UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended September 26, 2014

or

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

For the transition period from _____ to _____

Commission File Number : 001-35803

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

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 ☒ No ☐

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 ☐ No ☒

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 ☒ No ☐

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 ☒ No ☐

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. ☐

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

Large accelerated filer	☒		Accelerated filer	☐
Non-accelerated filer	☐	(Do not check if smaller reporting company)	Smaller reporting company	☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant (assuming solely for the purposes of this calculation that all directors and executive officers of the Registrant are "affiliates") as of March 28, 2014, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $3,676.1 million (based upon the closing price of $62.90 per share as reported by the New York Stock Exchange on that date).

The number of shares of the registrant's common stock outstanding as of November 14, 2014 was 116,278,655.

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 26, 2014, 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 specialty biopharmaceutical and medical imaging business that develops, manufactures, markets and distributes specialty pharmaceutical products and medical imaging agents. Therapeutic areas of focus include autoimmune and rare disease specialty areas (including neurology, rheumatology, nephrology and pulmonology), along with pain and attention-deficit hyperactivity disorder ("ADHD") for prescription by office- and hospital-based physicians. We also support the diagnosis of disease with nuclear medicine and contrast imaging. 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 65 countries. We believe our experience in the acquisition and management of highly regulated raw materials; deep regulatory expertise; and specialized chemistry, formulation and manufacturing capabilities, have created compelling competitive advantages that we anticipate will sustain future revenue growth.

We conduct business in the following two segments:

- *Specialty Pharmaceuticals* produces and markets branded pharmaceuticals and biopharmaceuticals, specialty generic pharmaceuticals and active pharmaceutical ingredients ("API") consisting of biologics, 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 and branded specialty pharmaceuticals. Our Global Medical Imaging segment traces its start from a series of innovations, including the introduction of barium in 1916, and now includes our CMDS business, including products for computed tomography ("CT") imaging and magnetic resonance imaging ("MRI"). We entered the nuclear imaging business in 1966 with technetium generators, and have subsequently expanded into "cold" kits and other radioisotopes.

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").

Fiscal 2014 was a transformational year for Mallinckrodt and today we provide a broad range of solutions to patients that will drive growth, improve profitability and deliver value to our shareholders. This was partially accomplished through the expansion of our portfolio of branded products with the acquisitions of H.P. Acthar® Gel ("Acthar"), for the treatment of autoimmune and rare diseases, and OFIRMEV® (acetaminophen) injection ("Ofirmev"), for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics and the reduction of fever. We believe these acquisitions have created a foundation and framework for future growth. In addition to product expansion, we also implemented significant actions under our 2013 restructuring program intended to improve our long-term gross profit margins and yield efficiencies from our spending on selling, general and administrative expenses ("SG&A").

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:

- *Ability to successfully execute strategies to drive growth.* We became an independent public company in June 2013. In March 2014, the Company acquired Cadence Pharmaceuticals, Inc. ("Cadence"), a biopharmaceutical company focused on commercializing products principally for use in the hospital setting, for total consideration of approximately $1.3 billion ("the Cadence Acquisition"). In August 2014, we acquired Questcor Pharmaceuticals, Inc. ("Questcor"), a high-growth biopharmaceutical company, for total consideration of approximately $5.9 billion ("the Questcor Acquisition"). Over the same period, we successfully completed the integration of Cadence, commenced the integration of Questcor and took restructuring actions, all of which are expected to drive efficiencies. These actions further diversified Mallinckrodt, significantly increasing our scale, revenues, profitability and cash flow.
- *Expertise in 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 2013, we estimated we received approximately 26% of the U.S. Drug Enforcement Administration's ("DEA") total annual quota for controlled substances that we manufacture. Based on IMS Health data for the same period, our Generics business had an approximately 30% market share of DEA Schedules II and III opioid and oral solid dose medications. 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. Department of Agriculture ("USDA"), 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 our operations.* We have specialized chemistry expertise in the formulation of new drug combinations, reformulation of existing drugs, and manufacture of controlled substances into a wide range of products, such as tablets, capsules, oral liquids, injectable and intrathecal products.
- *Distinctive high-quality manufacturing and distribution skills with vertical integration where there are competitive advantages.* We have expertise in the manufacturing of complex substances including those that come from naturally derived sources. Our manufacturing and supply chain capabilities enable highly efficient controlled substance tableting, packaging and distribution. We own 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.
- *Diversified business model with increasing shift towards high-margin Specialty Pharmaceuticals business with high cash flow conversion.* We have a diverse portfolio across our two different reporting segments, Specialty Pharmaceuticals and Global Medical Imaging. In the fourth quarter of fiscal 2014 net sales from our Specialty Pharmaceuticals segment represented 72.6% of net sales, excluding sales to our former parent, compared with 57.1% in the fourth quarter of fiscal 2013. We expect this percentage to increase in fiscal 2015 due to the inclusion of full year results from our fiscal 2014 acquisitions. These acquisitions have also increased the Specialty Phamaceuticals segment operating income from 25.3% in the fourth quarter of fiscal 2013 to 39.4% in the fourth quarter of fiscal 2014. The increased revenues and segment operating income positions us for strong cash flow generation, enabling us to potentially decrease leverage over time.
- *An extensive portfolio of generic products and controlled substance API for pain.* Our Generics and API businesses have a strong position in the controlled substance generics market. Our generics products are focused on pain and ADHD while our APIs are for a broad range of products. We believe this business offers 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 technical barriers, limited competition and long product life-cycles.

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 API controlled substances, 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 and the aging global infrastructure of nuclear reactors; our customer concentration; cost-containment efforts of our customers, purchasing groups, third-party payors and governmental organizations; developing or commercializing new products; expanding commercial opportunities for existing products; 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 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.

Specialty Pharmaceuticals

Our Specialty Pharmaceuticals segment has two businesses (1) Brands and (2) Generics and API, both of which we expect will generate growth and generate significant cash flows from operations.

Our Brands business markets branded pharmaceutical and biopharmaceutical drugs for pain management and autoimmune and rare diseases (including in the areas of neurology, rheumatology, nephrology and pulmonology). Our Generics business markets drugs that include a variety of product formulations containing hydrocodone, oxycodone and several other controlled substances. We have a pipeline of controlled substance 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 2014, our Specialty Pharmaceuticals segment accounted for 64.7% of net sales from our operating segments. We expect this segment will represent a larger percentage of our net sales in fiscal 2015 and beyond.

Brands

We started our Brands product portfolio in 2001 and shifted our focus to pain management with the 2010 launch of EXALGO® (hydromorphone HCl) extended-release tablets (CII) ("Exalgo"). Our exclusivity period for Exalgo expired and generic competition entered the market beginning in May 2014. In fiscal 2014, we significantly expanded our Brands product portfolio, with the March 2014 acquisition of Ofirmev and August 2014 acquisition of Acthar. Also in March 2014, the FDA approved our New Drug Application ("NDA") for XARTEMIS™ XR (oxycodone HCl and acetaminophen) extended-release tablets (CII) ("Xartemis XR"), which we launched shortly thereafter. Our development pipeline includes MNK-155, a hydrocodone combination product, which was accepted for review by the FDA in May 2014. Our long-term strategy is to increase patient access and utilization of our existing products, advance pipeline products and bring them to market, develop new and follow-on formulations for recently acquired products and selectively acquire or license products that are strategically aligned with our product portfolio to expand the size and profitability of our Brands business.

We promote our branded products directly to physicians in their offices, hospitals and ambulatory surgical centers (including pain specialists, anesthesiologists, pulmonologists, autoimmune specialists and primary care physicians) with our own direct sales force of over 400 sales representatives as of September 26, 2014. Our products are purchased by wholesale drug distributors, specialty pharmaceutical distributors 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:

- *Acthar* is an injectable biopharmaceutical drug approved by the FDA for use in 19 indications. The product currently generates substantially all of its net sales from nine of the on-label indications including the treatment of proteinuria in nephrotic syndrome of the idiopathic type ("NS"); the treatment of acute exacerbations of multiple sclerosis ("MS") in adults; the treatment of infantile spasms ("IS"), in infants and children under two years of age; and the treatment of certain rheumatology related conditions, including the treatment of the rare and closely related neuromuscular disorders, dermatomyositis and polymyositis. We may initiate commercial efforts for other on-label indications where there is high unmet medical need. The currently approved indications of Acthar are not subject to patent or other exclusivity, with the exception of IS which was granted orphan drug status from the FDA upon its approval in October 2010.

- *Ofirmev* is a proprietary intravenous formulation of acetaminophen indicated for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics and the reduction of fever. This product is marketed to hospitals and ambulatory surgical centers and provides us with an expanded presence in these channels. Ofirmev is protected by two Orange Book-listed patents that expire in August 2017 and June 2021 and we have the potential to obtain an additional six months of exclusivity for each patent if the FDA grants pediatric exclusivity. Settlement agreements have been reached in association with certain challenges to these patents, which allow for generic competitors to Ofirmev in December 2020, or earlier under certain circumstances.
- *Xartemis XR* is the first and only extended-release oral combination of oxycodone and acetaminophen. Xartemis XR is approved for the management of acute pain severe enough to require opioid treatment and in patients for whom alternative treatment options are ineffective, not tolerated or would otherwise be inadequate. In February 2014, we were granted a patent from the USPTO, which contains composition claims directed to unique design, formulation, pharmacokinetic and release characteristics of Xartemis XR. Xartemis XR received FDA approval and was launched in March 2014.
- *Exalgo*, which was acquired in June 2009, is the only branded 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. Our exclusivity period for Exalgo has expired and generic competition entered the market beginning in May 2014. In anticipation of this loss of exclusivity, we launched a generic form of Exalgo in May 2014. We expect sales of Exalgo, across both the branded and authorized generic product, to decrease in fiscal 2015 compared with net sales in fiscal 2014.

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 2013 we believe we received approximately 26% 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 product line of opioid and other controlled substances (primarily DEA Schedules II and III) currently available from a single manufacturer. 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 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.

We market our generic products principally through drug distributors, specialty pharmaceutical distributors, 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:

- hydrocodone (API) and hydrocodone-containing tablets;
- oxycodone (API) and oxycodone-containing tablets;
- methylphenidate HCl extended-release tablets USP (CII) ("Methylphenidate ER") and;
- other controlled substances, including acetaminophen (API) products.

On November 12, 2014, the Company was informed by the FDA that they believe that the Company's Methylphenidate ER products may not be therapeutically equivalent to the category reference listed drug. As a result, on November 13, 2014, the FDA reclassified Methylphenidate ER from freely substitutable at the pharmacy level (class AB) to presumed to be therapeutically inequivalent (class BX). The FDA has indicated that it has not identified any serious safety concerns with the products. The FDA indicated that its reclassification is attributable to concerns that the products may not produce the same therapeutic benefits for some patients as the reference listed drug. The FDA further indicated that Company's Methylphenidate ER product is still approved and can be prescribed. The FDA has requested that within six months, the Company demonstrate the bioequivalence of its products using the draft guidance for revised bioequivalence standards issued by the FDA on November 6, 2014 or voluntarily withdraw our products from the market. The Company expects that the FDA's action to reclassify our Methylphenidate ER products will significantly impact net sales and operating income unless the FDA revises its decision.

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 2014, our Global Medical Imaging segment accounted for 35.3% of net sales from our operating segments. We are focused on driving operating efficiencies in the Global Medical 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 non-ionic 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 11%, 14% and 17% of our total net sales in fiscal 2014, 2013 and 2012, 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 80% 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 radioactive materials used to manufacture the isotope generators and in dealing with products (isotopes) with an extremely short half-life, 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 in The Netherlands 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 driving efficiencies to maximize operating margins and cash flow. 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.

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 us of low enriched uranium ("LEU") from highly enriched uranium ("HEU"). We currently use HEU targets for the production of Mo-99, but ultimately intend to eliminate the use of HEU in favor of using LEU and have begun 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 80% 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 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 global broadening of access to healthcare, 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 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. 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 in satisfying the regulatory requirements relating to raw materials for nuclear radiopharmaceuticals provides competitive advantages versus other potential competitors. Currently, nuclear 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 pharmaceuticals products include Actavis, 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. Acthar, a biopharmaceutical product, has limited direct competition due to the unique nature of the product; however, it generally is prescribed by physicians when alternative treatments have not yielded favorable outcomes for patients. 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, reflecting both 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, third-party reimbursement, marketing effectiveness, customer service, reliability of supply, reputation and access to technical information.

The highly competitive environment of our Brands business requires us to continually seek out new products to treat diseases and conditions in areas of high unmet medical needs, create 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 either through 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 patent-conferred 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. Products which do not benefit from regulatory or patent exclusivity must rely on other competitive advantages, such as confidentiality agreements or product formulation trade secrets for difficult to replicate products.

Manufacturers of generic pharmaceuticals typically invest far less in R&D than research-based pharmaceutical companies, allowing generic versions to typically be significantly less expensive than the related branded products. The generic form of a drug may also enjoy a preferred position relative to the branded version under third-party reimbursement programs, or be routinely dispensed in substitution for the branded form 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 superior health outcomes but also cost advantages, as compared with other forms of care. Certain of our Brands products are specialized pharmaceuticals or biopharmaceuticals, for example Acthar, that may not be prescribed unless a clear benefit in efficacy or safety is demonstrated or until lower-cost alternatives have failed to provide positive patient outcomes or are not well tolerated by the patient.

In our Generics business, we face intense competition from other generic drug manufacturers, brand-name pharmaceutical companies marketing 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 confers certain competitive advantages that might not be available to 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 products we market. The maintenance of profitable operations in generic pharmaceuticals depends, in part, on our ability to select, develop and timely launch new generic products, to manufacture such new products in a cost efficient, high-quality manner and implement and maintain pricing actions.

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

In 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 effectively compete with other providers of contrast media will be impacted by ongoing 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 may 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. Acthar is not subject to patent or other exclusivity, with the exception of IS which was granted orphan drug status from the FDA upon its approval in October 2010. Acthar's commercial durability therefore relies partially upon product formulation trade secrets, confidentiality agreements and trademark and copyright laws. These items may not prevent our competitors from independently developing similar technology or duplicating our product.

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 $166.9 million, $165.7 million and $144.1 million in fiscal 2014, 2013 and 2012, respectively. We expect to continue to invest in R&D activities, as well as enter into license agreements and business development opportunities 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.

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 the development of extended-release opioid products with abuse deterrent properties and expanding the opportunities for existing products by documenting and publishing clinical experience and evidence that support health economic and patient outcomes. MNK-155 has completed Phase III clinical trials and our NDA filing was accepted for review by the FDA in May 2014. We have received notice of allowance from the USPTO related to composition claims directed to unique design, formulation, pharmacokinetic and release characteristics for MNK-155.

In accordance with a Pediatric Research Equity Act requirement included in the NDA approval for Ofirmev, Cadence began enrolling patients in 2012 in a post-marketing efficacy study of Ofirmev in infants and neonates. The data from this study will be used to satisfy a formal written request Cadence received from the FDA under Section 505A of the U.S. Food, Drug and Cosmetic Act that was made as part of the approval process for Ofirmev. The FDA has agreed to an August 2015 due date for completion of this study. Upon timely completion and the acceptance by the FDA of the data from this study, Ofirmev may be eligible for an additional six months of marketing exclusivity in the U.S. The FDA is also currently reviewing a supplemental NDA that Cadence submitted in December 2013, which would enable us to offer Ofirmev in flexible intravenous bags.

In regard to specialty generic product development, we are focused on controlled substances with difficult-to-replicate pharmacokinetic profiles. As of September 26, 2014, we had various ANDAs on file with the FDA. In addition, we are focused on process improvements to increase yields and reduce costs.

Global Medical Imaging. Our R&D efforts in our Global Medical Imaging segment are focused on driving efficiency and regulatory compliance throughout CMDS and Nuclear Imaging.

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 pharmaceutical products 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 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. 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 2015, the user fee rate has been set at $2,335,200 for a 505(b)(1) NDA and $1,167,600 for a NDA not requiring a complete clinical data package, 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 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 2015, the user fee rate is set at $58,730 for an ANDA and $29,370 for a prior approval supplement to an ANDA. These fees are expensed as incurred. In August 2013, it was reported that the average review time for an ANDA was about 35 months. The FDA anticipates that the approval process timeframe will begin to improve in fiscal 2015 with a target of approving 60% of ANDA submissions within 15 months of submission.

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 ("REMS"). 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. 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.

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. We also founded and provided the regulatory framework for Risk Evaluation and Mitigation Strategies - An Employer-Driven Continuing Medical Education Initiative for Efficacy and Safety ("REMEDIES"). The purpose of the REMEDIES initiative is to train prescribers on evidence-based

approaches to optimize the evaluation, treatment and management of chronic pain. 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.

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 2014, 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. On August 22, 2014, the DEA issued its final rule to reschedule hydrocodone combination products from Schedule III to Schedule II, which was effective on October 6, 2014. In accordance with the final rule, we have discontinued sales of Schedule III labeled products and launched Schedule II labeled products. The effects of the rescheduling resulted in increased returns of Schedule III labeled product, which did not have a material impact to our financial condition, results of operations and cash flows.

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") provided for major changes to the U.S. healthcare system, which impacted the delivery and payment for healthcare services in the U.S. Several provisions of the Healthcare Reform Act have already taken effect, including the elimination of lifetime caps and no rescission of policies or denial of coverage due to preexisting conditions, improving patients' ability to obtain and maintain health insurance. While significant components of the Healthcare Reform Act have been implemented, various other aspects are ongoing and there may still be challenges and uncertainties ahead. Such a comprehensive reform measure requires 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 continue to closely monitor the implementation of the Healthcare Reform Act and related legislative and regulatory developments. To date our business has been most notably impacted by 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 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, such as the United Kingdom ("U.K.") Bribery Act of 2010, 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 U.K. Anti-Bribery guidance, and other relevant guidance from government 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 with a strict policy of non-retaliation. We further demonstrated our commitment to our compliance programs by the addition of a Chief Compliance Officer that reports directly to the Chief Executive Officer and the Compliance Committee of our Board of Directors. The Compliance function is an independent of the manufacturing and commercial operations functions and is responsible for implementing our compliance programs.

As part of our compliance program, we have implemented internal cross-functional processes to review and approve 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, as

well as monitoring of sales representative expenses. 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 risks. We believe we have complied with reporting obligations of the U.S. Federal Physician Payment Sunshine Act and relevant state disclosure laws and have implemented a program across the Company to track and report data per Centers for Medicare & Medicaid Services ("CMS") guidance and state disclosure requirements.

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.

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 provide assurance 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 provide assurance 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 provide assurance 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 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 from 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. We received increased target irradiations from other reactors, purchased additional Mo-99 from other sources and outsourced Mo-99 processing to continue meeting customer orders; however, the additional Mo-99 and processing services we procured from alternative sources came at a higher than normal cost. The HFR resumed production of medical isotopes and irradiation of materials in February 2014 and the Mo-99 processing facility resumed production in April 2014. 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, specialty pharmacies, radiologists and radiology technicians. We distribute these products to major drug wholesalers, retail pharmacy chains, specialty pharmaceutical distributors, hospital networks, ambulatory surgical centers 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. In September 2014, we were notified by Premier U.S., Inc. ("Premier"), that we were no longer a preferred supplier of CMDS products after a 19 year relationship. While individual members of the Premier GPO may purchase our products, we expect the loss of preferred supplier status to negatively impact net sales for CMDS products.

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 2014, 2013 and 2012 were as follows:

	Fiscal Year		
	2014	2013	2012
Cardinal Health, Inc.	18%	18%	19%
McKesson Corporation	17%	15%	14%
Amerisource Bergen Corporation	11%	9%	9%

No other customer accounted for 10% or more of our net sales in the past three fiscal years. CuraScript Specialty Distributor distributes Acthar and is expected to account for more than 10% of our total net sales in fiscal 2015.

Manufacturing and Distribution

We presently have eleven 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 2014 (as measured by cost of production) was as follows:

U.S.	78%
Europe	13%
Canada	9%

We maintain distribution centers in 18 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.

We utilize contract manufacturing organizations ("CMOs") to manufacture certain of our finished goods that are available for resale. We most frequently utilize CMOs in the manufacture of our Brands products, including Acthar (for finish and filling of the product), Ofirmev and Xartemis XR.

Backlog

At September 26, 2014, the backlog of firm orders was less than 1% of net sales. We anticipate that substantially all of the backlog as of September 26, 2014 will be shipped during fiscal 2015.

Seasonality

We have historically experienced fluctuations in our business resulting from seasonality. DEA quotas for raw materials and final dosage products 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. As a result, net sales of DEA controlled products have historically been higher during the second and third fiscal quarters as compared with the first and fourth fiscal quarters. Acthar has experienced lower net sales during the first calendar quarter, our second fiscal quarter, which we believe is partially attributable to certain medical conditions being exacerbated by warm temperatures and effects of annual insurance deductibles. Lastly, we have experienced lower operating cash flows during our first fiscal quarter as we pay annual employee compensation and have experienced lower net sales in DEA controlled products. While we have experienced these fluctuations in the past, they may not be indicative of what we will experience in the future.

Employees

At September 26, 2014, 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.

Executive Officers

Set forth below are the names, ages as of November 1, 2014, and current positions of our executive officers.

Name	Age	Title
Mark Trudeau	53	President, Chief Executive Officer and Director
Matthew Harbaugh	44	Senior Vice President and Chief Financial Officer
Peter Edwards	53	Senior Vice President and General Counsel
Meredith Fischer	61	Senior Vice President, Communications and Public Affairs
Raymond Furey	46	Senior Vice President and Chief Compliance Officer
Sandra Hatten	57	Senior Vice President, Quality and Regulatory Compliance
Hugh O'Neill	51	Senior Vice President and President of Specialty Pharmaceuticals
Gary Phillips	48	Senior Vice President and President of Autoimmune and Rare Diseases
Mario Saltarelli	54	Senior Vice President and Chief Science Officer
Frank Scholz	45	Senior Vice President, Global Operations
Ian Watkins	52	Senior Vice President and Chief Human Resources Officer

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. In anticipation of the Separation, Mr. Trudeau joined Covidien in February 2012 as a Senior Vice President and President of its Pharmaceuticals business. He joined Covidien from Bayer HealthCare Pharmaceuticals LLC USA, the U.S. healthcare business of Bayer AG, where he served as Chief Executive Officer. He simultaneously served as President of Bayer HealthCare Pharmaceuticals, the U.S. organization of Bayer's global pharmaceuticals business. In addition, he 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 10-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 United Kingdom. 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 had held from July 2008 until June 2013, when Mallinckrodt became an independent public company. 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 served as Vice President and General Counsel of Covidien's Pharmaceuticals business from May 2010 until June 2013, when Mallinckrodt became an independent public company. Mr. Edwards previously served as Executive Vice President and General Counsel for the Solvay Group in Brussels, Belgium from June 2007 until April 2010 and previous to that, held positions of increasing responsibility with Eli Lilly and Company.

Meredith Fischer is our Senior Vice President, Communications and Public Affairs. In anticipation of our spin transaction with Covidien plc Ms. Fischer joined Covidien in February 2013 as Vice President, Communications and Public Affairs for its Pharmaceuticals business. Ms. Fischer was employed by Bayer Corporation from 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. She was also Vice President of Marketing and Communications at Pitney Bowes, where she was responsible for product marketing, sales communications and the establishment of professional best practices.

Raymond Furey is our Senior Vice President and Chief Compliance Officer, a role he assumed in August 2014. Previously, Mr. Furey served Questcor Pharmaceuticals, Inc. as Chief Compliance Officer since October 2011 and as its Senior Vice President since May 23, 2013. Mr. Furey has over 20 years of experience in the pharmaceutical industry. Prior to joining Questcor, Mr. Furey served as the Corporate Compliance Officer for OSI Pharmaceuticals and prior to OSI, he served 17 years in various capacities for Genentech, including healthcare compliance, commercial operations, finance, regulatory compliance and manufacturing.

Sandra Hatten is our Senior Vice President, Quality. Ms. Hatten joined Covidien's Pharmaceuticals business in October 2010 as its Director of Quality and in 2011, became a Senior Director of Quality-API Operations. In September 2012 she was appointed interim Vice President of Quality and became Vice President of Quality in February 2013. She was promoted to her current position in February 2014. Ms. Hatten was Vice President of Quality Assurance for KV Pharmaceuticals from August 2007 until August 2010. She was Director of Site Quality and Compliance for Catalent Pharmaceutical Solutions from March 2006 until August 2007. Previously, Ms. Hatten served as Director of Quality from December 2000 to March 2006 for Perrigo Company plc. Ms. Hatten has more than 30 years of experience in the pharmaceutical industry.

Hugh O'Neill is our Senior Vice President and President of U.S. 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, and 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.

Gary Phillips, M.D. is our Senior Vice President and President of our Autoimmune and Rare Disease business. Dr. Phillips joined Mallinckrodt in October 2013 and served as Senior Vice President and Chief Strategy Officer until he was appointed to his current position in August 2014. Before joining Mallinckrodt, Dr. Phillips served as head of Global Health and Healthcare Industries for the World Economic Forum in Geneva, Switzerland from January 2012 to September 2013. Previously, 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, M.D., Phd. is our Senior Vice President and Chief Science Officer. Prior to joining Mallinckrodt in October 2013, Dr. Saltarelli served as Senior Vice President, R&D for 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 increasing responsibility at Pfizer, and, prior to that, academic posts in the Department of Neurology at the Emory University School of Medicine in Atlanta.

Frank Scholz is our Senior Vice President of Global Operations. He joined Mallinckrodt in March 2014. His responsibilities include global manufacturing operations, procurement and supply chain, in addition to leading the global operations transformation. Prior to joining Mallinckrodt, Dr. Scholz was a partner with McKinsey & Co, a global management consulting firm first in its Hamburg, Germany office and then in its Chicago, Illinois office. Dr. Scholz was a leader in McKinsey's global pharmaceutical and operations practices. He joined McKinsey in 1997. Prior to joining McKinsey, Dr. Scholz was a research assistant at the Institute for Management and Accounting at the University of Hanover, Germany.

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.).

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.

Extensive laws and regulations govern the industry in which we operate and changes to those 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 that governs and influences the development, testing, manufacturing, processing, packaging, holding, record keeping, safety, efficacy, approval, advertising, promotion, sale, distribution and import/export of our products. Under these laws and regulations, we are subject to periodic inspection of our facilities, procedures and operations and/or the testing of our products by the FDA, the DEA and similar authorities within and outside the U.S., which conduct periodic inspections to confirm that we are in compliance with all applicable requirements. If we are found to have violated one or more applicable law or regulation, we could be subject to a variety of fines, penalties, and related administrative sanctions, and our competitive position, business, financial condition, results of operations and cash flows could be materially adversely affected. We are also required to report adverse events associated with our products to the FDA and other regulatory authorities. Unexpected or serious health or safety concerns associated with our products, including Acthar, could result in reduced sales of the affected products, product liability claims, labeling changes, recalls, market withdrawals or other regulatory actions, including withdrawal of product approvals, any of which could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

In addition, changes in laws, regulations and regulatory actions 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. When the FDA finds that a new formulation of a product has abuse-deterrent characteristics, the agency may have the authority to require that generic versions of that product also have abuse-deterrent characteristics. One of our ANDAs 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 for the abuse, overdose and diversion of controlled substances through various enforcement actions as well as the implementation of compliance practices for controlled substances, including suspicious ordering monitoring 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, 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.

Further, on November 12, 2014, the Company was informed by the FDA that they believe that the Company's Methylphenidate ER products may not be therapeutically equivalent to the category reference listed drug. As a result, on November 13, 2014, the FDA reclassified Methylphenidate ER from freely substitutable at the pharmacy level (class AB) to presumed to be therapeutically inequivalent (class BX). The FDA has indicated that it has not identified any serious safety concerns with the products. The FDA indicated that its reclassification is attributable to concerns that the products may not produce the same therapeutic benefits for some patients as the reference listed drug. The FDA further indicated that Company's Methylphenidate ER product is still approved and can be prescribed. The FDA has requested that within six months, the Company demonstrate the bioequivalence of its products using the draft guidance for revised bioequivalence standards issued by the FDA on November 6, 2014 or voluntarily withdraw our products from the market. The Company expects that the FDA's action to reclassify our Methylphenidate ER products will significantly impact net sales and operating income unless the FDA revises its decision.

We may be unable to identify, acquire or close acquisition targets successfully.

Part of our business strategy includes evaluating potential business development opportunities to grow the business through merger, acquisition or other business combinations. The process to evaluate potential targets may be complex, time-consuming and expensive. Once a potential target is identified, we may not be able to conclude negotiations of a potential transaction on terms that are satisfactory to us, which could result in a significant diversion of management and other employee time, as well as substantial out-of-pocket costs. In addition, there are a number of risks and uncertainties relating to our ability to close a potential transaction.

Any acquisitions of technologies, products and businesses, including our recently completed acquisitions of Questcor and Cadence may be difficult to integrate in the expected time frame and may adversely affect our business, financial condition and the results of operations.

