the translation of the financial statements and on transactions denominated in foreign currencies. The Company's policy is to use various forward and option contracts to manage

foreign currency exposures on accounts and notes receivable, accounts payable, intercompany loans, intercompany cash pooling arrangements and forecasted transactions that are denominated in certain foreign currencies. These contracts did not meet the necessary criteria to qualify for hedge accounting; accordingly, all associated changes in fair value were recognized in earnings.

The location and amount of the net gain (loss) on foreign exchange forward and option contracts not designated as hedging instruments was recorded as follows:

	Fiscal Year		
	2013	2012	2011
Cost of sales	$2.2	$(0.3)	$(3.7)
Selling, general and administrative	—	0.1	0.1
Other income, net	8.3	—	—
	$10.5	$(0.2)	$(3.6)

Foreign currency losses included within net income for fiscal 2013 and 2011 were $14.2 million and $4.3 million, respectively. The impact of foreign currency on net income in fiscal 2012 was immaterial.

The fair value of foreign exchange forward contracts are included in the following captions of our consolidated and combined balance sheets at the end of each period:

	September 27, 2013	September 28, 2012
Prepaid expenses and other current assets	$0.9	$ —
Accrued and other current liabilities	1.4	—

Commodities Exposure

Prior to the Separation, Covidien entered into gas commodity swap contracts on behalf of the Company, which were accounted for as cash flow hedges. The amounts of the net losses on these contracts were recorded as follows:

	Fiscal Year		
	2013	2012	2011
Cost of sales	$0.3	$0.9	$0.8
Selling, general and administrative	0.8	2.3	2.4
	$1.1	$3.2	$3.2

As of September 27, 2013, there were no outstanding gas commodity swap contracts; however, the Company may utilize such contracts in the future to mitigate price risk associated with its forecasted commodity purchases.

Interest Rate Exposure

MIFSA entered into three forward interest rate lock contracts in March 2013 and April 2013, each with a $300 million notional value and designated as cash flow hedges, against the risk of variability in market interest rates in advance of its anticipated issuance of its ten-year fixed rate senior notes due April 2023. Each interest rate lock contract was considered to be highly effective and the $7.6 million loss resulting from their settlements was recorded in accumulated other comprehensive income. As of September 27, 2013, $7.3 million of this loss remains in accumulated other comprehensive income and will be amortized to interest expense over the remaining term of the ten-year notes.

20. Financial Instruments and Fair Value Measurements

Fair value is defined as the exit price that would be received from the sale of an asset or paid to transfer a liability, using assumptions that market participants would use in pricing an asset or liability. The fair value guidance establishes a three-level fair value hierarchy, which maximizes the use of observable inputs and minimizes the use of unobservable inputs used in measuring fair value. The levels within the hierarchy are as follows:

Level 1— observable inputs such as quoted prices in active markets for identical assets or liabilities;

Level 2— significant other observable inputs that are observable either directly or indirectly; and

Level 3— significant unobservable inputs in which there is little or no market data, which requires the Company to develop its own assumptions.

The following tables provide a summary of the significant assets and liabilities that are measured at fair value on a recurring basis at the end of each period:

	September 27, 2013	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Debt and equity securities held in rabbi trusts	$ 35.3	$22.6	$12.7	$ —
Foreign exchange forward and option contracts	0.9	0.9	—	—
	$ 36.2	$23.5	$12.7	$ —
Liabilities:				
Deferred compensation liabilities	$ 13.5	$—	$13.5	$ —
Contingent consideration	6.9	—	—	6.9
Foreign exchange forward and option contracts	1.4	1.4	—	—
	$ 21.8	$1.4	$13.5	$ 6.9

	September 28, 2012	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Debt and equity securities held in rabbi trusts	$ 25.2	$13.7	$11.5	$ —
Liabilities:				
Deferred compensation liabilities	$ 9.3	$—	$9.3	$ —

Debt and equity securities held in rabbi trust. Debt securities held in the rabbi trust primarily consist of U.S. government and agency securities and corporate bonds. When quoted prices are available in an active market, the investments are classified as level 1. When quoted market prices for a security are not available in an active market, they are classified as level 2. Equity securities held in the rabbi trust primarily consist of U.S. common stocks, which are valued using quoted market prices reported on nationally recognized securities exchanges. The $10.1 million increase in debt and equity securities held in rabbi trust primarily reflects the transfer of these assets from Covidien in connection with the Separation.

