Mallinckrodt plc
Form 10-K
November 24, 2015

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 25, 2015

or

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

For the transition period from _____ to _____

Commission File Number : 001-35803

_____

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

_____

Ireland	98-1088325
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
Perth House, Millennium Way, Chesterfield, Derbyshire, United Kingdom, S41 8ND	

(Address of principal executive offices) (Zip Code)

Telephone: +44 424 626 3051

(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 website, 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. x

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 27, 2015, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $15,146.4 million (based upon the closing price of $129.61 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 16, 2015 was 115,947,044.

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 25, 2015, are incorporated by reference into Part III of this report.

MALLINCKRODT PLC
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Presentation of Information

Unless the context requires otherwise, references to "Mallinckrodt plc," "Mallinckrodt," "we," "us," "our" and "the Company" refer to Mallinckrodt plc, an Irish public limited company, and its consolidated subsidiaries for periods subsequent to its separation from Covidien plc on June 28, 2013. For periods prior to June 28, 2013, these terms refer to the combined historical business and operations of Covidien plc's Pharmaceuticals business as it was historically managed as part of Covidien plc. Unless the context requires otherwise, references to "Covidien" refer to Mallinckrodt's former parent company, Covidien plc, an Irish public limited company, and its consolidated subsidiaries (which was subsequently acquired by Medtronic plc). 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

Mallinckrodt plc and its subsidiaries (collectively, "Mallinckrodt" or "the Company"), is a global specialty biopharmaceutical and nuclear imaging business that develops, manufactures, markets and distributes specialty pharmaceutical and biopharmaceutical products and nuclear imaging agents. Therapeutic areas of focus include autoimmune and rare disease specialty areas (including neurology, rheumatology, nephrology and pulmonology); immunotherapy and neonatal respiratory critical care therapies; pain management; and central nervous system drugs. The Company also supports the diagnosis of disease with nuclear medicine imaging agents. The Company believes its 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 it anticipates will sustain future revenue growth.

During the first quarter of fiscal 2015, the Company changed its reportable segments to present the Specialty Brands and Specialty Generics businesses as reportable segments. The Company historically presented the Specialty Brands and Specialty Generics businesses within the Specialty Pharmaceuticals segment.

During the fourth quarter of fiscal 2015, the Company announced that it had entered into a definitive agreement to sell its global contrast media and delivery systems ("CMDS") business to Guerbet S.A. ("Guerbet"), which is expected to be completed during the first quarter of fiscal 2016. The CMDS business is deemed to be held for sale and the financial results of this business are presented as a discontinued operation. The CMDS business has been eliminated from the Global Medical Imaging segment, which was renamed Nuclear Imaging.

Prior year amounts have been recast to conform to current presentation.

The three reportable segments are further described below:

- Specialty Brands produces and markets branded pharmaceuticals and biopharmaceuticals;
- Specialty Generics produces specialty generic pharmaceuticals and active pharmaceutical ingredients ("API") consisting of biologics, medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients; and
- Nuclear Imaging manufactures and markets 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

The Company's Specialty Generics 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 Nuclear Imaging segment traces its origins to 1966 with technetium generators, and has 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").

Subsequent to the Separation, Mallinckrodt completed multiple acquisitions of specialty pharmaceuticals and specialty biopharmaceuticals businesses within our Specialty Brands segment. The Company believes these acquisitions have created a foundation and framework for future growth. In addition to these acquisitions, we also implemented significant actions under our 2013 restructuring program intended to improve our long-term profit margins and yield efficiencies from our spending on selling, general and administrative expenses ("SG&A"). In July 2015, Mallinckrodt announced that it had entered into a definitive agreement to sell its CMDS business in order to further increase the Company's focus on specialty pharmaceuticals.

In May 2015, the Board of Directors of the Company approved the migration of our principal executive offices to Perth House, Millennium Way, Chesterfield, Derbyshire, United Kingdom, where they are currently located. Our telephone number at this location is +44 424 626 3051. Our U.S. headquarters is located at 675 James S. McDonnell Boulevard, Hazelwood, Missouri 63042. Our telephone number at this location is (314) 654-2000.

Our Competitive Strengths

We believe we have the following strengths:

- Ability to successfully execute strategies to drive growth. We completed multiple acquisitions throughout fiscal 2015 and 2014 that created a framework for future organic volume growth and business development. We successfully completed the integration of our acquisitions, except for our acquisition of Therakos, Inc. ("Therakos") which was acquired on September 25, 2015, and generated synergies from these transactions, primarily associated with SG&A. We expect to realize further synergies in SG&A expenses during fiscal 2016. We continue to realign our cost structure due to the changing nature of our business and look for opportunities to achieve operating efficiencies. We have taken restructuring actions that have generated further savings, substantially within our SG&A expenses. These acquisitions and restructuring actions further diversified Mallinckrodt, significantly increasing our scale, net sales, 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 2014, we estimated that we received approximately 27% 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 Specialty Generics business had an approximately 21% 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 Nuclear 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. 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 Brands business with high cash flow conversion. We have a diverse portfolio across our three different reportable segments, Specialty Generics, Nuclear Imaging and the increasingly significant Specialty Brands. In July 2015, we further progressed our shift toward high-margin pharmaceuticals with the announcement that we entered into a definitive agreement to sell our CMDS business. In the fourth quarter of fiscal 2015, net sales from our Specialty Brands segment represented 53.9% of net sales from our reportable segments compared with 31.9% in the fourth quarter of fiscal 2014. We expect the Specialty Brands percentage to increase in fiscal 2016 due to the inclusion of full year results from our fiscal 2015 acquisitions, organic volume growth in Specialty Brands and increased competition in Specialty Generics. Specialty Brands segment operating income increased from 16.4% in the fourth quarter of fiscal 2014 to 46.2% in the fourth quarter of fiscal 2015. The increased revenues and segment operating income positions us for strong cash flow generation, enabling us to potentially decrease debt leverage over time.

An extensive portfolio of specialty generic products and controlled substance API for pain. Our Specialty Generics products are focused on pain and attention deficit hyperactivity disorder ("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 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 payers 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; the successful integration of acquisitions; the ability to grow net sales from existing and acquired products; 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 three reportable segments: Specialty Brands, Specialty Generics and Nuclear Imaging. Management measures and evaluates our operating segments based on segment net sales and operating income. Information regarding the product portfolios and business strategies of these segments is included in the following discussion. Financial information regarding each of our reportable segments, as well as other geographical information, is included in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and in Note 21 of Notes to Consolidated and Combined Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Specialty Brands

Our Specialty Brands segment markets branded pharmaceutical and biopharmaceutical products for autoimmune and rare diseases (including in the specialty areas of neurology, rheumatology, nephrology and pulmonology); immunotherapy and neonatal respiratory critical care therapies; and central nervous system drugs. In fiscal 2015, our Specialty Brands segment accounted for 49.2% of net sales from our operating segments.

We started our Specialty 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 Specialty Brands product portfolio, with the March 2014 acquisition of OFIRMEV® (acetaminophen) injection ("Ofirmev") and the August 2014 acquisition of H.P. Acthar® Gel ("Acthar"). In fiscal 2015, we continued to diversify our Specialty Brands product portfolio with the April 2015 acquisition of INOMAX® (nitric oxide) for inhalation ("Inomax") and immunotherapy treatment with the September 2015 acquisition of Therakos, Inc. ("Therakos"). Our long-term strategy is to increase patient access and appropriate utilization of our existing products, develop new and follow-on formulations for recently acquired products, advance pipeline products and bring them to market and selectively acquire or license products that are strategically aligned with our product portfolio to expand the size and profitability of our Specialty Brands segment.

We promote our branded products directly to physicians in their offices, hospitals and ambulatory surgical centers (including rheumatologists, neurologists, nephrologists, pulmonoligists, neonatologists, surgeons, and pharmacy directors) with our own direct sales force of over 550 sales representatives as of September 25, 2015. Our products are purchased by independent wholesale drug distributors, specialty pharmaceutical distributors, retail pharmacy chains and hospital procurement departments, among others, and are eventually dispensed by prescription to patients. We also contract directly with payer organizations to gain access to drug formularies and allow patients access to these medications.

The following is a description of select products in our Specialty 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; the treatment of the pulmonology indication of sarcoidosis; 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 approved 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 patents listed in the Orange Book: Approved Drug Products with Therapeutic Equivalence ("the Orange Book") 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 competition to Ofirmev in December 2020, or earlier under certain circumstances.

- Inomax is a vasodilator that, in conjunction with ventilatory support and other appropriate agents, is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks) neonates with hypoxic respiratory failure ("HRF") associated with clinical or echocardiographic evidence of pulmonary hypertension. Inomax is marketed as part of the Inomax Total Care Package, which includes the drug product, proprietary drug-delivery systems, technical and clinical assistance, 24/7/365 customer service, emergency supply and delivery and on-site training. The Inomax Total Care Package maintains a number of patents, the latest of which expire in 2031, that contain claims to nitric oxide delivery systems expressly required by the drug labeling for administration of Inomax, covering a number of important functions, including patient safety and product performance features.
- Therakos immunotherapy is focused on providing innovative immunotherapy treatment platforms that enhance the ability of a patient's immune system to fight disease. Therakos is the global leader in autologous immunotherapy delivered through extracorporeal photopheresis ("ECP"). Therakos provides the only integrated ECP system in the world. ECP involves drawing a portion of blood from the patient, separating white blood cells from plasma and red blood cells, which are returned to the patient, and treating the white blood cells with a Ultraviolet-A ("UVA") light activated drug. The treated white blood cells are immediately re-administered back into the patient. ECP is approved by the FDA for use in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (“CTCL”) that is unresponsive to other forms of treatment. Outside the United States, ECP is approved to treat several other serious diseases that arise from immune system imbalances. Therakos’ product suite, which is sold to hospitals, clinics, academic centers and blood banks, includes an installed system, a disposable procedural kit used for each treatment and a drug, UVADEX ® (methoxsalen) Sterile Solution (“UVADEX”), as well as instrument accessories and instrument maintenance and repair services.
- Exalgo is a long-acting, once-daily form of hydromorphone. Our exclusivity period for branded Exalgo expired and generic competition entered the market whereupon we launched our own generic form of Exalgo in May 2014.

Specialty Generics

Our Specialty Generics segment markets drugs that include a variety of product formulations containing hydrocodone, oxycodone and several other controlled substances. While our pipeline is limited, we do have products in development that are primarily focused on controlled substances. Our API business, which is included in the Specialty Generics segment, provides bulk API products, including opioids and acetaminophen, to a wide variety of pharmaceutical companies, many of which are direct competitors of our Specialty Generics finished dosage business. In addition, we use our API for internal manufacturing of our finished dosage products. In fiscal 2015, our Specialty Generics segment accounted for 37.9% of net sales from our operating segments.

We are among the world's largest manufacturers of bulk acetaminophen and the only producer of acetaminophen outside of Asia. We manufacture controlled substances under DEA quota restrictions and in calendar 2014 we estimated that we received approximately 27% of the total DEA quota provided to the U.S. market for the controlled substances we manufacture. We believe that our 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 Specialty Generics business. 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 Specialty Generics segment represents the broadest product line of opioid and other controlled substances (primarily DEA Schedules II and III) currently available from a single manufacturer. Historically, our primary competition has been other U.S. participants due to importation restrictions on controlled substance API and finished products.

We market our products principally through independent channels, including 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 Specialty Generics 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") under a class BX-rating issued by the FDA in November 2014 and;
- other controlled substances, including acetaminophen (API) products.

Nuclear Imaging

During the fourth quarter of fiscal 2015, the Company announced that it entered into a definitive agreement to sell its CMDS business to Guerbet, which is expected to be completed during the first quarter of fiscal 2016. The CMDS business is deemed to be held for sale and the financial results of this business are presented as a discontinued operation. The CMDS business has been eliminated from the Global Medical Imaging segment, which has been renamed Nuclear Imaging.

Our Nuclear Imaging segment develops, manufactures and markets products which provide radiopharmaceuticals used in single photon emission computed tomography ("SPECT") imaging for myocardial perfusion, cardiac imaging and bone scans. In fiscal 2015, our Nuclear Imaging segment accounted for 12.8% of net sales from our operating segments. We are focused on driving operating efficiencies in the Nuclear Imaging segment to maximize operating margins and cash flow.

Our Nuclear Imaging business manufactures radioactive isotopes for the diagnosis and treatment of disease. Our nuclear radiopharmaceutical product offering includes both "hot" radioisotopes 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. One key initiative identified was the conversion by research reactors and isotope production facilities 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 are the most common 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.