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 in the expected time frame, including our fiscal 2014 acquisitions of Cadence (completed on March 19, 2014) and Questcor (completed on August 14, 2014), we may not obtain the advantages and synergies that such 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 customers, licensors, suppliers and employees and may face difficulties in managing the expanded operations of a significantly larger and more complex company. 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. Many of these factors are outside of our control and any one of them could result in increased costs, decreases in the amount of expected revenues and diversion of management's time and energy, which could materially impact our business, financial condition and results of operations.

We may be unable to successfully develop or commercialize new or expand commercial opportunities for existing 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 or expand commercial opportunities for existing 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 delays in the commercialization of generic products by up to 30 months resulting from the listing of patents with the FDA; and
- effective execution of the product launches 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 is heightened with respect to the development of proprietary branded 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. 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. Finally, once developed and approved, new products may fail to achieve commercial acceptance due to the price of the product, third-party reimbursement of the product and the effectiveness of sales and marketing efforts to support the product.

We may be unable to protect our intellectual property rights, intellectual property rights may be limited 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, proprietary know-how, market exclusivity gained from the regulatory approval process and other intellectual property to support our business strategy, most notably in relation to Acthar and Ofirmev. 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 could adversely affect our business, financial condition and results of operations.

The composition patent for Acthar has expired and we may have no patent-based market exclusivity with respect to any indication or condition we might target. We rely on trade secrets and proprietary know-how to protect the commercial viability and value of Acthar. We currently obtain such protection, in part, through confidentiality and proprietary information agreements. These agreements may not provide meaningful protection or adequate remedies for proprietary technology in the event of unauthorized use or disclosure of confidential and proprietary information. The parties may not comply with or may breach these agreements. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, competitors.

The active ingredient in Ofirmev is acetaminophen. Patent protection is not available for the acetaminophen molecule itself in the territories licensed to us, which include the U.S. and Canada. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredient as Ofirmev so long as the competitors do not infringe any process or formulation patents that Cadence has in-licensed from Bristol-Myers Squibb Company ("BMS") and its licensor, SCR Pharmatop S.A. ("Pharmatop") or that we subsequently obtain.

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. For example, several third parties have challenged, and additional third parties may challenge, the patents covering Ofirmev, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. Such litigation and related matters are described 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.

The pursuit of or defense against patent infringement 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.

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, and hydrocodone. 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 2014, manufacturing and procurement quotas granted by the DEA have been sufficient to meet our sales and inventory requirements on most products. However, during calendar 2012, the initial hydrocodone manufacturing and procurement quota grants we received from the DEA were below the amounts requested and were 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.

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, large pharmacy chains and specialty pharmaceutical distributors. In turn, these wholesale drug distributors, large pharmacy chains and specialty pharmaceutical distributors 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 2014. CuraScript Specialty Distributor distributes Acthar and net sales to it are expected to account for more than 10% of our total net sales in fiscal 2015. If we were to lose the business of these distributors, if these distributors failed to fulfill their obligations, 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.

Our product concentration may materially adversely affect our financial condition and results of operations.

We sell a wide variety of products including branded pharmaceuticals, branded biopharmaceuticals and specialty generic pharmaceuticals, API and diagnostic imaging agents. However, following our acquisitions of Cadence and Questcor, both of which were completed in fiscal 2014, we expect that a small number of products, most notably Acthar and to a lesser extent, Ofirmev, will represent a significant percentage of our net sales. Our ability to maintain and increase net sales from these products depends on several factors, including:

- our ability to increase market demand for products through our own marketing and support of our sales force;

- our ability to implement and maintain pricing actions and continue to maintain or increase market demand for these products;
- our ability to maintain confidentiality of the proprietary know-how and trade secrets relating to Acthar;
- our ability to maintain and defend the patent protection and regulatory exclusivity of Ofirmev;
- our ability to continue to procure a supply of Acthar and Ofirmev from internal and third-party manufacturers in sufficient quantities and at acceptable quality and pricing levels in order to meet commercial demand;
- our ability to maintain fees and discounts payable to the wholesalers and distributors and group purchasing organizations, at commercially reasonable levels;
- whether the Federal Trade Commission ("FTC"), Department of Justice ("DOJ") or third parties seek to challenge and are successful in challenging patents or patent-related settlement agreements or our sales and marketing practices;
- warnings or limitations that may be required to be added to FDA-approved labeling;
- the occurrence of adverse side effects related to or emergence of new information related to the therapeutic efficacy of these products, and any resulting product liability claims or product recalls; and
- our ability to achieve hospital formulary acceptance, and maintain reimbursement levels by third-party payors.

Moreover, net sales of Acthar may also be materially impacted by the decrease in the relatively small number of prescriptions written for Acthar as compared to other products in our portfolio, given Acthar's use in treating rare diseases. Any disruption in our ability to generate net sales from Acthar could have an adverse impact on our 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. For example, in September 2014 we were notified by Premier, Inc., that we were no longer a preferred supplier of CMDS products. 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, our net sales and results of operations may be negatively affected by the loss of a contract with a GPO or IDN. In addition, 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 forming strategic alliances and 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.

Sales of our products are affected by the reimbursement practices of public and private insurers. In addition, reimbursement criteria or policies 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. The ability of patients 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 the U.S., there have been, and we expect there will continue to be, a number of state and federal proposals

that limit the amount that third-party payors may pay to reimburse the cost of drugs, for example with respect to Acthar. We believe the increasing emphasis on managed care in the U.S. has and will continue to put pressure on the usage and reimbursement of Acthar.

Reimbursement of highly-specialized products, such as Acthar, is typically reviewed and approved or denied on a patient-by-patient, case-by-case basis, after careful review of details regarding a patient's health and treatment history that is provided to the insurance carriers through a prior authorization submission, and appeal submission, if applicable. During this case-by-case review, the reviewer may refer to coverage guidelines issued by that carrier. These coverage guidelines are subject to on-going review by insurance carriers. Because of the large number of carriers, there is a large number of guideline updates issued each year.

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.

We are unable to predict what additional legislation or regulation or changes in third party coverage and reimbursement policies may be enacted or issued in the future or what effect such legislation, regulation and policy changes would have on our business.

Clinical trials demonstrating the efficacy for Acthar are limited. The absence of such clinical trial data could cause physicians not to prescribe Acthar, which could negatively impact our business, financial condition, results of operations and cash flows.

Our net sales of Acthar, are expected to comprise a significant portion of our overall product portfolio, could be negatively impacted by the level of clinical data available on the product. Acthar was originally approved by the FDA in 1952, prior to the enactment of the 1962 Kefauver Harris Amendment, or the "Drug Efficacy Amendment," to the Food, Drug, and Cosmetic Act. This Amendment introduced the requirement that drug manufacturers provide proof of the effectiveness (in addition to the previously required proof of safety) of their drugs in order to obtain FDA approval. As such, the FDA's original approval in 1952 was based on safety data as clinical trials evaluating efficacy were not then required. In the 1970s, the FDA reviewed the safety and efficacy of Acthar during its approval of Acthar for the treatment of acute exacerbations in multiple sclerosis and evaluated all other previous indications on the label through the Drug Efficacy Study Implementation ("DESI") process. In this process, the medical and scientific merits of the label and each indication on the label were evaluated based on publications, information from sponsors, and the judgment of the FDA. The label obtained after the DESI review and the addition of the multiple sclerosis indication is the Acthar label that was used until the most recent changes in 2010.

In 2010, in connection with its review of a supplemental New Drug Application, or "sNDA" for use of Acthar in treatment of infantile spasms, the FDA again reviewed evidence of safety and efficacy of Acthar, and added the IS indication to label of approved indications while maintaining approval of Acthar for treatment of acute exacerbations in multiple sclerosis and 17 other indications. In conjunction with its decision to retain these 19 indications on a modernized Acthar label, the FDA eliminated approximately 30 other indications from the label. The FDA review included a medical and scientific review of Acthar and each indication and an evaluation of available clinical and non-clinical literature as of the date of the review. The FDA did not require additional clinical trials for Acthar.

Accordingly, evidence of efficacy is based on physician's clinical experience with Acthar and does not include clinical trails except for the multiple sclorosis and infantile spasms indications. Despite recent increases in Acthar prescriptions for several of its on-label indications, this limited clinical data of efficacy could impact future sales of Acthar. We have initiated Phase 4 clinical trials to supplement the non-clinical evidence supporting the use of Acthar in the treatment of the on-label indications of idiopathic membraneous nephropathy and systemic lupus erythematosus. The completion of such ongoing or future clinical trials to provide further evidence on the efficacy of Acthar in the treatment of its approved indications could take several years to complete and will require the expenditure of significant time and financial and management resources. Such clinical trials may not result in data that supports the use of Acthar to treat any of its approved indications. In addition, a clinical trial to evaluate the use of Acthar to treat indications not on the current Acthar label may not provide a basis to pursue adding such indications to the current Acthar label.

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 accruals may have a higher inherent risk for material changes in estimates. 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 become subject to in this or other actions could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We may not achieve the anticipated benefits of price increases enacted on our pharmaceutical products, which may adversely affect our business.

From time to time, we initiate price increases on certain of our pharmaceutical products. There is no guarantee that our customers will be receptive to these price increases and continue to purchase the products at historical quantities. If customers do not maintain or increase existing sales volumes after price increases are enacted, and we are unable to replace lost sales with orders from other customers, it 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 our restructuring activities and our restructuring activities may adversely affect our business.

From time to time, we initiate restructuring activities 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 program. 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.

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. For example, 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. 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.

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. This competition may limit the effectiveness of any price increases we initiate. Following any price increase by us, competitors may elect to maintain a lower price point that may result in a decline in our sales volume. our current or future products could be rendered obsolete or uneconomical as a result of such competition. For further discussion on the competitive nature of our business, as well as the intellectual property rights and market exclusivity that play a key role in our business, refer to Item 1. Business 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.

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 with respect to, but not limited to, patent infringement, product liability, antitrust matters, securities class action lawsuits, breach of contract, Medicare and Medicaid reimbursements claims, and compliance with laws relating to the marketing and sale of controlled substances, such as those relating to the establishment of suspicious order monitoring 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 such retained liabilities. We believe this coverage level is adequate to address our current risk 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.

We are involved in an ongoing government investigation by the United States Department of Justice involving Questcor's promotional practices and related matters, the results of which may have a material adverse effect on our sales, financial condition, results of operations and cash flows.

In September 2012, Questcor received a subpoena from the United States Attorney's Office for the Eastern District of Pennsylvania (or "USAO"), requesting documents pertaining to an investigation of its promotional practices. Additionally, Questcor has been informed by the USAO for the Eastern District of Pennsylvania that the USAO for the Southern District of New York and the SEC are also participating in the investigation to review Questcor's promotional practices and related matters. We are cooperating with the USAO and the SEC with regard to this investigation.

If some of Questcor's existing business practices are challenged as unlawful, we may have to change those practices, which could have a material adverse effect on our business, financial condition and results of operations. If, as a result of this investigation, we are found to have violated one or more applicable laws, we could be subject to a variety of fines, penalties, and related administrative sanctions, and our business, financial condition and results of operations could be materially adversely affected.

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. The costs under these programs may exceed amounts we have accrued as asset retirement obligations. 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 requirements and operating expenditures. 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 26, 2014, it was probable that we would incur remedial costs in the range of $43.7 million to $106.9 million. We also concluded that, as of September 26, 2014, the best estimate within this range was $67.1 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 to address 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 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.

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

- potentially longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain non-U.S. legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and trade barriers;
- failure to successfully implement our new non-U.S. operating structure, and difficulties and costs of staffing and managing non-U.S. operations;
- exposure to global economic conditions; and
- exposure to potentially unfavorable movements in foreign currency exchange rates associated with international net sales and operating expense and intercompany debt financings.

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.

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. As described in Item 1. Business of this Annual Report on Form 10-K, the manufacturing process is complex, can be vulnerable due to the limited number of reactors and Mo-99 processing facilities worldwide, and is subject to short product half-lives. Given the product's radioactive decay, if we encounter delays in transporting Mo-99 to our generator facilities, or if the generator facilities experience unscheduled shutdowns or delays in loading Mo-99, we may be limited in the amount of Ultra-Technekow DTE generators that we are able to 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 fiscal 2013 and fiscal 2014, the HFR in the Netherlands, one of two primary reactors we utilize, experienced unscheduled shutdowns and in fiscal 2014 our own Mo-99 processing facility in the Netherlands experienced a shutdown. We were able to receive increased target irradiations from 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.

Future unplanned shutdowns of nuclear reactors that we use to irradiate targets and processing facilities 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. Mo-99 prices may also be impacted by higher operating costs of nuclear reactors and the elimination of governmental subsidies of nuclear reactors. Ongoing increased raw material and manufacturing costs will limit our ability to return the Global Medical Imaging segment to historical operating margins.

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. In addition, any unauthorized access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties, disrupt our operations, and damage our reputation, and cause a loss of confidence in our products and services, which could adversely affect our business.

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 due to various factors, including those described below.

- Prior to the Separation, our business was 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 continued to provide some of these functions to us for a period of time following the Separation 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 which expenses are less than the expenses we have incurred operating as an independent, publicly-traded company following the Separation.
- We 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, and increased auditing and legal fees. These expenses are 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 have made 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 have been 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. We have obtained and 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.

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 described in Note 1 of Notes to the Consolidated and Combined Financial Statements included within Item 8. Financial Statements and Supplementary Data in this Annual Report on Form 10-K.

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

The separation and distribution agreement that we entered into with Covidien in connection with the Separation 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 provides 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.

Risks Related to Our Indebtedness

Our substantial indebtedness could adversely affect our financial condition and prevent us from fulfilling our obligations.

We have substantial indebtedness, which could adversely affect our ability to fulfill our financial obligations and have a negative impact on our financing options and liquidity position. As of September 26, 2014, we had $3,972.7 million of total debt.

Our indebtedness may impose restrictions on us that could have material adverse consequences by:

- making it more difficult for us to satisfy our obligations with respect to our debt;
- limiting our ability to obtain additional financing in the future for working capital, capital expenditures, acquisitions or other corporate requirements;
- requiring a substantial portion of our cash flows to be dedicated to debt service payments instead of other purposes, thereby reducing the amount of cash flows available for working capital, capital expenditures, acquisitions and other general corporate purposes;
- making us more vulnerable to economic downturns and limiting our ability to withstand competitive pressures;
- limiting our flexibility in planning for and reacting to changes in the industry in which we compete;
- limiting our ability to refinance our indebtedness on terms acceptable to us or at all;
- imposing restrictive covenants on our operations;
- placing us at a competitive disadvantage to other less leveraged competitors; and
- increasing our costs of borrowing.

In addition, the documents that govern the terms of our indebtedness contain restrictive covenants that limit our ability to engage in activities that may be in our long-term best interest. Our failure to comply with those covenants could result in an event of default which, if not cured or waived, could result in the acceleration of repayment of our debt.

We may not be able to generate sufficient cash to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under our indebtedness, which may not be successful.

Our ability to make scheduled payments on or to refinance our debt obligations depends on our financial condition and operating performance, which are subject to prevailing economic and competitive conditions and to certain financial, business, legislative, regulatory and other factors beyond our control. We may be unable to maintain a level of cash flows from operating activities sufficient to permit us to fund our day-to-day operations or to pay the principal, premium, if any, and interest on our indebtedness, including the notes.

Our inability to generate sufficient cash flows to satisfy our debt obligations, or to refinance our indebtedness on commercially reasonable terms or at all, would materially and adversely affect our financial position and results of operations. If our cash flows and capital resources are insufficient to fund our debt service obligations and other cash requirements, we could face substantial liquidity

problems and could be forced to reduce or delay investments and capital expenditures or to sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We may not be able to effect any such alternative measures, if necessary, on commercially reasonable terms or at all and, even if successful, such alternative actions may not allow us to meet our scheduled debt service obligations. The agreements governing our indebtedness restrict (a) our ability to dispose of assets and use the proceeds from any such dispositions and (b) our ability to raise debt capital to be used to repay our indebtedness when it becomes due. We may not be able to consummate those dispositions or to obtain proceeds in an amount sufficient to meet any debt service obligations then due.

If we cannot make scheduled payments on our debt, we will be in default and, as a result, lenders under any of our indebtedness could declare all outstanding principal and interest to be due and payable, the lenders under our existing credit facilities could terminate their commitments to loan money, our secured lenders could foreclose against the assets securing such borrowings and we could be forced into bankruptcy or liquidation.

Despite current and anticipated indebtedness levels, we may still be able to incur substantially more debt. This could further exacerbate the risks described above.

We may be able to incur substantial additional indebtedness in the future. Although agreements governing our indebtedness restrict the incurrence of additional indebtedness, these restrictions are and will be subject to a number of qualifications and exceptions and the additional indebtedness incurred in compliance with these restrictions could be substantial. If new debt is added to our current debt levels, the related risks that we now face could intensify.

The terms of the agreements that govern our indebtedness restrict our current and future operations, particularly our ability to respond to changes or to pursue our business strategies.

The agreements that govern the terms of our indebtedness contain a number of restrictive covenants that impose significant operating and financial restrictions on us and may limit our ability to engage in acts that may be in our long-term best interest, including limitations or restrictions on our ability to:

- incur, assume or guarantee additional indebtedness;
- declare or pay dividends or make other distributions with respect to on or purchase or otherwise acquire or retire for value, equity interests
- make any principal payment on, or redeem or repurchase, subordinated debt;
- make loans, advances or other investments;
- sell or otherwise dispose of assets, including capital stock of subsidiaries;
- incur liens;
- enter into transactions with affiliates;
- enter into sale and leaseback transactions; and
- consolidate or merge with or into, or sell all or substantially all of our assets to, another person.

In addition, the restrictive covenants in the credit agreement governing our senior secured credit facilities require us to comply with a financial maintenance covenant in certain circumstances. Our ability to satisfy this financial maintenance covenant can be affected by events beyond our control and we cannot provide assurance that we will meet it.

A breach of the covenants under the agreements that govern the terms of any of our indebtedness could result in an event of default under the applicable indebtedness. Such a default may allow the creditors to accelerate the related debt and may result in the acceleration of any other debt to which a cross-acceleration or cross-default provision applies. In addition, an event of default under the credit agreement that governs our senior secured credit facilities would permit the lenders under such facilities to terminate all commitments to extend further credit thereunder. Furthermore, if we are unable to repay the amounts due and payable under our senior secured credit facilities, those lenders will be able to proceed against the collateral granted to them to secure that indebtedness. In the event our debtholders accelerate the repayment of our borrowings, we may not have sufficient assets to repay that indebtedness.

As a result of these restrictions, we may be:

- limited in how we conduct our business;
- unable to raise additional debt or equity financing to operate during general economic or business downturns; or
- unable to compete effectively, execute our growth strategy or take advantage of new business opportunities.

These restrictions may affect our ability to grow in accordance with our plans.

Our variable-rate indebtedness exposes us to interest rate risk, which could cause our debt service obligations to increase significantly.

Certain of our indebtedness, including borrowings under our senior secured credit facilities and our receivables securitization, are subject to variable rates of interest and expose us to interest rate risk. If interest rates increase, our debt service obligations on the variable-rate indebtedness would increase and our net income would decrease, even though the amount borrowed under the facilities remained the same. As of September 26, 2014, we had $1,990.3 million outstanding variable-rate debt on our senior secured term loan and $150.0 million outstanding variable-rate debt on our receivables securitization. The term loan has an interest rate as of September 26, 2014 of 3.50%, which is comprised of LIBOR plus margin of 2.75%. The LIBOR rate has a minimum value of 0.75%. The receivables securitization has an interest rate as of September 26, 2014 of 0.96%, which is comprised of LIBOR plus margin of 0.80%. An unfavorable 25 basis point increase in LIBOR, in excess of the 0.75% minimum value on the senior secured term loan, would increase our quarterly payments on our senior secured term loan by approximately $1.2 million and our interest expense under the receivable securitization by $0.1 million. As of September 26, 2014, we had no outstanding borrowings under our revolving credit facility. Although we may enter into interest rate swaps, involving the exchange of floating for fixed-rate interest payments, to reduce interest rate volatility, we cannot provide assurance that we will enter into such arrangements or that they will successfully mitigate such interest rate volatility.

Our current debt levels and 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 by our current debt levels or if there is a material decline in the demand for our products or in the solvency of our customers or suppliers or 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.

A lowering or withdrawal of the ratings assigned to our debt by rating agencies may increase our future borrowing costs and reduce our access to capital.

Our debt currently has a non-investment grade rating from Standard & Poor's Corporation ("S&P") and Moody's Investor Services, Inc. ("Moody's"). Any rating assigned could be lowered or withdrawn entirely by a rating agency if, in that rating agency's judgment, future circumstances relating to the basis of the rating, such as adverse changes, so warrant. Consequently, real or anticipated changes in our credit ratings will generally affect the market value of the notes. Any future lowering of our ratings likely would make it more difficult or more expensive for us to obtain additional debt financing.

Risks Related to Tax Matters

If the distribution completed in connection with the Separation 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 $113.6 million, excluding associated tax benefits from such payments, or $82.2 million, net of associated tax benefits, and will be subject to an overall limitation of $200 million, net of associated tax benefits. Payments to date qualifying under the overall limitation of $200 million are $33.0 million, net of associated tax 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 has 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 agreed 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.

Our status as a foreign corporation for U.S. federal tax purposes could be affected by a change in law.

We believe that, under current law, we are treated as a foreign corporation for U.S. federal tax purposes. However, changes to the inversion rules in Section 7874 or the U.S. Treasury Regulations promulgated thereunder or other IRS guidance could adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any such changes could have prospective or retroactive application to us and our shareholders and affiliates. In addition, recent legislative proposals have aimed to expand the scope of U.S. corporate tax residence, and such legislation, if passed, could have an adverse effect on us. For example, in March 2014, the President of the United States proposed legislation which would amend the anti-inversion rules. Although its application is limited to transactions closing after 2014, no assurance can be given that such proposal will not be changed in the legislative process to apply to prior transactions. Additionally, in September 2014, legislation was introduced in the U.S. Senate that seeks to address the practice of earnings stripping by companies that move their domicile overseas. Furthermore, the Department of the Treasury and the IRS provided notice in September 2014 that the agencies intend to issue regulations to reduce the tax benefits of or preclude entirely certain inversion transactions.

Future changes to U.S. and foreign tax laws could adversely affect us.

The U.S. Congress, the Organization for Economic Co-operation and Development and other government agencies in jurisdictions where we and our affiliates do business have had an extended focus on issues related to the taxation of multinational corporations. One example is in the area of "base erosion and profit shifting," where payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. As a result, the tax laws in the U.S. and other countries in which we and our affiliates do business could change on a prospective or retroactive basis, and any such changes could adversely affect us and our affiliates.

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

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 provide assurance 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;
- perceived impacts to our results from acquisitions of products, licenses rights or businesses;
- 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.

Volatility can also occur from short sellers becoming active in our stock. It is generally in the short seller’s interest for the price of a stock to decline. Prior to our acquisition of Questcor, Questcor experienced high levels of short interests in their stock. It has been alleged that short sellers may take various actions aimed at attempting to cause harm to a company’s business or reputation in an effort to cause such company’s stock to decline. There can be no assurance that short sellers will not become active in our stock.

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.

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. For example, we issued approximately 57 million ordinary shares in connection with the completion of our acquisition of Questcor in August 2014. 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 our 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.

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 a takeover offer may be considered beneficial by some shareholders and could delay or prevent an acquisition that our board of directors determines is not 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 are also 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 corporate headquarters are located at a facility in Dublin, Ireland, at the same location of a manufacturing site that we own. Our offices in the U.S. are located in a facility in Hazelwood, Missouri, which we own. As of September 26, 2014, we owned a total of 14 facilities in four countries. Our owned facilities consist of approximately 3.0 million square feet, and our leased facilities consist of approximately 0.6 million square feet. We presently have eleven manufacturing sites, six of which are used by our Global Medical Imaging segment, four of which are used by our Specialty Pharmaceuticals segment and one of which is shared by both segments. We have two manufacturing sites in Canada, one manufacturing site in each of 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. 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, unless indicated in Note 18 and 23 of the Notes to Consolidated and Combined Financial Statements included within Item 8. Financial Statements and Supplementary Data, that their ultimate resolution will not have a material adverse effect on our financial condition, results of operations and cash flows. For further information on pending legal proceedings, refer to Notes 18 and 23 of the Notes to Consolidated and Combined Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Item 4. Mine Safety Disclosures.

Not applicable.

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." 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. The following table presents the high and low sales prices of our ordinary shares for the periods indicated, as reported by the NYSE.

	FY2014		FY2013	
	High	Low	High	Low
First Quarter	$ 53.47	$ 42.01	$ —	$ —
Second Quarter	$ 72.81	$ 50.70	$ —	$ —
Third Quarter	$ 82.70	$ 60.28	$ —	$ —
Fourth Quarter	$ 90.00	$ 68.12	$ 47.16	$ 41.51

There were approximately 3,311 shareholders of record of our ordinary shares as of November 14, 2014.

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 currently intend to pay dividends in the foreseeable future. We have not initiated a share repurchase program to date.

During the quarter ended September 26, 2014, we repurchased 197,904 of our Ordinary Shares to satisfy tax withholding obligations in connection with the vesting of restricted stock issued to employees as follows:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Minimum Approximate Dollar Value of Shares that May Yet Be Purchased Under Publicly Announced Plans or Programs
6/28/2014 - 7/25/2014	1,103	$ 76.32	—	—
7/26/2014 - 8/29/2014	77	$ 77.31	—	—
8/30/2014 - 9/26/2014	196,724	$ 78.56	—	—
6/26/2014 - 9/26/2014	197,904	$ 78.55		

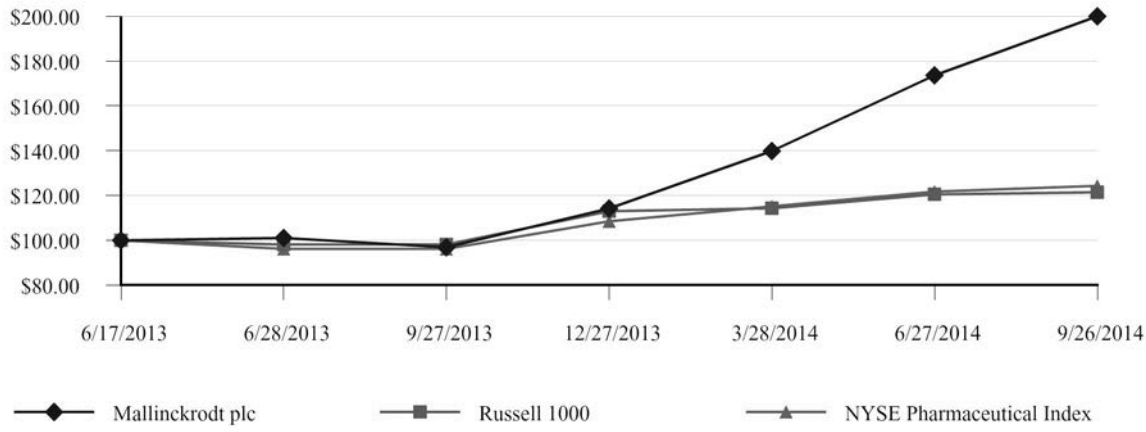
Performance Graph

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 26, 2014.

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
September 27, 2013	96.82	104.02	100.18
December 27, 2013	114.20	112.98	108.36
March 28, 2014	139.78	114.23	115.05
June 27, 2014	173.67	120.48	121.71
September 26, 2014	200.00	121.42	124.26

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 26, 2014.

Item 6. Selected Financial Data.

The following table sets forth selected financial data as of and for the fiscal years ended September 26, 2014, September 27, 2013, September 28, 2012, September 30, 2011 and September 24, 2010. 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 statement of income data for fiscal 2014, the consolidated and combined statement of income data for fiscal 2013, the combined statement of income data for fiscal 2012, and the consolidated balance sheet data as of September 26, 2014 and September 27, 2013 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 2011 and 2010 and the combined balance sheet data as of September 28, 2012 and 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 balance sheet data as of September 24, 2010 was 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]				
	2014	2013	2012	2011	2010
Consolidated and Combined Statement of Income Data:					
Net sales	$ 2,540.4	$ 2,204.5	$ 2,056.2	$ 2,021.8	$ 2,047.6
Gross profit	1,203.1	1,024.9	964.8	914.9	932.4
Research and development expenses [2]	166.9	165.7	144.1	141.5	119.1
Operating (loss) income [3] [4]	(284.1)	144.8	235.2	240.7	240.4
(Loss) income from continuing operations before income taxes	(363.4)	126.4	236.1	243.2	243.2
(Loss) income from continuing operations	(318.6)	57.8	141.3	157.0	145.9
Share Data [5]:					
Basic (loss) income from continuing operations per share	$ (4.91)	$ 1.00	$ 2.45	$ 2.72	$ 2.53
Diluted (loss) income from continuing operations per share	(4.91)	1.00	2.45	2.72	2.53
Cash dividends per ordinary share	—	—	—	—	—

	September 26, 2014	September 27, 2013	September 28, 2012	September 30, 2011	September 24, 2010 (unaudited)
Consolidated and Combined Balance Sheet Data:					
Total assets	$ 12,864.8	$ 3,556.6	$ 2,898.9	$ 2,832.2	$ 2,892.6
Long-term debt	3,951.5	918.3	8.9	10.4	11.6
Shareholders' equity	4,958.0	1,255.6	1,891.9	1,788.7	1,835.9

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

(2) Fiscal 2014 and 2013 each include a $5.0 million charge related to milestone payments related to the acceptance of pipeline products for filing with the FDA.