Foreign exchange forward and option contracts. Foreign currency option and forward contracts are used to economically manage the foreign exchange exposures of operations outside the U.S. Quoted prices are available in an active market; as such, these derivatives are classified as level 1.

Deferred compensation liabilities. Covidien maintains a non-qualified deferred compensation plan in the U.S., which permits eligible employees of the Company to defer a portion of their compensation. A recordkeeping account is set up for each participant and the participant chooses from a variety of funds for the deemed investment of their accounts. The measurement funds generally correspond to the funds offered in Covidien's U.S. tax-qualified defined contribution retirement plan and the account balance fluctuates with the investment returns on those funds.
Contingent consideration. In October 2012, the Company recorded contingent consideration of $6.9 million upon the acquisition of CNS Therapeutics. This contingent consideration, which could potentially total a maximum of $9.0 million, is primarily based on whether the FDA approves another concentration of Gablofen on or before December 31, 2016. The fair value of the contingent payments was measured based on the probability-weighted present value of the consideration expected to be transferred using a discount rate of 1.0%. There were no changes to the initial estimate of the fair value of the consideration during fiscal 2013.

Balance at September 28, 2012	$—
Fair value of contingent consideration	6.9
Balance at September 27, 2013	$6.9

Financial Instruments Not Measured at Fair Value
The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and the majority of other current assets and liabilities approximate fair value because of their short-term nature. The Company classifies cash on hand and deposits in banks, including commercial paper, money market accounts and other investments it may hold from time to time, with an original maturity to the Company of three months or less, as cash and cash equivalents (level 1). The fair value of restricted cash is equivalent to its carrying value of $24.0 million and $24.6 million as of September 27, 2013 and September 28, 2012, respectively (level 1), substantially all of which is included in other assets on the consolidated and combined balance sheets. The Company's life insurance contracts are carried at cash surrender value, which is based on the present value of future cash flows under the terms of the contracts (level 3). Significant assumptions used in determining the cash surrender value include the amount and timing of future cash flows, interest rates and mortality charges. The fair value of these contracts approximates the carrying value of $67.7 million and $47.6 million at September 27, 2013 and September 28, 2012, respectively. These contracts are included in other assets on the consolidated and combined balances sheets. The $20.1 million increase in the Company's life insurance contracts primarily reflects the transfer of these assets from Covidien in connection with the Separation.
The carrying value of the Company's loan payable approximates fair value due to its short term nature. Since the quoted market prices for the Company's 7.00%, 8.00% and 9.50% debentures are not available in an active market, they are classified as level 2 for purposes of developing an estimate of fair value. The Company's 3.50% and 4.75% notes are classified as level 1, as quoted prices are available in an active market for these notes. The following table presents the carrying values and estimated fair values of the Company's long-term debt, excluding capital leases, as of the end of each period:

	September 27, 2013		September 28, 2012	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Loan payable	$0.1	$0.1	$—	$—
7.00% debentures due December 2013	—	—	5.8	5.8
3.50% notes due April 2018	299.9	293.7	—	—
9.50% debentures due May 2022	10.4	14.3	—	—
8.00% debentures due March 2023	8.0	10.2	—	—
4.75% notes due April 2023	598.2	568.5	—	—

Concentration of Credit and Other Risks
Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of accounts receivable. The Company does not require collateral from customers. A portion of the Company's accounts

receivable outside the U.S. includes sales to government-owned or supported healthcare systems in several countries, which are subject to payment delays. Payment is dependent upon the financial stability and creditworthiness of those countries' national economies. Deteriorating credit and economic conditions in parts of Western Europe, particularly in Spain and Italy, may continue to increase the average length of time it takes the Company to collect its accounts receivables in certain regions within these countries.

The Company routinely evaluates all government receivables for potential collection risks associated with the availability of government funding and reimbursement practices. The Company has not incurred any significant losses on government receivables; however, if the financial condition of customers or the countries' healthcare systems continue to deteriorate such that their ability to make payments is uncertain, additional allowances may be required in future periods.