Competition

Specialty Brands and Specialty Generics

Several of our Specialty Brands products do not face direct competition from similar products, but instead compete against alternative forms of treatment that a prescriber may utilize. For example, Acthar, has limited direct competition due to the unique nature of the product; however, it generally is prescribed by physicians when numerous alternative treatments have not yielded favorable outcomes for patients. Our Specialty Generics 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 Generics products include Allergan, Inc. (formerly Actavis, Inc.), Endo Health Solutions Inc., Johnson & Johnson (including its Noramco, Inc. subsidiary), Johnson Matthey plc, Mylan N.V., Pfizer Inc., Purdue Pharma L.P. and Teva Pharmaceutical Industries Ltd., among others. Our secure sources of raw opioid material, vertically integrated manufacturing capabilities, broad offerings of API controlled substances and acetaminophen, comprehensive generic controlled substance product line and established relationships with independent 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 Specialty Brands segment 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 subsequently 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. Generally, 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 Specialty 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 Specialty Generics segment, 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 drive market volume.
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.

Nuclear Imaging

In Nuclear Imaging, we compete primarily on the ability of our products to capture market share. While we believe that the number of procedures using nuclear imaging may grow in emerging markets, due in part to increasing infrastructure and access to healthcare, we expect that our ability to effectively compete with other providers of nuclear imaging 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 to our Nuclear Imaging business include, among others:

- 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.

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 Specialty 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 infantile spasms ("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 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 technologies. We incurred R&D expenses from continuing operations of $185.1 million, $163.5 million and $157.9 million in fiscal 2015, 2014 and 2013, 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 and biopharmaceuticals areas, specifically investments to support our Specialty Brands and Specialty Generics segments, where we believe there is the greatest opportunity for growth and profitability.

Specialty Brands. 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 generating clinical and health economic data associated with our currently marketed products as well as generating clinical data in support of new indications for existing products, label expansion opportunities for Inomax and Therakos immunotherapy and development of pipeline products.

In accordance with a Pediatric Research Equity Act requirement included in the New Drug Application ("NDA") approval for Ofirmev, Cadence Pharmaceuticals, Inc. ("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 study is completed and is anticipated to be filed with the FDA in calendar 2016. Upon 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 would enable us to offer Ofirmev in flexible intravenous bags.

Specialty Generics. In regard to specialty generic product development, we are focused on controlled substances with difficult-to-replicate pharmacokinetic profiles and the development of products with abuse deterrent properties. As of September 25, 2015, we had various Abbreviated New Drug Applications ("ANDAs") on file with the FDA.

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

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 $2,374,200 for a 505(b)(1) NDA and $1,187,100 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 $76,030 for an ANDA and $38,020 for a prior approval supplement to an ANDA. These fees are expensed as incurred. The FDA has set goal dates by fiscal year for ANDA submissions to improve the average review time. Fiscal 2016 has a target of approving 75% 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 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 the 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.

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 2015, 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 August 2014, the DEA issued its final rule to reschedule hydrocodone combination products (such as Vicodin® (registered trademark of AbbVie Inc.) 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 rebates from the Medicaid Fee-For-Service Program and Medicaid Managed Care plans and the imposition of an annual fee on

branded prescription pharmaceutical manufacturers. Medicaid provisions reduced net sales by $82.3 million, $43.5 million, and $15.5 million in fiscal 2015, 2014, and 2013, respectively. The fiscal 2015 increase in provisions for Medicaid payments is primarily attributable to a $41.7 million increase associated with Acthar, as fiscal 2015 included a full year of results for the product, which was partially offset by lower net sales of Methylphenidate ER. The fiscal 2014 increase in provisions for Medicaid payments is primarily attributable to a $17.0 million increase in the Specialty Generics segment driven by increased Medicaid utilization and net sales of Methylphenidate ER. Fiscal 2014, also reflects a $5.2 million increase due to the addition of Acthar that was part of the acquisition of Questcor Pharmaceuticals, Inc. ("Questcor") on August 14, 2014. The Company was also impacted by the annual fee on branded prescription pharmaceutical manufactures, which is not tax deductible, and recorded expense of $20.0 million, $0.9 million, and $0.1 million in fiscal 2015, 2014, and 2013, respectively, within selling, general and administrative expenses. The fee increased in fiscal 2015 due to the inclusion of a full year of results associated with Acthar. We expect this branded pharmaceutical fee and Medicaid provisions to increase in future periods at rates that are consistent with net sales growth. There are a number of other provisions in the legislation that collectively are expected to have an immaterial impact to the Company.

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 who reports directly to the Chief Executive Officer and the Compliance Committee of our Board of Directors. The Compliance function is

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. In addition, 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 approved promotional and other 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, 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 and 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 19

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, most notably related to our Specialty Brands products, 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, finished goods, services 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 Specialty Generics 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, are 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.

In September 2015, the HFR experienced an unscheduled shutdown. We expect this disruption will have minimal impact to patients as we intend to obtain target irradiations from other reactors to meet patient needs. Similar to prior periods, the shutdown is expected to result in higher costs as we obtain irradiations from alternative sources. We expect this disruption will negatively impact operating income by approximately $10.0 million to $15.0 million during the first quarter of fiscal 2016, but somewhat less impact is expected in future quarters as the reactor is expected to return to full production in the first half of fiscal 2016. Our Mo-99 processing facility continues to operate as scheduled.

Sales, Marketing and Customers

Sales and Marketing

We market our branded, generic and nuclear products to physicians (including rheumatologists, neurologists, nephrologists, pulmonologists, neonatologists and surgeons), pharmacists, pharmacy buyers, hospital procurement departments, ambulatory surgical centers, specialty pharmacies, radiologists and radiology technicians. We distribute these products through independent channels, including wholesale drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, 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.

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 2015, 2014 and 2013 were as follows:

	Fiscal Year					
	2015		2014		2013	
CuraScript	31	%	6	%	—	%
McKesson Corporation	18	%	21	%	19	%
Cardinal Health, Inc.	14	%	22	%	24	%
AmerisourceBergen Corporation	9	%	14	%	11	%

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

Manufacturing and Distribution

We presently have thirteen manufacturing sites, including nine 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. Four of these manufacturing sites relate to our CMDS business and are to be sold in our transaction with Guerbet, which is expected to be completed during the first quarter of fiscal year 2016. We estimate that our manufacturing production by region in fiscal 2015 (as measured by cost of production) was as follows:

U.S.	72	%
Europe	16	%
Canada	12	%

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 Therakos immunotherapy products.

Backlog

At September 25, 2015, the backlog of firm orders was less than 1% of net sales. We anticipate that substantially all of the backlog as of September 25, 2015 will be shipped during fiscal 2016.

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 25, 2015, we had approximately 5,700 employees, approximately 4,400 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, 2015, and current positions of our executive officers.

Name	Age	Title
Mark Trudeau	54	President, Chief Executive Officer and Director
Matthew Harbaugh	45	Senior Vice President and Chief Financial Officer
Terrance Carlson	62	Senior Vice President and General Counsel - Interim
Meredith Fischer	62	Senior Vice President, Communications and Public Affairs
Raymond Furey	47	Senior Vice President and Chief Compliance Officer
Hugh O'Neill	52	Senior Vice President and President, Autoimmune and Rare Diseases
Gary Phillips	49	Senior Vice President and Chief Strategy Officer
Steven Romano	56	Senior Vice President and Chief Scientific Officer
Frank Scholz	46	Senior Vice President of Global Operations
Ian Watkins	53	Senior Vice President and Chief Human Resources Officer

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

Mark Trudeau is our President and Chief Executive Officer, and also serves on our board of directors. In anticipation of the Separation, Mr. Trudeau joined Covidien in February 2012 as a Senior Vice President and President of its Pharmaceuticals business. He joined Covidien from Bayer HealthCare Pharmaceuticals LLC USA, the U.S. healthcare business of Bayer AG, where he served as Chief Executive Officer. He simultaneously served as President of Bayer HealthCare Pharmaceuticals, the U.S. organization of Bayer’s global pharmaceuticals business. In addition, he served as Interim President of the global specialty medicine business unit from January to August 2010. Prior to joining Bayer in 2009, Mr. Trudeau headed the Immunoscience Division at Bristol-Myers Squibb. During his 10-plus years at Bristol-Myers Squibb, he served in multiple senior roles, including President of the Asia/Pacific region, President and

General Manager of Canada and General Manager/Managing Director in the United Kingdom. Mr. Trudeau was also with Abbott Laboratories, serving in a variety of executive positions, from 1988 to 1998. Mr. Trudeau holds a Bachelor's degree in chemical engineering and a M.B.A., both from the University of Michigan.

Matthew Harbaugh is our Senior Vice President and Chief Financial Officer. Mr. Harbaugh previously served as Vice President, Finance of Covidien's Pharmaceuticals business, a position he had held from July 2008 until June 2013, when Mallinckrodt became an independent public company. He also served as Interim President of Covidien's Pharmaceuticals business from November 2010 to January 2012. Mr. Harbaugh joined Covidien's Pharmaceuticals business in August 2007 as its Vice President and Controller, Global

Finance for the Global Medical Imaging business. Mr. Harbaugh was a Lead Finance Executive with Cerberus Capital Management, L.P. from April 2007 until August 2007. Mr. Harbaugh worked for Monsanto from 1997 to 2007 serving in senior U.S. roles in treasury, investor relations, financial planning and analysis and strategy, in addition to two international assignments in Canada and Argentina.

Terrance Carlson is our Senior Vice President and General Counsel - Interim. Mr. Carlson joined Mallinckrodt in June 2015. Since June 2012, Mr. Carlson has been an independent legal advisor focused on the healthcare and medical device space. From 2010 to 2012, Mr. Carlson served as Vice President and General Counsel at Synthes, Inc., a medical device manufacturer. Prior to joining Synthes, he served as Senior Vice President, General Counsel and Secretary of Medtronic, Inc., a medical device manufacturer. Mr. Carlson previously served in senior legal roles at PerkinElmer, Inc. and AlliedSignal Inc., and as a partner in the law firm of Gibson, Dunn & Crutcher.

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 25 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.

Hugh O'Neill is our Senior Vice President and President, Autoimmune and Rare Diseases. From September 2013 to April 2015, he served as Senior Vice President and President, 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 Chief Strategy Officer (a role he also held from October 2013 to August 2014). He served as Senior Vice President and President of our Autoimmune and Rare Disease business from August 2014 to January 2015. 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. Dr. Phillips serves as a director of Aldeyra Therapeutics, Inc. and Inotek Pharmaceuticals Corp.

Steven Romano is our Senior Vice President and Chief Scientific Officer. Dr. Romano joined Mallinckrodt in May 2015 and has executive responsibility for research and development (R&D), medical affairs and regulatory affairs functions. Dr. Romano is a board-certified psychiatrist with more than 20 years of experience in the pharmaceutical industry. Previously, Dr. Romano spent 16 years at Pfizer, Inc. where he held a series of senior medical and R&D roles of increasing responsibility, culminating in his most recent position as Senior Vice President, Head, Global Medicines Development, Global Innovative Pharmaceuticals Business. Prior to joining Pfizer, he spent four years at Eli Lilly & Co. After receiving his A.B. in Biology from Washington University in St. Louis and his medical degree

from the University of Missouri-Columbia, Dr. Romano completed his residency and fellowship at New York Hospital-Cornell Medical Center, continuing on the faculty of the medical school for six additional years.

Frank Scholz is our Senior Vice President of Global Operations. He joined Mallinckrodt in March 2014. His responsibilities include global manufacturing operations, quality, 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 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 Allergan, Inc. (formerly Actavis, Inc. and 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.

We use our website at www.mallinckrodt.com as a channel of distribution of important company information, such as press releases, investor presentations and other financial information. We also use our website to expedite public access to time-critical information regarding our company in advance of or in lieu of distributing a press release or a filing with the SEC disclosing the same information. Therefore, investors should look to the Investor Relations page of our website for important and time-critical information. Visitors to our website can also register to receive automatic e-mail and other notifications alerting them when new information is made available on the Investor Relations page of our website.

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 laws or regulations, 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 have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

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 acquisition of Therakos, 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, 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 have significant levels of goodwill and intangible assets which utilize our future projections of cash flows in impairment testing. Should we experience unfavorable variances from these projections these assets may have an increased risk of future impairment charges.

Our recent acquisitions have significantly increased goodwill and intangible assets, which were $3,649.4 million and $9,666.3 million, respectively, at September 25, 2015. At least annually, we review the carrying value of our goodwill and non-amortizing intangible assets, and for amortizing intangible assets when indicators of impairment are present. Conditions that could indicate impairment and necessitate an evaluation of goodwill and/or intangible assets include, but are not limited to, a significant adverse change in the business climate, legal or regulatory environment, or the deterioration of our market capitalization.

In performing our impairment tests, we utilize our future projections of cash flows. Projections of future cash flows are inherently subjective and reflect assumptions that may or may not ultimately be realized. Significant assumptions utilized in our projections include, but are not limited to, our evaluation of the market opportunity for our products, the current and future competitive landscape and resulting impacts to product pricing, future regulatory actions or the lack thereof, planned strategic initiatives, the ability to achieve cost synergies from acquisitions, the realization of benefits associated with our existing and anticipated patents and regulatory approvals. Given the inherent subjectivity and uncertainty in projections, we could experience significant unfavorable variances in future periods or revise our projections downward. This would result in an increased risk that that our goodwill and intangible assets may be impaired. If an impairment were recognized, this could have a material impact to our financial condition and results of operations.