(3) 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 2014, 2013, 2012 and 2011 include separation related costs of $9.6 million, $74.2 million, $25.5 million and $2.9 million, respectively. Fiscal 2014, 2013, 2012, 2011 and 2010 include restructuring charges, net, of $128.6 million, $33.2 million, $11.2 million, $8.4 million and $11.5 million, respectively. Fiscal 2014 includes $355.6 million of non-restructuring impairment charges, $49.6 million of environmental and legal charges and $65.1 million of transaction costs associated with the Cadence Acquisition and the Questcor Acquisition. Fiscal 2010 includes product liability charges of $31.3 million.

(4) Fiscal 2013, 2012, 2011, and 2010 include expense allocations from Covidien of $39.6 million, $49.2 million, $56.3 million and $60.8 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.

(5) 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 specialty biopharmaceutical and medical imaging business that develops, manufactures, markets and distributes specialty pharmaceutical products and medical imaging agents. Therapeutic areas of focus include autoimmune and rare disease specialty areas (including neurology, rheumatology, nephrology and pulmonology), along with pain and attention-deficit hyperactivity disorder ("ADHD") for prescription by office- and hospital-based physicians. We also support the diagnosis of disease with nuclear medicine and contrast imaging. 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 65 countries. We believe our experience in the acquisition and management of highly regulated raw materials; deep regulatory expertise; and specialized chemistry, formulation and manufacturing capabilities, 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 pharmaceuticals and biopharmaceuticals, specialty generic pharmaceuticals and active pharmaceutical ingredients ("API") consisting of biologics, 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").

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 and $49.2 million in fiscal 2013 and 2012, 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. The Company expects to substantially reduce the level of service provided by Covidien in fiscal 2015 as the Company has substantially completed the implementation of information systems in jurisdictions outside the U.S and terminated the transition services agreement during the first quarter of fiscal 2015.

Acquisitions

In August 2014, we acquired Questcor, a high-growth biopharmaceutical company, for total consideration of approximately $5.9 billion. The acquisition was funded through an issuance of approximately 57 million common shares, proceeds from the issuance of $900.0 million aggregate principle of senior unsecured notes, proceeds from the issuance of $700.0 million senior secured term loan facility, $150.0 million of cash from a receivable securitization program and cash on hand. Questcor is focused on the treatment of patients with serious, difficult-to-treat autoimmune and rare diseases. Questcor's primary product, H.P. Acthar® Gel (repository corticotropin injection), is an injectable drug that is approved by the FDA for use in 19 indications, including the areas of neurology, rheumatology, nephrology and pulmonology. Questcor also supplies specialty contract manufacturing services to the global pharmaceutical and biotechnology industry through its wholly-owned subsidiary, BioVectra Inc. The Questcor Acquisition is expected to provide a strong and sustainable platform for future revenue and earnings growth within the Company's Specialty Pharmaceuticals segment. The consolidated statement of income for fiscal 2014 included $122.9 million of net sales for Acthar.

In March 2014, we acquired Cadence, a biopharmaceutical company focused on commercializing products principally for use in the hospital setting for approximately $1.3 billion. The acquisition was primarily funded through a $1.3 billion senior secured term loan credit facility. Cadence's sole product, OFIRMEV® (acetaminophen) injection ("Ofirmev"), is a proprietary intravenous formulation of acetaminophen for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics and the reduction of fever. The Cadence Acquisition added a growth product to the Specialty Pharmaceuticals product portfolio and provides us with an opportunity to expand its reach into the adjacent hospital market, in which Cadence had established a presence. The consolidated statement of income for fiscal 2014 included $124.4 million of net sales for Ofirmev.

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, net of cash acquired, of $95.0 million. Gablofen (baclofen injection), the primary product of CNS Therapeutics, is 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 statements of income for fiscal 2014 and 2013 included $32.9 million and $29.2 million of net sales, respectively, of intrathecal products added to our portfolio with this acquisition.

License of Intellectual Property

We were involved in patent disputes with a counterparty relating to certain intellectual property relevant to extended-release oxymorphone. In December 2013, the counterparty agreed to pay us an upfront cash payment of $4.0 million and contractually obligated future payments of $8.0 million through July 2018, in exchange for the withdrawal of all claims associated with the intellectual property and a license to utilize our intellectual property. We completed the earnings process associated with the agreement and recorded an $11.7 million gain, included within gain on divestiture and license, during fiscal 2014.

Divestitures

During fiscal 2011, we 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, we recorded an $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 $2.9 million of contingent payments during fiscal 2014, 2013 and 2012.

Royalty and Milestone Payments

We are required to pay royalties and milestone payments for various product acquisitions and license agreements we entered into with third parties. We incurred royalty expense of $72.0 million, $51.6 million and $48.4 million in fiscal 2014, 2013 and 2012, respectively, under our product acquisitions and license agreements, including those discussed below.

We acquired the exclusive development and commercialization rights to Ofirmev in the U.S. and Canada, as well as the rights to the patents and technology. Under this license agreement, we may be obligated to make future milestone payments of up to $25.0 million upon the achievement of certain levels of net sales, in addition to on-going royalties on the sales of the product.

For Exalgo, we are obligated to make additional payments based on the successful completion of specified development and regulatory milestones payments of up to $73.0 million based on the successful completion of specified development and regulatory milestones. Through fiscal 2014, $65.0 million of additional payments have been made, with $55.0 million being capitalized as an

intangible asset. We are also required to pay royalties on sales of the product. In January 2014, the Company purchased royalty rights associated with Exalgo for $7.2 million, which have been classified as an intangible asset.

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. Under this license agreement, the Company may be obligated to pay up to $64.0 million in development milestone payments. Through fiscal 2014, approximately $22.0 million of these payments have been made by the Company. During fiscal 2014, upon approval by the FDA for Xartemis XR, we made a milestone payment of $10.0 million, which was capitalized as an intangible asset. In addition, subsequent to FDA's acceptance of our NDA for MNK-155 in July 2014, the Company made a milestone payment of $5.0 million, which was expensed as incurred as it was made prior to regulatory approval. During fiscal 2013 and 2012, milestone payments of $5.0 million and an insignificant amount, respectively, were expensed as incurred as they were also made prior to regulatory approval. In addition, an insignificant amount of royalties have been paid through fiscal 2014.

In 2009, we also entered into a licensing agreement which granted rights to market and distribute Pennsaid and Pennsaid 2%. We were responsible for all future development activities and expenses and were required to make milestone payments of up to $120.0 million based upon the successful completion of specified regulatory and sales milestones. Through fiscal 2014, $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. We were also required to pay royalties on sales of the products under this agreement. During the fourth quarter of fiscal 2014, we reached an agreement in principle with Nuvo to settle various claims associated with our license of Pennsaid. As part of the legal settlement, the Company agreed to return the license to Nuvo, which resulted in the Company recording an impairment of $11.1 million during the fourth quarter of fiscal 2014.

Nuclear Imaging

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 from 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. We received increased target irradiations from other reactors, purchased additional Mo-99 from other sources and outsourced Mo-99 processing to continue meeting customer orders; however, the additional Mo-99 and processing services we procured from alternative sources came at a higher than normal cost. The HFR resumed production of medical isotopes and irradiation of materials in February 2014 and the Mo-99 processing facility resumed production in April 2014. Ongoing increased raw material and manufacturing costs will limit our ability to return the Global Medical Imaging segment to historical operating margins.

Lower Passaic River Environmental Reserve

On April 11, 2014, the U.S. Environmental Protection Agency ("EPA") issued its revised Focused Feasibility Study ("FFS"), with remedial alternatives to address cleanup of the lower 8-mile stretch of the Lower Passaic River Study Area ("the River"), which also included a "no action" option. The EPA estimates the cost for the alternatives range from $365.0 million to $3.2 billion. The EPA's preferred approach would involve bank-to-bank dredging of the lower 8-mile stretch of the River and installing an engineered cap at a discounted, estimated cost of $1.7 billion. Based on the issuance of the EPA's revised FFS, we recorded a $23.1 million accrual in the second quarter of fiscal 2014 representing our estimate of our allocable share of the joint and several remediation liability resulting from this matter. Despite the issuance of the revised FFS, there are many uncertainties associated with the final agreed upon remediation and our allocable share of the remediation. Given those uncertainties, the amounts accrued may not be indicative of the amounts for which will be ultimately responsible and will be refined as events in the remediation process occur.

Business Factors Influencing the Results of Operations

Products

In March 2014, the FDA approved our NDA for Xartemis XR, for the management of acute pain severe enough to require opioid treatment and in patients for whom alternative treatment options are ineffective, not tolerated or would otherwise be inadequate. Xartemis XR is the first and only extended-release oral combination of oxycodone and acetaminophen. In February 2014, we were granted a patent from the U.S. Patent and Trademark Office ("USPTO"), which contains composition claims directed to unique design, formulation, pharmacokinetic and release characteristics of Xartemis XR. Pursuant to the terms of our licensing agreement, we paid and capitalized as an intangible asset, a $10.0 million milestone payment to Depomed, Inc., in connection with the FDA approval of Xartemis XR. Xartemis XR received FDA approval and was launched in March 2014.

In December 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 ADHD 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 July 2013, a competitor received FDA approval to manufacture all strengths of Methylphenidate ER and entered the marketplace. As our exclusivity has expired, other competitors may also enter the market for Methylphenidate ER. Net sales of Methylphenidate ER were $209.6 million and $148.3 million in fiscal 2014 and 2013, respectively. The Company expects that the FDA's action will reclassify our Methylphenidate ER products will significantly impact net sales and operating income unless the FDA revises its decision.

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. In May 2014, we launched an authorized generic version of Exalgo and shortly thereafter a competitor entered the market. Net sales of Exalgo were $76.1 million, $126.1 million and $91.9 million in fiscal 2014, 2013 and 2012, respectively. We expect sales of Exalgo, across both the branded and authorized generic product, to decrease in fiscal 2015 compared with net sales in fiscal 2014.

We completed two acquisitions that added Ofirmev and Acthar to our product portfolio in fiscal 2014. Net sales in fiscal 2014 from these products was $247.3 million. As a result of these transactions, we increased the value of inventory on-hand at the acquisition dates to its fair value and recorded approximately $6.9 billion in intangible assets primarily related to the completed technology associated with Ofirmev and Acthar. Our fiscal 2014 cost of sales, includes $25.7 million of expense recognition associated with the fair value adjustment of acquired inventory and $121.0 million of amortization associated with these intangible assets. Additionally, we incurred and expensed $65.1 million of transaction costs in fiscal 2014 associated with these transactions, which are reflected in SG&A in our consolidated statement of income. We expect net sales of these products to increase in fiscal 2015 due to inclusion of the full year of net sales.

Restructuring Initiatives

Following the Separation, we have focused on realigning our cost structure due to the changing nature of our business and looked for opportunities to achieve operating efficiencies. As such, in July 2013 our board of directors approved a restructuring program in the amount of $100.0 million to $125.0 million that is expected to occur over a two to three-year period, from the approval of the program, with a two-year cost recovery period. Through September 26, 2014, we incurred restructuring charges of $89.4 million under our July 2013 program which are primarily expected to generate savings within our selling, general and administrative expenses. In addition to the July 2013 program, we have taken restructuring actions to generate synergies from our fiscal 2014 acquisitions.

During fiscal 2014, 2013 and 2012, we incurred restructuring and related charges, net, of $129.1 million, $35.8 million and $19.2 million, respectively, which included accelerated depreciation costs of $0.5 million, $2.6 million and $8.0 million, respectively. The restructuring charges incurred during fiscal 2014 primarily related to employee severance and benefits across both our segments, consulting costs and non-cash charges. The non-cash charges included $25.7 million of asset impairments, most notably associated with the termination of a related-party supply agreement, and $35.1 million of accelerated share based compensation associated with Questcor unvested equity awards that were converted to Mallinckrodt awards at the date of the Questcor Acquisition. Restructuring charges in fiscal 2013 and 2012 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.

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 the development of extended-release opioid products with abuse deterrent properties and expanding the opportunities for existing products by documenting and publishing clinical experience and evidence that support health economic and patient outcomes. MNK-155 has completed Phase III clinical trials and our NDA filing was accepted for review by the FDA in May 2014. We have received notice of allowance from the USPTO related to composition claims directed to unique design, formulation, pharmacokinetic and release characteristics for MNK-155.

In accordance with a Pediatric Research Equity Act requirement included in the NDA approval for Ofirmev, Cadence began enrolling patients in 2012 in a post-marketing efficacy study of Ofirmev in infants and neonates. The data from this study will be used to satisfy a formal written request Cadence received from the FDA under Section 505A of the U.S. Food, Drug and Cosmetic Act that was made as part of the approval process for Ofirmev. The FDA has agreed to an August 2015 due date for completion of this study. Upon timely completion and acceptance by the FDA of the data from this study, Ofirmev may be eligible for an additional six months of marketing exclusivity in the U.S. The FDA is also currently reviewing a supplemental NDA that Cadence submitted in December 2013, which would enable us to offer Ofirmev in flexible intravenous bags.

In regard to specialty generic product development, we are focused on controlled substances with difficult-to-replicate pharmacokinetic profiles. As of September 26, we had various ANDAs on file with the FDA. In addition, we are focused on process improvements to increase yields and reduce costs.

Global Medical Imaging. Our R&D efforts in our Global Medical Imaging segment are focused on driving efficiency and regulatory compliance throughout CMDS and Nuclear Imaging.

Results of Operations

Fiscal Year Ended September 26, 2014 Compared with Fiscal Year Ended September 27, 2013

Net Sales

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

	Fiscal Year		Percentage Change
	2014	2013	
U.S.	$ 1,899.8	$ 1,518.7	25.1%
Europe, Middle East and Africa	394.0	404.3	(2.5)
Other	246.6	281.5	(12.4)
Net sales	$ 2,540.4	$ 2,204.5	15.2

Net sales in fiscal 2014 increased $335.9 million, or 15.2%, to $2,540.4 million, compared with $2,204.5 million in fiscal 2013. This increase was primarily attributable to increased Specialty Generics and API net sales, driven by strategic initiatives on certain specialty controlled substance generics and increased Methylphenidate ER net sales. Brands net sales also contributed to the increase due to net sales of the newly acquired Acthar and Ofirmev. These increases were partially offset by a decrease in CMDS net sales. 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 2014 increased $178.2 million, or 17.4%, to $1,203.1 million, compared with $1,024.9 million in fiscal 2013. The increase in gross profit primarily resulted from increased net sales from strategic initiatives and a further shift in net sales to the higher margin Specialty Pharmaceuticals segment, including the newly acquired Acthar and Ofirmev products. These increases were partially offset by a $126.9 million increase in amortization primarily associated with Acthar and Ofirmev, $25.7 million of expense recognition associated with the fair value adjustment of acquired Acthar and Ofirmev inventory, a $16.7 million increase in inventory provision expense and higher raw material costs in the Global Medical Imaging segment, including the unscheduled shutdowns of our Mo-99 processing facility and the HFR that supplies us with Mo-99. Gross profit margin was 47.4% during fiscal 2014, compared with 46.5% during fiscal 2013. The fiscal 2014 profit margin includes the increased amortization and expense recognition of inventory fair value adjustments.

Selling, general and administrative expenses. Selling, general and administrative expenses for fiscal 2014 were $842.1 million, compared with $609.9 million for fiscal 2013, an increase of $232.2 million, or 38.1%. The increase primarily resulted from higher internal and third-party expenses associated with being an independent, publicly-traded company, $93.0 million from the inclusion of selling, administration and integration costs associated with Acthar and Ofirmev, $65.1 million of transaction costs associated with our fiscal 2014 acquisitions, a $23.1 million environmental remediation charge, and $29.6 million of higher selling expenses in our Brands business related to the launch of Xartemis XR and Pennsaid 2%. These increases were partially offset by benefits from restructuring actions and certain prior year costs that did not recur in fiscal 2014. In fiscal 2013, selling, general and administrative expenses included higher legal settlement costs and $39.6 million of allocations from Covidien for general corporate

expenses. These allocations 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. Selling, general and administrative expenses were 33.1% of net sales for fiscal 2014 and 27.7% of net sales for fiscal 2013.

Research and development expenses. R&D expenses increased $1.2 million, or 0.7%, to $166.9 million in fiscal 2014, compared with $165.7 million in fiscal 2013. As products, such as Xartemis XR, Pennsaid 2% and MNK-155, moved toward or through the FDA review process, we devoted additional resources to other potential products in our R&D pipeline and the continued pursuit of abuse-deterrent labeling for Xartemis XR. As a percentage of our net sales, R&D expenses were 6.6% and 7.5% in fiscal 2014 and 2013, respectively.

Separation costs. During fiscal 2014 and 2013, we incurred separation costs of $9.6 million and $74.2 million, respectively, primarily related to legal, accounting, tax and other professional fees. Separation costs were higher in the prior year period as we approached and completed the Separation on June 28, 2013. We have continued 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 historical levels.

Restructuring and related charges, net. During fiscal 2014, we recorded $129.1 million of restructuring and related charges, net, of which $0.5 million related to accelerated depreciation and was included in cost of sales. The remaining $128.6 million primarily related to severance and benefits across both our segments, consulting costs and non-cash charges. The non-cash charges included $25.7 million of asset impairments, most notably associated with the termination of a related-party supply agreement, and $35.1 million of accelerated share based compensation associated with Questcor unvested equity awards that were converted to Mallinckrodt awards at the date of the Questcor Acquisition. During fiscal 2013, we recorded restructuring and related charges, net of $35.8 million, 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.

Non-restructuring impairment charges. During fiscal 2014, we recorded $355.6 million of non-restructuring impairment charges. The charges consisted of $219.7 million associated with impairment of goodwill in the Global Medical Imaging Segment and $65.9 million and $52.4 million of property, plant & equipment and intangible asset impairments, respectively, of assets included within our CMDS asset group. These impairment charges are partially the result of receiving notification that we lost preferred supplier status with a significant GPO and that we terminated a related-party supply contract, both of which occurred in the fourth quarter of fiscal 2014. Further, the Company recorded other impairments of $17.6 million, which primarily relate to the the impairment of Pennsaid intangibles upon the return of our product rights to Nuvo as part of a fourth quarter legal settlement.

Gain on divestiture and license. During fiscal 2014 and 2013, we recorded gains on divestiture and license of $15.6 million and $2.9 million, respectively. The $15.6 million gain recorded during fiscal 2014 primarily resulted from an $11.7 million gain from the license of extended-release oxymorphone intellectual property to a third-party.

Non-Operating Items

Interest expense and interest income. During fiscal 2014 and fiscal 2013, net interest expense was $81.1 million and $19.2 million, respectively. Net interest expense is primarily attributable to our $900.0 million issuance of senior unsecured notes in April 2013, $1.3 billion of debt associated with our March 2014 acquisition of Cadence and approximately $1.8 billion of debt associated with our August 2014 acquisition of Questcor. Interest expense during 2014 and 2013 includes $7.7 million and $1.1 million, respectively, of non-cash interest expense.

Other income, net. During fiscal 2014 and 2013, we recorded other income, net of $1.8 million and $0.8 million, respectively, which represents miscellaneous items, including gains and losses on intercompany financing foreign currency transactions and related hedging instruments.

Provision for income taxes. In fiscal 2014, we recognized an income tax benefit of $44.8 million on a loss from continuing operations before income taxes of $363.4 million. In fiscal 2013, income tax expense was $68.6 million on income from continuing operations before income taxes of $126.4 million. Our effective tax rate was 12.3% compared with 54.3% for fiscal 2014 and 2013, respectively. Our effective tax rate for fiscal 2014 was impacted by only receiving a $17.4 million tax benefit on $74.7 million of transaction and Separation costs, $39.4 million of tax benefit associated with $129.1 million of restructuring costs, $8.5 million of tax benefit associated with accrued income tax liabilities and uncertain tax positions, $12.4 million of tax benefit associated with the favorable rate difference between non-U.S. and U.S. jurisdictions (excluding impact of below referenced impairments), $4.8 million of tax benefit associated with the U.S. Domestic Manufacturing Deduction, a $20.0 million expense associated with an adjustment to the Company's wholly owned partnership investment, and a $45.3 million tax benefit associated with the $355.6 million impairment of tangible and intangible assets and goodwill. 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, $2.5 million of tax benefit associated with the U.S.

Domestic Manufacturing Deduction and $2.2 million of tax benefit associated with the favorable rate difference between non-U.S. and U.S. jurisdictions, which includes the benefit of intercompany debt transferred to the Company at the Separation.

Income (loss) from discontinued operations, net of income taxes. We recorded a $0.7 million loss and $1.0 million gain on discontinued operations, net of income taxes, during fiscal 2014 and 2013, 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 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		Percentage Change
	2013	2012	
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 margin was 46.5% in fiscal 2013, compared with 46.9% in 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, compared with 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%.

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% 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 fiscal 2013 as we approached and completed the Separation on June 28, 2013.

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 benefit costs incurred in the Global Medical Imaging segment.

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

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% and 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.

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.

Business Segment Results

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

Specialty Pharmaceuticals

- *Brands* include branded pharmaceutical drugs, primarily for pain management, and a biopharmaceutical drug for autoimmune and rare diseases.
- *Generics and API* produces generic pharmaceutical products (including those to treat ADHD and addiction), medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients.

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 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, non-restructuring impairments 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 Ended September 26, 2014 Compared with Fiscal Year Ended September 27, 2013

Net Sales

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

	Fiscal Year		Percentage Change
	2014	2013	
Specialty Pharmaceuticals	$ 1,612.9	$ 1,217.6	32.5%
Global Medical Imaging	881.5	935.7	(5.8)
Net sales of operating segments	2,494.4	2,153.3	15.8
Other [1]	46.0	51.2	(10.2)
Net sales	$ 2,540.4	$ 2,204.5	15.2

(1) Represents products that were sold to Covidien.

Specialty Pharmaceuticals. Net sales for fiscal 2014 increased $395.3 million, or 32.5%, to $1,612.9 million, compared with $1,217.6 million for fiscal 2013. The increase in net sales was primarily driven by $124.4 million of net sales of Ofirmev, $122.9 million of net sales from Acthar, $157.4 million of increased net sales from other controlled substances and oxycodone-related products resulting from certain strategic initiatives that offset lower volume, a $61.3 million increase in Methylphenidate ER from favorable comparisons due to timing of the product launch in fiscal 2013. These increases were partially offset by a $50.0 million decrease in branded Exalgo as we launched an authorized generic version and a competitor entered the market, and a $40.6 million decrease in hydrocodone-related products due to lower pricing from competitive pressures.

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

	Fiscal Year		Percentage Change
	2014	2013	
U.S.	$ 1,485.0	$ 1,097.9	35.3%
Europe, Middle East and Africa	103.4	104.1	(0.7)
Other	24.5	15.6	57.1
Net sales	$ 1,612.9	$ 1,217.6	32.5

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

	Fiscal Year		Percentage Change
	2014	2013	
Methylphenidate ER	$ 209.6	$ 148.3	41.3%
Oxycodone (API) and oxycodone-containing tablets	155.2	139.0	11.7
Hydrocodone (API) and hydrocodone-containing tablets	99.4	140.0	(29.0)
Other controlled substances	584.5	443.3	31.9
Other	150.7	140.6	7.2
Specialty Generics and API	1,199.4	1,011.2	18.6
Exalgo	76.1	126.1	(39.7)
Offirmev	124.4	—	—
Acthar	122.9	—	—
Other	90.1	80.3	12.2
Brands	413.5	206.4	100.3
Specialty Pharmaceuticals	$ 1,612.9	$ 1,217.6	32.5

Global Medical Imaging. Net sales for fiscal 2014 decreased $54.2 million, or 5.8%, to $881.5 million compared with $935.7 million for fiscal 2013. The decrease was primarily driven by a $48.3 million decline in net sales of CMDS products, which were impacted by certain restructuring actions aimed at improving profitability. Nuclear sales decreased only slightly despite supply chain disruptions in the current year. During the fourth quarter of fiscal 2014, we received notification that we lost preferred supplier status with a significant GPO which may negatively impact Global Medical Imaging net sales in fiscal 2015.

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

	Fiscal Year		Percentage Change
	2014	2013	
U.S.	$ 414.7	$ 418.2	(0.8)%
Europe, Middle East and Africa	290.6	300.2	(3.2)
Other	176.2	217.3	(18.9)
Net sales	$ 881.5	$ 935.7	(5.8)

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

	Fiscal Year		Percentage Change
	2014	2013	
Optiray	$ 284.0	$ 318.5	(10.8)%
Other	165.8	179.6	(7.7)
Contrast Media and Delivery Systems	449.8	498.1	(9.7)
Nuclear Imaging	431.7	437.6	(1.3)
Global Medical Imaging	$ 881.5	$ 935.7	(5.8)

Operating Income

Operating income by segment and as a percentage of segment net sales for fiscal 2014 and 2013 is shown in the following table (dollars in millions):

	Fiscal Year			
	2014		2013	
Specialty Pharmaceuticals	$ 566.8	35.1%	$ 311.7	25.6%
Global Medical Imaging	47.1	5.3	112.3	12.0
Segment operating income	613.9	24.6	424.0	19.7
Unallocated amounts:				
Corporate and allocated expenses	(241.4)		(133.8)	
Intangible asset amortization	(162.3)		(35.4)	
Restructuring and related charges, net [(1)]	(129.1)		(35.8)	
Non-restructuring impairment charges	(355.6)		—	
Separation costs	(9.6)		(74.2)	
Total operating (loss) income	$ (284.1)		$ 144.8	

(1) Includes restructuring-related accelerated depreciation of $0.5 million and $2.6 million for fiscal 2014 and 2013, respectively.

Specialty Pharmaceuticals. Operating income for fiscal 2014 increased $255.1 million to $566.8 million, compared with $311.7 million for fiscal 2013. Our operating margin increased to 35.1% for fiscal 2014, compared with 25.6% for fiscal 2013. The increase in operating income and margin was primarily due to higher net sales of high margin products, such as Acthar and Ofirmev, benefits from strategic initiatives on certain specialty controlled substance generic products, and the $11.7 million gain on the license of intellectual property to a third-party. These increases were partially offset by a $139.3 million increase in selling, general and administrative expenses and $25.7 million of expense recognition associated with the fair value adjustment of acquired inventory. The increase in selling, general and administrative expenses is primarily associated with expenses to sell and market Acthar and Ofirmev and combined with costs from integrating both products into our business.

Global Medical Imaging. Operating income for fiscal 2014 decreased $65.2 million to $47.1 million, compared with $112.3 million for fiscal 2013. Our operating margin decreased to 5.3% for fiscal 2014, compared with 12.0% for fiscal 2013. The decrease in operating income was attributable to lower net sales, increased nuclear manufacturing and raw material costs and higher regulatory compliance costs. Our increased nuclear manufacturing and raw material costs were most significantly impacted by the unscheduled shutdowns of our Mo-99 processing facility and the HFR that supplies us with Mo-99, which decreased operating income by approximately $21.0 million compared to the prior year period. These increases were partially offset by a $23.1 million decrease in selling, general and administrative expenses primarily attributable to benefits from restructuring actions. Ongoing materials and manufacturing costs and lower net sales will very likely limit our ability to return the Global Medical Imaging segment to historical operating margins.

Corporate and allocated expenses. Corporate and allocated expenses were $241.4 million and $133.8 million for fiscal 2014 and 2013, respectively. The increase primarily resulted from $65.1 million of transaction costs associated with our Questcor and Cadence acquisitions, a $23.1 million environmental remediation charge, increased internal and third-party costs of being an independent publicly-traded company, which was partially offset by certain prior year costs that did not recur in fiscal 2014. We were allocated general corporate expenses of $39.6 million during fiscal 2013 for certain services provided by Covidien. These allocations ceased in periods following the completion of the Separation on June 28, 2013.

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 32 mg 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
Methylphenidate ER	$ 148.3	$ —	—%
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	443.3	439.5	0.9
Other	140.6	134.7	4.4
Specialty Generics and API	1,011.2	848.8	19.1
Exalgo	126.1	91.9	37.2
Offirmev	—	—	—
Acthar	—	—	—
Other	80.3	64.5	24.5
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. 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)%
Other	179.6	189.8	(5.4)
Contrast Media and Delivery Systems	498.1	542.0	(8.1)
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.

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.

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 2015, we expect our total capital expenditures to be in the range of $130 million to $150 million. While we intend to fund these capital expenditures with cash generated from operations, we also have an undrawn $250 million revolving credit facility. At September 26, 2014, we had capital expenditure commitments of $6.3 million.