The Company's accounts receivable, net of allowance for doubtful accounts, in Spain and Italy at the end of each period are as follows:

	September 27, 2013	September 28, 2012
Spain	$ 9.2	$ 15.0
Italy	12.6	12.5

Net sales to customers in Spain and Italy totaled $51.7 million, $55.0 million and $60.2 million for fiscal 2013, 2012 and 2011, respectively.

The following table shows net sales attributable to distributors that accounted for 10% or more of the Company's total net sales:

	Fiscal Year					
	2013		2012		2011	
Cardinal Health, Inc.	18	%	19	%	19	%
McKesson Corporation	15	%	14	%	13	%
Amerisource Bergen Corporation	9	%	9	%	10	%

The following table shows accounts receivable attributable to distributors that accounted for 10% or more of the Company's gross accounts receivable at the end of each period:

	September 27, 2013		September 28, 2012	
Cardinal Health, Inc.	18	%	19	%
McKesson Corporation	22	%	20	%
Amerisource Bergen Corporation	14	%	10	%

The following table shows net sales attributable to products that accounted for 10% or more of the Company's total net sales:

	Fiscal Year					
	2013		2012		2011	
Optiray (CMDS)	14	%	17	%	19	%
Acetaminophen products (API)	10	%	11	%	11	%

Molybdenum-99 ("Mo-99") is a key raw material in the Company's Ultra-Technekow DTE technetium generators that are sold by its Global Medical Imaging segment. There are only eight suppliers of this raw material worldwide. The Company has agreements to obtain Mo-99 from three nuclear research reactors and relies predominantly upon two of these reactors for its Mo-99 supply. Accordingly, a disruption in the commercial supply or a significant increase in the cost of this material from these sources could have a material adversed effect on the Company's financial condition, results of operations and cash flows.

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21. Segment and Geographical Data

The Company is engaged in the development, manufacture and distribution of pharmaceuticals and diagnostic imaging agents. The Company manages and operates its business through 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 CMDS and radiopharmaceuticals (nuclear medicine).

Management measures and evaluates the Company's operating segments based on segment net sales and operating income. Management excludes corporate expenses from segment operating income. In addition, certain amounts that management considers to be non-recurring or non-operational are excluded from segment operating income because management evaluates the operating results of the segments excluding such items. These items include revenues and expenses associated with sales of products to Covidien, intangible asset amortization, net restructuring and related charges, and separation costs. Although these amounts are excluded from segment operating income, as applicable, they are included in reported consolidated and combined operating income and in the reconciliations presented below. Selected information by business segment is as follows:

	Fiscal Year		
	2013	2012	2011
Net sales:			
Specialty Pharmaceuticals	$1,217.6	$1,005.2	$909.4
Global Medical Imaging	935.7	996.8	1,060.0
Net sales of operating segments [1]	2,153.3	2,002.0	1,969.4
Other [2]	51.2	54.2	52.4
Net sales	$2,204.5	$2,056.2	$2,021.8
Operating income:			
Specialty Pharmaceuticals	$311.7	$162.8	$121.5
Global Medical Imaging	112.3	214.3	232.4
Segment operating income	424.0	377.1	353.9
Unallocated amounts:			
Corporate and allocated expenses [3]	(133.8)	(69.9)	(73.3)
Intangible asset amortization	(35.4)	(27.3)	(27.0)
Restructuring and related charges, net [4]	(35.8)	(19.2)	(10.0)
Separation costs	(74.2)	(25.5)	(2.9)
Operating income	$144.8	$235.2	$240.7
Total assets:			
Specialty Pharmaceuticals	$1,666.6	$1,571.6	
Global Medical Imaging	1,158.6	1,085.7	
Corporate [5]	731.4	241.6	
Total assets	$3,556.6	$2,898.9	
Depreciation and amortization [6]:			
Specialty Pharmaceuticals	$97.6	$88.7	$77.5
Global Medical Imaging	42.0	42.2	42.3
Depreciation and amortization	$139.6	$130.9	$119.8

(1) Amounts represent sales to external customers. There were no intersegment sales.

(2) Represents products that were sold to Covidien, which is discussed in Note 16.

(3)

Includes administration expenses and certain compensation, environmental and other costs not charged to the Company's operating segments.