We may be unable to successfully develop or commercialize new products 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 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, Ofirmev, Inomax and Therakos immunotherapy products. 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 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.

Certain patents related to the use of therapeutic nitric oxide for treating or preventing bronchoconstriction or reversible pulmonary vasoconstriction expired in 2013. Prior to their expiration, Ikaria, Inc. ("Ikaria") depended, in part, upon these patents to provide it with exclusive marketing rights for its product for some period of time. Ikaria has obtained new patents, which expire at various dates through 2031, on methods of identifying patients at risk of serious adverse events when nitric oxide is administered to patients with particular heart conditions which the FDA has approved for inclusion on the Inomax warning label, and that may have the effect of inhibiting development of competitive generic products.

Extracorporeal photopheresis is autologous immune cell therapy for skin manifestations of CTCL. In the ECP process, blood is drawn from the patient, the leukocytes are separated, and the plasma and red blood cells are immediately returned to the patient. The separated leukocytes are treated with UVADEX followed by UVA radiation in the photopheresis instrument. Patents related to the methoxsalen composition have expired. UVADEX is sold as a sterile solution of 20 mcg/mL in 10 mL amber glass vials and is approved to be used in combination with the Therakos ECP Systems to extracorporeally treat leukocytes. Therakos manufactures two systems, the CELLEX® Photopheresis System ("CELLEX"), which is the only FDA-approved closed ECP system, and the

UVAR XTS® Photopheresis System ("UVAR XTS"). In addition, disposable, sterile kits are supplied to be used with each of the systems. The kits are single use and discarded after a treatment. Certain key patents related to the UVAR XTS system, disposable kit and overall photopheresis method expire in 2020. Key patents related to the CELLEX system, disposable kit and overall photopheresis method expire in 2023. We continue to pursue additional patentable enhancements to the Therakos ECP system. A patent application was filed in 2015 relating to improvements to the CELLEX system, disposable kit and overall photopheresis method, that if approved may offer patent protection through approximately 2035.

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. Such litigation and related matters are described in Note 19 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.

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 DEA is the U.S. 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 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 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 2015, 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 sell a significant amount of our products to a limited number of independent 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 four of our distributors that supply our products to many end user customers, AmerisourceBergen, Cardinal Health, Inc., CuraScript Inc. and McKesson Corporation, each accounted for 10% or more of our total net sales in at least one of the past three fiscal years. 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 nuclear imaging agents. However, our fiscal 2015 and 2014 acquisitions brought a small number of relatively significant products, most notably Acthar and to a lesser extent, Ofirmev and Inomax, that 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 and continue to maintain or increase market volume 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 and Inomax;
- our ability to continue to procure raw materials or finished goods, as applicable, of Acthar, Ofirmev, Inomax and Therakos immunotherapy 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 FTC, 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 payers.

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

While having a contract with a GPO or IDN for a given product can facilitate sales to members of that GPO or IDN, having a contract is no assurance that sales volume of those products will be maintained. GPOs and IDNs increasingly are awarding contracts to multiple suppliers for the same product category. Even when we are the sole contracted supplier of a GPO or IDN for a certain product, members of the GPO or IDN generally are free to purchase from other suppliers.

Furthermore, GPO and IDN contracts typically are terminable without cause upon 60 to 90 days prior notice. Accordingly, 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 also 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 business, financial condition, results of operations and cash flows.

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 payers. The ability of patients to obtain appropriate reimbursement for products and services from these third-party payers 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 payers 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 are 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 payers 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, which has and is 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 NDA 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 the 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 trials except for the multiple sclerosis 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 membranous 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, state 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 may 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. If 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. We are currently experiencing and expect continued increased competition in our Specialty Generics segment, such that we believe fiscal 2016 net sales in this segment will decrease approximately 15% to 20% compared with fiscal 2015 results. 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 reimbursement claims, promotional practices and compliance with laws relating to the manufacturing and sale of controlled substances, such as those relating to the operation of a suspicious order monitoring program. 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, changes in business practices 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 $12.5 million per claim of the first $25 million of a loss in our primary liability policies and purchase an additional $150 million using a combination of umbrella/excess liability

policies. 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 ("USAO") for the Eastern District of Pennsylvania, requesting documents pertaining to an investigation of its promotional practices. Additionally, 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 25, 2015, it was probable that we would incur remedial costs in the range of $39.8 million to $113.1 million. We also concluded that, as of September 25, 2015, the best estimate within this range was $76.5 million. For further information on our environmental obligations, refer to Item 3. Legal Proceedings and Note 19 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.

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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. In addition, in September 2015 the HFR experienced another unscheduled shutdown which is expected to result in higher costs through the duration of the shutdown as we obtain irradiations from alternative sources. We expect this disruption will negatively impact operating income by approximately $10.0 million to $15.0 million during the first quarter of fiscal 2016, but somewhat less impact is expected in future quarters as the reactor is expected to return to full production in the first half of fiscal 2016.

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 may limit the profitability of the Nuclear Imaging segment.

Inomax and ECP are each marketed by us in the U.S. for only one indication. We will not be permitted to market these products in the U.S. for any other indication unless we receive FDA approval for any such indication. If we do not receive approval to market these products for additional uses, our ability to grow revenues may be materially adversely affected.

Inomax is approved for sale in the U.S. only for the treatment of HRF associated with pulmonary hypertension in term and near-term infants, and ECP is approved for sale in the U.S. only for the palliative treatment of the skin manifestations of CTCL in persons who have not been responsive to other forms of treatment. In order to market these products in the U.S. for any other indications, we will need to conduct appropriate clinical trials, obtain positive results from those trials, and obtain regulatory approval for such proposed indications. Obtaining regulatory approval is uncertain, time consuming and expensive. Even well-conducted studies of effective drugs will sometimes appear to be negative in either safety or efficacy results. The regulatory review and approval process to obtain marketing approval for a new indication can take many years, often requires multiple clinical trials and requires the expenditure of substantial resources. This process can vary substantially based on the type, complexity, novelty and indication of the product candidate involved. The FDA and other regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that any data submitted is insufficient for approval and require additional studies or clinical trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a new indication for a product candidate. If we do not receive approval to market these products in the U.S. for additional indications, we will not be permitted to market them for any other indication and our ability to grow revenues may be materially adversely

affected.

A significant portion of our revenues from Inomax and ECP is derived from unapproved uses. We have no control over physicians' use of these products for unapproved uses, we are not permitted to promote or market these products for unapproved uses and we cannot assure you that physicians will continue to prescribe these products for unapproved uses at the same rate, or at all.

The FDA and other foreign regulatory authorities approve drugs and medical devices for the treatment of specific indications, and products may only be promoted or marketed for the indications for which they have been approved. However, the FDA does not attempt to regulate physicians' use of approved products, and physicians are free to prescribe most approved products for purposes outside the indication for which they have been approved. This practice is sometimes referred to as "off-label" use. While physicians are free to prescribe approved products for unapproved uses, it is unlawful for drug and device manufacturers to market

or promote a product for an unapproved use.The laws and regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA and other government agencies. Promotion of a product for unapproved use is prohibited; however, certain activities that we and others in the pharmaceutical industry engage in are permitted by the FDA.

Over the past several years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the Food, Drug and Cosmetic Act, the False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "qui tam" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim, or caused a false claim to be submitted, to the government for payment. The person bringing a "qui tam" suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a qui tam suit, the government must decide whether to intervene and prosecute the case. If the government declines to intervene and prosecute the case, the individual may pursue the case alone.

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses in connection with past or future activities, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions could have an adverse effect on our revenue, business, financial prospects and reputation.

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.

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 25, 2015, we had $6,606.5 million of total debt.

Our degree of debt leverage could have significant consequences, including the following:

- 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;
- 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;
- 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; 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.

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.

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 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 essentially 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, make other distributions with respect to equity interests, or purchase or otherwise acquire or retire 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 or entity.

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 assure you that we will be able to comply.

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 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. If 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 25, 2015, we had $1,978.5 million outstanding variable-rate debt on our senior secured term loans, $500.0 million outstanding on our revolving credit facility and $153.0 million outstanding variable-rate debt on our receivables securitization. An unfavorable movement in interest rates, primarily LIBOR, could result in higher interest expense and cash payments for the Company. Although we may enter into interest rate swaps, involving the exchange of floating for fixed-rate interest payments, to reduce interest rate volatility, we cannot provide assurance that we will enter into such arrangements or

that they will successfully mitigate such interest rate volatility.

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

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

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

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

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

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

Risks Related to Tax Matters

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

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

The IRS ruling and tax opinion rely on certain facts and assumptions, certain representations from Covidien and us regarding the past and future conduct of our respective businesses and other matters, and certain undertakings made by Covidien and us. Notwithstanding the IRS ruling and tax opinion, the IRS could determine on audit that the distribution should be treated as a taxable transaction if it determines that any of these facts, assumptions, representations or undertakings is not correct or has been violated, or that the distribution should be taxable for other reasons, including as a result of a significant change in stock or asset ownership after the distribution, or if the IRS

were to disagree with the conclusions of the tax opinion that are not covered by the IRS ruling. If the distribution is ultimately determined to be taxable, the distribution could be treated as a taxable dividend to shareholders of Mallinckrodt, who acquired their shares through distribution to Covidien shareholders at the Separation date, for U.S. federal income tax purposes, and they could incur significant U.S. federal income tax liability. In addition, Covidien or we could incur significant U.S. federal income tax liabilities or tax indemnification obligations, whether under applicable law or the tax matters agreement ("the Tax Matters Agreement") that we entered into with Covidien, if it is ultimately determined that certain related transactions undertaken in anticipation of the distribution are taxable.

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

Our tax returns are subject to examination by various tax authorities, including the IRS. The IRS is examining our U.S. federal income tax returns for periods during which certain of our subsidiaries and operations were those of Covidien. In addition, the IRS continues to examine the U.S. federal income tax returns of Tyco International Ltd. ("Tyco International") for periods during which certain of our subsidiaries and operations were those of Tyco International. Our potential liability under the Tax Matters Agreement with Covidien for any taxes related to periods prior to the Separation (after taking into account certain tax benefits realized by us), including those which are subject to the provisions of the tax sharing agreement by and among Covidien, Tyco International and TE Connectivity Ltd. ("the Tyco Tax Sharing Agreement"), is anticipated to be approximately $91.0 million, excluding associated tax benefits from such payments, or $65.4 million, net of associated tax benefits, and will be subject to an overall limitation of $200.0 million, net of associated tax benefits. Payments to date qualifying under the overall limitation of $200.0 million are $51.6 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 $200.0 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 February 2015, the President of the United States proposed legislation which would amend the anti-inversion rules. Although its application is limited to transaction closing after 2015, 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 and November 2015 that the agencies intend to issue regulations to reduce the tax benefits of or preclude entirely certain inversion transactions. In the November 2015 notice, the Secretary of the Treasury communicated the intention to explore potential guidance on earnings stripping and take further action in the coming months.

Future changes to U.S. and foreign tax laws could adversely affect us.
The Group of Twenty ("the G20"), the Organization for Economic Co-operation and Development ("the OECD"), the U.S. Congress and Treasury Department 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. 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. 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. In October 2015, the OECD presented the final package of measures for a comprehensive, coherent and co-ordinated reform of the international tax rules.

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 the United Kingdom and other jurisdictions could change in the future, and such changes could cause a material change in our effective tax rate.

The change in our tax residency could have a negative effect on our future profitability and taxes on dividends.

Under current Irish legislation, a company is regarded as resident in Ireland for tax purposes if it is centrally managed and controlled in Ireland, or, in certain circumstances, if it is incorporated in Ireland. Under current U.K. legislation, a company is regarded as resident in the U.K. for tax purposes if it is centrally managed and controlled in the U.K. Where a company is treated as tax resident under the domestic laws of both the U.K. and Ireland then the provisions of article 4(3) of the Double Tax Convention between Ireland and the U.K. provide that such company shall be treated as resident only in the jurisdiction in which its place of effective management is situated. Since May 2015, we have managed, and we intend to continue to manage, the affairs of Mallinckrodt plc so that it is effectively managed and controlled in the U.K. and therefore be treated as resident only in the U.K. for tax purposes, by operation of the Double Taxation Convention. However, we cannot provide assurance that Mallinckrodt plc will continue to be resident only in the U.K. for tax purposes. It is possible that in the future, whether as a result of a change in law or a change in the practice or conduct of the affairs of any relevant tax authority, Mallinckrodt plc could become, or be regarded as having become resident in a jurisdiction other than the U.K. If Mallinckrodt plc were considered to be a tax resident of Ireland, it could become liable for Irish corporation tax and any dividends paid by it could be subject to Irish dividend withholding tax.