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

	Fiscal Year		
	2014	2013	2012
Net cash provided by (used in):			
Operating activities	$ 373.4	$ 135.9	$ 255.8
Investing activities	(2,890.8)	(234.7)	(152.2)
Financing activities	2,953.9	373.0	(103.6)
Effect of currency exchange rate changes on cash and cash equivalents	(4.2)	1.3	—
Net increase in cash and cash equivalents	$ 432.3	$ 275.5	$ —

Operating Activities

Net cash provided by operating activities was $373.4 million for fiscal 2014 was primarily attributable to income from continuing operations, as adjusted for non-cash items, and a $66.9 million inflow from net investment in working capital. The working capital inflow was primarily driven by a $56.0 million decrease in inventory as we reduced inventory levels in fiscal 2014 and a $110.5 million increase in other accrued liabilities. The increase in other accrued liabilities includes higher incentive compensation reserves, current year accruals for unpaid legal settlements and higher accrued interest balances reflecting our fiscal 2014 financing transactions, all of which were offset by declines in accrued branded rebates following the introduction of generic alternatives to Exalgo. These increases were offset by $54.8 million in payments to taxing authorities, a $51.3 million increase in accounts receivable driven by increased net sales and a $32.9 million decrease in accounts payable after completing our fiscal 2014 acquisitions.

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 non-cash items, 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.

Investing Activities

Net cash used in investing activities increased $2,656.1 million to $2,890.8 million for fiscal 2014, compared with $234.7 million for fiscal 2013. The increase primarily resulted from fiscal 2014 payments, net of cash acquired, of $1,490.5 million and $1,286.0 million related to the acquisition of Questcor and Cadence, respectively, and $17.3 million for the acquisition of other intangible assets; compared with an $88.1 million payment made during fiscal 2013 to acquire CNS Therapeutics. This net increase was partially offset by a $29.5 million increase in other cash inflows, which include proceeds from the sale of investments and assets, and a $20.1 million decrease in capital expenditures in fiscal 2014 compared with fiscal 2013.

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 2013 to acquire rights to Roxicodone.

Financing Activities

Net cash provided by financing activities was $2,953.9 million for fiscal 2014, compared with net cash provided by financing activities of $373.0 million for fiscal 2013. The $2,580.9 million increase in cash provided by financing activities resulted from the receipt of $2,971.5 million of cash proceeds from the issuance of external debt used to fund the Cadence and Questcor acquisitions, net of debt financing costs, compared with $886.1 million from the issuance of debt in the prior year. This net increase was partially offset by a $33.5 million increase in debt and capital lease repayments, primarily related to debt assumed in the Cadence acquisition, and prior year net transfers to Covidien of $515.9 million, which reflected the remittance of the net proceeds from the issuance of debt partially offset by funding of the CNS Therapeutics, Inc. acquisition and funding of capital expenditures.

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.

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.

Debt and Capitalization

At September 26, 2014, total debt was $3,972.7 million compared with total debt at September 27, 2013 of $919.8 million. The increase in total debt resulted from financing transactions to fund our fiscal 2014 acquisitions. The total debt at September 26, 2014 is comprised of $1,990.3 million of variable rate term loans, $1,830.6 million of fixed rate instruments, $150.0 million of borrowings under a variable rate receivable securitization program and $1.8 million of capital lease obligations. The variable rate term loan interest rates are based on LIBOR, subject to minimum LIBOR level of 0.75%, with interest payments generally expected to be payable every 90 days and requires quarterly principal payments equal to 0.25% of the original principal amount. As of September 26, 2014 our fixed rate instruments have a weighted-average interest rate of 5.07% and pay interest at various dates throughout the fiscal year. Our receivable securitization program bears interest based on one month LIBOR plus a rate margin of 0.80% and has a capacity of $160.0 million that may, subject to certain conditions, be increased to $300.0 million.

At September 26, 2014, $21.2 million of our total debt is classified as current as these payments are expected to be made within the next fiscal year.

In addition to the additional borrowing capacity under our receivable securitization program, we have a $250.0 million revolving credit facility. At September 26, 2014, we had no borrowings or letters of credit outstanding against our revolving credit facility. As such the entire $250.0 million under the revolving credit facility is available for borrowing.

As of September 26, 2014, 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.

Additional discussion of the related to our debt is presented in Note 12 of Notes to the Consolidated and Combined Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Capitalization

Shareholders' equity was $4,958.0 million, at September 26, 2014, compared with $1,255.6 million, at September 27, 2013. The increase in shareholder's equity is primarily attributable to the issuance of approximately 57 million shares to the former shareholders of Questcor, which increased shareholders' equity by $3,979.6 million. The remaining differences are comprised of share-based compensation, share option exercises, fiscal year 2014 net loss and changes in accumulated other comprehensive income.

Dividends

We currently do not anticipate paying any cash dividends for the foreseeable future, as we intend to retain earnings to finance R&D, acquisitions and the operation and expansion of our business. The recommendation, declaration and payment of 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 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 26, 2014 (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	$ 3,970.9	$ 19.8	$ 195.2	$ 342.8	$ 3,413.1
Interest on long-term debt obligations [1]	1,185.9	161.0	325.6	309.2	390.1
Capital lease obligations [1]	1.8	1.4	0.4	—	—
Operating lease obligations	95.0	21.5	30.5	18.0	25.0
Purchase obligations [2]	281.2	93.8	123.3	64.1	—
Total contractual obligations	$ 5,534.8	$ 297.5	$ 675.0	$ 734.1	$ 3,828.2

(1) Interest on debt and capital lease obligations are projected for future periods using interest rates in effect as of September 26, 2014. 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 $651.9 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.

Non-current income taxes payable, primarily related to unrecognized tax benefits, is included within other income tax liabilities on the consolidated and combined balances sheet and, as of September 26, 2014, was $122.6 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 26, 2014, we had net unfunded pension and postretirement benefit obligations of $64.8 million and $52.0 million, respectively. The timing and amounts of long-term funding requirements for pension and postretirement obligations are uncertain. The Company does not anticipate making material involuntary contributions in fiscal 2015, but may elect to make voluntary contributions to its defined pension plans or its postretirement benefit plans during fiscal 2015.

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 26, 2014, we believe that it is probable that we will incur investigation and remedial costs of approximately $67.1 million, of which $7.2 million is included in accrued and other current liabilities on our consolidated balance sheet at September 26, 2014. 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 Note 18 of the Notes to Consolidated and Combined Financial Statements included within Item 8. Financial Statements and Supplementary Data. 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 26, 2014 was $16.6 million, of which $13.9 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 26, 2014. As of September 26, 2014, the maximum future payments we could be required to make under these indemnification obligations was $71.4 million. We were required to pay $30.0 million into an escrow account as collateral to the purchaser, of which $19.4 million remained in other assets on the consolidated balance sheet at September 26, 2014.

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 surety bonds totaling $57.2 million.

In addition, as of September 26, 2014, we had a $21.1 million letter of credit to guarantee decommissioning costs associated with our Saint Louis, Missouri plant upon closure, though we do not intend to close this facility. As of September 26, 2014, we had various other letters of credit and guarantee and surety bonds totaling $36.2 million.

We exchanged title to $27.4 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 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 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
Provisions	1,668.6	84.5	93.7	1,846.8
Payments or credits	(1,642.5)	(31.3)	(96.0)	(1,769.8)
Acquisitions	30.1	0.5	—	30.6
Balance at September 26, 2014	$ 313.3	$ 103.8	$ 13.4	$ 430.5

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, 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 2014 showed that the fair value of our Brands and Generics and API reporting units exceeded their respective carrying values. The fair value of our Global Medical Imaging reporting unit was less than the carrying value of the reporting unit and the Company recorded a $219.7 million goodwill impairment. The impairment of Global Medical Imaging goodwill was primarily attributable to the fourth quarter of fiscal 2014, as we received notification that we lost preferred supplier status with a significant GPO and that we terminated a related-party supply contract.

For further information our goodwill impairment analysis, refer to Notes 2 and 11of the Notes to Consolidated and Combined Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

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, generally using the straight-line method over three 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. 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. We considered the fourth quarter 2014 loss of preferred supplier status with a significant GPO and termination of a related-party supply contract to be a triggering event for the CMDS asset group, including an intangible asset. The undiscounted cash flows were less than the carrying value of the CMDS asset group. Therefore, we compared the fair value of the CMDS asset group to its carrying value and recorded impairment charges of $65.9 million and $52.4 million to the property, plant and equipment and long-lived amortizing intangible assets, respectively, included in the CMDS asset group. 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.

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 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. 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 provisions are 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 $34.7 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 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 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

Our exposure to interest rate risk relates primarily to our variable-rate debt instruments, which bear interest based on LIBOR plus margin. As of September 26, 2014, our outstanding debt included $1,990.3 million variable-rate debt on our senior secured term loan and $150 million variable-rate debt on our receivables securitization. Assuming a one percent increase in the applicable interest rates, in excess of applicable minimum floors, annual interest expense would increase by approximately $21.4 million.

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 26, 2014, there were no outstanding borrowings under this credit facility.

The remaining outstanding debt as of September 26, 2014 is fixed-rate debt. Changes in market interest rates generally affect the fair value of fixed-rate debt, but do not impact earnings or cash flows.

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 26, 2014 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 $37.2 million as of September 26, 2014. 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 26, 2014 that measures the change in the net financial position arising from a hypothetical 10% adverse movement in the exchange rates of the Euro, the Mexican Peso 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 $48.0 million as of September 26, 2014. 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 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 balance sheets of Mallinckrodt plc and subsidiaries (the "Company") as of September 26, 2014 and September 27, 2013, 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 26, 2014. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated and combined financial statements present fairly, in all material respects, the financial position of Mallinckrodt plc and subsidiaries as of September 26, 2014 and September 27, 2013, and the results of their operations and their cash flows for each of the three years in the period ended September 26, 2014, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present 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.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of September 26, 2014, based on the criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated November 24, 2014 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP
St. Louis, Missouri
November 24, 2014

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

	Fiscal Year		
	2014	**2013**	**2012**
Net sales	$ 2,540.4	$ 2,204.5	$ 2,056.2
Cost of sales	1,337.3	1,179.6	1,091.4
Gross profit	1,203.1	1,024.9	964.8
Selling, general and administrative expenses	842.1	609.9	551.7
Research and development expenses	166.9	165.7	144.1
Separation costs	9.6	74.2	25.5
Restructuring charges, net	128.6	33.2	11.2
Non-restructuring impairment charges	355.6	—	—
Gain on divestiture and license	(15.6)	(2.9)	(2.9)
Operating (loss) income	(284.1)	144.8	235.2
Interest expense	(82.6)	(19.5)	(0.5)
Interest income	1.5	0.3	0.4
Other income, net	1.8	0.8	1.0
Income (loss) from continuing operations before income taxes	(363.4)	126.4	236.1
Provision for (benefit from) income taxes	(44.8)	68.6	94.8
Income (loss) from continuing operations	(318.6)	57.8	141.3
Income (loss) from discontinued operations, net of income taxes	(0.7)	1.0	(6.7)
Net income (loss)	$ (319.3)	$ 58.8	$ 134.6
Basic earnings (loss) per share (Note 8):			
Income (loss) from continuing operations	$ (4.91)	$ 1.00	$ 2.45
Income (loss) from discontinued operations, net of income taxes	(0.01)	0.02	(0.12)
Net income (loss)	(4.92)	1.02	2.33
Basic weighted-average shares outstanding	64.9	57.7	57.7
Diluted earnings (loss) per share (Note 8):			
Income (loss) from continuing operations	$ (4.91)	$ 1.00	$ 2.45
Income (loss) from discontinued operations, net of income taxes	(0.01)	0.02	(0.12)
Net income (loss)	(4.92)	1.02	2.33
Diluted weighted-average shares outstanding	64.9	57.8	57.7

See Notes to Consolidated and Combined Financial Statements.

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

	Fiscal Year		
	2014	**2013**	**2012**
Net income (loss)	$ (319.3)	$ 58.8	$ 134.6
Other comprehensive income (loss), net of tax			
Currency translation adjustments	(27.6)	1.5	(2.9)
Unrecognized gain (loss) on derivatives, net of $(0.2), $- and $- tax	0.5	(7.3)	—
Unrecognized gain (loss) on benefit plans, net of $7.3, $(23.9) and $4.6 tax	(15.7)	34.2	(10.7)
Total other comprehensive income (loss), net of tax	(42.8)	28.4	(13.6)
Comprehensive income (loss)	$ (362.1)	$ 87.2	$ 121.0

See Notes to Consolidated and Combined Financial Statements.

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

	September 26, 2014	September 27, 2013
Assets		
Current Assets:		
Cash and cash equivalents	$ 707.8	$ 275.5
Accounts receivable, less allowance for doubtful accounts of $6.6 and $4.6	545.6	400.8
Inventories	396.6	403.1
Deferred income taxes	165.2	171.1
Prepaid expenses and other current assets	255.8	134.4
Total current assets	2,071.0	1,384.9
Property, plant and equipment, net	949.2	997.4
Goodwill	2,401.9	532.0
Intangible assets, net	7,112.2	422.1
Other assets	330.5	220.2
Total Assets	$ 12,864.8	$ 3,556.6
Liabilities and Shareholders' Equity		
Current Liabilities:		
Current maturities of long-term debt	$ 21.2	$ 1.5
Accounts payable	128.7	120.9
Accrued payroll and payroll-related costs	125.1	66.5
Accrued royalties	68.0	13.2
Accrued branded rebates	15.1	34.6
Accrued and other current liabilities	546.7	363.5
Total current liabilities	904.8	600.2
Long-term debt	3,951.5	918.3
Pension and postretirement benefits	119.1	108.0
Environmental liabilities	59.9	39.5
Deferred income taxes	2,398.6	310.1
Other income tax liabilities	122.6	153.1
Other liabilities	350.3	171.8
Total Liabilities	7,906.8	2,301.0
Commitments and contingencies (Note 18)		
Shareholders' Equity:		
Preferred shares, $0.20 par value, 500,000,000 authorized; none issued or outstanding	—	—
Ordinary A shares, €1.00 par value, 40,000 authorized; none issued or outstanding	—	—
Ordinary shares, $0.20 par value, 500,000,000 authorized; 116,160,353 and 57,713,873 issued; 115,929,588 and 57,713,390 outstanding	23.2	11.5
Ordinary shares held in treasury at cost, 230,765 and 483	(17.5)	—
Additional paid-in capital	5,172.4	1,102.1
Retained earnings	(285.8)	33.5
Accumulated other comprehensive income	65.7	108.5
Total Shareholders' Equity	4,958.0	1,255.6
Total Liabilities and Shareholders' Equity	$ 12,864.8	$ 3,556.6

See Notes to Consolidated and Combined Financial Statements.

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

	Fiscal Year		
	2014	**2013**	**2012**
Cash Flows From Operating Activities:			
Net income (loss)	$ (319.3)	$ 58.8	$ 134.6
(Income) loss from discontinued operations, net of income taxes	0.7	(1.0)	6.7
Income (loss) from continuing operations	(318.6)	57.8	141.3
Adjustments to reconcile net cash provided by operating activities:			
Depreciation and amortization	275.9	139.6	130.9
Share-based compensation	67.7	16.2	10.7
Deferred income taxes	(107.5)	(9.0)	9.0
Non-cash impairment charges	381.2	—	—
Inventory provisions	32.1	15.5	2.7
Other non-cash items	(24.3)	(5.2)	(13.4)
Changes in assets and liabilities, net of the effects of acquisitions:			
Accounts receivable, net	(51.3)	(181.2)	(6.8)
Inventories	56.0	27.7	(62.8)
Accounts payable	(32.9)	7.2	(8.3)
Income taxes	(54.8)	60.7	79.4
Accrued and other liabilities	110.5	22.6	(38.7)
Other	39.4	(16.0)	11.8
Net cash provided by operating activities	373.4	135.9	255.8
Cash Flows From Investing Activities:			
Capital expenditures	(127.8)	(147.9)	(144.2)
Acquisitions and intangibles, net of cash acquired	(2,793.8)	(88.1)	(13.2)
Restricted cash	4.1	—	—
Other	26.7	1.3	5.2
Net cash (used in) investing activities	(2,890.8)	(234.7)	(152.2)
Cash Flows From Financing Activities:			
Issuance of external debt	3,043.2	898.1	—
Repayment of external debt and capital leases	(34.8)	(1.3)	(1.3)
Excess tax benefit from share-based compensation	8.9	3.4	1.7
Debt financing costs	(71.7)	(12.0)	—
Net transfers to parent	—	(515.9)	(104.0)
Proceeds from exercise of share options	25.8	0.6	—
Repurchase of shares	(17.5)	—	—
Other	—	0.1	—
Net cash provided by (used in) financing activities	2,953.9	373.0	(103.6)
Effect of currency rate changes on cash	(4.2)	1.3	—
Net increase in cash and cash equivalents	432.3	275.5	—
Cash and cash equivalents at beginning of period	275.5	—	—
Cash and cash equivalents at end of period	$ 707.8	$ 275.5	$ —
Supplemental Disclosures of Cash Flow Information:			
Cash paid for interest, net	$ 57.2	$ 0.8	$ 0.6
Cash paid for income taxes, net	128.0	15.0	4.9

See Notes to Consolidated and Combined Financial Statements.

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

	Ordinary Shares		Treasury Shares							
	Number	Par Value	Number	Amount	Additional Paid-In Capital	Retained Earnings	Contributed Surplus	Parent Company Investment	Accumulated Other Comprehensive Income	Total Shareholders' Equity
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
Net loss	—	—	—	—	—	(319.3)	—	—	—	(319.3)
Currency translation adjustments	—	—	—	—	—	—	—	—	(27.6)	(27.6)
Change in derivatives, net of tax	—	—	—	—	—	—	—	—	0.5	0.5
Minimum pension liability, net of tax	—	—	—	—	—	—	—	—	(15.7)	(15.7)
Ordinary shares issued in connection with the Questcor acquisition	57.3	11.4	—	—	3,968.2	—	—	—	—	3,979.6
Share options exercised	0.8	0.2	—	—	25.6	—	—	—	—	25.8
Vesting of restricted shares	0.4	0.1	—	—	(0.1)	—	—	—	—	—
Excess tax benefit from share-based compensation	—	—	—	—	8.9	—	—	—	—	8.9
Share-based compensation	—	—	—	—	67.7	—	—	—	—	67.7
Repurchase of ordinary shares	—	—	0.2	(17.5)	—	—	—	—	—	(17.5)
Balance at September 26, 2014	116.2	$ 23.2	0.2	$ (17.5)	$ 5,172.4	$ (285.8)	$ —	$ —	$ 65.7	$ 4,958.0

See Notes to Consolidated and Combined Financial Statements.

1. Background and Basis of Presentation

Background

Mallinckrodt plc, and its subsidiaries (collectively, "Mallinckrodt" or "the Company"), is a global specialty biopharmaceutical and medical imaging business that develops, manufactures, markets and distributes specialty pharmaceutical products and medical imaging agents. Therapeutic areas of focus include autoimmune and rare disease specialty areas (including neurology, rheumatology, nephrology and pulmonology), along with pain and attention-deficit hyperactivity disorder ("ADHD") for prescription by office- and hospital-based physicians. We also support the diagnosis of disease with nuclear medicine and contrast imaging. 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 65 countries. The Company believes our experience in the acquisition and management of highly regulated raw materials; deep regulatory expertise; and specialized chemistry, formulation and manufacturing capabilities, have created compelling competitive advantages that we anticipate will sustain future revenue growth.

The Company conducts its business in the following two segments:

- *Specialty Pharmaceuticals* produces and markets branded pharmaceuticals and biopharmaceuticals, specialty generic pharmaceuticals and active pharmaceutical ingredients ("API") consisting of biologics, 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").

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 separately presented to conform to the current year presentation, such as the separate presentation of accrued royalties in the consolidated balance sheets, which had no impact on previously reported net income.

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 and $49.2 million for fiscal 2013 and 2012, 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 expects to substantially reduce the level of service provided by Covidien in fiscal 2015 as the Company has substantially completed the implementation of information systems in jurisdictions outside the U.S. and terminated the transition services agreement during the first quarter of fiscal 2015.

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. 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 26, 2014. 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.

Fiscal Year

The Company reports its results based on a "52-53 week" year ending on the last Friday of September. Fiscal 2014, 2013 and 2012 each consisted of 52 weeks. Unless otherwise indicated, fiscal 2014, 2013 and 2012 refer to the Company's fiscal years ended September 26, 2014, September 27, 2013 and September 28, 2012, 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 directly 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 $55.8 million, $56.5 million and $59.1 million in fiscal 2014, 2013 and 2012, 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 $7.4 million, $7.5 million and $8.8 million in fiscal 2014, 2013 and 2012, 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. During fiscal 2014 and 2013, $0.6 million of foreign currency gains and $14.2 million of foreign currency losses, respectively, were included within net income. The Company entered into derivative instruments to mitigate the exposure of movements in certain of these foreign currency transactions and recognized a $7.9 million loss in fiscal 2014 and a $10.5 million gain in fiscal 2013. The impact of foreign currency transactions and derivatives was not material to net income in fiscal 2012.

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 generally based upon the following estimated useful lives, using the straight-line method:

Buildings	10	to	45 years
Leasehold improvements	1	to	20 years
Capitalized software	1	to	10 years
Machinery and equipment	1	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 or asset groups using undiscounted cash flows whenever events or circumstances indicate that the carrying value of an asset or asset group may not be recoverable. If an asset or asset group is found to be impaired, the amount recognized for impairment is equal to the difference between the carrying value of the asset or asset group and its 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 fair value of in-process research and development ("IPR&D") is determined using the discounted cash flow method. In determining the fair 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 fair 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.

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 fiscal year, or more frequently if impairment indicators arise. The impairment tests is comprised of 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 (a level three measurement technique) 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, with the Company allocating 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 generally using the straight-line method over the following estimated useful lives of the assets, except for customer relationships which are amortized over the estimated pattern of benefit from these relationships:

Completed technology	5	to	25 years
License agreements	8	to	30 years
Trademarks	3	to	30 years
Customer relationships			12 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, or the asset group they are part of, 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, or the asset group they are part of, with their carrying value. The fair value of the intangible asset, or the asset group they are part of, is estimated using an income approach. If the fair value is less than the carrying value of the intangible asset, or the asset group they are part of, the amount recognized for impairment is equal to the difference between the carrying value of the asset and the fair value of the asset. 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. 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.

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 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 balance sheet 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, associated with uncertain tax positions, are included in the provision for income taxes. Interest on transactions treated as installment sales are included within interest expense.

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 balance sheets as payment is not expected within one year.

Parent Company Investment

Parent company investment in periods prior to the Separation 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 was effective for the Company in the first quarter of fiscal 2014. The adoption did not have a material impact on the Company's 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 was effective for the Company in the first quarter of fiscal 2014. The adoption did not have a material impact on the Company's 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. Based on the assessment to date, the Company does not believe the adoption of this pronouncement will have a material impact to the Company’s financial condition, results of operations and cash flows.

FASB issued ASU 2013-11, "Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists," in July 2013. This update provides guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss or a tax credit carryforward exists, to eliminate diversity in practice in the presentation of unrecognized tax benefits in those instances. Except in certain circumstances, an unrecognized tax benefit, or a portion of an unrecognized tax benefit, should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss or a tax credit carryforward. This guidance is effective for the Company in the first quarter of fiscal 2015. The Company has completed its assessment and does not believe the adoption of this pronouncement will have a material impact to the Company’s financial condition, results of operations and cash flows.

FASB issued ASU 2014-08, "Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity," in April 2014. Under the new guidance, only disposals representing a strategic shift in a company's operations and financial results should be reported as discontinued operations, with expanded disclosures. In addition, disclosure of the pre-tax income attributable to a disposal of a significant part of an organization that does not qualify as a discontinued operation is required. This guidance is effective for the Company in the first quarter of fiscal 2016, with early adoption permitted. The Company did not have any recent significant disposals. The Company will assess the impact of the pronouncement to prospective disposals, if applicable, disclosures in future filings and the potential early adoption of the standard.

FASB issued ASU 2014-09, "Revenue from Contracts with Customers," in May 2014. The issuance of ASU 2014-09 and International Financial Reporting Standards ("IFRS") 15, "Revenue from Contracts with Customers," completes the joint effort by FASB and the International Accounting Standards Board to clarify the principles for recognizing revenue and develop a common revenue standard for U.S. GAAP and IFRS. Under the new guidance, an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services, applying the following steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. The guidance is effective for the Company in the first quarter of fiscal 2018. Early adoption is not permitted for public companies. The Company will assess the impact of the pronouncement.

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 2014, 2013 and 2012, the Company recorded a loss of $0.7 million, a gain of $1.0 million, and a loss of $6.7 million, respectively. These gains and losses were primarily related to the indemnification obligations to the purchaser, which are discussed in Note 17.

License of Intellectual Property

The Company was involved in patent disputes with a counterparty relating to certain intellectual property relevant to extended-release oxymorphone. In December 2013, the counterparty agreed to pay the Company an upfront cash payment of $4.0 million and contractually obligated future payments of $8.0 million through July 2018, in exchange for the withdrawal of all claims associated with the intellectual property and a license to utilize the Company's intellectual property. The Company has completed the earnings process associated with the agreement and recorded an $11.7 million gain, included within gains on divestiture and license, during fiscal 2014.

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 fiscal 2014, 2013 and 2012.

5. Acquisitions and License Agreements

Business Acquisitions

Questcor Pharmaceuticals

On August 14, 2014, the Company acquired all of the outstanding common stock of Questcor Pharmaceuticals, Inc. ("Questcor"), a biopharmaceutical company, for total consideration of approximately $5.9 billion, comprised of cash consideration of $30.00 per share, 0.897 ordinary shares of the Company for each share of Questcor common stock owned and the portion of outstanding equity awards deemed to have been earned as of August 14, 2014 ("the Questcor Acquisition"). The acquisition was funded through an issuance of approximately 57 million common shares, proceeds from the issuance of $900.0 million aggregate principle of senior unsecured notes, proceeds from the issuance of $700.0 million senior secured term loan facility, $150.0 million of cash from a receivable securitization program, as further discussed in Note 12, and cash on hand. Acthar® Gel (repository corticotropin injection) ("Acthar"), Questcor's primary product, is focused on the treatment of patients with serious, difficult-to-treat autoimmune and rare diseases. Acthar is an injectable drug that is approved by the U.S. Food and Drug Administration ("FDA") for use in 19 indications, including the areas of neurology, rheumatology, nephrology and pulmonology. Questcor also supplies specialty contract manufacturing services to the global pharmaceutical and biotechnology industry through its wholly-owned subsidiary, BioVectra Inc.

Cadence Pharmaceuticals

On March 19, 2014, the Company acquired all of the outstanding common stock of Cadence Pharmaceuticals, Inc. ("Cadence"), a biopharmaceutical company focused on commercializing products principally for use in the hospital setting, for total consideration of $14.00 per share in cash, or approximately $1.3 billion ("the Cadence Acquisition"). The acquisition was primarily funded through a $1.3 billion senior secured term loan credit facility, as further discussed in Note 12. Cadence's sole product, OFIRMEV® (acetaminophen) injection ("Ofirmev"), is a proprietary intravenous formulation of acetaminophen for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics and the reduction of fever. The Cadence Acquisition added a growth product to the Specialty Pharmaceuticals segment and provides the Company an opportunity to expand its reach into the adjacent hospital market, in which Cadence had established a presence.

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, net of cash acquired, 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 19. 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.

Fair Value Allocation

The following amounts represent the preliminary allocation of the fair value of the identifiable assets acquired and liabilities assumed for the Cadence Acquisition and Questcor Acquisition and final allocation of the fair value of the identifiable assets acquired and liabilities assumed for CNS Therapeutics acquisition:

	Questcor Pharmaceuticals	Cadence Pharmaceuticals	CNS Therapeutics
Cash	$ 445.1	$ 43.2	$ 3.6
Inventory	67.9	21.0	—
Intangible assets	5,601.1	1,300.0	91.9
Goodwill (non-tax deductible)	1,771.5	318.1	24.5
Other assets, current and non-current	273.9	18.0	9.7
Total assets acquired	8,159.5	1,700.3	129.7
Current liabilities	159.8	60.1	4.0
Unpaid purchase consideration (current)	128.8	—	—
Other liabilities (non-current)	183.7	18.7	—
Deferred tax liabilities, net (non-current)	1,900.7	292.3	27.1
Contingent consideration (non-current)	—	—	6.9
Total liabilities assumed	2,373.0	371.1	38.0
Net assets acquired	$ 5,786.5	$ 1,329.2	$ 91.7

The following reconciles the total consideration to net assets acquired:

	Questcor Pharmaceuticals	Cadence Pharmaceuticals	CNS Therapeutics
Total consideration, net of cash	$ 5,470.2	$ 1,286.0	$ 95.0
Plus: cash assumed in acquisition	445.1	43.2	3.6
Total consideration	5,915.3	1,329.2	98.6
Less: unpaid purchase consideration	(128.8)	—	—
Less: contingent consideration	—	—	(6.9)
Net assets acquired	$ 5,786.5	$ 1,329.2	$ 91.7

Intangible assets acquired consist of the following:

Questcor Pharmaceuticals	Amount	Weighted-Average Amortization Period
Completed technology	$ 5,343.3	18 years
Trademark	5.2	13 years
Customer relationships	34.3	12 years
In-process research and development	218.3	Non-Amortizable
	$ 5,601.1	

The completed technology intangible asset relates to Acthar. The trademark and customer relationship intangible assets relate to BioVectra, Inc., a wholly-owned subsidiary of Questcor. The in-process research and development relates to the development of Synacthen, a synthetic pharmaceutical product. The fair value of the intangible assets were determined using the income approach, which is a valuation technique that provides an estimate of the fair value of the asset based on market participant expectations of the cash flows an asset would generate. The cash flows were discounted at various discount rates commensurate with the level of risk associated with each asset or their projected cash flows. Completed technology, customer relationships, trademark and in-process research and development intangibles utilized discount rates of 14.5%, 10.0%, 10.0% and 16.0%, respectively. The in-process research and development discount rate was developed after assigning a probability of success to achieving the projected cash flows based on the current stage of development, inherent uncertainty in the FDA approval process and risks associated with commercialization of a new product. Based on the Company's preliminary estimate, the excess of purchase price over net tangible and intangible assets acquired resulted in goodwill, which represents the assembled workforce, anticipated synergies and the tax status of the transaction. The goodwill is not deductible for U.S. income tax purposes. All assets acquired are included within the Company's Specialty Pharmaceuticals segment.