(4) Includes restructuring-related accelerated depreciation of $2.6 million, $8.0 million and $1.6 million for fiscal 2013, 2012 and 2011, respectively.

(5) Consists of assets used in managing the Company's total business and not allocated to any one segment.

(6) Depreciation for certain shared facilities is allocated based on occupancy percentage.

Net sales by business within the Company's segments are as follows:

	Fiscal Year		
	2013	2012	2011
Generics and API	$1,011.2	$848.8	$824.7
Brands	206.4	156.4	84.7
Specialty Pharmaceuticals	1,217.6	1,005.2	909.4
Contrast Media and Delivery Systems	498.1	542.0	595.5
Nuclear Imaging	437.6	454.8	464.5
Global Medical Imaging	935.7	996.8	1,060.0
Net sales of operating segments	2,153.3	2,002.0	1,969.4
Other [1]	51.2	54.2	52.4
Net sales	$2,204.5	$2,056.2	$2,021.8

(1) Represents products that were sold to Covidien, which is discussed in Note 16.

Selected information by geographic area is as follows:

	Fiscal Year		
	2013	2012	2011
Net sales [1]:			
U.S.	$1,518.7	$1,350.2	$1,293.8
Europe, Middle East and Africa	404.3	411.0	419.7
Other	281.5	295.0	308.3
	$2,204.5	$2,056.2	$2,021.8
Long-lived assets [2]:			
U.S.	$893.3	$847.7	$802.0
Europe, Middle East and Africa [3]	81.0	72.2	81.3
Other	51.8	52.1	48.1
	$1,026.1	$972.0	$931.4

(1) Net sales are attributed to regions based on the location of the entity that records the transaction, none of which relate to the country of Ireland.

(2) Long-lived assets are primarily composed of property, plant and equipment.

(3) Includes long-lived assets located in Ireland of $48.7 million, $45.5 million and $48.9 million at the end of fiscal 2013, 2012 and 2011, respectively.

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22. Selected Quarterly Financial Data (Unaudited)

	Fiscal 2013 (by quarter)			
	Q1	Q2	Q3 [1]	Q4
Net sales	$504.0	$585.3	$570.0	$545.2
Gross profit	233.5	273.5	265.8	252.1
Income (loss) from continuing operations	19.8	34.5	(27.7)	31.2
(Loss) income from discontinued operations	(0.6)	(0.5)	(0.2)	2.3
Net income (loss)	19.2	34.0	(27.9)	33.5
Basic earnings (loss) per share from continuing operations [2][3]	$0.34	$0.60	$(0.48)	$0.54
Diluted earnings (loss) per share from continuing operations [2][3]	0.34	0.60	(0.48)	0.54

	Fiscal 2012 (by quarter)			
	Q1	Q2	Q3	Q4
Net sales	$503.7	$523.1	$516.3	$513.1
Gross profit	234.8	253.5	243.2	233.3
Income from continuing operations	36.6	42.3	35.1	27.3
Loss from discontinued operations	(0.3)	(3.4)	(1.9)	(1.1)
Net income	36.3	38.9	33.2	26.2
Basic earnings per share from continuing operations [2][3]	$0.63	$0.73	$0.61	$0.47
Diluted earnings per share from continuing operations [2][3]	0.63	0.73	0.61	0.47

(1) Operations in the third quarter of fiscal 2013 were impacted by the Separation.

(2) Quarterly and annual computations are prepared independently. Therefore, the sum of each quarter may not necessarily total the fiscal period amounts noted elsewhere within this Annual Report on Form 10-K.

(3) The computation of basic and diluted earnings per share assumes that the number of shares outstanding for the first three quarters of fiscal 2013 and each quarter in fiscal 2012 was equal to the number of ordinary shares of Mallinckrodt outstanding on June 28, 2013, immediately following the distribution of one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien.

23. Subsequent Events

None.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended ("the Exchange Act"), is recorded, processed, summarized and reported within the specified time periods, and that such information is accumulated and communicated to management, including our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our CEO and CFO, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our CEO and CFO concluded that, as of that

date, our disclosure controls and procedures were effective.