Our installment sale arrangements result in a deferral of tax obligations payable to the IRS, which are subject to variable-rate interest rate risk, which could result in higher cost associated with deferring these tax obligation.
As part of the integration of Questcor, the Company entered into an internal installment sale transaction related to certain Acthar intangible assets during the fiscal year ended September 25, 2015. The installment sale transaction resulted in a taxable gain. In accordance with Internal Revenue Code Section 453 the gain is considered taxable in the period in which installment payments are received. The U.S. Internal Revenue Service ("IRS") charges interest based on the deferred tax liability outstanding as of the end of a company's fiscal year, regardless of amounts outstanding during the fiscal year. The interest payable on the deferred tax liability is subject to fluctuations in interest rates, which may increase in future periods. As of September 25, 2015, the Company had an aggregate $1,447.4 million of interest bearing U.S. deferred tax liabilities associated with outstanding installment notes.

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 Act, 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 interest in its 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. Short sellers have recently been 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, among 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 principal executive offices are located at a facility in Chesterfield, United Kingdom. Our U.S. headquarters are located in a facility in Hazelwood, Missouri, which we own. As of September 25, 2015, we owned a total of fifteen facilities in three countries. Four of our owned facilities relate to our CMDS business and are to be sold in our transaction with Guerbet, which is expected to be completed during the first quarter of fiscal year 2016. Our owned facilities consist of approximately 3.1 million square feet, and our leased facilities consist of approximately 1.6 million square feet. CMDS facilities consist of 0.5 million of the total square feet of owned facilities and 0.2 million square feet of leased facilities. We have thirteen manufacturing sites, two of which are used by our Nuclear Imaging segment, seven of which are used by our Specialty Brands and Specialty Generics segments, four of which are used by the CMDS business. We have two manufacturing sites in Canada, one manufacturing site in each of Ireland and the Netherlands and nine 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 19 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 Note 19 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

Our ordinary shares are traded on the New York Stock Exchange ("NYSE") under the ticker symbol "MNK." The following table presents the high and low closing prices of our ordinary shares for the periods indicated, as reported by the NYSE.

	FY2015		FY2014	
	High	Low	High	Low
First Quarter	$99.73	$83.19	$53.47	$42.01
Second Quarter	132.51	93.89	72.81	50.70
Third Quarter	130.13	113.18	82.70	60.28
Fourth Quarter	126.51	68.45	90.00	68.12

There were approximately 3,166 shareholders of record of our ordinary shares as of November 16, 2015.

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.

During the quarter ended September 25, 2015, we repurchased 839,964 of our ordinary shares related to both our $300.0 million share repurchase program, announced on January 23, 2015, and the satisfaction of 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	Maximum Approximate Dollar Value of Shares that May Yet Be Purchased Under The Plans or Programs
6/27/2015 - 7/24/2015	7,584	$118.00	—	$300.0
7/25/2015 - 8/28/2015	589,678	93.48	588,361	245.0
8/29/2015 - 9/25/2015	242,702	85.74	235,231	225.0
6/27/2015 - 9/25/2015	839,964	91.46		

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 25, 2015.

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
September 27, 2013	96.82	104.02	100.18
September 26, 2014	200.00	121.42	124.26
September 25, 2015	152.11	118.54	122.72

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 25, 2015.

Item 6. Selected Financial Data.

The following table sets forth selected financial data as of and for the fiscal years ended September 25, 2015, September 26, 2014, September 27, 2013, September 28, 2012 and September 30, 2011. 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 2015 and 2014, the consolidated and combined statement of income data for fiscal 2013, and the consolidated balance sheet data as of September 25, 2015 and September 26, 2014 were derived from our consolidated and combined financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K. The September 27, 2013 and September 28, 2012 balance sheets were derived from our audited combined financial statements that are not included in this Annual Report on Form 10-K. In fiscal 2015, the Company announced that it had entered into a definitive agreement to sell its CMDS business to Guerbet. Accordingly, the combined statement of income data for fiscal 2012 and 2011 and balance sheet as of September 30, 2011 are derived from our unaudited consolidated financial statements that are not included in this annual report, as amounts have been recast to reflect the CMDS business as a discontinued operation.

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]				
	2015	2014	2013	2012	2011
Consolidated and Combined Statement of Income Data:					
Net sales	$3,346.9	$ 2,082.0	$ 1,712.3	$ 1,533.0	$1,423.7
Gross profit	1,853.6	1,060.2	822.3	718.9	663.0
Research and development expenses [2]	185.1	163.5	157.9	138.4	134.7
Operating income (loss) [3] [4]	461.8	(75.9)	73.5	122.8	130.7
Income (loss) from continuing operations before income taxes	215.3	(153.9)	55.7	123.7	133.2
Income (loss) from continuing operations	308.2	(143.8)	8.2	58.5	71.4
Share Data [5]:					
Basic income (loss) from continuing operations per share	$2.64	$ (2.22)	$ 0.14	$ 1.01	$1.24
Diluted income (loss) from continuing operations per share	2.61	(2.22)	0.14	1.01	1.24
Cash dividends per ordinary share	—	—	—	—	—
	September 25, 2015	September 26, 2014	September 27, 2013	September 28, 2012	September 30, 2011
Consolidated and Combined Balance Sheet Data:					
Total assets	$16,404.1	$ 12,787.3	$ 3,556.6	$ 2,898.9	$2,832.2
Long-term debt	6,474.3	3,874.0	918.3	8.9	10.4

Shareholders' equity	5,311.2	4,958.0	1,255.6	1,891.9	1,788.7

(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 2015, 2014, 2013, 2012, and 2011 include restructuring charges, net, of $40.4 million, $81.4 million, $23.7 million, $8.4 million and $11.5 million, respectively. Fiscal 2015 includes $86.3 million of environmental and legal charges, $80.6 million of incremental equity costs associated with the Questcor Acquisition and $53.4 million of transaction costs associated with the Ikaria Acquisition and the Therakos Acquisition. Fiscal 2014 includes $151.6 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 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.

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

(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 nuclear imaging business that develops, manufactures, markets and distributes specialty pharmaceutical and biopharmaceutical products and nuclear imaging agents. Therapeutic areas of focus include autoimmune and rare disease specialty areas (including neurology, rheumatology, nephrology and pulmonology); immunotherapy and neonatal respiratory critical care therapies; and central nervous system drugs. The Company also supports the diagnosis of disease with nuclear medicine imaging agents. The Company believes its 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 it anticipates will sustain future revenue growth.

During the first quarter of fiscal 2015, the Company changed its reportable segments to present the Specialty Brands and Specialty Generics businesses as reportable segments. The Company historically presented the Specialty Brands and Specialty Generics businesses within the Specialty Pharmaceuticals segment.

During the fourth quarter of fiscal 2015, the Company announced that it had entered into a definitive agreement to sell its CMDS business to Guerbet, which is expected to be completed during the first quarter of fiscal 2016. The CMDS business is deemed to be held for sale and the financial results of this business are presented as a discontinued operation. The CMDS business has been eliminated from the Global Medical Imaging segment, which was renamed Nuclear Imaging.

Prior year amounts have been recast to conform to current presentation.

The three reportable segments are further described below:

- Specialty Brands produces and markets branded pharmaceuticals and biopharmaceuticals;
- Specialty Generics produces specialty generic pharmaceuticals and API consisting of biologics, medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients; and
- Nuclear Imaging manufactures and markets 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. 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.

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 are 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 in fiscal 2013. 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 were 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 were rendered may not have been as favorable as those allocated to us by Covidien. The Company terminated the transition services agreement during the first quarter of fiscal 2015.

Acquisitions

On September 25, 2015, we acquired Therakos through the acquisition of all the outstanding common stock of TGG Medical Solutions, Inc., the parent holding company of Therakos, in a transaction valued at approximately $1.3 billion, net of cash acquired ("the Therakos Acquisition"). Consideration for the transaction consisted of approximately $1.0 billion in cash paid to TGG Medical Solutions, Inc. shareholders and the assumption of approximately $0.3 billion of Therakos third-party debt, which was repaid in conjunction with the Therakos Acquisition. The acquisition and immediate repayment of debt was funded through the issuance of $750.0 million aggregate principal amount of senior unsecured notes, a $500.0 million borrowing under our revolving credit facility and cash on hand. Therakos' primary immunotherapy products relate to the administering of extracorporeal photopheresis therapies through their UVAR XTS® and CELLEX.

In April 2015, we acquired Ikaria through the acquisition of all the outstanding common stock of Compound Holdings II, Inc., the parent holding company of Ikaria, in a transaction valued at approximately $2.3 billion, net of cash acquired ("the Ikaria Acquisition"). Consideration for the transaction consisted of approximately $1.2 billion in cash paid to Compound Holdings II, Inc. shareholders and the assumption of approximately $1.1 billion of Ikaria third-party debt, which was repaid in conjunction with the Ikaria Acquisition. The acquisition and immediate repayment of debt was funded through the issuance of $1.4 billion aggregate principal amount of senior unsecured notes, a $240.0 million borrowing under a revolving credit facility, which was subsequently repaid following the transaction, and cash on hand. Ikaria's primary product is Inomax, a vital treatment option in neonatal critical care.

In August 2014, we acquired Questcor, a biopharmaceutical company, for total consideration of approximately $5.9 billion ("the Questcor Acquisition"). The acquisition was funded through the 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's primary product, Acthar, is focused on the treatment of patients with serious, difficult-to-treat autoimmune and rare diseases. Acthar is an injectable drug that is approved by the FDA for use in 19 indications, including the areas of neurology, rheumatology, nephrology and pulmonology. As part of the acquisition, we also acquired BioVectra, Inc. ("BioVectra"), a specialty contract manufacturer that provides services to the global pharmaceuticals and biotechnology industry.

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 Cadence Acquisition"). The acquisition was primarily funded through a $1.3 billion senior secured term loan credit facility. Cadence's sole product, 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 Brands product portfolio and provided us the opportunity to expand our reach into the hospital market, in which Cadence had an established presence.

License of Intellectual Property

We were involved in patent disputes with a counterparty relating to certain intellectual property related 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 the fourth quarter of fiscal 2015, we announced that we entered into a definitive agreement to sell our global CMDS business to Guerbet, which is expected to be completed during the first quarter of fiscal 2016. The CMDS business is deemed to be held for sale and the financial results of this business are presented as a discontinued operation. The CMDS business has been eliminated from the Global Medical Imaging segment, which was renamed Nuclear Imaging.

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 $92.3 million, $56.3 million, and $49.8 million in fiscal 2015, 2014 and 2013, 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. Through fiscal 2015, $10.0 million of milestone payments had been made.

For Exalgo, we may be obligated to make payments of up to $73.0 million based on the successful completion of specified development and regulatory milestones. Through fiscal 2015, $65.0 million of these payments had 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 was capitalized 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 2015, approximately $22.0 million of these payments had been made. During fiscal 2014, upon approval by the FDA of Xartemis XR, we made a milestone payment of $10.0 million, which was capitalized as an intangible asset.

In 2009, we entered into a licensing agreement with Nuvo 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. We paid $15.0 million of these payments, all of which were capitalized as an intangible asset as the payment related to the fiscal 2010 FDA approval of the Pennsaid NDA. 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 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 an 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.

In September 2015, the HFR experienced another unscheduled shutdown. We expect this disruption will have minimal impact to patients as we intend to obtain target irradiations from other reactors to meet patient needs. Similar to prior periods, the shutdown is expected to result in higher costs as we obtain irradiations from alternative sources. We expect this disruption will negatively impact operating income by approximately $10.0 million to $15.0 million during the first quarter of fiscal 2016, but somewhat less impact is expected in future quarters as the reactor is expected to return to full production in the first half of fiscal 2016. Our Mo-99 processing facility continues to operate as scheduled. Ongoing increased raw material and manufacturing costs may limit the profitability of the Nuclear Imaging segment.

Lower Passaic River Environmental Reserve

In April 2014, the 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 estimated the cost for the alternatives to 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 the estimate of our allocable share of the joint and several remediation liability resulting from this matter.

In April 2015, the Lower Passaic Cooperating Parties Group ("CPG") presented a draft of the remedial investigation and feasibility study ("RI/FS") of the River to the EPA. The CPG's RI/FS included alternatives that ranged from "no action," targeted remediation of the entire 17-mile stretch of the River to remedial actions consistent with the EPA's preferred approach for the lower 8-

mile stretch of the River and also included remediation alternatives for the upper 9-mile stretch of the River. The discounted cost estimates for the CPG remediation alternatives ranged from $483.4 million to $2.7 billion. We recorded an additional charge of $13.3 million in the second quarter of fiscal 2015 based on our estimate of our allocable share of the joint and several remediation liability resulting from this matter.

Despite the issuance of the revised FFS by the EPA and the RI/FS by the CPG, there are many uncertainties associated with the final agreed-upon remediation and our allocable share of the remediation. As of November 20, 2015, the Company withdrew from the CPG, but remains liable for its obligations under the two above-referenced AOCs, as well as potential future liabilities. Given those uncertainties, the amounts accrued may not be indicative of the amounts for which the Company may be ultimately responsible and will be refined as events in the remediation process occur.