Cadence Pharmaceuticals	Amount	Amortization Period
Completed technology	$ 1,300.0	8 years

The completed technology intangible asset relates to Ofirmev, the rights to which have been in-licensed from Bristol-Myers Squibb Company ("BMS"). The fair value of the intangible asset was determined using the income approach, which is a valuation technique that provides an estimate of the fair value of the asset based on market participant expectations of the cash flows an asset would generate. The cash flows were discounted at a 13.0% rate. For more information on the BMS license agreement, refer to "License Agreement" below. The excess of purchase price over net tangible and intangible assets acquired resulted in goodwill, which represents the assembled workforce, anticipated synergies and the tax status of the transaction. The goodwill is not deductible for U.S. income tax purposes. All assets acquired are included within the Company's Specialty Pharmaceuticals segment.

CNS Therapeutics	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 goodwill is not deductible for U.S. income tax purposes. All assets acquired are included within the Company's Specialty Pharmaceuticals segment.

Financial Results - The amount of net sales and earnings included in the Company's fiscal 2014 results for each of the fiscal 2014 acquisitions discussed above were as follows:

Net Sales		
Questcor	$	129.2
Cadence		124.4
	$	253.6
Operating income (loss)		
Questcor	$	17.4
Cadence		(66.9)
	$	(49.5)

Acquisition-Related Costs - Acquisition-related costs incurred in fiscal 2014 for each of the fiscal 2014 acquisitions discussed above were as follows:

Questcor		47.5
Cadence		17.6
	$	65.1

Unaudited Pro Forma Financial Information - The following unaudited pro forma information presents a summary of the results of operations for the periods indicated as if the Questcor Acquisition and Cadence Acquisition had been completed as of September 29, 2012. The pro forma financial information is based on the historical financial information for Mallinckrodt, Questcor and Cadence, along with certain pro forma adjustments. These pro forma adjustments consist primarily of:

- non-recurring costs related to the step-up in fair value of acquired inventory and transaction costs related to the acquisitions;
- increased amortization expense related to the intangible assets acquired in the acquisitions;
- elimination of direct acquisition transaction costs from the period of acquisition;
- increased interest expense to reflect the variable-rate term loan and revolving credit facility entered into in connection with the acquisition of Cadence (utilizing the interest rate in effect at September 26, 2014 of 3.50%) and the fixed-rate senior unsecured notes and variable-rate term loan entered into in connection with the acquisition of Questcor (utilizing the interest rate in effect at September 26, 2014 of 3.50%), including interest and amortization of deferred financing costs and original issue discount; and
- the related income tax effects.

The following unaudited pro forma information has been prepared for comparative purposes only and is not necessarily indicative of the results of operations as they would have been had the acquisition occurred on the assumed date, nor is it necessarily an indication of future operating results. In addition, the unaudited pro forma information does not reflect the cost of any integration activities, benefits from any synergies that may be derived from the acquisition or revenue growth that may be anticipated.

	2014	2013
Net sales	$ 3,487.1	$ 3,015.5
Net income (loss)	(326.8)	(61.5)
Basic earnings (loss) per share	$ (2.84)	$ (0.54)
Diluted earnings (loss) per share	(2.84)	(0.54)

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 2014 and 2013 were $13.1 million and $8.4 million, respectively. There are no ongoing royalty payments under this agreement.

License Agreements

Bristol-Myers Squibb

As part of the Cadence Acquisition, the Company acquired the exclusive development and commercialization rights to Ofirmev in the U.S. and Canada, as well as the rights to the patents and technology, which were originally in-licensed by Cadence from BMS in March 2006. BMS sublicensed these rights to Cadence under a license agreement with SCR Pharmatop S.A. ("Pharmatop"), and the Company has the right to grant sublicenses to third parties. Under this license agreement, the Company may be obligated to make future milestone payments of up to $25.0 million upon the achievement of certain levels of net sales, in addition to on-going royalties on the sales of the product. From the date of acquisition to the end of fiscal 2014, the Company paid royalties of $13.2 million.

Exalgo

In 2009, the Company's Specialty Pharmaceuticals segment acquired the rights to market and distribute the pain management drug EXALGO® (hydromorphone HCl) extended-release tablets (CII) ("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 2014, $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 2014, 2013 and 2012, the Company paid royalties of $22.0 million, $24.0 million and $16.1 million, respectively.

In January 2014, the Company purchased royalty rights associated with Exalgo for $7.2 million, which have been classified as an intangible asset.

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 2014, approximately $22.0 million of these payments have been made by the Company. During fiscal 2014, upon approval by the FDA for XARTEMIS™ XR (oxycodone HCl and acetaminophen) extended release tablets CII ("Xartemis XR"), the Company made a milestone payment of $10.0 million, which has been capitalized as an intangible asset. In addition, subsequent to FDA's acceptance of our NDA for MNK-155 in July 2014, the Company made a milestone payment of $5.0 million, which was expensed as incurred as they were made prior to regulatory approval. During fiscal 2013 and 2012, milestone payments of $5.0 million and an insignificant amount, respectively, were expensed as incurred as they were also made prior to regulatory approval. In addition, an insignificant amount of royalties have been paid through fiscal 2014.

Pennsaid

In 2009, the Company's Specialty Pharmaceuticals segment entered into a licensing agreement which granted it rights to market and distribute Pennsaid and Pennsaid 2%, a formulation of diclofenac sodium topical solution which was approved in February 2014 by the FDA and indicated for the treatment of pain associated with osteoarthritis of the knee. The Company was responsible for all future development activities and expenses and were required to make milestone payments of up to $120.0 million based upon the successful completion of specified regulatory and sales milestones. Through fiscal 2014, $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 2014, 2013 and 2012, the Company paid royalties of $4.3 million, $3.9 million and $7.5 million, respectively. For further discussion regarding Pennsaid, refer to Note 18.

During the fourth quarter of fiscal 2014, the Company reached an agreement in principle with Nuvo to settle various claims associated with our license of Pennsaid obtained from Nuvo. As part of the legal settlement, the Company agreed to return the license to Nuvo, which resulted in the Company recording an impairment of $11.1 million during the fourth quarter of fiscal 2014. For more information on the Nuvo matter, refer to Note 18.

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 both segments, as well as within corporate functions. The Company expects to incur charges of $100.0 million to $125.0 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.

Prior to Separation, Covidien initiated restructuring programs, which also applied to its Pharmaceutical business. These programs were substantially completed as of September 26, 2014.

Net restructuring and related charges by segment are as follows:

	Fiscal Year		
	2014	2013	2012
Specialty Pharmaceuticals	$ 66.8	$ 16.4	$ 11.3
Global Medical Imaging	60.9	16.4	7.9
Corporate	1.4	3.0	—
Restructuring and related charges, net	129.1	35.8	19.2
Less: accelerated depreciation	(0.5)	(2.6)	(8.0)
Restructuring charges, net	$ 128.6	$ 33.2	$ 11.2

Net restructuring and related charges are comprised of the following:

	Fiscal Year		
	2014	2013	2012
2013 Mallinckrodt Program	$ 74.5	$ 14.9	$ —
Acquisition programs	56.4	—	—
Other programs	(1.8)	20.9	19.2
Total programs	129.1	35.8	19.2
Less: non-cash charges, including impairments and accelerated share based compensation expense	(61.3)	(2.6)	(6.2)
Total charges expected to be settled in cash	$ 67.8	$ 33.2	$ 13.0

Non-cash charges in fiscal 2014 include $35.1 million of accelerated share based compensation expense related to employee terminations, primarily related to our Questcor acquisition, and $25.6 million of property, plant and equipment asset impairments. The following table summarizes cash activity for restructuring reserves, substantially all of which related to employee severance and benefits, with the exception of $8.5 million related to consulting costs associated with restructuring initiatives:

	2013 Mallinckrodt Program	Acquisition Programs	Other Programs	Total
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
Charges	58.2	22.9	2.5	83.6
Changes in estimate	(9.4)	(1.6)	(4.8)	(15.8)
Cash payments	(34.8)	(13.4)	(6.8)	(55.0)
Reclassifications [1]	(1.3)	—	(1.0)	(2.3)
Currency translation	(1.0)	—	(0.1)	(1.1)
Balance at September 26, 2014	$ 26.6	$ 7.9	$ 0.4	$ 34.9

(1) Represents the reclassification of pension and other postretirement benefits from restructuring reserves to pension and postretirement obligations.

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

Specialty Pharmaceuticals	$ 12.6
Global Medical Imaging	71.5
Corporate	5.3
	$ 89.4

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

7. Income Taxes

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

	2014	2013	2012
U.S.	$ (334.7)	$ 70.0	$ 174.6
Non-U.S.	(28.7)	56.4	61.5
Total	$ (363.4)	$ 126.4	$ 236.1

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

	2014	2013	2012
Current:			
U.S.:			
Federal	$ 49.8	$ 45.7	$ 61.1
State	1.5	9.2	7.2
Non-U.S.	11.4	22.7	17.5
Current income tax provision	62.7	77.6	85.8
Deferred:			
U.S.:			
Federal	(68.3)	(11.7)	5.3
State	(17.0)	(1.2)	2.4
Non-U.S.	(22.2)	3.9	1.3
Deferred income tax (benefit) provision	(107.5)	(9.0)	9.0
	$ (44.8)	$ 68.6	$ 94.8

The fiscal 2014 U.S. federal and state current income tax provisions reflect a utilization of $221.3 million of net operating losses and $8.6 million of U.S. Research credits. The net operating loss utilization is comprised of $187.8 million of net operating losses acquired in conjunction with the acquisition of Cadence and the remainder utilization relating to net operating losses carried forward from fiscal 2013.

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:

	2014	2013	2012
Notional U.S. federal income taxes at the statutory rate	$ (127.2)	$ 44.3	$ 82.6
Adjustments to reconcile to income tax provision:			
U.S. state income tax provision, net [1]	(7.9)	4.8	7.1
Rate difference between non-U.S. and U.S. jurisdictions [2] [3]	(5.8)	(2.2)	(3.5)
Domestic manufacturing deduction	(4.8)	(2.5)	(3.0)
Valuation allowances, nonrecurring	(2.4)	3.4	—
Adjustments to accrued income tax liabilities and uncertain tax positions [3]	(0.5)	8.6	1.2
Interest and penalties on accrued income tax liabilities and uncertain tax positions [3]	(8.0)	4.7	1.1
Investment in partnership	20.0	—	—
Credits, principally research [4]	(0.7)	(6.2)	(0.8)
Impairments, nondeductible	76.9	—	—
Permanently nondeductible and nontaxable items [5]	15.0	12.0	8.1
Other	0.6	1.7	2.0
Provision for income taxes	$ (44.8)	$ 68.6	$ 94.8

(1) Fiscal 2014 includes approximately $4.4 million of tax benefit associated with the favorable impact of the Questcor acquisition on the Company's measurement of its net deferred tax liabilities.

(2) 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.

(3) Fiscal years 2013 and 2012 include impact of items relating to entities retained by Covidien in connection with the Separation.

(4) 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. Due to the December 31, 2013 tax law expiration, fiscal 2014 includes $0.7 million for the period September 28, 2013 through December 31, 2013.

(5) Includes the impact of nondeductible transaction and separation costs.

As of September 26, 2014, September 27, 2013 and September 28, 2012, 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 $82.0 million, $100.1 million and $13.4 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:

	2014	2013	2012
Balance at beginning of fiscal year	$ 100.1	$ 165.5	$ 168.4
Unrecognized tax benefits retained by Covidien	—	(153.7)	—
Unrecognized tax benefits transferred from Covidien	—	84.2	—
Additions related to current year tax positions	3.2	3.5	1.3
Additions related to prior period tax positions	30.6	6.6	1.6
Reductions related to prior period tax positions	(33.0)	(4.3)	(1.9)
Settlements	(6.9)	(1.6)	(1.7)
Lapse of statute of limitations	(12.0)	(0.1)	(2.2)
Balance at end of fiscal year	82.0	100.1	165.5
Cash advance paid in connection with proposed settlements	—	—	(23.5)
Balance at end of fiscal year, net of cash advance	$ 82.0	$ 100.1	$ 142.0

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 asset was retained by Covidien in connection with the Separation. During fiscal 2014, the Company made a $35.9 million advanced payment to the IRS in connection with the proposed settlement of certain tax matters for 2005 through 2007. This payment was comprised of $27.3 million of tax and $8.6 million of interest. As of September 26, 2014, the 2005 through 2007 U.S. federal tax years were considered to have been effectively settled. Therefore, this advance payment, associated unrecognized tax benefits and interest were moved to Accrued and other current liabilities.

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

	September 26, 2014	September 27, 2013
Accrued and other current liabilities	$ 6.5	$ 23.4
Other income tax liabilities	70.7	76.7
Deferred income taxes (non-current liability)	4.8	—
	$ 82.0	$ 100.1

Included within total unrecognized tax benefits at September 26, 2014, September 27, 2013 and September 28, 2012, were $82.0 million, $96.3 million and $144.3 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 2014, the Company accrued $7.0 million of additional interest and released interest of $24.0 million. During fiscal 2013 and 2012, the Company accrued additional interest of $2.4 million and $1.4 million, respectively. The total amount of accrued interest related to uncertain tax positions was $45.1 million, $62.1 million and $33.9 million, respectively. 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.

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 could decrease by up to $19.8 million. Interest and penalties could decrease by up to $13.4 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.

	September 26, 2014	September 27, 2013
Accrued and other current liabilities	$ 17.7	$ 28.2
Other income tax liabilities	122.6	153.1
	$ 140.3	$ 181.3

Other assets includes $14.8 million of tax payments associated with non-current deferred intercompany transactions. Prepaid expenses and other current assets includes a receivable of $60.0 million associated with the Questcor acquisition and tax payments of $3.6 million associated with current deferred intercompany transactions.

	September 26, 2014	September 27, 2013
Other assets	14.8	—
Prepaid expenses and other current assets	76.6	5.4
	$ 91.4	$ 5.4

Covidien continues to be examined by various taxing authorities for periods the Company was included within the consolidated results of Covidien. 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 26, 2014, 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 26, 2014	September 27, 2013
Deferred tax assets:		
Accrued liabilities and reserves	$ 79.1	$ 35.5
Inventories	22.1	30.5
Tax loss and credit carryforwards	102.0	53.6
Environmental liabilities	29.5	27.3
Rebate reserves	41.1	43.4
Expired product	38.9	18.4
Postretirement benefits	36.3	31.2
Federal and state benefit of uncertain tax positions and interest	29.6	47.1
Deferred intercompany interest	—	19.2
Share-based compensation	28.0	12.3
Other	31.5	25.6
	438.1	344.1
Deferred tax liabilities:		
Property, plant and equipment	(110.0)	(160.5)
Intangible assets	(2,176.5)	(113.1)
Installment sale	(93.5)	—
Investment in partnership	(191.3)	(173.6)
	(2,571.3)	(447.2)
Net deferred tax (liability) asset before valuation allowances	(2,133.2)	(103.1)
Valuation allowances	(77.5)	(30.0)
Net deferred tax (liability) asset	$ (2,210.7)	$ (133.1)

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

	September 26, 2014	September 27, 2013
Deferred income taxes (current asset)	$ 165.2	$ 171.1
Other non-current assets	24.1	7.5
Accrued and other current liabilities	(1.4)	(1.6)
Deferred income taxes (non-current liability)	(2,398.6)	(310.1)
Net deferred tax (liability) asset	$ (2,210.7)	$ (133.1)

The Company's current deferred tax asset decreased from $171.1 million at September 27, 2013 to $165.2 million at September 26, 2014 primarily due to an increase in deferred tax assets of $21.4 million as a result of the acquisition of Questcor, offset by the Company's utilization of its U.S. federal net operating losses and the utilization of U.S. Research credits. Additionally, the Company's non-current deferred tax liability increased from $310.1 million at September 27, 2013 to $2,398.6 million at September 26, 2014, primarily due to $292.3 million related to the acquisition of Cadence, $1,900.7 million related to the acquisition of Questcor, $20.0 million related to an adjustment to the Company's indefinite lived deferred tax liability on its wholly owned partnership investment resulting from pre-Separation income tax adjustments to Covidien and its predecessor affiliates, $43.3 million of decreases associated with amortization of intangibles, $25.7 million of decreases associated with impairments, and increases to operational deferred tax assets due to normal operating activities.

The acquisition of Cadence resulted in a net deferred tax liability increase of $292.3 million. Significant components of this increase include $487.2 million of deferred tax liability associated with the Ofirmev intangible asset, $197.4 million of deferred tax asset associated with U.S. federal and state net operating losses, $6.4 million of deferred tax assets associated with federal and state tax credits, and a $12.5 million valuation allowance related to the uncertainty of the utilization of certain deferred tax assets. Following the Cadence Acquisition, the Company entered into an internal installment sale transaction that resulted in a decrease of $272.7 million to the deferred tax liability associated with the Ofirmev intangible asset, a $93.6 million increase to the deferred tax liability associated with an installment sale note receivable, and a $182.7 million decrease to the deferred tax asset associated with the U.S. federal and state net operating losses.

The acquisition of Questcor resulted in a net deferred tax liability increase of $1,900.7 million. Significant components of this increase include $1,928.8 million of deferred tax liability associated with the Acthar intangible asset, $10.8 million of deferred tax liability associated with other intangible assets, $16.2 million of deferred tax liability associated with inventory, $34.1 million of deferred tax assets associated with share-based compensation and associated merger cash consideration, and $18.5 million of deferred tax assets associated with accrued royalties.

At September 26, 2014, the Company had approximately $50.6 million of net operating loss carryforwards in certain non-U.S. jurisdictions, of which $41.3 million have no expiration and the remaining $9.3 million will expire in future years through 2024. The Company had $33.1 million of U.S. federal and state net operating loss carryforwards and $3.3 million of primarily U.S. federal capital loss carryforwards at September 26, 2014, which will expire during fiscal 2015 through 2034.

At September 26, 2014 the Company also had $15.9 million of tax credits available to reduce future income taxes payable, primarily in jurisdictions within the U.S., of which $5.2 million have no expiration and the remainder expire during fiscal 2015 through 2029.

The deferred tax asset valuation allowances of $77.5 million and $30.0 million at September 26, 2014 and September 27, 2013, respectively, relate principally to the uncertainty of the utilization of certain deferred tax assets, primarily non-U.S. 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 2014, 2013 and 2012, the Company provided for U.S. and non-U.S. income and withholding taxes in the amount of $1.4 million, $0.2 million and $0.4 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 26, 2014, the cumulative amount of such undistributed earnings was approximately $1.1 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

In fiscal 2014, basic and diluted earnings (loss) per share were computed using the two-class method. The two-class method is an earnings allocation that determines earnings per share for each class of common stock and participating securities according to dividends declared and participation rights in undistributed earnings. The Company’s restricted stock awards, issued in conjunction with the Questcor Acquisiton in August 2014, are considered participating securities as holders are entitled to receive non-forfeitable dividends during the vesting term. Diluted earnings per share includes securities that could potentially dilute basic earnings per share during a reporting period, for which the Company includes all share based compensation awards other than participating securities. Dilutive securities, including participating securities, are not included in the computation of loss per share when the Company reports a net loss from continuing operations as the impact would be anti-dilutive.

In periods prior to fiscal 2014, basic earnings (loss) per share was computed by dividing net income by the number of weighted-average shares outstanding during the period. Diluted earnings (loss) per share was computed using the weighted-average shares outstanding and, if dilutive, potential ordinary shares outstanding during the period. Potential ordinary shares represent the incremental ordinary shares issuable for restricted share units and share option exercises. The Company calculated 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 conversion of Questcor share-based awards with the Questcor Acquisition, 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 2014 and 2013, calculated under the methodologies outlined above, weighted appropriately for the portion of the period they were outstanding.

	2014	2013	2012
Weighted-average shares for basic earnings (loss) per share	64.9	57.7	57.7
Effect of share options and restricted shares	—	0.1	—
Weighted-average shares for diluted earnings (loss) per share	64.9	57.8	57.7

As the Company incurred a net loss in fiscal 2014, there was no allocation of the undistributed loss to participating securities because the effect would have been anti-dilutive to basic and diluted earnings per share. The computation of diluted earnings per share for fiscal 2014 and 2013 excludes approximately 5.7 million and 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 26, 2014	September 27, 2013
Raw materials and supplies	$ 73.6	$ 68.8
Work in process	212.1	191.5
Finished goods	110.9	142.8
Inventories	$ 396.6	$ 403.1

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 26, 2014	September 27, 2013
Land	$ 59.9	$ 60.4
Buildings	330.6	316.6
Capitalized software	97.6	76.4
Machinery and equipment	1,202.1	1,226.6
Construction in process	198.2	193.7
	1,888.4	1,873.7
Less: accumulated depreciation	(939.2)	(876.3)
Property, plant and equipment, net	$ 949.2	$ 997.4

The amounts above include property under capital leases of $16.9 million and $17.8 million at September 26, 2014 and September 27, 2013, respectively, consisting primarily of buildings. Accumulated amortization of capitalized leased assets was $15.8 million and $15.8 million at the end of fiscal 2014 and 2013, respectively.

Depreciation expense, including amounts related to capitalized leased assets, was $113.6 million, $104.2 million and $103.6 million for fiscal 2014, 2013 and 2012, respectively. Depreciation expense included depreciation on demonstration equipment of $4.3 million, $3.6 million and $3.4 million for fiscal 2014, 2013 and 2012, respectively. Demonstration equipment was included within other assets on the consolidated balance sheets.

Long-Lived Asset Impairment Analysis

During the fourth quarter of fiscal 2014, the Company received notification that we lost preferred supplier status with a significant group purchasing organization ("GPO") and that a related-party supply contract was terminated by the Company. The Company determined that these events constituted a triggering event with respect to our CMDS asset group within the Global Medical Imaging segment and assessed the recoverability of the CMDS asset group. The Company determined that the undiscounted cash flows of this asset group were less than its net book value. This would require the Company to record an impairment charge if the fair value of the CMDS asset group was less than its net book value.

The Company determined the fair value of the CMDS asset group using the income approach, a level three measurement technique. For purposes of determining fair value the Company made various assumptions regarding estimated future cash flows, discount rates and other factors in determining the fair values of each reporting unit using the income approach. The Company's projections of future cash flows were then discounted based on a weighted-average cost of capital ("WACC") determined from relevant market comparisons, adjusted upward for specific risks (primarily the uncertainty of achieving projected operating cash

flows). A terminal value growth rate was applied to the terminal year cash flows, both of which represent the Company's estimate of stable, sustainable growth. The fair value of the asset group represents the sum of the discounted cash flows from the discrete period and the terminal year cash flows.

The Company's projections in the CMDS asset group included long-term net sales and operating income at lower than historical levels. The decrease in net sales and operating income is reflective of the notification of the loss of a significant customer, termination of a supply contract with a related party and increased competition in the marketplace. The Company utilized a WACC of 8.0%, which reflects the lower inherent risk with the decreasing revenue trends. These assumptions resulted in a fair value of the CMDS asset group that was less than its net book value. Therefore, the Company recorded impairment charges of $65.9 million and $52.4 million to the property, plant and equipment and long-lived amortizing intangible assets, respectively, included in the CMDS asset group. The Global Medical Imaging reporting unit could be subject to further impairment should the Company experience greater than expected revenue declines, revise our long-term projections downward or utilize higher discount rates.

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 27, 2013	$ 312.3	$ 219.7	$ 532.0
Acquisitions	2,089.6	—	2,089.6
Impairment	—	(219.7)	(219.7)
Goodwill at September 26, 2014	$ 2,401.9	$ —	$ 2,401.9

Goodwill Impairment Analysis

The Company has identified the Brands and Generics and API businesses to be the reporting units within our Specialty Pharmaceuticals segment and that the Global Medical Imaging business represents both a segment and reporting unit. For purposes of assessing impairment and the recoverability of goodwill for each reporting unit the Company makes various assumptions regarding estimated future cash flows, discount rates and other factors in determining the fair values of each reporting unit using the income approach. The Company's projections of future cash flows were then discounted based on a WACC determined from relevant market comparisons, adjusted upward for specific reporting unit risks (primarily the uncertainty of achieving projected operating cash flows). A terminal value growth rate was applied to the terminal year cash flows, both of which represent the Company's estimate of stable, sustainable growth. The fair value of the reporting unit represents the sum of the discounted cash flows from the discrete period and the terminal year cash flows. The fair values of the reporting units were assessed for reasonableness by aggregating the fair values and comparing this to the Company's market capitalization with a control premium.

The Company's projections in our Brands business include long-term revenue and operating income at levels higher than historical levels which is primarily associated with revenue growth for Ofirmev, Xartemis XR and the introduction of MNK-155. The projections also reflect the potential impacts from the future loss of exclusivity related to Ofirmev. The Company utilized a WACC of 10.5%. These assumptions resulted in a fair value of the Brands business in excess of its net book value. The Company does not believe that the Brands reporting unit is at risk of impairment; however, should we fail to experience growth in the aforementioned products, revise our long-term projections for these products downward or market conditions dictate utilization of higher discount rates, the Brands reporting unit could be subject to impairment in future periods.

The Company's projections in our Generics and API reporting unit include long-term revenue and operating income at higher than historical levels primarily attributable to long-term, single-digit net sales growth. The Company utilized a WACC of 10.5%. These assumptions resulted in a fair value of the Generics and API reporting unit that was significantly in excess of its net book value. Therefore, the Company does not believe that the Generics and API reporting unit is at risk of impairment.

The Company's projections in the Global Medical Imaging reporting unit include long-term net sales and operating income at lower than historical levels. The decrease in net sales and operating income is reflective of the notification that we lost preferred supplier status with a significant GPO, that a related-party supply contract was terminated and increased competition in the marketplace. During the fourth quarter of fiscal 2014, the Company received notification that we lost preferred supplier status with a significant GPO and that a related-party supply contract was terminated by the Company. The Company utilized a WACC of 8.0%, which reflects the Company's risk premium associated with the projected cash flows. These assumptions resulted in a fair value of the Global Medical Imaging segment that was less than its net book value, after recording the impairments to long-lived assets discussed in Note 10. Therefore, the Company recognized a $219.7 million goodwill impairment in the Global Medical Imaging segment.

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

	September 26, 2014		September 27, 2013	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortizable:				
Completed technology	$ 7,040.1	$ 339.7	$ 449.2	$ 196.6
Licenses	185.1	87.3	191.1	79.3
Customer relationships	33.8	0.6	—	—
Trademarks	13.0	4.1	7.9	3.8
Other	6.7	5.0	—	—
Total	$ 7,278.7	$ 436.7	$ 648.2	$ 279.7
Non-Amortizable:				
Trademarks	$ 35.0		$ 35.0	
In-process research and development	235.2		18.6	
Total	$ 270.2		$ 53.6	

Long-Lived Asset Impairment Analysis

During the fourth quarter of fiscal 2014, the Company received notification that we lost preferred supplier status with a significant GPO and that a related-party supply contract was terminated by the Company. The Company determined that these events constituted a triggering event with respect to our CMDS asset group, including a finite-lived intangible asset, within the Global Medical Imaging segment and assessed the recoverability of the CMDS asset group. As discussed further in Note 10, the Company recorded a $52.4 million impairment to a finite-lived completed technology intangible asset.

Finite-lived intangible asset amortization expense was $162.3 million, $35.4 million and $27.3 million in fiscal 2014, 2013 and 2012, respectively. The estimated aggregate amortization expense on intangible assets owned by the Company is expected to be as follows:

Fiscal 2015	$ 496.5
Fiscal 2016	494.3
Fiscal 2017	492.4
Fiscal 2018	483.3
Fiscal 2019	483.0

12. Debt

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

	September 26, 2014	September 27, 2013
Current maturities of long-term debt:		
2.85% term loan due April 2016	$ 0.4	$ —
Term loan due March 2021	18.2	—
4.00% term loan due February 2022	1.2	—
Capital lease obligation	1.4	1.4
Loan payable	—	0.1
Total current debt	21.2	1.5
Long-term debt:		
Variable rate receivable securitization	150.0	—
2.85% term loan due April 2016	2.7	—
3.50% notes due April 2018	300.0	299.9
Term loan due March 2021	1,972.1	—
4.00% term loan due February 2022	9.6	—
9.50% debentures due May 2022	10.4	10.4
5.75% notes due August 2022	900.0	—
8.00% debentures due March 2023	8.0	8.0
4.75% notes due April 2023	598.3	598.2
Capital lease obligation	0.4	1.8
Total long-term debt	3,951.5	918.3
Total debt	$ 3,972.7	$ 919.8

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 was scheduled to mature in June 2018 ("the Credit Facility"). Borrowings under the Credit Facility initially accrued interest at LIBOR plus 1.50% per annum (subject to adjustment pursuant to a ratings-based pricing grid). The Credit Facility was replaced by the Revolver (defined below) in March 2014. There were no borrowings or letters of credit issued under the Credit Facility.