Internal Control Over Financial Reporting

Under the rules and regulations of the SEC, we are not required to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 until we file our Annual Report on Form 10-K for the fiscal year ending September 26, 2014. In our Annual Report on Form 10-K for the fiscal year ending September 26, 2014, management and our independent registered public accounting firm will be required to provide an assessment as to the effectiveness of our internal controls over financial reporting.

Changes in Internal Control over Financial Reporting

Historically, we have relied on Covidien's financial controls and resources to manage certain aspects of our business and report our results. As a result of the Separation, we are in the process of reviewing, revising and adopting policies, as needed, to meet all regulatory requirements applicable to us as an independent, publicly-traded company. While many of these changes in staffing, policies and systems were accomplished prior to September 27, 2013, we continue to review and document our internal controls over financial reporting and may, from time to time, make changes aimed at enhancing their effectiveness. These efforts may lead to changes in our internal control over financial reporting.

Other than those noted above, there have not been any changes in our internal control over financial reporting that occurred during our fiscal quarter ended September 27, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

On November 21, 2013, the Human Resources and Compensation Committee ("the Committee") of the board of directors of Mallinckrodt plc ("the Company") approved certain compensation related actions. At its meeting, and subject to the completion by Deloitte & Touche LLP of its audit, the Committee approved a one-time special discretionary bonus award to Mark C. Trudeau, President and Chief Executive Officer, in the amount of $100,000 to recognize his leadership and work related to the Company's separation from Covidien plc, including the advancement of strategic initiatives in fiscal 2013 to position the Company for success as an independent, publicly-traded company.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information regarding our directors required under this Item 10. Directors, Executive Officers and Corporate Governance will be included in our definitive proxy statement for our annual general meeting of shareholders, which will be filed with the United States Securities and Exchange Commission within 120 days after September 27, 2013.

Information regarding our executive officers required under this Item 10. Directors, Executive Officers and Corporate Governance is included in Item 1. Business of this Annual Report on Form 10-K.

We have adopted the Mallinckrodt Pharmaceuticals Guide to Business Conduct, which meets the requirements of a "code of ethics" as defined by Item 406 of Regulation S-K, as well as the requirements of a code of business conduct and ethics under the listing standards of the New York Stock Exchange. Our Guide of Business Conduct applies to all employees, officers and directors of Mallinckrodt, including, without limitation, our Chief Executive Officer, Chief Financial Officer and other senior financial officers. Our Guide to Business Conduct is posted on our website at www.mallinckrodt.com under the heading "Investor Relations - Corporate Governance." We will also provide a copy of our Guide to Business Conduct to shareholders upon request. We intend to disclose any amendments to our Guide to Business Conduct, as well as any waivers for executive officers or directors, on our website.

Item 11. Executive Compensation.

Information regarding the compensation of our named executive officers and directors required under this Item 11. Executive Compensation will be included in our definitive proxy statement for our annual general meeting of shareholders, which will be filed with the United States Securities and Exchange Commission within 120 days after September 27, 2013.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information regarding individuals or groups which own more than 5% of our ordinary shares, as well as information regarding the security ownership of our executive officers and directors, and other shareholder matters required under this Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters will be included in our definitive proxy statement for our annual general meeting of shareholders, which will be filed with the United States Securities and Exchange Commission within 120 days after September 27, 2013.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information regarding transactions with related parties and director independence required under this Item 13. Certain Relationships and Related Transactions, and Director Independence will be included in our definitive proxy statement for our annual general meeting of shareholders, which will be filed with the United States Securities and Exchange Commission within 120 days after September 27, 2013.

Item 14. Principal Accounting Fees and Services.

Information regarding the services provided by and the fees paid to Deloitte and Touche LLP, our independent auditors, required under this Item 14. Principal Accounting Fees and Services will be included in our definitive proxy statement for our annual general meeting of shareholders, which will be filed with the United States Securities and Exchange Commission within 120 days after September 27, 2013.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

Documents filed as part of this report:

1) Financial Statements. The following are included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

- Report of Independent Registered Public Accounting Firm
- Consolidated and Combined Statements of Income for the fiscal years ended September 27, 2013, September 28, 2012 and September 30, 2011
- Consolidated and Combined Statements of Comprehensive Income for the fiscal years ended September 27, 2013, September 28, 2012 and September 30, 2011
- Consolidated Balance Sheet as of September 27, 2013 and Combined Balance Sheet as of September 28, 2012
- Consolidated and Combined Statements of Cash Flows for the fiscal years ended September 27, 2013, September 28, 2012 and September 30, 2011
- Consolidated and Combined Statement of Changes in Shareholders' Equity for the period September 24, 2010 to September 27, 2013
- Notes to Consolidated and Combined Financial Statements

2) Financial Statement Schedules. The financial statement schedule is included below. All other schedules have been omitted because they are not applicable, not required or the information in included in the financial statements or notes thereto.