Business Factors Influencing the Results of Operations

Products

As a result of acquisitions in fiscal 2015 and 2014, we obtained the sales and marketing rights to Inomax on April 16, 2015; Acthar on August 14, 2014; and Ofirmev on March 19, 2014. The addition of these products to our Specialty Brands product portfolio provided us with three products that significantly contributed to the net sales and operating income within this segment. Net sales of these products were $1,485.5 million during the fiscal year ended September 25, 2015 compared with $247.3 million in the fiscal year ended September 26, 2014. Our cost of sales for fiscal 2015 and 2014 included $44.1 million and $25.7 million, respectively, of expense recognition associated with the fair value adjustments of acquired inventory and $515.0 million and $120.3 million, respectively, of amortization associated with intangibles recognized from these acquisitions. Additionally, we expensed $53.4 million and $65.1 million of transaction costs, respectfully, in fiscal 2015 and 2014 associated with our transactions, including the Therakos acquisition on September 25, 2015, which are reflected in SG&A in our consolidated statement of income.

In December 2012, we received approval from the FDA to manufacture Methylphenidate ER. In July 2013, a competitor received FDA approval to manufacture Methylphenidate ER and entered the marketplace. In November 2014, we were informed by the FDA that it believes that our Methylphenidate ER products may not be therapeutically equivalent to the category reference listed drug and 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. We continue to market our Methylphenidate ER products as a class BX-rated drug. The FDA's action to reclassify our Methylphenidate ER products had, and is expected to continue to have a negative impact on net sales and operating income unless the FDA reverses its decision. Net sales of Methylphenidate ER were $136.5 million, $209.6 million and $148.3 million in fiscal 2015, 2014 and 2013, respectively.

In May 2014, we launched an authorized generic version of Exalgo, and subsequently additional competitors entered the market. Net sales of Exalgo were $39.4 million, $76.1 million and $126.1 million in fiscal 2015, 2014 and 2013, respectively. Net sales across the branded and authorized generic products during fiscal 2015 were less than those of the branded products during fiscal 2014.

Restructuring Initiatives

We continue to realign our cost structure due to the changing nature of our business and look for opportunities to achieve operating efficiencies. In July 2013 our board of directors approved a restructuring program in the amount of $100.0 million to $125.0 million ("the 2013 Mallinckrodt Program") that was planned to occur over a three-year period from the approval of the program, with a two-year cost recovery period. Through September 25, 2015, we incurred restructuring charges of $96.9 million under the 2013 Mallinckrodt Program, which have and are expected to continue to generate savings, substantially within our SG&A expenses. In addition to the 2013 Mallinckrodt Program, we have taken restructuring actions to generate synergies from our acquisitions.

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Results of Operations
Fiscal Year Ended September 25, 2015 Compared with Fiscal Year Ended September 26, 2014

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

	Fiscal Year			
	2015	2014	Percentage Change	
U.S.	$2,973.2	$1,780.9	66.9	%
Europe, Middle East and Africa	236.2	250.3	(5.6	)
Other	137.5	50.8	170.7	
Net sales	$3,346.9	$2,082.0	60.8	

Net sales in fiscal 2015 increased $1,264.9 million, or 60.8%, to $3,346.9 million, compared with $2,082.0 million in fiscal 2014. This increase was primarily attributable to the inclusion of a full year of net sales of Acthar and Ofirmev, following their acquisition in fiscal 2014, and the April 2015 acquisition of Inomax. Specialty Generics net sales increased due to higher net sales of hydrocodone-related products and the inclusion of a full year of net sales from BioVectra, partially offset by decreased net sales of Methylphenidate ER. Net sales in the Nuclear Imaging segment decreased slightly from fiscal 2014. 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 2015 increased $793.4 million, or 74.8%, to $1,853.6 million, compared with $1,060.2 million in fiscal 2014. The increase in gross profit primarily resulted from increased net sales from Acthar, Ofirmev and Inomax. These increases were partially offset by a $390.2 million increase in amortization, primarily associated with Acthar, Ofirmev and Inomax intangibles, and an $18.4 million increase of expense recognition associated with fair value adjustments of inventory acquired, primarily related to Acthar and Inomax. Gross profit in the Nuclear Imaging segment increased $48.7 million from fiscal 2014, when the segment experienced unscheduled shutdowns of our Mo-99 processing facility and the HFR that supplies us with Mo-99. Overall, gross profit margin was 55.4% during fiscal 2015, compared with 50.9% during fiscal 2014.
Selling, general and administrative expenses. SG&A expenses for fiscal 2015 were $1,169.8 million, compared with $745.0 million for fiscal 2014, an increase of $424.8 million, or 57.0%. The increase primarily resulted from the addition of $377.1 million of costs associated with our fiscal 2015 and 2014 acquisitions, $73.0 million in legal charges related to Questcor shareholder litigation, DEA investigative matters and Synacthen related litigation and a $67.6 million increase in share-based compensation associated with Questcor unvested equity awards that were converted into Mallinckrodt awards at the date of the Questcor Acquisition. These factors, were partially offset by an $11.5 million legal settlement related to Ofirmev during fiscal 2014, $15.0 million in other legal settlements in fiscal 2014, a $9.8 million decrease in environmental charges related to the Lower Passaic River environmental reserve and an $11.7 million decrease in transaction costs. The remaining decrease in SG&A expenses was primarily attributable to benefits from restructuring actions. SG&A expenses were 35.0% of net sales for fiscal 2015 and 35.8% of net sales for fiscal 2014.
Research and development expenses. R&D expenses increased $21.6 million, or 13.2%, to $185.1 million in fiscal 2015, compared with $163.5 million in fiscal 2014. Current R&D activities focus on performing clinical studies and publishing clinical and non-clinical experiences and evidence that support health economic and patient outcomes. As a percentage of our net sales, R&D expenses were 5.5% and 7.9% in fiscal 2015 and 2014, respectively.
Separation costs. During fiscal 2014, we incurred separation costs of $9.6 million, primarily related to our transition services agreement with our former parent, our costs to implement information and accounting systems, and share-based compensation related to the conversion of equity awards associated with the separation from our former

parent.

Restructuring and related charges, net. During fiscal 2015, we recorded $40.7 million of restructuring and related charges, net, of which $0.3 million related to accelerated depreciation and was included in cost of sales. The remaining $40.4 million primarily related to $9.8 million of accelerated share-based compensation associated with Questcor unvested equity awards that were converted into Mallinckrodt awards at the date of the Questcor Acquisition and employee severance and benefits within the

Specialty Brands and Specialty Generics segments. During fiscal 2014, we recorded restructuring and related charges, net of $81.9 million, of which $0.5 million related to accelerated depreciation and was included in cost of sales. The remaining $81.4 million primarily related to $35.1 million of accelerated share-based compensation associated with Questcor employees, employee severance and benefits incurred across all our segments, and a $2.3 million asset impairment.

Non-restructuring impairment charges. During fiscal 2014, we recorded $151.6 million of non-restructuring impairment charges. The charges consisted of $119.5 million associated with impairment of goodwill in the Nuclear Imaging segment, $19.2 million of property, plant & equipment, and intangible asset impairments of $12.8 million, which primarily relate to the impairment of Pennsaid intangibles upon the return of our product rights to Nuvo as part of a legal settlement.

Gain on divestiture and license. During fiscal 2015 and 2014, we recorded gains on divestiture and license of $3.5 million and $15.0 million, respectively. The $15.0 million gain recorded during fiscal 2014 primarily resulted from an $11.7 million gain from the license of extended-release oxymorphone intellectual property to a third-party. The remaining gain in both periods primarily related to the sale of the rights to market TussiCaps™ extended-release capsules in fiscal 2011.

Non-Operating Items

Interest expense and interest income. During fiscal 2015 and fiscal 2014, net interest expense was $254.6 million and $81.1 million, respectively. The increase in net interest expense was primarily related to the issuance of approximately $1.3 billion of debt associated with the Cadence Acquisition, approximately $1.8 billion of debt associated with the Questcor Acquisition, approximately $1.4 billion of debt associated with the Ikaria Acquisition, approximately $1.3 billion of debt associated with the Therakos Acquisition and $36.5 million of interest accrued on deferred tax liabilities associated with outstanding installment notes. Interest expense during fiscal 2015 and 2014 included $23.4 million and $7.7 million, respectively, of non-cash interest expense.

Other income, net. During fiscal 2015 and 2014, we recorded other income, net of $8.1 million and $3.1 million, respectively, which represents miscellaneous items, including gains and losses on foreign currency intercompany financing transactions and related hedging instruments.

Provision for (benefit from) income taxes. In fiscal 2015, we recognized an income tax benefit of $92.9 million on income from continuing operations before income taxes of $215.3 million. In fiscal 2014, income tax benefit was $10.1 million on a loss from continuing operations before income taxes of $153.9 million. Our effective tax rate was negative 43.1% compared with 6.6% for fiscal 2015 and 2014, respectively. Our effective tax rate for fiscal 2015 was impacted by receiving a $10.4 million tax benefit on $53.4 million of transaction costs, $14.1 million of tax benefit associated with $40.7 million of restructuring costs, $6.6 million of tax benefit associated with accrued income tax liabilities and uncertain tax positions, $8.1 million of tax benefit associated with U.S. credits, and $138.6 million of tax benefit associated with the rate difference between U.K. and non-U.K. jurisdictions. Our effective tax rate for fiscal 2014 was impacted by receiving a $17.4 million tax benefit on $74.7 million of transaction and Separation costs, $25.3 million of tax benefit associated with $81.9 million of restructuring costs, $9.4 million of tax benefit associated with accrued income tax liabilities and uncertain tax positions, $4.1 million of tax benefit associated with the U.S. Domestic manufacturing deduction, $20.0 million of tax expense associated with an adjustment to the Company's wholly owned partnership investment, $6.8 million of tax benefit associated with the $138.5 million impairment of tangible and intangible assets and goodwill, and $3.5 million of tax benefit associated with the rate difference between U.S. and non-U.S. jurisdictions (excluding impact of above referenced impairments).

Income (loss) from discontinued operations, net of income taxes. We recorded income of $16.5 million and a loss of $175.5 million on discontinued operations, net of income taxes, during fiscal 2015 and 2014, respectively. The income in fiscal 2015 primarily related to the expiration of a $22.5 million tax indemnification obligation associated with a business that was originally disposed of in fiscal 1997 and a $5.9 million loss from our CMDS business which is classified as held for sale. Fiscal 2014 primarily reflects a $174.8 million loss from our CMDS business, primarily related to $204.0 million of goodwill, intangible and property, plant and equipment impairment charges and $47.2

million of restructuring charges. The remaining amounts, in both periods, were related to indemnification obligations provided to the purchaser of our Specialty Chemicals business (formerly known as Mallinckrodt Baker), which was sold during fiscal 2010.

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.	$1,780.9	$1,421.6	25.3	%
Europe, Middle East and Africa	250.3	250.1	0.1	
Other	50.8	40.6	25.1	
Net sales	$2,082.0	$1,712.3	21.6	

Net sales in fiscal 2014 increased $369.7 million, or 21.6%, to $2,082.0 million, compared with $1,712.3 million in fiscal 2013. This increase was primarily attributable to increased net sales in our Specialty Generics segment, driven by strategic initiatives on certain specialty controlled substance generics and increased Methylphenidate ER net sales. Specialty Brands net sales also contributed to the increase due to net sales of the fiscal 2014 acquisitions of Acthar and Ofirmev. These increases were partially offset by a decrease in Nuclear Imaging net sales. For further information on changes in our net sales, refer to "Business Segment Results" within this Item 7.

Operating Income

Gross profit. Gross profit for fiscal 2014 increased $237.9 million, or 28.9%, to $1,060.2 million, compared with $822.3 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 Brands 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 Nuclear Imaging segment, including the unscheduled shutdowns of our Mo-99 processing facility and the HFR that supplies us with Mo-99. Overall, gross profit margin was 50.9% in fiscal 2014, compared with 48.0% in fiscal 2013. The fiscal 2014 profit margin includes the increased amortization and expense recognition of inventory fair value adjustments.

Selling, general and administrative expenses. SG&A expenses for fiscal 2014 were $745.0 million, compared with $495.9 million for fiscal 2013, an increase of $249.1 million, or 50.2%. 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 SG&A 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, SG&A 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. SG&A expenses were 35.8% of net sales for fiscal 2014 and 29.0% of net sales for fiscal 2013.

Research and development expenses. R&D expenses increased $5.6 million, or 3.5%, to $163.5 million in fiscal 2014, compared with $157.9 million in fiscal 2013. As products, such as Xartemis XR, Pennsaid 2% and MNK-155, moved toward or through the FDA review process, we devoted additional resources to other potential products in our R&D pipeline and the pursuit of abuse-deterrent labeling for Xartemis XR. As a percentage of our net sales, R&D expenses were 7.9% and 9.2% fiscal 2014 and 2013, respectively.

Separation costs. During fiscal 2014 and 2013, we incurred separation costs of $9.6 million and $74.2 million, respectively, primarily related to legal, accounting, tax and other professional fees. Separation costs were higher in

fiscal 2013 as we approached and completed the Separation on June 28, 2013. We continued to incur costs related to the Separation as a result of our transition services agreement with Covidien, our costs to implement information and accounting systems, share-based compensation related to the conversion of Covidien awards to Mallinckrodt awards, and other transitional costs.