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. 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, which commenced 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.

In March 2014, Mallinckrodt International Finance S.A. ("MIFSA") and Mallinckrodt CB LLC ("MCB"), each a wholly-owned subsidiary of the Company, entered into senior secured credit facilities consisting of a $1.3 billion term loan facility due 2021 ("the Term Loan") and a $250.0 million revolving credit facility due 2019 ("the Revolver") (collectively, "the Facilities"). The Facilities are fully and unconditionally guaranteed by Mallinckrodt plc, certain of its direct or indirect wholly-owned U.S. subsidiaries and each of its direct or indirect wholly-owned subsidiaries that owns directly or indirectly any such wholly-owned U.S. subsidiary (collectively, "the Guarantors"). The Facilities are secured by a security interest in certain assets of MIFSA, MCB and the Guarantors. The Facilities contain customary affirmative and negative covenants, which include, among other things, restrictions on the Company's ability to declare or pay dividends, create liens, incur additional indebtedness, enter into sale and lease-back transactions, make investments, dispose of assets and merge or consolidate with any other person. In addition, the Revolver contains a financial covenant that may limit the Company's total net leverage ratio, which is defined as the ratio of (i) the Company's consolidated debt, less any unrestricted cash and cash equivalents, to (ii) the Company's adjusted consolidated EBITDA, as defined in the credit agreement. The Facilities bear

interest at LIBOR plus a margin based on the Company's total net leverage ratio, and the Term Loan is subject to a minimum LIBOR level of 0.75%. Interest payment dates are variable based on the LIBOR rate utilized, but the Company generally expects interest to be payable every 90 days. The Term Loan requires quarterly principal amortization payments in an amount equal to 0.25% of the original principal amount of the Term Loan payable on the last day of each calendar quarter, which commenced on June 30, 2014, with the remaining balance payable on the due date, March 19, 2021. The Company incurred an original issue discount of 0.25%, or $3.3 million, associated with the Term Loan. The Revolver contains a $150.0 million letter of credit provision, of which none had been issued as of September 26, 2014. Unused commitments on the Revolver are subject to an annual commitment fee determined by reference to the Company's public debt rating, which was 0.375% as of September 26, 2014, and the fee applied to outstanding letters of credit is based on the interest rate applied to borrowings. As of September 26, 2014, the applicable interest rate on outstanding borrowings under the Revolver would have been approximately 3.00%; however, there were no outstanding borrowings.

In July 2014, Mallinckrodt Securitization S.À.R.L. ("Mallinckrodt Securitization"), a wholly-owned special purpose subsidiary of the Company, entered into a $160.0 million accounts receivable securitization facility that matures in July 2017 ("the Receivable Securitization"). Mallinckrodt Securitization may, from time to time, obtain up to $160.0 million in third-party borrowings secured by certain receivables. The borrowings under the Receivable Securitization are to be repaid as the secured receivables are collected. Loans under the Receivable Securitization will bear interest (including facility fees) at a rate equal to one month LIBOR rate plus a margin of 0.80%. Unused commitments on the Receivables Securitization are subject to an annual commitment fee of 0.35%. The Receivable Securitization agreements contain customary representations, warranties, and affirmative and negative covenants. The size of the securitization facility may be increased to $300.0 million upon approval of the third-party lenders subject to certain conditions. As of September 26, 2014, the applicable interest rate on outstanding borrowings under the Receivable Securitization was 0.96% and outstanding borrowings totaled $150.0 million.

In August 2014, MIFSA and MCB issued $900 million aggregate principal amount of 5.75% senior unsecured notes due August 1 2022 ("the 2022 Notes”). The 2022 Notes are guaranteed on an unsecured basis by certain of MIFSA's subsidiaries. The 2022 Notes are subject to an indenture that contains certain customary covenants and events of default (subject in certain cases to customary grace and cure periods). The occurrence of an event of default under the indenture could result in the acceleration of the 2022 Notes and could cause a cross-default that could result in the acceleration of other indebtedness of Mallinckrodt plc and its subsidiaries. MIFSA may redeem some or all of the 2022 Notes prior to August 1, 2017 by paying a make-whole premium. MIFSA may redeem some or all of the 2022 Notes on or after August 1, 2017 at specified redemption prices. In addition, prior to August 1, 2017, MIFSA may redeem up to 40% of the aggregate principal amount of the 2022 Notes with the net proceeds of certain equity offerings. The Issuers are obligated to offer to repurchase the 2022 Notes at a price of (a) 101% of their principal amount plus accrued and unpaid interest, if any, as a result of certain change of control events and (b) 100% of their principal amount plus accrued and unpaid interest, if any, in the event of certain asset sales. These obligations are subject to certain qualifications and exceptions. MIFSA will pay interest on the 2022 Notes semiannually in arrears on February 1 and August 1 of each year, commencing on February 1, 2015.

In August 2014, MIFSA and MCB entered into a $700 million senior secured term loan facility ("the New Term Loan”). The New Term Loan is an incremental tranche under the credit agreement governing our existing Term Loan and Revolver, entered into in March 2014, (collectively, with the New Term Loan, represent "the Senior Secured Credit Facilities"). New Term Loan has substantially similar terms to the Term Loan (other than pricing); including the determination of interest rates and quarterly principal amortization payments equal to 0.25% of the original principal amount of the New Term Loan. The quarterly principal payments commence on December 31, 2014, with the remaining balance payable on the due date of March 19, 2021. Mallinckrodt plc and its subsidiaries (other than MIFSA, MCB and the subsidiaries of MIFSA that guarantee the Facilities) will not guarantee the New Term Loan, and the New Term Loan will not be secured by the assets of such entities. The New Term Loan bears interest under the same terms of the Term Loan entered into in March 2014, including the use of LIBOR rates with a minimum floor.

As of September 26, 2014, the applicable interest rate for the Term Loan and New Term Loan was 3.50% and outstanding borrowings under these agreements totaled approximately $2.0 billion.

As of September 26, 2014, the Company was, and expects to remain, in compliance with the provisions and covenants associated with its Credit Agreement, the Notes, the 2022 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 2015	$	21.2
Fiscal 2016		24.3
Fiscal 2017		171.3
Fiscal 2018		321.3
Fiscal 2019		21.5

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 26, 2014, U.S. plans represented 71% 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.

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		
	2014	2013	2012	2014	2013	2012
Service cost	$ 5.1	$ 5.0	$ 5.0	$ 0.1	$ 0.1	$ 0.1
Interest cost	19.6	18.2	21.2	2.1	2.4	3.1
Expected return on plan assets	(24.6)	(29.6)	(24.5)	—	—	—
Amortization of net actuarial loss	8.1	12.3	11.7	—	0.3	0.2
Amortization of prior service cost	(0.6)	0.6	0.7	(9.3)	(9.1)	(9.2)
Plan settlements loss	3.8	6.8	(0.2)	—	—	—
Net periodic benefit cost (credit)	$ 11.4	$ 13.3	$ 13.9	$ (7.1)	$ (6.3)	$ (5.8)

The following table represents the changes in benefit obligations, plan assets and the net amounts recognized on the consolidated balance sheets for pension and postretirement benefit plans at the end of fiscal 2014 and 2013:

	Pension Benefits		Postretirement Benefits	
	2014	2013	2014	2013
Change in benefit obligation:				
Projected benefit obligations at beginning of year	$ 501.7	$ 533.2	$ 53.2	$ 80.3
Service cost	5.1	5.0	0.1	0.1
Interest cost	19.6	18.2	2.1	2.4
Employee contributions	0.6	0.3	—	—
Actuarial (gain) loss	60.0	(24.0)	0.5	(9.3)
Benefits and administrative expenses paid	(21.9)	(21.9)	(3.9)	(3.8)
Plan amendments	—	(9.0)	—	(16.5)
Plan settlements	(17.6)	(24.2)	—	—
Plan combinations	—	18.4	—	—
Currency translation	(9.1)	5.7	—	—
Projected benefit obligations at end of year	$ 538.4	$ 501.7	$ 52.0	$ 53.2
Change in plan assets:				
Fair value of plan assets at beginning of year	$ 456.0	$ 432.0	$ —	$ —
Actual return on plan assets	59.7	17.3	—	—
Employer contributions	4.9	44.4	3.9	3.8
Employee contributions	0.6	0.3	—	—
Benefits and administrative expenses paid	(21.9)	(21.9)	(3.9)	(3.8)
Plan settlements	(17.6)	(24.2)	—	—
Plan combinations	—	2.3	—	—
Currency translation	(8.1)	5.8	—	—
Fair value of plan assets at end of year	$ 473.6	$ 456.0	$ —	$ —
Funded status at end of year	$ (64.8)	$ (45.7)	$ (52.0)	$ (53.2)

	Pension Benefits		Postretirement Benefits	
	2014	2013	2014	2013
Amounts recognized on the consolidated balance sheet:				
Non-current assets	$ 9.8	$ 17.1	$ —	$ —
Current liabilities	(2.7)	(3.1)	(4.8)	(4.9)
Non-current liabilities	(71.9)	(59.7)	(47.2)	(48.3)
Net amount recognized on the consolidated balance sheet	$ (64.8)	$ (45.7)	$ (52.0)	$ (53.2)
Amounts recognized in accumulated other comprehensive income consist of:				
Net actuarial loss	$ (115.1)	$ (102.9)	$ (2.9)	$ (2.4)
Prior service credit (cost)	6.9	7.9	18.8	28.2
Net amount recognized in accumulated other comprehensive income	$ (108.2)	$ (95.0)	$ 15.9	$ 25.8

The estimated amounts that will be amortized from accumulated other comprehensive income into net periodic benefit cost (credit) in fiscal 2015 are as follows:

	Pension Benefits	Postretirement Benefits
Amortization of net actuarial loss	$ 9.4	$ —
Amortization of prior service cost	(0.6)	(3.9)

The accumulated benefit obligation for all pension plans at the end of fiscal 2014 and 2013 was $533.6 million and $499.9 million, respectively. Additional information related to pension plans is as follows:

	2014	2013
Pension plans with accumulated benefit obligations in excess of plan assets:		
Accumulated benefit obligation	$ 394.7	$ 377.6
Fair value of plan assets	321.6	316.2

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		
	2014	2013	2012	2014	2013	2012
Discount rate	4.2%	3.5%	4.4%	3.5%	4.0%	5.2%
Expected return on plan assets	6.5%	7.9%	7.5%	3.1%	3.5%	4.0%
Rate of compensation increase	—%	—%	2.8%	3.5%	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		
	2014	2013	2012	2014	2013	2012
Discount rate	3.9%	4.3%	3.5%	2.5%	3.7%	4.0%
Rate of compensation increase	—%	—%	—%	3.4%	3.5%	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 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.

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

	2014	2013	2012
Net periodic benefit cost	4.0%	3.2%	4.1%
Benefit obligations	3.7%	4.0%	3.2%

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

	2014	2013
Healthcare cost trend rate assumed for next fiscal year	7.1%	7.3%
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	$ —	$ —
Effect on postretirement benefit obligation	0.4	(0.3)

Plan Assets

The Company's U.S. pension plans have a target allocation of 24% equity securities and 76% 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, 55% debt securities and 6% 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	
	2014	2013	2014	2013
Equity securities	28%	42%	8%	7%
Debt securities	70	56	2	3
Cash and cash equivalents	1	1	—	—
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 2014 and 2013:

		Basis of Fair Value Measurement		
	Fiscal 2014	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	$ 16.6	$ 16.6	$ —	$ —
U.S. large cap	50.2	50.2	—	—
International	39.8	28.7	11.1	—
Debt securities:				
Diversified fixed income funds [1]	218.7	216.6	2.1	—
High yield bonds	13.0	13.0	—	—
Emerging market funds	9.5	9.5	—	—
Diversified/commingled funds	—	—	—	—
Insurance contracts	119.8	—	—	119.8
Other	6.0	2.6	3.4	—
Total	$ 473.6	$ 337.2	$ 16.6	$ 119.8

		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	—	—
Insurance contracts	112.0	—	—	112.0
Other	6.0	3.1	2.9	—
Total	$ 456.0	$ 329.5	$ 14.5	$ 112.0

(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.

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 2014 and 2013:

	Insurance Contracts
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
Net unrealized gains	15.5
Net purchases, sales and issuances	(0.6)
Currency translation	(7.1)
Balance at September 26, 2014	$ 119.8

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 2014 and 2013, the Company made $4.9 million and $44.4 million in contributions, respectively, to the Company's pension plans, including a voluntary contribution of $37.5 million made by Covidien prior to the Separation in fiscal 2013. The Company does not anticipate making material involuntary contributions in fiscal 2015, but may elect to make voluntary contributions to its defined pension plans or its postretirement benefit plans during fiscal 2015.

Expected Future Benefit Payments

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

	Pension Benefits	Postretirement Benefits
Fiscal 2015	$ 45.8	$ 4.8
Fiscal 2016	34.9	4.5
Fiscal 2017	33.9	4.2
Fiscal 2018	33.4	4.0
Fiscal 2019	32.7	3.7
Fiscal 2020 - 2024	149.8	16.1

Defined Contribution Retirement Plans

The Company maintains one active tax-qualified 401(k) retirement plan and one active non-qualified deferred compensation plan in the U.S. The 401(k) retirement plan provides for an automatic Company contribution of three percent of an eligible employee's pay, with an additional Company 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. The deferred compensation plan permits eligible employees to defer a portion of their compensation. Total defined contribution expense related to continuing operations was $22.5 million, $22.7 million and $20.9 million for fiscal 2014, 2013 and 2012, respectively.

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 balance sheets. Note 19 provides additional information regarding the debt and equity securities. The carrying value of the 135 life insurance contracts held by these trusts was $56.3 million and $54.6 million at September 26, 2014 and September 27, 2013, respectively. These contracts had a total death benefit of $145.7 million and $143.1 million at September 26, 2014 and September 27, 2013, respectively. However, there are outstanding loans against the policies amounting to $38.2 million and $35.3 million at September 26, 2014 and September 27, 2013, respectively.

The Company has insurance contracts which serve as collateral for certain of the Company's non-U.S. pension plan benefits, which totaled $12.7 million and $13.1 million at September 26, 2014 and September 27, 2013, respectively. These amounts were also included in other assets on the consolidated balance sheets.

14. Share Plans

Total share-based compensation cost was $67.7 million, $16.2 million and $11.1 million for fiscal 2014, 2013 and 2012, respectively. These amounts are generally included within selling, general and administrative expenses in the consolidated and combined statements of income. In conjunction with the the Questcor Acquisition, Questcor equity awards were converted to Mallinckrodt equity awards resulted in post-combination expense of $48.2 million in fiscal 2014, included in the above total share-based compensation, of which $13.1 million is included within selling, general and administrative expenses and $35.1 million is included within restructuring charges, net. Consistent with the prior fiscal year, the incremental fair value associated with the conversion of Covidien equity awards into Mallinckrodt equity awards is included in separation costs. The Company recognized a related tax benefit associated with this expense of $24.4 million, $5.8 million and $3.8 million in fiscal 2014, 2013 and 2012, 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

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 ("PSUs"). 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 26, 2014, all equity awards held by the Company's employees were either converted from Covidien equity awards at the Separation, converted from Questcor equity awards, 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 September 27, 2013	2,760,231	$ 37.30		
Granted	675,921	52.63		
Converted from Questcor Acquisition	1,292,736	25.08		
Exercised	(878,330)	30.96		
Expired/Forfeited	(323,769)	41.83		
Outstanding at September 26, 2014	3,526,789	36.84	6.4	$ 187.5
Vested and unvested expected to vest as of September 26, 2014	3,362,751	36.27	6.5	180.7
Exercisable at September 26, 2014	832,680	31.32	4.7	48.8

As of September 26, 2014, there was $54.0 million of total unrecognized compensation cost related to unvested share option awards, which is expected to be recognized over a weighted-average period of 1.7 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 in fiscal 2013 subsequent to the Separation are included within the discussion of modification expense above. The weighted-average assumptions used in the Black-Scholes pricing model for shares granted in fiscal 2014, along with the weighted-average grant-date fair value, were as follows:

	2014
Expected share price volatility	32%
Risk-free interest rate	1.96%
Expected annual dividend per share	—%
Expected life of options (in years)	5.5
Fair value per option	$ 17.38

In fiscal 2013, subsequent to the Separation, the total intrinsic value of share options exercised and the related tax benefit was not significant. In fiscal 2014, the total intrinsic value of options exercised and related tax benefit was $34.2 million and $12.0 million, respectively.

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	724,269	$ 40.62
Granted	229,281	55.40
Converted from Questcor Acquisition	30,747	70.88
Vested	(300,237)	34.77
Forfeited	(94,838)	42.48
Non-vested at September 26, 2014	589,222	47.88

The total fair value of Mallinckrodt restricted share unit awards granted during fiscal 2014 was $12.7 million. The total fair value of Mallinckrodt restricted share units vested during fiscal 2014 was $16.5 million. As of September 26, 2014, there was $20.4 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.

Performance share units. Similar to recipients of RSUs, recipients of PSUs have no voting rights and receive dividend equivalent units. The grant date fair value of PSUs, adjusted for estimated forfeitures, is generally recognized as expense on a straight-line basis from the grant date through the end of the performance period. The vesting of PSUs and related dividend equivalent units is generally based on various performance metrics and relative total shareholder return (total shareholder return for the Company as compared to total shareholder return of the PSU peer group), measured over a three-year performance period. The PSU peer group is comprised of various healthcare companies which replicate the Company's mix of businesses. Depending on Mallinckrodt's relative performance during the performance period, a recipient of the award is entitled to receive a number of ordinary shares equal to a percentage, ranging from 0% to 200%, of the award granted.

PSU activity is as follows [(1)]:

	Shares	Weighted-Average Grant-Date Fair Value
Non-vested at September 27, 2013	—	$ —
Granted	79,230	63.40
Performance metric adjustment	—	—
Vested	—	—
Forfeited	(6,490)	62.65
Non-vested at September 26, 2014	72,740	63.46

(1) The number of shares disclosed within this table are at the target number of 100%.

The Company generally uses the Monte Carlo model to estimate the probability of satisfying the performance criteria and the resulting fair value of PSU awards. The assumptions used in the Monte Carlo model for PSUs granted during each year were as follows:

	2014
Expected stock price volatility	28%
Peer group stock price volatility	33%
Correlation of returns	17%

The weighted-average grant-date fair value per share of PSUs granted was $63.40 in fiscal 2014. As of September 26, 2014, there was $5.2 million of unrecognized compensation cost related to PSUs, which is expected to be recognized over a weighted-average period of 2.0 years.

Restricted stock awards. Recipients of restricted stock awards ("RSAs") pertain solely to converted awards from the Questcor Acquisition, which were converted at identical terms to their original award. The converted RSAs maintain voting rights and a non-forfeitable right to receive dividends. RSAs are subject to accelerated vesting as prescribed by the terms of the original award

based on a change in control, and substantially all of which will vest over a thirteen month period of time from the date of the Questcor Acquisition. Restrictions on RSAs lapse upon normal retirement, death or disability of the employee. The grant-date fair value of RSAs, adjusted for estimated forfeitures, is recognized as expense on a straight-line basis over the service period.

	Shares	Weighted-Average Grant-Date Fair Value
Non-vested at September 27, 2013	—	$ —
Granted	—	—
Converted from Questcor Acquisition	1,829,164	70.88
Vested	(390,731)	70.88
Forfeited	(6,402)	70.88
Non-vested at September 26, 2014	1,432,031	70.88

The total fair value of Mallinckrodt RSAs converted as part of the Questcor Acquisition was $129.7 million. The total fair value of Mallinckrodt restricted share awards vested during fiscal 2014 was $30.8 million. As of September 26, 2014, there was $61.4 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 1.2 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 and fiscal 2015) of the employee's payroll deduction up to a $25,000 per 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 30, 2011	$ 160.0	$ —	$ (61.5)	$ 98.5
Other comprehensive income (loss), net	(2.9)	—	(10.7)	(13.6)
Balance at September 28, 2012	157.1	—	(72.2)	84.9
Other comprehensive income (loss), net	1.5	(7.3)	29.4	23.6
Balance at September 27, 2013	158.6	(7.3)	(42.8)	108.5
Other comprehensive loss before reclassification	(27.6)	—	(17.1)	(44.7)
Reclassification to other comprehensive income (loss)	—	0.5	1.4	1.9
Balance at September 26, 2014	$ 131.0	$ (6.8)	$ (58.5)	$ 65.7

The following summarizes reclassifications out of accumulated other comprehensive income for the 2014 fiscal year:

	Amount Reclassified from Accumulated Other Comprehensive Income	
	September 26, 2014	Line Item in the Condensed Consolidated Statement of Income
Amortization of unrealized gain on derivatives	$ 0.6	Interest expense
Income tax provision	(0.1)	Provision for income taxes
Net of income taxes	0.5	
Amortization of pension and post-retirement benefit plans:		
Net actuarial loss	8.1	(1)
Prior service credit	(9.9)	(1)
Plan settlements	3.8	(1)
Total before tax	2.0	
Income tax provision	(0.6)	Provision for income taxes
Net of income taxes	1.4	
Total reclassifications for the period	$ 1.9	

(1) These accumulated other comprehensive income components are included in the computation of net periodic benefit cost. See Note 13 for additional details.

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, including a Separation Distribution Agreement, a Tax Matters Agreement and a transition services agreement. These agreements 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 2014, 2013 and 2012, the Company sold inventory to Covidien in the amount of $46.0 million, $51.2 million and $54.2 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 $28.9 million, $38.4 million and $34.7 million during fiscal 2014, 2013 and 2012, 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 and $49.2 million for fiscal 2013 and 2012, respectively, and are included within selling, general and administrative expenses.

Balance Sheet Impacts

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 26, 2014 includes $82.2 million of amounts due to the Company from Covidien, within prepaid expenses and other current assets, and $84.5 million of amounts the Company owes Covidien, included within accrued and other liabilities.

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 the 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. The Company has made $33.0 million of payments, net of benefits, for periods prior to September 29, 2012. 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. The Company expects to substantially reduce the level of service provided by Covidien in fiscal 2015 as the Company has substantially completed the implementation of information systems in jurisdictions outside the U.S. and terminated the transition services agreement during the first quarter of fiscal 2015.

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 believes, given the information currently available, that their ultimate resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

In connection with the sale of the Specialty Chemical business (formerly known as 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 balance sheets at September 26, 2014 and September 27, 2013 was $16.6 million and $20.1 million, respectively, of which $13.9 million and $17.2 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 26, 2014 and September 27, 2013. As of September 26, 2014, the maximum future payments the Company could be required to make under these indemnification obligations was $71.4 million. The Company was required to pay $30.0 million into an escrow account as collateral to the purchaser, of which $19.4 million and $23.5 million remained in other assets on the consolidated balance sheets at September 26, 2014 and September 27, 2013, 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 the Company believes, given the information currently available, that their ultimate resolution 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 surety bonds totaling $57.2 million.

In addition, as of September 26, 2014, the Company had a $21.1 million letter of credit to guarantee decommissioning costs associated with its Saint Louis, Missouri plant. As of September 26, 2014, the Company had various other letters of credit and guarantee and surety bonds totaling $36.2 million.

In addition, the separation and distribution agreement entered into with Covidien at the Separation 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 26, 2014, such obligations were as follows:

Fiscal 2015	$ 93.8
Fiscal 2016	63.1
Fiscal 2017	60.2
Fiscal 2018	60.2
Fiscal 2019	3.9

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 believes, unless indicated below, given the information currently available, that their ultimate resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

Governmental Proceedings

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.

On September 24, 2012, Questcor received a subpoena from the United States Attorney's Office (the "USAO") for the Eastern District of Pennsylvania for information relating to its promotional practices. Questcor has also been informed by the USAO for the Eastern District of Pennsylvania that the USAO for the Southern District of New York and the SEC are also participating in the investigation to review Questcor's promotional practices and related matters.

On June 11, 2014, Questcor received a subpoena and Civil Investigative Demand ("CID") from the Federal Trade Commission ("FTC") seeking documentary materials and information regarding the FTC's investigation into whether Questcor's acquisition of certain rights to develop, market, manufacture, distribute, sell and commercialize Synacthen Depot from Novartis violates the antitrust laws.

We are in the process of responding to each of the subpoenas and the CID and we intend to cooperate fully in each such investigation.

Mallinckrodt Inc. v. U.S. Food and Drug Administration and United States of America The Company filed a Complaint for Declaratory and Injunctive Relief in the U.S. District Court for the District of Maryland Greenbelt Division against the FDA and the United States of America on November 17, 2014 for judicial review of what the Company believes is FDA's inappropriate and unlawful reclassification of the Company's methylphenidate hydrochloride extended-release tablets in the Orange Book: Approved Drug Products with Therapeutic Equivalence (Orange Book) on November 13, 2014. In its complaint, the Company has asked the court to: issue an injunction to (a) set aside the FDA's reclassification of the Company's methylphenidate ER products from AB (freely substitutable at the pharmacy level) to BX (presumed to be therapeutically inequivalent) in the Orange Book and (b) prohibit the FDA from reclassifying Mallinckrodt's methylphenidate ER products in the future without following applicable legal requirements; and issue a declaratory judgment that the FDA's action reclassifying Mallinckrodt's methylphenidate ER products in the Orange Book is unlawful. Mallinckrodt concurrently filed a motion with the same court requesting an expedited hearing to issue a temporary restraining order (TRO) directing FDA to reinstate the Orange Book AB rating for the company's methylphenidate ER drug on a temporary basis.

Patent/Antitrust Litigation

Tyco Healthcare Group LP, et al. v. Mutual Pharmaceutical Company, Inc. In March, 2007, 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"), after Mutual submitted an Abbreviated New Drug Application ("ANDA") 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 and on August 6, 2014, the Federal Circuit issued a split decision, affirming the trial court in part and remanding to the trial court certain counterclaims for further proceedings.

'222 and '218 Patent Litigation: Exela Pharma Sciences, LLC. In August 2011, Cadence, a subsidiary of the Company, and Pharmatop, the owner of the two U.S. patents licensed exclusively by Cadence, filed suit in the U.S. District Court for the District of Delaware against Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc. (collectively, "Exela"), alleging that Exela infringed U.S. Patent Nos. 6,028,222 ("the '222 patent") and 6,992,218 ("the '218 patent"), by submitting an ANDA to the FDA seeking to sell a generic version of Ofirmev. The filing of the lawsuit triggered a stay of FDA approval of the Exela ANDA until the earlier of the expiration of a 30-month period, the expiration of the '222 and '218 patents, the entry of a settlement order or consent decree stating that the '222 and '218 patents are invalid or not infringed, a decision in the case concerning infringement or validity that is favorable to Exela, or such shorter or longer period as the court may order. After a bench trial, the court ruled in favor of Cadence in November 2013 and found that Exela's ANDA infringed the '222 and '218 patents. On December 20, 2013, Excela appealed the decision and oral arguments in the appeal occurred on November 7, 2014. It is not possible at this time to predict the outcome of this appeal.

'222 and '218 Patent Litigation: InnoPharma Licensing LLC and InnoPharma, Inc. In September 2014, Cadence and Mallinckrodt IP, subsidiaries of the Company, filed suit in the U.S. District Court for the District of Delaware against InnoPharma Licensing LLC and InnoPharma, Inc. (collectively "InnoPharma") following receipt of an August 2014 notice from InnoPharma concerning its submission of a New Drug Application ("NDA"), containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev.

'222 and '218 Patent Litigation: Agila Specialties Private Limited, Inc. and Agila Specialties Inc. (a Mylan Inc. Company), (collectively "Agila"). In November 2014, Cadence and Mallinckrodt IP, subsidiaries of the Company, received notice from Agila concerning its submission of a New Drug Application ("NDA") containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev. The Company is currently evaluating the notice and will be analyzing the Agila submission to make a timely determination regarding potentially filing suit against Agila.

The Company intends to vigorously enforce its intellectual property rights relating to Ofirmev to prevent the marketing of infringing generic or competing products prior to the expiration of the Cadence patents. An adverse outcome in either the Exela or InnoPharma matters ultimately could result in the launch of one or more generic versions of Ofirmev before the expiration of the last of the listed patents on June 6, 2021 (or December 6, 2021 if pediatric exclusivity is granted), which could adversely affect the Company's ability to successfully maximize the value of Ofirmev and have an adverse effect on our financial condition, results of operations and cash flows.