Schedule II - Valuation and Qualifying Accounts
(in millions)

Description	Balance at Beginning of Period	Charged to Income	Additions and Other	Deductions	Balance at End of Period
Allowance for doubtful accounts:					
Fiscal year ended September 27, 2013	$9.4	$1.4	$—	$(6.2)	$4.6
Fiscal year ended September 28, 2012	5.7	4.5	—	(0.8)	9.4
Fiscal year ended September 30, 2011	7.4	0.8	—	(2.5)	5.7
Sales reserve accounts:					
Fiscal year ended September 27, 2013	$279.8	$1,316.9	$—	$(1,273.8)	$322.9
Fiscal year ended September 28, 2012	271.2	1,157.8	—	(1,149.2)	279.8
Fiscal year ended September 30, 2011	249.7	1,306.4	—	(1,284.9)	271.2
Tax valuation allowance:					
Fiscal year ended September 27, 2013	$15.3	$11.7	$3.0	$—	$30.0
Fiscal year ended September 28, 2012	15.6	(0.3)	—	—	15.3
Fiscal year ended September 30, 2011	16.2	(0.6)	—	—	15.6

3) Exhibits. The exhibits are included in the Exhibit Index that appears at the end of this Annual Report on Form 10-K.

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.

MALLINCKRODT PUBLIC LIMITED COMPANY

Date: December 13, 2013

By: /s/ Matthew K. Harbaugh
Matthew K. Harbaugh
Senior Vice President and Chief Financial Officer
(principal financial officer)

Pursuant to the requirements of the Securities Exchange Act 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.

Signature	Title	Date
/s/ Mark C. Trudeau Mark C. Trudeau	President, Chief Executive Officer and Director (principal executive officer)	December 13, 2013
/s/ Matthew K. Harbaugh Matthew K. Harbaugh	Senior Vice President and Chief Financial Officer (principal financial officer)	December 13, 2013
/s/ Kathleen A. Schaefer Kathleen A. Schaefer	Vice President and Corporate Controller (principal accounting officer)	December 13, 2013
* Melvin D. Booth	Chairman of the Board of Directors	December 13, 2013
* David R. Carlucci	Director	December 13, 2013
* J. Martin Carroll	Director	December 13, 2013
* Diane H. Gulyas	Director	December 13, 2013
* Nancy S. Lurker	Director	December 13, 2013
* JoAnn A. Reed	Director	December 13, 2013
* Kneeland C. Youngblood, M.D.	Director	December 13, 2013

*	Director	December 13, 2013
Joseph A. Zaccagnino		

* Peter G. Edwards, by signing his name hereto, does sign this document on behalf of the above noted individuals, pursuant to powers of attorney duly executed by such individuals which have been filed as an Exhibit to this Annual Report on Form 10-K.
/s/ Peter G. Edwards
Peter G. Edwards, Attorney-in-fact