Restructuring and related charges, net. During fiscal 2014, we recorded restructuring and related charges, net of $81.9 million, of which $0.5 million related to accelerated depreciation and was included in cost of sales. The remaining $81.4 million primarily

related to $35.1 million of accelerated share-based compensation associated with Questcor employees, severance and benefits incurred across all our segments, and a $2.3 million asset impairment. During fiscal 2013, we recorded restructuring and related charges, net of $26.3 million, of which $2.6 million related to accelerated depreciation and was included in cost of sales. The remaining $23.7 million primarily related to severance and employee benefit costs incurred across all our segments.

Non-restructuring impairment charges. During fiscal 2014, we recorded $151.6 million of non-restructuring impairment charges. The charges consisted of $119.5 million associated with impairment of goodwill in the Nuclear Imaging segment, $19.2 million of property, plant & equipment, and intangible asset impairments of $12.8 million, which primarily relate to the impairment of Pennsaid intangibles upon the return of our product rights to Nuvo as part of a legal settlement.

Gain on divestitures. During fiscal 2014 and 2013, we recorded gains on divestiture and license of $15.0 million and $2.9 million, respectively. The $15.0 million gain recorded during fiscal 2014 primarily resulted from an $11.7 million gain from the license of extended-release oxymorphone intellectual property to a third-party.

Non-Operating Items

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

Other income, net. During fiscal 2014 and 2013, we recorded other income, net, of $3.1 million and $1.4 million, respectively, which represents miscellaneous items, including gains and losses on foreign currency intercompany financing transactions and related hedging instruments.

Provision for (benefit from) income taxes. In fiscal 2014, we recognized an income tax benefit of $10.1 million on a loss from continuing operations before income taxes of $153.9 million. In fiscal 2013, income tax expense was $47.5 million on income from continuing operations before income taxes of $55.7 million. Our effective tax rate was 6.6% compared with 85.3% for fiscal 2014 and 2013, respectively. Our effective tax rate for fiscal 2014 was impacted by receiving a $17.4 million tax benefit on $74.7 million of transaction and Separation costs, $25.3 million of tax benefit associated with $81.9 million of restructuring costs, $9.4 million of tax benefit associated with accrued income tax liabilities and uncertain tax positions, $4.1 million of tax benefit associated with the U.S. Domestic manufacturing deduction, $20.0 million of tax expense associated with an adjustment to the Company’s wholly owned partnership investment, $6.8 million of tax benefit associated with the $138.5 million impairment of tangible and intangible assets and goodwill, and $3.5 million of tax benefit associated with the rate difference between U.S. and non-U.S. jurisdictions (excluding impact of above referenced impairments). Our effective tax rate for fiscal 2013 was impacted by receiving a $4.2 million tax benefit on $74.2 million of separation costs due to the tax-free status of the Separation, $9.7 million of tax expense associated with uncertain tax positions, $2.5 million of tax benefit associated with the U.S. Domestic manufacturing deduction, and $3.3 million of tax expense associated with the rate difference between U.S. and non-U.S. jurisdictions, which includes the benefit of intercompany debt transferred to the Company at the Separation.

Income (loss) from discontinued operations, net of income taxes. We recorded a loss of $175.5 million and income of $50.6 million from discontinued operations, net of income taxes, during fiscal 2014 and 2013, respectively. Fiscal 2014 reflected a $174.8 million loss from our CMDS business, primarily related to $204.0 million of goodwill, intangible and property, plant and equipment impairment charges and $47.2 million of restructuring charges. Fiscal 2013 reflected $49.6 million of income from our CMDS business. The remaining amounts in each period related to indemnification obligations to the purchaser of our Specialty Chemicals business (formerly known as Mallinckrodt Baker), which was sold during fiscal 2010.

Business Segment Results

The businesses included within our reportable segments are described below:

- Specialty Brands includes biopharmaceutical drugs for autoimmune and rare diseases and pharmaceutical drugs for immunotherapy and neonatal respiratory critical care, and central nervous system drugs.
- Specialty Generics produces specialty generic pharmaceuticals and API consisting of biologics, medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients.

- Nuclear Imaging
manufactures and markets radioactive isotopes and associated pharmaceuticals used for the diagnosis and treatment of disease.

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

Fiscal Year Ended September 25, 2015 Compared with Fiscal Year Ended September 26, 2014

Net Sales

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

	Fiscal Year			
	2015	2014	Percentage Change	
Specialty Brands	$1,622.8	$413.5	292.5	%
Specialty Generics	1,251.6	1,199.4	4.4	
Nuclear Imaging	423.8	431.7	(1.8	)
Net sales of operating segments	3,298.2	2,044.6	61.3	
Other [(1)]	48.7	37.4	30.2	
Net sales	$3,346.9	$2,082.0	60.8	

(1) Represents historical CMDS-related intercompany transactions that represent Mallinckrodt continuing operations under an ongoing supply agreement with the acquirer of the CMDS business.

Specialty Brands. Net sales for fiscal 2015 increased $1,209.3 million, or 292.5%, to $1,622.8 million, compared with $413.5 million for fiscal 2014. The increase in net sales was primarily driven by the inclusion of a full year of net sales of Acthar and Ofirmev, following their acquisition in fiscal 2014, which increased net sales by $914.4 million and $138.6 million, respectively. The April 2015 acquisition of Inomax further increased net sales by $185.2 million. These factors were partially offset by a $36.7 million decline in net sales from branded Exalgo products following the loss of exclusivity in May 2014.

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

	Fiscal Year			
	2015	2014	Percentage Change	
U.S.	$1,610.3	$413.1	289.8	%
Europe, Middle East and Africa	9.9	0.4	2,375.0	
Other	2.6	—	—	
Net sales	$1,622.8	$413.5	292.5	

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

	Fiscal Year			
	2015	2014	Percentage Change	
Acthar	$1,037.3	$122.9	744.0	%
Ofirmev	263.0	124.4	111.4	
Inomax	185.2	—	—	
Exalgo	39.4	76.1	(48.2	)
Other	97.9	90.1	8.7	
Specialty Brands	$1,622.8	$413.5	292.5	

Specialty Generics. Net sales for fiscal 2015 increased $52.2 million, or 4.4%, to $1,251.6 million, compared with $1,199.4 million for fiscal 2014. The increase in net sales was primarily driven by a $67.8 million increase in net sales of hydrocodone-related products and $72.5 million from the acquisition of BioVectra in August 2014. These increases were partially offset by a $73.1 million decrease in Methylphenidate ER and a $12.3 million decrease in other controlled substances. The increase in net sales of hydrocodone-related products was related to the conversion from Schedule III to Schedule II by the DEA in October 2014. Net sales of oxycodone-related products reflect the implementation of strategic initiatives during fiscal 2014, which also resulted in $24.4 million of payments during fiscal 2014 as a consequence of these initiatives. The decrease in Methylphenidate ER net sales was primarily attributable to the reclassification of these products by the FDA to therapeutically inequivalent status. Net sales in the Specialty Generics segment are expected to decrease approximately 15% to 20% in fiscal 2016 due to increased competition and market pricing pressures.

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

	Fiscal Year			
	2015	2014	Percentage Change	
U.S.	$1,036.7	$1,071.9	(3.3	)%
Europe, Middle East and Africa	100.5	103.0	(2.4	)
Other	114.4	24.5	366.9	
Net sales	$1,251.6	$1,199.4	4.4	

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

	Fiscal Year			
	2015	2014	Percentage Change	
Hydrocodone (API) and hydrocodone-containing tablets	$167.2	$99.4	68.2	%
Oxycodone (API) and oxycodone-containing tablets	154.6	155.2	(0.4	)
Methylphenidate ER	136.5	209.6	(34.9	)
Other controlled substances	572.2	584.5	(2.1	)
Other	221.1	150.7	46.7	
Specialty Generics	$1,251.6	$1,199.4	4.4	

Nuclear Imaging. Net sales for fiscal 2015 decreased $7.9 million, or 1.8%, to $423.8 million compared with $431.7 million for fiscal 2014. The decrease was primarily driven by a $22.8 million unfavorable impact from exchange rates, particularly by changes in the Euro and Canadian Dollar.

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

	Fiscal Year		
	2015	2014	Percentage Change
U.S.	$277.5	$258.5	7.4 %
Europe, Middle East and Africa	125.8	146.9	(14.4)
Other	20.5	26.3	(22.1)
Net sales	$423.8	$431.7	(1.8)

Operating Income

Operating income by segment and as a percentage of segment net sales for fiscal 2015 and 2014 is shown in the following table (dollars in millions):

	Fiscal Year					
	2015			2014		
Specialty Brands	$651.3	40.1	%	$(50.6)	(12.2)	%
Specialty Generics	622.0	49.7		617.4	51.5	
Nuclear Imaging	66.4	15.7		(16.7)	(3.9)	
Segment operating income	1,339.7	40.6		550.1	26.9	
Unallocated amounts:						
Corporate and allocated expenses	(286.9)			(228.1)		
Intangible asset amortization	(550.3)			(154.8)		
Restructuring and related charges, net [(1)]	(40.7)			(81.9)		
Non-restructuring impairment charges	—			(151.6)		
Separation costs	—			(9.6)		
Total operating income (loss)	$461.8			$(75.9)		

(1) Includes restructuring-related accelerated depreciation.

Specialty Brands. Operating income for fiscal 2015 increased $701.9 million to $651.3 million, compared with a $50.6 million loss for fiscal 2014. Our operating margin increased to 40.1% for fiscal 2015, compared with negative 12.2% for fiscal 2014. The increase in operating income and margin was impacted by the $1,209.3 million increase in net sales, primarily attributable to the timing of acquisitions of Acthar, Ofirmev and Inomax. These higher net sales were partially offset by a $309.4 million increase in selling, general and administrative costs primarily associated with these acquisitions, a $67.6 million increase in share-based compensation expense associated with Questcor unvested equity awards that were converted into Mallinckrodt awards at the date of the Questcor Acquisition, and a $28.4 million increase in research and development. The operating loss for fiscal 2014 reflected selling and marketing expenses incurred principally to support Xartemis XR.

Specialty Generics. Operating income for fiscal 2015 increased $4.6 million to $622.0 million, compared with $617.4 million for fiscal 2014. Our operating margin decreased to 49.7% for fiscal 2015, compared with 51.5% for fiscal 2014. The increase in operating income was impacted by the higher gross profit from the $52.2 million increase in net sales partially offset by an $11.7 million gain in fiscal 2014 from the license of extended-release oxymorphone intellectual property. The decrease in the operating margin was primarily attributable to lower net sales of high-margin Methylphenidate ER in fiscal 2015.

Nuclear Imaging. Operating income for fiscal 2015 increased $83.1 million to $66.4 million, compared with a $16.7 million loss in fiscal 2014. Our operating margin increased to 15.7% for fiscal 2015, compared with negative 3.9% for fiscal 2014. The increase in operating income and margin was primarily attributable to a $48.7 million increase in gross profit, despite lower net sales, due to higher costs in fiscal 2014 from the unscheduled shutdown of our Mo-99 processing facility and the HFR that supplies our Mo-99. In addition, there was a $26.0 million decrease in selling, general and administrative costs primarily due to benefits from restructuring actions. We expect that another

unscheduled HFR shutdown, commencing in September 2015, will negatively impact operating income by approximately $10.0 million to $15.0 million during the first quarter of fiscal 2016 and a lesser impact during the second quarter of fiscal 2016.

Corporate and allocated expenses. Corporate and allocated expenses were $286.9 million and $228.1 million for fiscal 2015 and 2014, respectively. Fiscal 2015 included $73.0 million in legal charges related to Questcor shareholder litigation, DEA

investigation matters and Synacthen related litigation, a $13.3 million environmental remediation charge and $53.4 million of transaction costs associated with the Ikaria and Therakos acquisitions. Fiscal 2014 included a $23.1 million environmental remediation charge, an $11.5 million settlement agreement accrual and $65.1 million in transaction costs primarily related to the Questcor and Cadence acquisitions. The remaining increase was primarily attributable to higher professional fees associated with strategic initiatives.

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

Net Sales

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

	Fiscal Year			
	2014	2013	Percentage Change	
Specialty Brands	$413.5	$206.4	100.3	%
Specialty Generics	1,199.4	1,011.2	18.6	
Nuclear Imaging	431.7	437.6	(1.3	)
Net sales of operating segments	2,044.6	1,655.2	23.5	
Other [(1)]	37.4	57.1	(34.5	)
Net sales	$2,082.0	$1,712.3	21.6	

(1) Represents historical CMDS-related intercompany transactions that represent Mallinckrodt continuing operations under an ongoing supply agreement with the acquirer of the CMDS business.

Specialty Brands. Net sales for fiscal 2014 increased $207.1 million, or 100.3%, to $413.5 million, compared with $206.4 million for fiscal 2013. The increase in net sales was primarily driven by $124.4 million of net sales of Ofirmev and $122.9 million of net sales from Acthar. These increases were partially offset by a $50.0 million decrease in net sales for branded Exalgo as we launched an authorized generic version and a competitor entered the market.