'222 and '218 Patents: Ex Parte Reexamination. In September 2012, Exela filed with the U.S. Patent and Trademark Office ("USPTO"), a Request for Ex Parte Reexamination of the '222 patent and the USPTO granted that request. The reexamination process requires the USPTO to consider the scope and validity of the patent based on substantial new questions of patentability raised by a third party or the USPTO. Cadence and Pharmatop have filed, with the USPTO, a patent owner's statement commenting on the reexamination request, and thereafter the parties have made various submissions. In July 2014, a Second Final Office Action was issued by the USPTO in which certain claims were indicated to be allowable and certain claims were rejected. A subsequent amendment was filed in September 2014, but the USPTO did not enter that amendment. In October 2014, Cadence and Pharmatop filed a notice of appeal and petitioned the Commissioner of Patents, requesting that certain claim amendments be entered so that set of claims are of record for consideration in any future appeal.

In addition, in January 2014, an unidentified third party filed, with the USPTO, a Request for Ex Parte Reexamination of the '218 patent. The reexamination request was granted on March 14, 2014. In July 2014, the USPTO issued a Non-Final Office Action in the '218 reexamination in which it rejected certain claims. In September 2014, Cadence and Pharmatop filed an Amendment and Response to the Office Action.

All of the claims of the '222 and '218 patents remain valid and in force during the reexamination proceedings. Because we and Pharmatop believe that the scope and validity of the patent claims in these patents are appropriate and that the USPTO's prior issuances of the patents were correct, the Company, in conjunction with Pharmatop, will vigorously defend these patents. It is not possible, at this time, to determine with certainty whether we will ultimately succeed in maintaining the scope and validity of the claims of these patents during reexamination. If any of the patent claims in these patents ultimately are narrowed during prosecution before the USPTO, the extent of the patent coverage afforded to Ofirmev could be impaired, which could have a material adverse effect on the Company's financial condition, results of operations and cash flows.

'218 Patent Litigation: Exela Pharma Sciences, LLC. In April 2012, Exela filed suit against David J. Kappos and the USPTO in the U.S. District Court for the Eastern District of Virginia for declaratory judgment seeking a reversal of the USPTO's decision not to act on a petition by Exela to vacate the USPTO's April 2003 order reviving the international application for the '218 patent. The lawsuit followed the USPTO's rejection of Exela's petition to the USPTO filed in November 2011, which sought to vacate the April 2003 order. The USPTO determined that Exela lacked standing to seek such relief. Exela also seeks declaratory judgment that the USPTO's rules and regulations that allow for revival of abandoned, international patent applications under the "unintentional" standard are invalid, and seeks similar relief in connection with one or more counterclaims it has filed in the Delaware litigation. Cadence intervened in this lawsuit and in December 2012, the district court dismissed the case with prejudice as barred by the applicable statute

of limitations. In February 2013, Exela appealed the dismissal to the Court of Appeals for the Federal Circuit, oral argument was held in February 2014 and a final decision has not been issued.

'222 and '218 Patent Litigation Settlement: Fresenius Kabi USA, LLC. In January 2013, Cadence filed suit in the U.S. District Court for the Southern District of California against Fresenius Kabi USA, LLC ("Fresenius"), alleging that Fresenius infringed the '222 and '218 patents by submitting a NDA to the FDA seeking to sell a competing version of Ofirmev. The filing of the lawsuit triggered a stay of FDA approval of the Fresenius NDA until the earlier of the expiration of a 30-month period, the expiration of the '222 and '218 patents, the entry of a settlement order or consent decree stating that the '222 and '218 patents are invalid or not infringed, a decision in the case concerning infringement or validity that is favorable to Fresenius, or such shorter or longer period as the court may order. In August 2014, Cadence entered into a settlement agreement and license agreement with Fresenius, dismissing with prejudice the lawsuit and granting to Fresenius the non-exclusive right to market an intravenous acetaminophen product in the U.S. under the Fresenius NDA beginning December 6, 2020, or earlier under certain circumstances. Under a related supply agreement, an affiliate of Fresenius will develop, manufacture and supply commercial quantities of Ofirmev to us if certain regulatory approvals are obtained. As a result of these agreements we recorded an $11.5 million charge during the third quarter of fiscal 2014.

Other '222 and '218 Patent Litigation Settlements. Three other similar cases involving generic versions of Ofirmev have previously settled. In each settlement, the defendant was granted the non-exclusive right to market a generic intravenous acetaminophen product in the U.S. under its respective ANDA after December 6, 2020, or earlier under certain circumstances. In connection with those settlements, one settling party was granted the exclusive right of first refusal to negotiate an agreement with Cadence to market an authorized generic of Ofirmev in the U.S. in the event that Cadence elects to launch an authorized generic version of the product. If that settling party elects not to exercise its right of first refusal, Cadence has agreed to grant a similar right of first refusal to another settling party.

Commercial and Securities Litigation

Retrophin Litigation. In January 2014, Retrophin Inc. filed a lawsuit against Questcor in the United States District Court for the Central District of California, alleging a variety of federal and state antitrust violations based on Questcor's acquisition from Novartis of certain rights to develop, market, manufacture, distribute, sell and commercialize Synacthen. Discovery has commenced, and the Court set July 10, 2015, as the deadline for filing dispositive motions. While it is not possible at this time to determine with certainty the outcome of this investigation, the Company believes, given the information currently available, that its ultimate resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

Glenridge Litigation. In June 2011, Glenridge Pharmaceuticals LLC ("Glenridge"), filed a lawsuit against Questcor in the Superior Court of California, Santa Clara County, alleging that Questcor had underpaid royalties to Glenridge under a royalty agreement related to net sales of Acthar. In August 2012, Questcor filed a separate lawsuit against the three principals of Glenridge, as well as Glenridge, challenging the enforceability of the royalty agreement. In August 2013, the two lawsuits were consolidated into one case in the Superior Court of California, Santa Clara County. On October 29, 2014, the parties entered into a binding term sheet settling the lawsuit. Under the terms of the settlement, the royalty rate payable by Questcor was reduced, royalties were capped instead of being payable for so long as Acthar was sold and Questcor agreed to pay Glenridge a reduced amount in satisfaction of royalties Questcor had withheld in the course of the lawsuit.

Putative Class Action Securities Litigation. On September 26, 2012, a putative class action lawsuit was filed against Questcor and certain of its officers and directors in the United States District Court for the Central District of California, captioned *John K. Norton v. Questcor Pharmaceuticals, et al.*, No. SACvl2-1623 DMG (FMOx). The complaint purports to be brought on behalf of shareholders who purchased Questcor common stock between April 26, 2011 and September 21,2012. The complaint generally alleges that Questcor and certain of its officers and directors engaged in various acts to artificially inflate the price of Questcor stock and enable insiders to profit through stock sales. The complaint asserts that Questcor and certain of its officers and directors violated sections l0 (b) and/or 20(a) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), by making allegedly false and/or misleading statements concerning the clinical evidence to support the use of Acthar for indications other than infantile spasms, the promotion of the sale and use of Acthar in the treatment of MS and nephrotic syndrome, reimbursement for Acthar from third-party insurers, and Questcor's outlook and potential market growth for Acthar. The complaint seeks damages in an unspecified amount and equitable relief against the defendants. This lawsuit has been consolidated with four subsequently-filed actions asserting similar claims under the caption: *In re Questcor Securities Litigation*, No. CV 12-01623 DMG (FMOx). On October 1, 2013, the District Court granted in part and denied in part Questcor's motion to dismiss the consolidated amended complaint. On October 29, 2013, Questcor filed an answer to the consolidated amended complaint. Discovery is currently ongoing. The Court set a jury trial for December 1, 2015.

Federal Shareholder Derivative Litigation. On October 4, 2012, another alleged shareholder filed a derivative lawsuit in the United States District Court for the Central District of California captioned *Gerald Easton v. Don M Bailey, et al.*, No. SACV12-01716 DOC (JPRx). The suit asserts claims substantially identical to those asserted in the *do Valle* derivative action described below against the same defendants. This lawsuit has been consolidated with five subsequently-filed actions asserting similar claims under the caption: *In re Questcor Shareholder Derivative Litigation*, CV 12- 01716 DMG (FMOx). Following the resolution of

the motion to dismiss in the consolidated putative securities class action, the court issued an order staying the federal derivative action until the earlier of: (a) 60 days after the resolution of any motion for summary judgment filed in the putative class action lawsuit, (b) 60 days after the deadline to file a motion for summary judgment in the putative class action lawsuit, if none is filed, or (c) the execution of any settlement agreement (including any partial settlement agreement) to resolve the putative class action lawsuit.

State Shareholder Derivative Litigation. On October 2, 2012, an alleged shareholder filed a derivative lawsuit purportedly on behalf of Questcor against certain of its officers and directors in the Superior Court of the State of California, Orange County, captioned *Monika do Valle v. Virgil D. Thompson, et al.*, No. 30-2012-00602258-CU-SL-CXC. The complaint asserted claims for breach of fiduciary duty, abuse of control, mismanagement and waste of corporate assets arising from substantially similar allegations as those contained in the putative securities class action described above, as well as from allegations relating to sales of our common stock by the defendants and repurchases of Questcor common stock. The complaint sought an unspecified sum of damages and equitable relief. On October 24, 2012, another alleged shareholder filed a derivative lawsuit purportedly on behalf of Questcor against certain of its officers and directors in the Superior Court of the State of California, Orange County, captioned *Jones v. Bailey, et al.*, Case No. 30-2012-00608001-CU-MC-CXC. The suit asserted claims substantially identical to those asserted in the *do Valle* derivative action. On February 19, 2013, the court issued an order staying the state derivative actions until the putative federal securities class action and federal derivative actions are resolved. On May 17, 2014, the Court granted plaintiffs' request for dismissal without prejudice of the *Jones* action. On November 18, 2014, the *do Valle* matter was voluntarily dismissed.

Put Options Securities Action. In March 2013, individual traders of put options filed a securities complaint in the United States District Court for the Central District of California captioned *David Taban, et al. v. Questcor Pharmaceuticals, Inc.,* No. SACV13-0425. The complaint generally asserts claims against Questcor and certain of its officers and directors for violations of the Exchange Act and for state law fraud and fraudulent concealment based on allegations similar to those asserted in the putative securities class action described above. The complaint seeks compensatory and punitive damages of an unspecified amount. Following the resolution of the motion to dismiss in the consolidated putative securities class action, the court issued an order staying this action until the earlier of: (a) sixty (60) days after the resolution of any motion for summary judgment filed in the putative class action lawsuit, (b) sixty (60) days after the deadline to file a motion for summary judgment in the putative class action lawsuit, if none is filed, or (c) the execution of any settlement agreement (including any partial settlement agreement) to resolve the putative class action lawsuit. The case remains stayed.

Pricing Litigation

State of Utah v. Actavis US, Inc., et al. The Company, along with numerous other pharmaceuticals companies, are defendants in this matter which was filed May 8, 2008, and is pending in the Third Judicial Circuit of Salt Lake County, Utah. The State of Utah alleges, generally, that the defendants 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 is seeking monetary damages and attorneys' fees. The Company believes that it has meritorious defenses to these claims and is vigorously defending against them. While it is not possible at this time to determine with certainty the outcome of the case, the Company believes, given the information currently available, that its 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 26, 2014, it was probable that it would incur remedial costs in the range of $43.7 million to $106.9 million. The Company also concluded that, as of September 26, 2014, the best estimate within this range was $67.1 million, of which $7.2 million was included in accrued and other current liabilities and the remainder was included in environmental liabilities on the consolidated balance sheet at September 26, 2014.

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 U.S. Environmental Protection Agency ("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 ("AOC") 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 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, given the information currently available, 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 another former owner, assumed responsibility for the Millsboro Site cleanup under the Alternative Superfund Program administered by the EPA. The Company and another PRP have entered into two AOCs with the EPA to perform investigations to abate, mitigate or eliminate the release or threat of release of hazardous substances at the Millsboro Site and to conduct an Engineering Evaluation/Cost Analysis to characterize the nature and extent of the contamination. The Company, along with the other party, continues to conduct the studies and prepare remediation plans in accordance with the AOCs. While it is not possible at this time to determine with certainty the ultimate outcome of this matter, the Company believes, given the information currently available, that the ultimate 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 named as a defendant in numerous tort complaints filed between February 2012 and September 2014 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 allegedly 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, given the information currently available, that the ultimate resolution of all known claims will not have a material adverse effect on its financial condition, results of operations and cash flows.

Lower Passaic River, New Jersey. The Company and approximately 70 other companies comprise the Lower Passaic Cooperating Parties Group ("the CPG") and are parties to a May 2007 AOC with the EPA to perform a RI/FS of the 17-mile stretch known as the Lower Passaic River Study Area ("the River"). The Company's potential liability stems from former operations at Lodi and Belleville, New Jersey. In June 2007, the EPA issued a draft Focused Feasibility Study ("FFS") that considered interim remedial options for the lower 8-miles of the river, in addition to a "no action" option. As an interim step related to the 2007 AOC, the CPG voluntarily entered into an AOC on June 18, 2012 with the EPA for remediation actions focused solely at mile 10.9 of the River. The Company's estimated costs related to the RI/FS and focused remediation at mile 10.9, based on interim allocations, are immaterial and have been accrued.

On April 11, 2014, the EPA issued its revised FFS, with remedial alternatives to address cleanup of the lower 8-mile stretch of the River, which also included a "no action" option. The EPA estimates the cost for the alternatives range from $365.0 million to $3.2 billion. The EPA's preferred approach would involve bank-to-bank dredging of the lower 8-mile stretch of the River and installing an engineered cap at a discounted, estimated cost of $1.7 billion. Based on the issuance of the EPA's revised FFS, the Company recorded a $23.1 million accrual in fiscal 2014 representing the Company's estimate of its allocable share of the joint and several remediation liability resulting from this matter. Despite the issuance of the revised FFS, there are many uncertainties associated with the final agreed upon remediation and the Company's allocable share of the remediation. Given those uncertainties, the amounts accrued may not be indicative of the amounts for which the Company is ultimately responsible and will be refined as events in the remediation process occur.

Products Liability Litigation

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 26, 2014, there were approximately 11,900 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 balance sheets. 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, given the information currently available, that the ultimate resolution 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 Petten, the Netherlands and Maryland Heights, Missouri. Substantially all of these obligations are included in other liabilities on the consolidated balance sheets. The following table provides a summary of the changes in the Company's asset retirement obligations for fiscal 2014 and 2013:

	2014	2013
Balance at beginning of period	$ 50.6	$ 46.4
Additions and adjustments	(11.6)	0.4
Accretion expense	3.2	2.9
Payments	—	(0.2)
Currency translation	(1.4)	1.1
Balance at end of period	$ 40.8	$ 50.6

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 $19.9 million, $16.9 million and $15.5 million for fiscal 2014, 2013 and 2012, 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 26, 2014:

	Operating Leases	Capital Leases
Fiscal 2015	$ 21.5	$ 1.4
Fiscal 2016	16.6	0.4
Fiscal 2017	13.9	—
Fiscal 2018	9.8	—
Fiscal 2019	8.2	—
Thereafter	25.0	—
Total minimum lease payments	$ 95.0	1.8
Less: interest portion of payments		—
Present value of minimum lease payments		$ 1.8

The Company exchanged title to $27.4 million of its plant assets in return for an equal amount of Industrial Revenue Bonds ("IRB") issued by Saint Louis County. The Company also simultaneously leased such assets back from Saint Louis County under a capital lease expiring December 2025, 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 ten-year property tax abatement 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 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, given the information currently available, that established liabilities are reasonable and that the ultimate 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 2007. The Company considers such uncertain tax positions associated with these years as having been effectively settled. All but one of the matters associated with these audits 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 liability 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, given the information currently available, that it will not have a material adverse effect on its financial condition, results of operations and cash flows.

Acquisition-Related Litigation

Several purported class action lawsuits have been filed in February 2014 and March 2014 by purported holders of Cadence common stock in connection with the Cadence Acquisition, including in the Delaware Court of Chancery (consolidated under the caption *In re Cadence Pharmaceuticals, Inc. Stockholders Litigation*), and in California State Court, San Diego County (*Denny v. Cadence Pharmaceuticals, Inc., et al., Militello v. Cadence Pharmaceuticals, Inc., et al.,* and *Schuon v. Cadence Pharmaceuticals, Inc., et al.*). The actions bring claims against, and generally allege that, the board of directors of Cadence breached their fiduciary duties in connection with the the Cadence Acquisition by, among other things, failing to maximize shareholder value, and the Delaware and *Schuon* actions further allege that Cadence omitted to disclose allegedly material information in its Schedule 14D-9. The lawsuits also allege, among other things, that the Company aided and abetted the purported breaches of fiduciary duty. The lawsuits seek various forms of relief, including but not limited to, rescission of the transaction, damages and attorneys' fees and costs. On March 7, 2014, following expedited discovery, the parties in the consolidated Delaware action entered into a Memorandum of Understanding ("the MOU"), which sets forth the parties' agreement in principle for a settlement of those actions. The settlement contemplated by the MOU will include, among other things, a release of all claims relating to the Cadence Acquisition as set forth in the MOU. The settlement is subject to a number of conditions, including, among other things, final court approval following notice to the class. There have been no substantive proceedings in any of the California actions. On July 29, 2014, the *Militello* case was voluntarily dismissed without prejudice. On September 8, 2014, the Denny case was voluntarily dismissed without prejudice. While it is not possible at this time to determine with certainty the ultimate outcomes of these matters, the Company believes, given the information available to it today, that they will not have a material adverse effect on its financial condition, results of operations and cash flows.

Since the announcement of the merger with Questcor on April 7, 2014, several putative class actions have been filed by purported holders of Questcor common stock in connection with the Company's acquisition of Questcor (*Hansen v. Thompson, et al., Heng v. Questcor Pharmaceuticals, Inc., et al., Buck v. Questcor Pharmaceuticals, Inc., et al., Ellerbeck v. Questcor Pharmaceuticals, Inc, et al., Yokem v. Questcor Pharmaceuticals, Inc., et al., Richter v. Questcor Pharmaceuticals, Inc., et al., Tramantano v. Questcor Pharmaceuticals, Inc., et al., Crippen v. Questcor Pharmaceuticals, Inc., et al., Patel v. Questcor Pharmaceuticals, Inc., et al., and Postow v. Questcor Pharmaceuticals, Inc., et al.*). The actions were consolidated on June 3, 2014. The consolidated complaint names as defendants, and generally alleges that, the directors of Questcor breached their fiduciary duties in connection with the acquisition by, among other things, agreeing to sell Questcor for inadequate consideration and pursuant to an inadequate process. The consolidated complaint also alleges that the Questcor directors breached their fiduciary duties by failing to disclose purportedly material information to shareholders in connection with the merger. The consolidated complaint also alleges, among other things, that we aided and abetted the purported breaches of fiduciary duty. The lawsuit seeks various forms of relief, including but not limited to, rescission of the transaction, damages and attorney's fees and costs.

On July 29, 2014, the defendants reached an agreement in principle with the plaintiffs in the consolidated actions, and that agreement is reflected in a memorandum of understanding. In connection with the settlement contemplated by the memorandum of understanding, Questcor agreed to make certain additional disclosures related to the proposed transaction with the Company, which are contained in the Company's Current Report on Form 8-K filed with the SEC on July 30, 2014. Additionally, as part of the settlement and pursuant to the memorandum of understanding, the Company agreed to forbear from exercising certain rights under the Merger Agreement with Questcor, as follows: the four business day period referenced in Section 5.3(e) of the Merger Agreement will be reduced to three business days. The memorandum of understanding contemplates that the parties will enter into a stipulation of settlement.

The stipulation of settlement will be subject to customary conditions, including court approval. In the event that the parties enter into a stipulation of settlement, a hearing will be scheduled at which the California Superior Court will consider the fairness, reasonableness, and adequacy of the settlement. If the settlement is finally approved by the court, it will resolve and release all claims in all actions that were or could have been brought challenging any aspect of the proposed transaction, the Merger Agreement, and any disclosures made in connection therewith, including the definitive joint proxy statement/prospectus relating to the Questcor Acquisition, pursuant to terms that will be disclosed to shareholders prior to final approval of the settlement. In addition, in connection with the settlement, the parties contemplate that they shall negotiate in good faith regarding the amount of attorney's fees and expense that shall be paid to plaintiffs' counsel in connection with the actions. There can be no assurance that the parties will ultimately enter into a stipulation of settlement or that the California Superior Court will approve the settlement even if the parties were to enter into such stipulation. In such event, the proposed settlement as contemplated by the memorandum of understanding may be terminated.

While it is not possible at this time to determine with certainty the ultimate outcomes of these matters, the Company believes, given the information available to it today, that they 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. 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 26, 2014	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	$ 35.7	$ 22.9	$ 12.8	$ —
	$ 35.7	$ 22.9	$ 12.8	$ —
Liabilities:				
Deferred compensation liabilities	$ 15.0	$ —	$ 15.0	$ —
Contingent consideration and acquired contingent liabilities	202.8	—	—	202.8
Foreign exchange forward and option contracts	0.2	0.2	—	—
	$ 218.0	$ 0.2	$ 15.0	$ 202.8

	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

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.

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. The Company 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 recordkeeping accounts generally correspond to the funds offered in the Company's U.S. tax-qualified defined contribution retirement plan and the account balance fluctuates with the investment returns on those funds.

Goodwill. The Company performs an annual goodwill impairment assessment using an income approach based on the present value of future cash flows. See further discussion in Notes 2 and 11.

Contingent consideration and acquired contingent liabilities. 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%. At September 26, 2014, the fair value of this contingent consideration was $7.0 million.

In August 2014, the Company recorded acquired contingent liabilities of $195.4 million from the Questcor Acquisition. The contingent liabilities relate to Questcor's contingent obligations associated with their acquisition of an exclusive, perpetualy and irrevocable license to develop, market, manufacture, distribute, sell and commercialize Synacthen and Synacthen Depot (collectively "Synacthen") from Novartis AG and Novartis Pharma AG (collectively "Novartis") and their acquisition of BioVectra. The fair value of these contingent consideration obligations at September 26, 2014 were $195.8 million.

Under the terms of the license agreement with Novartis, the Company is obligated to make a $25 million payment in each of fiscal 2015 and 2016, make annual payments of $25 million subsequent to fiscal 2016 until such time that the Company obtains FDA approval of Synacthen and make a $25 million payment upon obtaining FDA approval of Synacthen. If FDA approval is obtained, the Company will pay an annual royalty to Novartis based on a percentage of net sales of the products in the U.S. market. As of both, the Questcor Acquisition date and September 26, 2014, the total remaining payments under the license agreement shall not exceed $215.0 million. The terms of the license agreement do allow the Company to terminate the license agreement at our discretion following the fiscal 2018 payment or upon the occurrence of certain events following the fiscal 2016 payment. The Company measured the fair value of the contingent payments based on a probability-weighted present value of the consideration expected to be transferred using a discount rate of 4.7%. Under the terms of the license agreement, the Company was required to maintain deposits equal to the the fiscal 2015 and 2016 annual $25 million payments which are included in prepaid expenses and other current assets and other assets in the consolidated balance sheets.

Based on the terms of the acquisition agreement with the former shareholders of BioVectra, the Company may be obligated to pay, as of both the Questcor Acquisition date and September 26, 2014, additional cash consideration of $45.0 million CAD based on BioVectra's financial results from January 2013 through a portion of fiscal 2016. The Company measured the fair value of the contingent payments based on a probability-weighted present value of the consideration expected to be transferred suing a discount rate of 1.3%.

Balance at September 27, 2013	$	6.9
Acquisition date fair value of acquired contingent liabilities		195.4
Accretion expense		1.1
Effect of currency rate change		(0.6)
Balance at September 26, 2014	$	202.8

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 $69.8 million and $24.0 million as of September 26, 2014 and September 27, 2013, respectively (level 1), substantially all of which is included in other assets on the consolidated 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 $69.0 million and $67.7 million at September 26, 2014 and September 27, 2013, respectively. These contracts are included in other assets on the consolidated and combined balances sheets.

The carrying values of the Company's loan payable and variable rate receivable securitization approximate the fair values due to the short-term nature of these instruments. The carrying values of the 2.85% and 4.00% term loans approximate the fair values of these instruments, as calculated using the discounted exit price for each instrument, and are therefore classified as level 3. Since the quoted market prices for the Company's term loans and 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%, 4.75%, and 5.75% 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 26, 2014		September 27, 2013	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Loan payable	$ —	$ —	$ 0.1	$ 0.1
Variable rate receivable securitization	150.0	150.0	—	—
2.85% term loan due April 2016	3.1	3.1	—	—
3.50% notes due April 2018	300.0	290.2	299.9	293.7
Term loans due March 2021	1,990.3	1,970.4	—	—
4.00% term loan due February 2022	10.8	10.8	—	—
9.50% debentures due May 2022	10.4	14.2	10.4	14.3
5.75% notes due August 2022	900.0	907.3	—	—
8.00% debentures due March 2023	8.0	10.2	8.0	10.2
4.75% notes due April 2023	598.3	563.8	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.

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

	Fiscal Year		
	2014	2013	2012
Cardinal Health, Inc.	18%	18%	19%
McKesson Corporation	17%	15%	14%
Amerisource Bergen Corporation	11%	9%	9%

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 26, 2014	September 27, 2013
Cardinal Health, Inc.	17%	18%
McKesson Corporation	24%	22%
Amerisource Bergen Corporation	13%	14%
CuraScript, Inc.	13%	—

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

	Fiscal Year		
	2014	2013	2012
Optiray (CMDS)	11%	14%	17%
Acetaminophen products (API)	8%	10%	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 adverse effect on the Company's financial condition, results of operations and cash flows.

20. 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 pharmaceuticals and biopharmaceuticals, specialty generic pharmaceuticals and active pharmaceutical ingredients consisting of biologics, 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).

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, non-restructuring impairments 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 following reconciliations. Selected information by business segment is as follows:

	Fiscal Year		
	2014	2013	2012
Net sales:			
Specialty Pharmaceuticals	$ 1,612.9	$ 1,217.6	$ 1,005.2
Global Medical Imaging	881.5	935.7	996.8
Net sales of operating segments [1]	2,494.4	2,153.3	2,002.0
Other [2]	46.0	51.2	54.2
Net sales	$ 2,540.4	$ 2,204.5	$ 2,056.2
Operating income:			
Specialty Pharmaceuticals	$ 566.8	$ 311.7	$ 162.8
Global Medical Imaging	47.1	112.3	214.3
Segment operating income	613.9	424.0	377.1
Unallocated amounts:			
Corporate and allocated expenses [3]	(241.4)	(133.8)	(69.9)
Intangible asset amortization	(162.3)	(35.4)	(27.3)
Restructuring and related charges, net [4]	(129.1)	(35.8)	(19.2)
Non-restructuring impairments	(355.6)	—	—
Separation costs	(9.6)	(74.2)	(25.5)
Operating (loss) income	$ (284.1)	$ 144.8	$ 235.2
Total assets:			
Specialty Pharmaceuticals	$ 10,913.7	$ 1,666.6	
Global Medical Imaging	663.3	1,158.6	
Corporate [5]	1,287.8	731.4	
Total assets	$ 12,864.8	$ 3,556.6	
Depreciation and amortization [6]:			
Specialty Pharmaceuticals	$ 230.7	$ 97.6	$ 88.7
Global Medical Imaging	45.2	42.0	42.2
Depreciation and amortization	$ 275.9	$ 139.6	$ 130.9

(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 $0.5 million, $2.6 million and $8.0 million for fiscal 2014, 2013 and 2012, 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 product family within the Company's segments are as follows:

	Fiscal Year		
	2014	2013	2012
Methylphenidate ER	$ 209.6	$ 148.3	$ —
Oxycodone (API) and oxycodone-containing tablets	155.2	139.0	144.1
Hydrocodone (API) and hydrocodone-containing tablets	99.4	140.0	130.5
Other controlled substances	584.5	443.3	439.5
Other	150.7	140.6	134.7
Specialty Generics and API	1,199.4	1,011.2	848.8
Exalgo	76.1	126.1	91.9
Offirmev	124.4	—	—
Acthar	122.9	—	—
Other	90.1	80.3	64.5
Brands	413.5	206.4	156.4
Specialty Pharmaceuticals	1,612.9	1,217.6	1,005.2
Optiray	284.0	318.5	352.2
Other	165.8	179.6	189.8
Contrast Media and Delivery Systems	449.8	498.1	542.0
Nuclear Imaging	431.7	437.6	454.8
Global Medical Imaging	881.5	935.7	996.8
Other [1]	46.0	51.2	54.2
Net sales	$ 2,540.4	$ 2,204.5	$ 2,056.2

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

Selected information by geographic area is as follows:

	Fiscal Year		
	2014	2013	2012
Net sales [1]:			
U.S.	$ 1,899.8	$ 1,518.7	$ 1,350.2
Europe, Middle East and Africa	394.0	404.3	411.0
Other	246.6	281.5	295.0
	$ 2,540.4	$ 2,204.5	$ 2,056.2
Long-lived assets [2]:			
U.S.	$ 854.2	$ 893.3	$ 847.7
Europe, Middle East and Africa [3]	61.9	81.0	72.2
Other	57.4	51.8	52.1
	$ 973.5	$ 1,026.1	$ 972.0

(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 $26.9 million, $48.7 million and $45.5 million at the end of fiscal 2014, 2013 and 2012, respectively.

