Mallinckrodt plc
Form 10-K
November 25, 2014

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

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FORM 10-K

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

For the fiscal year ended September 26, 2014

or

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

For the transition period from _____ to _____

Commission File Number : 001-35803

_____

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

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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 x No o
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

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

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
INDEX TO FORM 10-K

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.

4

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:

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- 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	%

20

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

21

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.

37

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			
	2014	2013	Percentage Change	
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