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

	Fiscal Year			
	2014	2013	Percentage Change	
U.S.	$413.1	$206.4	100.1	%
Europe, Middle East and Africa	0.4	—	—	
Other	—	—	—	
Net sales	$413.5	$206.4	100.3	

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

	Fiscal Year			
	2014	2013	Percentage Change	
Acthar	$122.9	$—	—	%
Ofirmev	124.4	—	—	
Exalgo	76.1	126.1	(39.7	)
Other	90.1	80.3	12.2	
Specialty Brands	$413.5	$206.4	100.3	

Specialty Generics. Net sales for fiscal 2014 increased $188.2 million, or 18.6%, to $1,199.4 million, compared with $1,011.2 million for fiscal 2013. The increase in net sales was primarily driven by a $157.4 million net sales increase from other controlled substances and oxycodone-related products, following certain strategic initiatives that offset lower volume, and a $61.3 million increase in Methylphenidate ER from favorable comparisons due to timing of the product launch in fiscal 2013. These increases were partially offset by a $40.6 million decrease in hydrocodone-related products due to increased competition and lower pricing.

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

	Fiscal Year		
	2014	2013	Percentage Change
U.S.	$1,071.9	$891.5	20.2 %
Europe, Middle East and Africa	103.0	104.1	(1.1)
Other	24.5	15.6	57.1
Net sales	$1,199.4	$1,011.2	18.6

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

	Fiscal Year		
	2014	2013	Percentage Change
Hydrocodone (API) and hydrocodone-containing tablets	$99.4	$140.0	(29.0)%
Oxycodone (API) and oxycodone-containing tablets	155.2	139.0	11.7
Methylphendiate ER	209.6	148.3	41.3
Other controlled substances	584.5	443.3	31.9
Other	150.7	140.6	7.2
Specialty Generics	$1,199.4	$1,011.2	18.6

Nuclear Imaging. Net sales for fiscal 2014 decreased $5.9 million, or 1.3%, to $431.7 million compared with $437.6 million for fiscal 2013. Nuclear sales decreased only slightly despite supply chain disruptions in fiscal 2014.

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

	Fiscal Year		
	2014	2013	Percentage Change
U.S.	$258.5	$264.0	(2.1)%
Europe, Middle East and Africa	146.9	146.0	0.6
Other	26.3	27.6	(4.7)
Net sales	$431.7	$437.6	(1.3)

Operating Income

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

	Fiscal Year					
	2014			2013		
Specialty Brands	$(50.6)	(12.2)%		$(36.2)	(17.5)%	
Specialty Generics	617.4	51.5		347.9	34.4	
Nuclear Imaging	(16.7)	(3.9)		24.5	5.6	
Segment operating income	550.1	26.9		336.2	20.3	
Unallocated amounts:						
Corporate and allocated expenses	(228.1)			(134.3)		
Intangible asset amortization	(154.8)			(27.9)		
Restructuring and related charges, net [1]	(81.9)			(26.3)		
Non-restructuring impairment charges	(151.6)			—		
Separation costs	(9.6)			(74.2)		
Total operating (loss) income	$(75.9)			$73.5		

(1) Includes restructuring-related accelerated depreciation.

Specialty Brands. Operating income for fiscal 2014 decreased $14.4 million to a loss of $50.6 million, compared with a loss of $36.2 million for fiscal 2013. Our operating margin improved to negative 12.2% for fiscal 2014, compared with negative 17.5% for fiscal 2013. The most significant impact to the Specialty Brands segment was associated with the inclusion of Acthar and Ofirmev, which were acquired in August 2014 and March 2014, respectively. The increased loss was attributable to including $25.7 million of expense recognition associated with the fair value adjustment of acquired Acthar and Ofirmev inventory in fiscal 2014. The Specialty Brands segment experienced a $160.9 million increase in selling, general and administrative costs that includes $91.4 million of costs associated with the inclusion of Acthar and Ofirmev and higher expenses associated with the launch of Xartemis XR. These higher expenses were partially offset by the $207.1 million increase in Specialty Brands net sales in fiscal 2014 compared with fiscal 2013.

Specialty Generics. Operating income for fiscal 2014 increased $269.5 million to $617.4 million, compared with $347.9 million for fiscal 2013. Our operating margin increased to 51.5% for fiscal 2014, compared with 34.4% for fiscal 2013. The increase in operating income and margin was primarily due to benefits from strategic initiatives on certain specialty controlled substance generic products. In addition, the Specialty Generics segment recognized an $11.7 million gain on the license of intellectual property to a third-party in fiscal 2014.

Nuclear Imaging. Operating income for fiscal 2014 decreased $41.2 million to a $16.7 million loss, compared with $24.5 million of income in fiscal 2013. Our operating margin decreased to negative 3.9% for fiscal 2014, compared with 5.6% for fiscal 2013. The decrease in operating income and margin was primarily attributable to unscheduled shutdowns of our Mo-99 processing facility and the HFR, which decreased operating income by approximately $21.0 million compared to the prior year period, and lower net sales.

Corporate and allocated expenses. Corporate and allocated expenses were $228.1 million and $134.3 million for fiscal 2014 and 2013, respectively. The increase primarily resulted from $65.1 million of transaction costs associated with our Questcor and Cadence acquisitions, a $23.1 million environmental remediation charge, increased internal and third-party costs of being an independent publicly-traded company, which was partially offset by certain prior year costs that did not recur in fiscal 2014. We were allocated general corporate expenses of $39.6 million during fiscal 2013 for certain services provided by Covidien. These allocations ceased in periods following the completion of the Separation on June 28, 2013.

Liquidity and Capital Resources

Significant factors driving our liquidity position include cash flows generated from operating activities, financing transactions, capital expenditures and cash paid in connection with acquisitions and license agreements. Historically, we have typically generated, and expect to continue to generate, positive cash flow from operations. Through June 28, 2013, as part of Covidien, our cash was swept regularly by Covidien at its discretion. Covidien also funded our operating and investing activities as needed prior to the Separation. The cash and cash equivalents held by Covidien at the corporate level were not specifically identifiable or otherwise allocable to us and, as such, were not reflected on the combined balance sheets for dates prior to June 28, 2013. Cash flows related to

financing activities prior to the Separation reflect changes in Covidien's investments in us. Transfers of cash to and from Covidien were reflected as a component of parent company investment within parent company equity on our combined balance sheets through June 28, 2013. Our cash flows for periods prior to June 28, 2013, may not be indicative of our future performance and do not necessarily represent the cash flows that would have been generated had we operated as an independent, publicly-traded company for the entirety of the periods presented.

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

In fiscal 2016, we intend to fund capital expenditures with cash generated from operations. At September 25, 2015, we had capital expenditure commitments of $25.2 million.

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

	Fiscal Year		
	2015	2014	2013
Net cash (used in) provided by:			
Operating activities	$896.4	$373.4	$135.9
Investing activities	(2,296.6)	(2,890.8)	(234.7)
Financing activities	1,069.9	2,953.9	373.0
Effect of currency exchange rate changes on cash and cash equivalents	(11.6)	(4.2)	1.3
Net (decrease) increase in cash and cash equivalents	$(341.9)	$432.3	$275.5

Operating Activities

Net cash provided by operating activities of $896.4 million for fiscal 2015 was primarily attributable to income from continuing operations, as adjusted for non-cash items, and a $33.4 million inflow from net investment in working capital. The working capital inflow was primarily driven by a $61.3 million decrease in inventory as we reduced inventory levels in fiscal 2015, a $30.2 million increase in net tax related balances and a $20.4 million increase in accounts payable after completing our fiscal 2015 acquisitions. These increases were offset by $79.2 million decrease in other assets and liabilities, which was driven primarily by increased restructuring and royalty payments in fiscal 2015.

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

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

consolidated and combined statement of cash flows.

Investing Activities

Net cash used in investing activities decreased $594.2 million to $2,296.6 million for fiscal 2015, compared with $2,890.8 million for fiscal 2014. The decrease primarily resulted from fiscal 2015 payments, net of cash acquired, of $978.4 million and $1,176.3 million related to the acquisitions of Therakos and Ikaria, respectively; compared with fiscal 2014 payments, net of cash acquired, of $1,490.5 million and $1,286.0 million related to the acquisition of Questcor and Cadence, respectively, and $17.3 million for the acquisition of other intangible assets. This decrease was partially offset by a $24.7 million decrease in other cash inflows, which

included proceeds from the sale of investments and assets in the prior year, and a $20.2 million increase in capital expenditures in fiscal 2015 compared with fiscal 2014.

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

Financing Activities

Net cash provided by financing activities decreased $1,884.0 million to $1,069.9 million for fiscal 2015, compared with $2,953.9 million for fiscal 2014. The decrease largely resulted from $1,848.4 million of cash outflows from the repayment of external debt and capital leases, offset by $2,970.1 million of cash proceeds, net of financing costs, from the issuance of external debt to fund the Ikaria and Therakos acquisitions and increases in the accounts receivable securitization facility. Comparatively, fiscal 2014 included only $34.8 million of cash outflows from the repayment of external debt and capital leases, offset by $2,971.5 million of cash proceeds, net of financing costs, from the issuance of external debt to fund the Cadence and Questcor acquisitions. The increased debt repayment was most significantly impacted by the assumption and immediate repayment of $1,118.5 million of Ikaria third-party debt and $344.8 million of Therakos third-party debt, and the repayment of the $240.0 million of fiscal 2015 borrowings under the revolving credit facility. Additionally, there was $28.1 million of cash outflows resulting from payments of the BioVectra and Synacthen contingent considerations in fiscal 2015. These increases in cash outflows were partially offset by a $33.8 million increase in cash inflows from the excess tax benefit derived from share-based compensation and proceeds from stock option exercises.

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

Inflation

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

Foreign Currency

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

Concentration of Credit and Other Risks

Financial instruments that potentially subject us to concentrations of credit risk primarily consist of accounts receivable. We generally do not require collateral from customers. A portion of our accounts receivable outside the U.S. includes sales to government-owned or supported healthcare systems in several countries, which are subject to payment delays. Payment is dependent upon the financial stability and creditworthiness of those countries' national economies.

Debt and Capitalization

At September 25, 2015, total debt principal was $6,606.5 million compared with total debt principal at September 26, 2014 of $3,980.8 million. The increase in total debt principal resulted from financing transactions to fund our fiscal 2015 acquisitions. Total debt principal at September 25, 2015 is comprised of $1,978.5 million of variable rate term loans, $3,972.7 million of fixed rate instruments, $500.0 million of borrowings under our variable rate revolving credit facility, $153.0 million of borrowings under a variable rate receivable securitization program and $2.3 million of capital lease obligations. The variable-rate term loan interest rates are based on LIBOR, subject to a minimum LIBOR level of 0.75% with interest payments generally expected to be payable every 90 days, and requires quarterly principal payments equal to 0.25% of the original principal amount. As of September 25, 2015 our fixed-rate instruments had a weighted-average interest rate of 5.2% and pay interest at various dates throughout the fiscal year. As of September 25, 2015, the applicable interest rate on outstanding borrowings under the Revolver was 2.6%, which is determined as LIBOR plus margin of 2.25%. As of September 25, 2015, the applicable interest rate on outstanding borrowings under the Receivable Securitization was 1.0%, which is determined as the one month LIBOR rate plus a margin of 0.80%. The receivable securitization has a capacity of $250.0 million that may, subject to certain conditions, be increased to $300.0 million.

At September 25, 2015, $22.3 million of our total debt is classified as current as these payments are expected to be made within the next fiscal year.

In addition to the borrowing capacity under our receivable securitization program, we have a $500.0 million revolving credit facility. At September 25, 2015, we had fully utilized our revolving credit facility. As such the was no additional borrowing capacity under our revolving credit facility.

As of September 25, 2015, we were, and expect to remain, in compliance with the provisions and covenants associated with our debt agreements.

In November 2015, our Board of Directors authorized us to reduce our outstanding debt at our discretion. As market conditions warrant, we may from time to time repurchase debt securities issued by us, in the open market, in privately negotiated transactions, by tender offer or otherwise. Such repurchases, if any, will depend on prevailing market conditions, our liquidity requirements and other factors. The amounts involved may be material.

For additional information regarding our debt agreements, refer to Note 12 of Notes to the Consolidated and Combined Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Capitalization

Shareholders' equity was $5,311.2 million, at September 25, 2015, compared with $4,958.0 million, at September 26, 2014. The increase in shareholder's equity is primarily attributed to fiscal year 2015 net income, share-based compensation, share option exercises and changes in accumulated other comprehensive income, partially offset by repurchases of common shares

In January 2015, our Board of Directors approved a share repurchase program of up to $300.0 million of ordinary shares. Through September 25, 2015, the Company has repurchased approximately 0.8 million shares under this program at an aggregate purchase price of $75.0 million. In November 2015, our Board of Directors approved an incremental share repurchase program of up to $500.0 million of ordinary shares, which supplements the January 2015 program. As market conditions warrant, we may from time to time repurchase equity securities issued by us, in the open market.