EXHIBIT INDEX

Exhibit Number	Exhibit
2.1	Separation and Distribution Agreement between Covidien plc and Mallinckrodt plc, dated June 28, 2013 (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed July 1, 2013).
3.1	Certificate of Incorporation of Mallinckrodt plc (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed July 1, 2013).
3.2	Amended and Restated Memorandum and Articles of Association of Mallinckrodt plc (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed July 1, 2013).
4.1	Rights Agreement between Mallinckrodt plc and Computershare Trust Company, N.A., dated as of June 28, 2013, which includes the form of Right Certificate as Exhibit B thereto and the Summary of Rights to Purchase Preferred Shares as Exhibit C thereto (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed July 1, 2013).
4.2	Indenture, dated as of April 11, 2013, by and among Mallinckrodt International Finance S.A., Covidien International Finance S.A. and Deutsche Bank Trust Company Americas, as trustee (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed July 1, 2013).
4.3	Supplemental Indenture, dated as of June 28, 2013, by and among Mallinckrodt plc, Mallinckrodt International Finance S.A. and Deutsche Bank Trust Company Americas, as trustee (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed July 1, 2013).
4.4	Registration Rights Agreement, dated as of April 11, 2013, by and among Mallinckrodt International Finance S.A., Goldman, Sachs & Co., J.P. Morgan Securities LLC and the other purchasers named therein (incorporated by reference to Exhibit 4.2 to the Company's Amendment No. 2 to Form 10 filed May 8, 2013).
10.1	Tax Matters Agreement between Covidien plc and Mallinckrodt plc, dated June 28, 2013 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 1, 2013).
10.2	Employee Matters Agreement between Covidien plc and Mallinckrodt plc, dated June 28, 2013 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 1, 2013).
10.3	Transition Services Agreement between Covidien plc and Mallinckrodt plc, dated June 28, 2013 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed July 1, 2013).
10.4	Credit Agreement, dated as of March 25, 2013, by and among Mallinckrodt International Finance S.A., JPMorgan Chase Bank, National Association, as administrative agent, and the other lenders and agents party thereto (incorporated by reference to Exhibit 10.4 to the Company's Amendment No. 2 to Form 10 filed May 8, 2013).
10.5	Form of Deed of Indemnification by and between Mallinckrodt plc and Directors and Secretary (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed July 1, 2013).
10.6	Form of Indemnification Agreement by and between Mallinckrodt Brand Pharmaceuticals, Inc. and Directors and Secretary (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed July 1, 2013).
10.7*	Mallinckrodt Pharmaceuticals Severance Plan for U.S. Officers and Executives (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed July 1, 2013).
10.8*	Mallinckrodt Pharmaceuticals Change in Control Severance Plan for Certain U.S. Officers and Executives (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed July 1, 2013).

10.9*	Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Restricted Unit Award for Chief Executive Officer (incorporated by reference to Exhibit 10.8 to the Company's Current Report on Form 8-K filed July 1, 2013).
10.10*	Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Option Award (incorporated by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K filed July 1, 2013).
10.11*	Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Restricted Unit Award (incorporated by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K filed July 1, 2013).
10.12*	Letter Agreement, dated as of February 9, 2012, by and between Covidien plc and Mark Trudeau (incorporated by reference to Exhibit 10.5 to the Company's Amendment No. 2 to Form 10 filed May 8, 2013).
10.13*	Letter Agreement, dated as of August 1, 2011, by and between Covidien plc and Matthew K. Harbaugh (incorporated by reference to Exhibit 10.6 to the Company's Amendment No. 2 to Form 10 filed May 8, 2013).
10.14*	Letter Agreement, dated as of August 1, 2011, by and between Covidien plc and David E. Silver (incorporated by reference to Exhibit 10.7 to the Company's Amendment No. 2 to Form 10 filed May 8, 2013).
10.15*	Letter Agreement, dated as of August 1, 2011, by and between Covidien plc and Peter G. Edwards (incorporated by reference to Exhibit 10.9 to the Company's Amendment No. 2 to Form 10 filed May 8, 2013).
10.16*	Separation Agreement, dated as of June 28, 2013, by and between Mallinckrodt Enterprises, LLC and David Silver.
10.17*	Separation Agreement, dated as of October 7, 2013, by and between Mallinckrodt Enterprises, LLC and Thomas Berry.
10.18*	Separation Agreement, dated as of October 9, 2013, by and between Mallinckrodt Enterprises, LLC and Stefano Carchedi.

21.1	Subsidiaries of Mallinckrodt plc.
23.1	Consent of Deloitte & Touche LLP.
24.1	Powers of Attorney
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Mallinckrodt plc Annual Report on Form 10-K for the fiscal year ended September 27, 2013 formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated and Combined Statements of Income, (ii) the Consolidated and Combined Statements of Comprehensive Income, (iii) the Consolidated and Combined Balance Sheets, (iv) the Consolidated and Combined Statements of Cash Flows, (v) the Consolidated and Combined Statements of Shareholders' Equity and (vi) related notes.

*Compensation plans or arrangements.