21. Selected Quarterly Financial Data (Unaudited)

	Fiscal 2014 (by quarter)			
	Q1	Q2	Q3	Q4
Net sales	$ 540.2	$ 557.8	$ 653.1	$ 789.3
Gross profit	255.6	262.6	284.3	400.6
Income (loss) from continuing operations	46.4	11.7	(24.3)	(352.4)
(Loss) income from discontinued operations	(0.8)	(0.1)	0.2	—
Net income (loss)	45.6	11.6	(24.1)	(352.4)
Basic earnings (loss) per share from continuing operations [(2)]	$ 0.80	$ 0.20	$ (0.42)	$ (4.14)
Diluted earnings (loss) per share from continuing operations [(2)]	0.79	0.20	(0.42)	(4.14)

	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

(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 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.

22. Condensed Consolidating and Combining Financial Statements

In November 2012, 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.

MIFSA is the borrower under the Notes, which are fully and unconditionally guaranteed by Mallinckrodt plc. The following information provides the composition of the Company's comprehensive income, assets, liabilities, equity and cash flows by relevant group within the Company: Mallinckrodt plc as guarantor of the Notes, MIFSA as issuer of the Notes and the operating companies that represent assets of MIFSA. There are no subsidiary guarantees related to the Notes.

Set forth below are the condensed consolidating financial statements for the as of and for the fiscal years ended September 26, 2014 and September 27, 2013. Eliminations represent adjustments to eliminate investments in subsidiaries and intercompany balances and transactions between or among Mallinckrodt plc, MIFSA and the other subsidiaries. Condensed consolidating and combining financial information for Mallinckrodt plc and MIFSA, on a standalone basis, has been presented using the equity method of accounting for subsidiaries.

Consolidating financial information for Mallinckrodt plc and MIFSA have only been presented for fiscal years 2014 and 2013 as they were formed during fiscal 2013.

MALLINCKRODT PLC
CONDENSED CONSOLIDATING BALANCE SHEET
As of September 26, 2014
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Assets					
Current Assets:					
Cash and cash equivalents	$ 0.3	$ 18.5	$ 689.0	$ —	$ 707.8
Accounts receivable, net	—	—	545.6	—	545.6
Inventories	—	—	396.6	—	396.6
Deferred income taxes	—	—	165.2	—	165.2
Prepaid expenses and other current assets	0.5	10.8	244.5	—	255.8
Intercompany receivable	13.5	—	25.7	(39.2)	—
Total current assets	14.3	29.3	2,066.6	(39.2)	2,071.0
Property, plant and equipment, net	—	—	949.2	—	949.2
Goodwill	—	—	2,401.9	—	2,401.9
Intangible assets, net	—	—	7,112.2	—	7,112.2
Investment in subsidiaries	586.8	10,645.7	4,945.1	(16,177.6)	—
Intercompany loan receivable	4,385.0	—	1,941.6	(6,326.6)	—
Other assets	—	76.5	254.0	—	330.5
Total Assets	$ 4,986.1	$ 10,751.5	$ 19,670.6	$ (22,543.4)	$ 12,864.8
Liabilities and Shareholders' Equity					—
Current Liabilities:					
Current maturities of long-term debt	$ —	$ 18.2	$ 3.0	$ —	$ 21.2
Accounts payable	1.2	0.2	127.3	—	128.7
Accrued payroll and payroll-related costs	0.1	—	125.0	—	125.1
Accrued royalties	—	—	68.0	—	68.0
Accrued branded rebates	—	—	15.1	—	15.1
Accrued and other current liabilities	1.1	50.9	494.7	—	546.7
Intercompany payable	25.7	—	13.5	(39.2)	—
Total current liabilities	28.1	69.3	846.6	(39.2)	904.8
Long-term debt	—	3,770.4	181.1	—	3,951.5
Pension and postretirement benefits	—	—	119.1	—	119.1
Environmental liabilities	—	—	59.9	—	59.9
Deferred income taxes	—	—	2,398.6	—	2,398.6
Other income tax liabilities	—	—	122.6	—	122.6
Intercompany loans payable	—	1,966.6	4,360.0	(6,326.6)	—
Other liabilities	—	—	350.3	—	350.3
Total liabilities	28.1	5,806.3	8,438.2	(6,365.8)	7,906.8
Shareholders' equity	4,958.0	4,945.2	11,232.4	(16,177.6)	4,958.0
Total Liabilities and Shareholders' Equity	$ 4,986.1	$ 10,751.5	$ 19,670.6	$ (22,543.4)	$ 12,864.8

MALLINCKRODT PLC
CONDENSED CONSOLIDATING BALANCE SHEET
As of September 27, 2013
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Assets					
Current Assets:					
Cash and cash equivalents	$ 1.2	$ 56.5	$ 217.8	$ —	$ 275.5
Accounts receivable, net	—	—	400.8	—	400.8
Inventories	—	—	403.1	—	403.1
Deferred income taxes	—	—	171.1	—	171.1
Prepaid expenses and other current assets	1.0	—	133.4	—	134.4
Intercompany receivable	2.7	—	12.2	(14.9)	—
Total current assets	4.9	56.5	1,338.4	(14.9)	1,384.9
Property, plant and equipment, net	—	—	997.4	—	997.4
Goodwill	—	—	532.0	—	532.0
Intangible assets, net	—	—	422.1	—	422.1
Investment in subsidiaries	1,266.1	2,520.4	—	(3,786.5)	—
Intercompany loan receivable	—	2.4	409.6	(412.0)	—
Other assets	—	11.2	209.0	—	220.2
Total Assets	$ 1,271.0	$ 2,590.5	$ 3,908.5	$ (4,213.4)	$ 3,556.6
Liabilities and Shareholders' Equity					
Current Liabilities:					
Current maturities of long-term debt	$ —	$ —	$ 1.5	$ —	$ 1.5
Accounts payable	0.1	—	120.8	—	120.9
Accrued payroll and payroll-related costs	0.1	—	66.4	—	66.5
Accrued royalties	—	—	13.2	—	13.2
Accrued branded rebates	—	—	34.6	—	34.6
Accrued and other current liabilities	0.6	18.3	344.6	—	363.5
Intercompany payable	12.2	—	2.7	(14.9)	—
Total current liabilities	13.0	18.3	583.8	(14.9)	600.2
Long-term debt	—	898.1	20.2	—	918.3
Pension and postretirement benefits	—	—	108.0	—	108.0
Environmental liabilities	—	—	39.5	—	39.5
Deferred income taxes	—	—	310.1	—	310.1
Other income tax liabilities	—	—	153.1	—	153.1
Intercompany loans payable	2.4	409.6	—	(412.0)	—
Other liabilities	—	—	171.8	—	171.8
Total liabilities	15.4	1,326.0	1,386.5	(426.9)	2,301.0
Shareholders' equity	1,255.6	1,264.5	2,522.0	(3,786.5)	1,255.6
Total Liabilities and Shareholders' Equity	$ 1,271.0	$ 2,590.5	$ 3,908.5	$ (4,213.4)	$ 3,556.6

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME
Fiscal year ended September 26, 2014
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Net sales	$ —	$ —	$ 2,540.4	$ —	$ 2,540.4
Cost of sales	—	—	1,337.3	—	1,337.3
Gross profit	—	—	1,203.1	—	1,203.1
Selling, general and administrative expenses	38.6	7.3	796.2	—	842.1
Research and development expenses	—	—	166.9	—	166.9
Separation costs	2.5	—	7.1	—	9.6
Restructuring charges, net	35.3	—	93.3	—	128.6
Non-restructuring impairments	—	—	355.6	—	355.6
Gains on divestiture and license	—	—	(15.6)	—	(15.6)
Operating (loss) income	(76.4)	(7.3)	(200.4)	—	(284.1)
Interest expense	—	(86.3)	—	3.7	(82.6)
Interest income	—	—	5.2	(3.7)	1.5
Other income (expense), net	30.9	—	(29.1)	—	1.8
Intercompany interest and fees	(9.0)	—	9.0	—	—
Equity in net income of subsidiaries	(264.8)	(171.2)	(300.2)	736.2	—
Income (loss) from continuing operations before income taxes	(319.3)	(264.8)	(515.5)	736.2	(363.4)
Income tax expense (benefit)	—	—	(44.8)	—	(44.8)
Income (loss) from continuing operations	(319.3)	(264.8)	(470.7)	736.2	(318.6)
Loss from discontinued operations, net of income taxes	—	—	(0.7)	—	(0.7)
Net income (loss)	(319.3)	(264.8)	(471.4)	736.2	(319.3)
Other comprehensive loss, net of tax	(42.8)	(42.8)	(84.1)	126.9	(42.8)
Comprehensive income (loss)	$ (362.1)	$ (307.6)	$ (555.5)	$ 863.1	$ (362.1)

MALLINCKRODT PLC
CONDENSED COMBINING STATEMENT OF COMPREHENSIVE INCOME
Fiscal year ended September 27, 2013
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Combined
Net sales	$ —	$ —	$ 2,204.5	$ —	$ 2,204.5
Cost of sales	—	—	1,179.6	—	1,179.6
Gross profit	—	—	1,024.9	—	1,024.9
Selling, general and administrative expenses	5.4	0.1	604.4	—	609.9
Research and development expenses	—	—	165.7	—	165.7
Separation costs	3.2	0.6	70.4	—	74.2
Restructuring charges, net	—	—	33.2	—	33.2
Gains on divestiture and license	—	—	(2.9)	—	(2.9)
Operating (loss) income	(8.6)	(0.7)	154.1	—	144.8
Interest expense	—	(19.6)	0.1	—	(19.5)
Interest income	—	—	0.3	—	0.3
Other income (expense), net	0.2	—	0.6	—	0.8
Intercompany interest and fees	(9.5)	—	9.5	—	—
Equity in net income of subsidiaries	76.4	96.7	—	(173.1)	—
Income from continuing operations before income taxes	58.5	76.4	164.6	(173.1)	126.4
Income tax expense	(0.3)	—	68.9	—	68.6
Income from continuing operations	58.8	76.4	95.7	(173.1)	57.8
Loss from discontinued operations, net of income taxes	—	—	1.0	—	1.0
Net income	58.8	76.4	96.7	(173.1)	58.8
Other comprehensive loss, net of tax	28.4	28.4	35.7	(64.1)	28.4
Comprehensive income	$ 87.2	$ 104.8	$ 132.4	$ (237.2)	$ 87.2

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS
Fiscal year ended September 26, 2014
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Cash Flows From Operating Activities:					
Net cash (used in) provided by operating activities	$ 18.2	$ (65.0)	$ 420.2	$ —	$ 373.4
Cash Flows From Investing Activities:					
Capital expenditures	—	—	(127.8)	—	(127.8)
Acquisitions and intangibles, net of cash acquired	—	—	(2,793.8)	—	(2,793.8)
Intercompany loan investment	(25.0)	(298.1)	(915.8)	1,238.9	—
Subsidiary dividend proceeds	—	300.5	—	(300.5)	—
Investment in subsidiary	—	(3,735.5)	—	3,735.5	—
Restricted cash	—	—	4.1	—	4.1
Other	—	—	26.7	—	26.7
Net cash (used in) provided by investing activities	(25.0)	(3,733.1)	(3,806.6)	4,673.9	(2,890.8)
Cash Flows From Financing Activities:					
Issuance of external debt	—	2,893.3	149.9	—	3,043.2
Repayment of external debt and capital leases	—	(3.3)	(31.5)	—	(34.8)
Excess tax benefit from share-based compensation	—	—	8.9	—	8.9
Debt financing costs	—	(70.7)	(1.0)	—	(71.7)
Net transfers to parent	—	—	—	—	—
Proceeds from exercise of share options	25.8	—	—	—	25.8
Subsidiary dividend payment	—	—	(300.5)	300.5	—
Intercompany loan borrowings	(2.4)	940.8	300.5	(1,238.9)	—
Capital contribution	—	—	3,735.5	(3,735.5)	—
Repurchase of shares	(17.5)	—	—	—	(17.5)
Other	—	—	—	—	—
Net cash provided by (used in) financing activities	5.9	3,760.1	3,861.8	(4,673.9)	2,953.9
Effect of currency rate changes on cash	—	—	(4.2)	—	(4.2)
Net increase in cash and cash equivalents	(0.9)	(38.0)	471.2	—	432.3
Cash and cash equivalents at beginning of period	1.2	56.5	217.8	—	275.5
Cash and cash equivalents at end of period	0.3	18.5	689.0	—	707.8

MALLINCKRODT PLC
CONDENSED COMBINING STATEMENT OF CASH FLOWS
Fiscal year ended September 27, 2013
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Cash Flows From Operating Activities:					
Net cash (used in) provided by operating activities	$ (1.8)	$ (8.4)	$ 146.1	$ —	$ 135.9
Cash Flows From Investing Activities:					
Capital expenditures	—	—	(147.9)	—	(147.9)
Acquisitions and intangibles, net of cash acquired	—	—	(88.1)	—	(88.1)
Intercompany loan investment	—	(2.4)	(409.6)	412.0	—
Investment in subsidiary	—	(68.0)	—	68.0	—
Other	—	—	1.3	—	1.3
Net cash (used in) provided by investing activities	—	(70.4)	(644.3)	480.0	(234.7)
Cash Flows From Financing Activities:					
Issuance of external debt	—	898.1	—	—	898.1
Repayment of external debt and capital leases	—	—	(1.3)	—	(1.3)
Excess tax benefit from share-based compensation	—	—	3.4	—	3.4
Debt financing costs	—	(12.0)	—	—	(12.0)
Net transfers to parent	—	(1,160.4)	644.5	—	(515.9)
Proceeds from exercise of share options	0.6	—	—	—	0.6
Intercompany loan borrowings	2.4	409.6	—	(412.0)	—
Capital contribution	—	—	68.0	(68.0)	—
Other	—	—	0.1	—	0.1
Net cash provided by (used in) financing activities	3.0	135.3	714.7	(480.0)	373.0
Effect of currency rate changes on cash	—	—	1.3	—	1.3
Net increase in cash and cash equivalents	1.2	56.5	217.8	—	275.5
Cash and cash equivalents at beginning of period	—	—	—	—	—
Cash and cash equivalents at end of period	$ 1.2	$ 56.5	$ 217.8	$ —	$ 275.5

23. Subsequent Events

On November 12, 2014, the Company was informed by the FDA that they believe that the Company's Methylphenidate ER products may not be therapeutically equivalent to the category reference listed drug. As a result, on November 13, 2014, the FDA reclassified Methylphenidate ER from freely substitutable at the pharmacy level (class AB) to presumed to be therapeutically inequivalent (class BX). The FDA has indicated that it has not identified any serious safety concerns with the products. The FDA indicated that its reclassification is attributable to concerns that the products may not produce the same therapeutic benefits for some patients as the reference listed drug. The FDA further indicated that Company's Methylphenidate ER product is still approved and can be prescribed. The FDA has requested that within six months, the Company demonstrate the bioequivalence of its products using the draft guidance for revised bioequivalence standards issued by the FDA on November 6, 2014 or voluntarily withdraw our products from the market. The Company expects that the FDA's action to reclassify our Methylphenidate ER products will significantly impact net sales and operating income unless the FDA revises its decision.

Mallinckrodt Inc. v. U.S. Food and Drug Administration and United States of America The Company filed a Complaint for Declaratory and Injunctive Relief in the U.S. District Court for the District of Maryland Greenbelt Division against the FDA and the United States of America on November 17, 2014 for judicial review of what the Company believes is FDA’s inappropriate and unlawful reclassification of the Company’s methylphenidate hydrochloride extended-release tablets in the Orange Book: Approved Drug Products with Therapeutic Equivalence (Orange Book) on November 13, 2014. In its complaint, the Company has asked the court to: issue an injunction to (a) set aside the FDA’s reclassification of the Company’s methylphenidate ER products from AB (freely substitutable at the pharmacy level) to BX (presumed to be therapeutically inequivalent) in the Orange Book and (b) prohibit the FDA from reclassifying Mallinckrodt’s methylphenidate ER products in the future without following applicable legal requirements; and issue a declaratory judgment that the FDA’s action reclassifying Mallinckrodt’s methylphenidate ER products in the Orange Book is unlawful. Mallinckrodt concurrently filed a motion with the same court requesting an expedited hearing to issue a temporary restraining order (TRO) directing FDA to reinstate the Orange Book AB rating for the company’s methylphenidate ER drug on a temporary basis.

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 and 15d-15 under the Exchange Act) as of September 26, 2014. Based on that evaluation, our CEO and CFO concluded that, as of that date, our disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined under Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company’s assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that the Company’s receipts and expenditures are being made only in accordance with authorizations of the Company’s management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of September 26, 2014. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control—Integrated Framework (2013)*. Management’s assessment included an evaluation of the design of the Company’s internal control over financial reporting and testing of the operational effectiveness of its internal control over financial reporting. Based on our assessment, we believe that our internal controls over financial reporting were effective as of September 26, 2014.

Management’s assessment of internal control over financial reporting, as discussed above, excluded Cadence Pharmaceuticals, Inc. (“Cadence”) and Questcor Pharmaceuticals, Inc. (“Questcor”), both acquired by the Company in Fiscal 2014, which represented approximately 10% of our total net sales and approximately 77% of our total assets as of and for the period ended September 26, 2014, respectively. Because management’s assessment of internal control over financial reporting included the accounting for goodwill and intangible assets- from these acquisitions, the percentage of total assets at September 26, 2014 that was excluded from management’s assessment of internal control over financial reporting was approximately 7%.

Our internal control over financial reporting as of September 26, 2014 has been audited by Deloitte & Touche LLP, the independent registered public accounting firm that audited and reported on the consolidated financial statements included in this annual report on Form 10-K. This report is included below.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 26, 2014 that have materially affected, or are likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Mallinckrodt plc:

We have audited the internal control over financial reporting of Mallinckrodt plc and subsidiaries (the "Company") as of September 26, 2014, based on the criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. As described in *Management's Report on Internal Control over Financial Reporting*, management excluded from its assessment the internal control over financial reporting at Cadence Pharmaceuticals, Inc. (“Cadence”) and Questcor Pharmaceuticals, Inc. (“Questcor”), both acquired by the Company in Fiscal 2014, which represented approximately 10% of total net sales and approximately 7% of total assets as of and for the period ended September 26, 2014, respectively. Accordingly, our audit did not include the internal control over financial reporting at Cadence or Questcor. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying *Management's Report on Internal Control over Financial Reporting*. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 26, 2014, based on the criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended September 26, 2014 of the Company and our report dated November 24, 2014 expressed an unqualified opinion on those financial statements and financial statement schedule and included an explanatory paragraph regarding the fact that 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 had it operated as an independent, publicly-traded company for the entirety of the periods presented.

/s/ DELOITTE & TOUCHE LLP
St. Louis, Missouri
November 24, 2014

Item 9B. Other Information.

On November 20, 2014, the Human Resources and Compensation Committee (the "Committee") of the Board of Directors (the "Board") of Mallinckrodt plc ("Mallinckrodt" or the "Company") determined that it will allow eligible employees, including the Company's named executive officers, beginning with annual performance bonuses earned for fiscal 2015, an opportunity to exchange up to 100% of such eligible employee's target annual incentive compensation opportunity, and receive a Company match, in the form of restricted units. Eligible employees who elect such exchange will receive restricted units for the cash amount exchanged (the "Exchange Units") and an additional number of restricted units equal to 25% of the cash amount exchanged ("Match Units"). The restricted units will vest in equal annual installments over three years, provided that, in the event of (i) an involuntary termination without cause or good reason, any unvested Exchange Units will vest in full and any unvested Match Units will vest on a pro rata basis; (ii) a change in control, any unvested Exchange Units and Match Units will vest in full or (iii) a termination for cause, any unvested Exchange Units and Match Units will be forfeited.

Additionally, the Committee approved, with respect to our named executive officers (except our CEO) and on November 20, 2014, our Board approved, with respect to our CEO, certain compensation related actions. With respect to Mr. Peter G. Edwards, the Company's Senior Vice President and General Counsel, the Committee increased Mr. Edward's annual base salary, effective December 29, 2014 from $430,000 to $450,000 and increased his long-term incentive compensation award target as a percentage of annual base salary from 120% to 250% effective with the 2015 long-term incentive grant. With respect to Mr. Ian J. Watkins, the Company's Senior Vice President and Chief Human Resources Officer, the Committee increased his annual base salary, effective December 29, 2014 from $400,000 to $425,000 and increased his long-term incentive compensation award target as a percentage of annual base salary from 120% to 200% effective with the 2015 long-term incentive grant.

Also, the Committee, with respect to our named executive officers (except our CEO) and the Board, with respect to our CEO, determined the target grant date dollar value of long-term incentive compensation for the fiscal 2015 annual long-term incentive awards, which will be granted on January 2, 2015 ("the Grant Date"). The table below sets forth the target grant date fair value awarded by the Committee to each of our named executive officers:

Fiscal 2014 Long-Term Incentive Compensation

Name and Title	Target Grant Date Fair Value
Mark C. Trudeau	$ 7,750,000
Chief Executive Officer	
Matthew K. Harbaugh	$ 1,855,000
Senior Vice President and Chief Financial Officer	
Peter G. Edwards	$ 1,125,000
Senior Vice President and General Counsel	
Ian J. Watkins	$ 850,000
Senior Vice President and Chief Human Resources Officer	

The dollar value awarded to each named executive officer for fiscal 2015 grants will be allocated between the long-term incentive vehicles as follows:

- 40% of the target grant date fair value will be allocated to performance shares ("PSUs") with performance-based vesting over a three-year vesting period (September 27, 2014 up to and including September 29, 2017) based on total return of shareholders against a defined peer group (weighted 50%) and adjusted EBITDA margin as measured as of September 29, 2017 (weighted 50%). The actual number of PSUs will be determined on the Grant Date by taking the dollar value allocated to PSUs and dividing such amount by the grant date fair value of a PSU using, for 50% of the value, a Monte Carlo simulation model and for the remaining 50% of the value, the closing price of our ordinary shares on the Grant Date. Depending on Mallinckrodt's performance during the performance period, the named executive officer is entitled to receive a number of ordinary shares equal to a percentage, ranging from 0% to 200%, of the award granted.

- 40% of the target grant date fair value will be allocated to stock options vesting ratably over a four-year period on the anniversary of the Grant Date. The actual number of stock options will be determined on the Grant Date by taking the dollar value allocated to stock options and dividing such amount by the grant date fair value of an option using a Black-Scholes valuation model; and

- 20% of the target grant date fair value will be allocated to restricted stock units ("RSUs") vesting ratably over a four-year period on the anniversary of the Grant Date. The actual number of RSUs will be determined on the Grant Date by taking the dollar value allocated to RSUs and dividing such amount by Fair Market Value (as defined in the Mallinckrodt Pharmaceuticals Stock and Incentive Plan) of the Company's ordinary shares on the Grant Date.

The performance share, stock option and restricted stock unit awards will be made pursuant to the terms and conditions of the Mallinckrodt Pharmaceuticals Stock and Incentive Plan and pursuant to the terms and conditions of the applicable award agreements.

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 26, 2014.

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 26, 2014.

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 26, 2014.

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 26, 2014.

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 26, 2014.

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 Statement of Income for the fiscal year ended September 26, 2014 and the Consolidated and Combined Statements of Income for the fiscal years ended September 27, 2013 and September 28, 2012
- Consolidated Statement of Comprehensive Income for the fiscal year ended September 26, 2014 and the Consolidated and Combined Statements of Comprehensive Income for the fiscal years ended September 27, 2013 and September 28, 2012
- Consolidated Balance Sheets as of September 26, 2014 and September 27, 2013
- Consolidated Statement of Cash Flows for the fiscal year ended September 26, 2014 and the Consolidated and Combined Statements of Cash Flows for the fiscal years ended September 27, 2013 and September 28, 2012
- Consolidated Statement of Changes in Shareholders' Equity for the period from September 27, 2013 to September 26, 2014 and the Consolidated and Combined Statement of Changes in Shareholders' Equity for the period from September 30, 2011 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 26, 2014	$ 4.6	$ 2.3	$ —	$ (0.3)	$ 6.6
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
Sales reserve accounts:					
Fiscal year ended September 26, 2014	$ 322.9	$ 1,846.8	$ 30.6	$ (1,769.8)	$ 430.5
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
Tax valuation allowance:					
Fiscal year ended September 26, 2014	$ 30.0	$ 33.4	$ 14.1	$ —	$ 77.5
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

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: November 24, 2014

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)*	November 24, 2014
/s/ Matthew K. Harbaugh Matthew K. Harbaugh	Senior Vice President and Chief Financial Officer *(principal financial officer)*	November 24, 2014
/s/ Kathleen A. Schaefer Kathleen A. Schaefer	Vice President and Corporate Controller *(principal accounting officer)*	November 24, 2014
* Melvin D. Booth	Chairman of the Board of Directors	November 24, 2014
* Don M. Bailey	Director	November 24, 2014
* David R. Carlucci	Director	November 24, 2014
* J. Martin Carroll	Director	November 24, 2014
* Diane H. Gulyas	Director	November 24, 2014
* Nancy S. Lurker	Director	November 24, 2014
* JoAnn A. Reed	Director	November 24, 2014
* Angus C. Russell	Director	November 24, 2014
* Virgil D. Thompson	Director	November 24, 2014
* Kneeland C. Youngblood, M.D.	Director	November 24, 2014
* Joseph A. Zaccagnino	Director	November 24, 2014

* 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).
2.2	Agreement and Plan of Merger, dated as of February 10, 2014, by and among Mallinckrodt plc, Madison Merger Sub, Inc. and Cadence Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed February 11, 2014).
2.3	Agreement and Plan of Merger, dated as of April 5, 2014, by and among Mallinckrodt plc, Quincy merger Sub, Inc. and Questcor Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed April 7, 2014).
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	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).
4.2	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).
4.3	Indenture, dated as of August 13, 2014, among Mallinckrodt International Finance, S.A., Mallinckrodt CB LLC, the Guarantors party thereto from time to time and Deutsche Bank Trust Company Americas, as trustee (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed August 14, 2014).
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 19, 2014, among Mallinckrodt plc, Mallinckrodt International Finance S.A., Mallinckrodt CB LLC, the lenders party thereto from time to time and Deutsche Bank AG New York Branch, as Administrative Agent (incorporated herein by reference to Exhibit (b)(3) of the Schedule TO/A filed by Mallinckrodt plc and Madison Merger Sub, Inc. on March 19, 2014).
10.5	Note Purchase Agreement, dated as of July 28, 2014, among Mallinckrodt Securitization S.À R.L., the persons from time to time party thereto as purchasers, PNC Bank, National Association, as administrative agent, and Mallinckrodt LLC, as initial servicer (incorporated by reference to Exhibit 10.1 to the Company's Current Report filed July 30. 2014).
10.6	Purchase and Sale Agreement, dated as of July 28, 2014, among the various entities party thereto from time to time as originators, Mallinckrodt LLC, as initial servicer, and Mallinckrodt Securitization S.À R.L., as buyer (incorporated by reference to Exhibit 10.2 to the Company's Current Report filed July 30. 2014).
10.7	Sale Agreement, dated as of July 28, 2014, between Liebel-Flarsheim Company LLC and Mallinckrodt LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report filed July 30. 2014).
10.8	Performance Guaranty, dated as of July 28, 2014, by Mallinckrodt International Finance S.A. in favor of PNC Bank, National Association, as administrative agent (incorporated by reference to Exhibit 10.4 to the Company's Current Report filed July 30. 2014).
10.9	Incremental Assumption Agreement No. 1, dated as of August 14, 2014, among Mallinckrodt International Finance, S.A., Mallinckrodt CB LLC, the subsidiaries of MIFSA party thereto and Deutsche Bank AG New York Branch, as administrative agent, as acknowledged by and consented to by Mallinckrodt plc and Mallinckrodt Quincy S.à r.l. incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 14, 2014).
10.10	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).
10.11	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).
10.12	IV APAP Agreement (U.S. and Canada), dated as of February 21, 2006, by and between Cadence Pharmaceuticals, Inc. and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.11 to Amendment No. 2 of Cadence Pharmaceuticals, Inc.'s Registration Statement on Form S-1 filed September 25, 2006).

12.13	License Agreement, dated as of December 23, 2002, by and among SCR Pharmatop and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.12 to Amendment No. 2 of Cadence Pharmaceuticals, Inc.'s Registration Statement on Form S-1 filed September 25, 2006).
10.14*	Mallinckrodt Pharmaceuticals Severance Plan for U.S. Officers and Executives dated May 1, 2014.
10.15*	Mallinckrodt Pharmaceuticals Change in Control Severance Plan for Certain U.S. Officers and Executives dated as of May 1, 2014.
10.16 *	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).
10.17*	Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Restricted Unit Award (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed May 8, 2014).
10.18*	Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Option Award (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed May 8, 2014).
10.19*	Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Performance Unit Award FY14-FY16 Performance Cycle (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed May 8, 2014).
10.20*	Letter Agreement dated as of August 27, 2013 by and between Mallinckrodt LLC and Frank Scholz.
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 26, 2014 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 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.

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