Dividends

We currently do not anticipate paying any cash dividends for the foreseeable future, as we intend to retain earnings to finance R&D, acquisitions and the operation and expansion of our business. The recommendation, declaration and payment of dividends in the future by us will be subject to the sole discretion of our board of directors and will depend upon many factors, including our financial condition, earnings, capital requirements of our operating subsidiaries,

covenants associated with certain of our debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by our board of directors. Moreover, if we determine to pay dividends in the future, there can be no assurance that we will continue to pay such dividends.

Commitments and Contingencies

Contractual Obligations

The following table summarizes our contractual obligations as of September 25, 2015 (in millions):

	Payments Due By Period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Long-term debt obligations	$6,604.2	$21.0	$495.2	$1,242.4	$4,845.6
Interest on long-term debt obligations [1]	1,935.6	269.5	575.2	527.7	563.2
Capital lease obligations [1]	2.3	1.3	1.0	—	—
Operating lease obligations	95.0	21.1	32.7	20.6	20.6
Purchase obligations [2]	235.0	125.9	101.2	7.9	—
Total contractual obligations	$8,872.1	$438.8	$1,205.3	$1,798.6	$5,429.4

(1) Interest on debt and capital lease obligations are projected for future periods using interest rates in effect as of September 25, 2015. Certain of these projected interest payments may differ in the future based on changes in market interest rates.

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

The preceding table does not include other liabilities of $556.8 million, primarily consisting of obligations under our pension and postretirement benefit plans, unrecognized tax benefits for uncertain tax positions and related accrued interest and penalties, contingent consideration liabilities, environmental liabilities and asset retirement obligations, because the timing of their future cash outflow is uncertain. The most significant of these liabilities are discussed below.

Non-current income taxes payable, primarily related to unrecognized tax benefits, is included within other income tax liabilities on the consolidated and combined balance sheet and, as of September 25, 2015, was $121.3 million. Payment of these liabilities is uncertain and, even if payments are determined to be necessary, they are subject to the timing of rulings by the Internal Revenue Service of tax positions we take. For further information on income tax related matters, refer to Note 7 of Notes to Consolidated and Combined Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

As of September 25, 2015, we had net unfunded pension and postretirement benefit obligations of $55.6 million and $52.2 million, respectively. The timing and amounts of long-term funding requirements for pension and postretirement obligations are uncertain. The Company does not anticipate making material involuntary contributions in fiscal 2016, but may elect to make voluntary contributions to its defined pension plans or its postretirement benefit plans during fiscal 2016.

We are involved in various stages of investigation and cleanup related to environmental remediation matters at a number of sites. These projects relate to a variety of activities, including decontamination and decommissioning of radioactive materials and removal of solvents, metals and other hazardous substances from soil and groundwater. The ultimate cost of cleanup and timing of future cash outlays is difficult to predict given uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations and alternative cleanup methods. As of September 25, 2015, we believe that it is probable that we will incur investigation and remedial costs of approximately $76.5 million, of which $3.2 million is included in accrued and other current liabilities on our consolidated balance sheet at September 25, 2015. Note 19 of Notes to Consolidated and Combined Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K provides additional information regarding environmental matters, including asset retirement obligations.

Legal Proceedings

We are subject to various legal proceedings and claims, including patent infringement claims, product liability matters, environmental matters, employment disputes, contractual disputes and other commercial disputes, including those described in Note 19 of the Notes to Consolidated and Combined Financial Statements included within Item 8.

Financial Statements and Supplementary Data. Although it is not feasible to predict the outcome of these matters, management believes that their ultimate resolution will not have a material adverse effect on our financial condition, results of operations and cash flows.

Guarantees

In disposing of assets or businesses, we have historically provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to the assets, environmental risks involved in the sale of real estate, liability to investigate and remediate environmental contamination at waste disposal sites and manufacturing facilities, and unidentified tax liabilities related to periods prior to disposition. The Company assesses the probability of potential liabilities related to such

representations, warranties and indemnities and adjusts potential liabilities as a result of changes in facts and circumstances. The Company has no reason to believe that these uncertainties would have a material adverse effect on its financial condition, results of operations and cash flows. These representations, warranties and indemnities are discussed in Note 18 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.

Off-Balance Sheet Arrangements

We are required to provide the U.S. Nuclear Regulatory Commission financial assurance demonstrating our ability to fund the decommissioning of our Maryland Heights, Missouri radiopharmaceuticals production facility upon closure, though we do not intend to close this facility. We have provided this financial assurance in the form of surety bonds totaling $57.2 million. As of September 25, 2015, we had various other letters of credit and guarantee and surety bonds totaling $39.4 million.

In April 2015, the Company terminated a letter of credit to guarantee decommissioning costs associated with its Saint Louis, Missouri plant and placed $21.1 million of restricted cash on deposit with a trustee. This restricted cash is included within prepaid expenses and other current assets in the condensed consolidated balance sheet as of September 25, 2015.

We exchanged title to $88.0 million of our plant assets in return for an equal amount of Industrial Revenue Bonds ("IRB") issued by Saint Louis County. We also simultaneously leased such assets back from Saint Louis County under a capital lease expiring through December 2025, the terms of which provide us with the right of offset against the IRBs.The lease also provides an option for us to repurchase the assets at the end of the lease for nominal consideration. These transactions collectively result in a property tax abatement ten years from the date the property is placed in service. Due to right of offset, the capital lease obligation and IRB asset are recorded net in the consolidated balance sheets. The Company expects that the right of offset will be applied to payments required under these arrangements.

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

Critical Accounting Policies and Estimates

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

Revenue Recognition

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

under a contract with us. We enter into agreements with some indirect customers to establish contract pricing for certain products. These indirect customers then independently select a wholesaler from which to purchase the products at these contracted prices. Alternatively, we may enter into agreements with wholesalers at a contract price to offer our products to other indirect customers. Under either arrangement, we provide credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price. Such credit is called a chargeback.

When we recognize net sales, we simultaneously record an adjustment to revenue for estimated chargebacks, rebates, product returns and other sales deductions. These provisions are estimated based upon historical experience, estimated future trends, estimated customer inventory levels, current contracted sales terms with customers, level of utilization of our products and other competitive factors. We adjust reserves for rebates and chargebacks, product returns and other sales deductions to reflect differences between estimated and actual experience. Such adjustments impact the amount of sales we recognize in the period of adjustment.

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

	Rebates and Chargebacks	Product Returns	Other Sales Deductions	Total
Balance at September 28, 2012	$188.0	$34.7	$12.3	$235.0
Provisions	1,081.7	33.4	56.8	1,171.9
Payments or credits	(1,046.6)	(18.9)	(53.7)	(1,119.2)
Balance at September 27, 2013	223.1	49.2	15.4	287.7
Provisions	1,543.8	86.1	91.0	1,720.9
Payments or credits	(1,507.6)	(33.3)	(93.4)	(1,634.3)
Acquisitions	30.1	0.5	—	30.6
Balance at September 26, 2014	289.4	102.5	13.0	404.9
Provisions	2,080.1	13.0	94.7	2,187.8
Payments or credits	(2,059.1)	(43.9)	(91.7)	(2,194.7)
Acquisitions	0.2	1.1	—	1.3
Balance at September 25, 2015	$310.6	$72.7	$16.0	$399.3

Provisions presented in the table above are recorded as reductions to net sales.

Total provisions for fiscal 2015 increased $466.9 million compared with fiscal 2014. The increase in rebates and chargebacks of $536.3 million primarily related to a $456.1 million increase in Specialty Generics rebates and chargebacks following strategic pricing actions and a $38.8 million increase in Medicaid provisions related to including a full year of Acthar results in fiscal 2015. Provisions for returns decreased by $73.1 million due to a $53.5 million decrease in Specialty Brands and a $19.5 million decrease in Specialty Generics, primarily due to hydrocodone rescheduling. The Specialty Brands decrease reflected a fiscal 2014 charge of $33.8 million provision for Exalgo following loss of exclusivity on the product, while fiscal 2015 included a $9.0 million favorable change in estimate associated with the Exalgo returns reserves based on returns activity to date. Other sales deductions increased by $3.7 million, primarily attributable to the Specialty Generics strategic pricing actions.

Total provisions recorded in fiscal 2014 increased by $549.0 million compared with fiscal 2013. The increase in rebates and chargebacks of $462.1 million primarily related to a $450.0 million increase in Specialty Generics rebates and chargebacks following strategic pricing actions and a full year of Methylphenidate ER that increased both gross sales, and rebates and chargebacks. The remaining difference primarily included a $30.1 million increase associated with fiscal 2014 acquisitions that was partially offset by a decrease in Nuclear Imaging on lower volume. Provisions for returns increased by $52.7 million primarily attributable to a $33.8 million provision for potential Exalgo returns following the loss of exclusivity during fiscal 2014. Other sales deductions increased by $34.2 million, primarily attributable to the Specialty Generics strategic pricing actions.

Goodwill and Other Intangible Assets

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

growth rates, discount factors and income tax rates. Changes in economic and operating conditions impacting these assumptions could result in goodwill impairment in future periods.

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

the value of a reporting unit over the amounts assigned to its assets and liabilities represents the implied fair value of goodwill. The results of our annual goodwill impairment test for fiscal 2015 showed that the fair value of our Specialty Brands and Specialty Generics reporting units' exceeded their respective carrying values. In fiscal 2014, a goodwill impairment was recorded related to our former Global Medical Imaging reporting unit (which included the CMDS business that is now presented as a discontinued operation and the remaining Nuclear Imaging reporting unit). For further information on our goodwill impairment analysis, refer to Notes 2 and 11 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.

Intangible assets include completed technology, licenses, trademarks and in-process research and development. We record intangible assets at cost and amortize finite-lived intangible assets, generally using the straight-line method over eight to thirty years. When a triggering event occurs, we evaluate potential impairment of finite-lived intangible assets by first comparing undiscounted cash flows associated with the asset to its carrying value. We utilize similar assumptions as utilized in our goodwill valuation. If the carrying value is greater than the undiscounted cash flows, the amount of potential impairment is measured by comparing the fair value of the assets with their carrying value. The fair value of the intangible asset is estimated using an income approach. If the fair value is less than the carrying value of the intangible asset, the amount recognized for impairment is equal to the difference between the carrying value of the asset and the present value of future cash flows. Changes in economic and operating conditions impacting these assumptions could result in goodwill impairment in future periods. We assess the remaining useful life and the recoverability of finite-lived intangible assets whenever events or circumstances indicate that the carrying value of an asset may not be recoverable. No impairments of intangible assets were recorded in fiscal 2015. Impairments of an intangible assets, most notably associated with our CMDS business that is now presented as a discontinued operation, were recorded in fiscal 2014. For more information on our intangible impairment analysis, refer to Notes 2, 10 and 11 of the Notes to the Consolidated and Combined Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Acquisitions

Amounts paid for acquisitions are allocated to the tangible assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. The Company then allocates the purchase price in excess of net tangible assets acquired to identifiable intangible assets, including purchased research and development. The fair value of identifiable intangible assets is based on detailed valuations. These valuations rely on a number of factors including operating results, business plans, economic projections, anticipated future cash flows, transactions and market place data. There are inherent uncertainties related to these factors and judgment in applying them to estimate the fair value of individual assets acquired in a business combination. Due to these inherent uncertainties, there is risk that the carrying value of our recorded intangible assets and goodwill may be overstated or understated, which may result in an increased risk of impairment in future periods. We perform our intangible asset valuations using an income approach based on the present value of future cash flows. This approach incorporates many assumptions including future growth rates, discount factors and income tax rates. Changes in economic and operating conditions impacting these assumptions could result in impairment in future periods.

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

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

The fair value attributable to IPR&D projects at the time of acquisition is capitalized as an indefinite-lived intangible asset and tested for impairment until the project is completed or abandoned. Upon completion of the project, the indefinite-lived intangible asset is then accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is abandoned, the indefinite-lived intangible asset is charged to expense.

Contingencies

We are involved, either as a plaintiff or a defendant, in various legal proceedings that arise in the ordinary course of business, including, without limitation, patent infringement, product liability and environmental matters, as further discussed in Note 19 of Notes to Consolidated and Combined Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on form 10-K. Accruals recorded for various contingencies, including legal proceedings, self-insurance and other claims, are based on judgment, the probability of losses and, where applicable, the consideration of opinions of internal and/or external legal counsel, internal and/or external technical consultants and actuarially determined estimates. When a range is established

but a best estimate cannot be made, we record the minimum loss contingency amount. These estimates are often initially developed substantially earlier than the ultimate loss is known, and the estimates are reevaluated each accounting period as additional information becomes available. When we are initially unable to develop a best estimate of loss, we record the minimum amount of loss, which could be zero. As information becomes known, additional loss provisions are recorded when either a best estimate can be made or the minimum loss amount is increased. When events result in an expectation of a more favorable outcome than previously expected, our best estimate is changed to a lower amount. We record receivables from third-party insurers up to the amount of the related liability when we have determined that existing insurance policies will provide reimbursement. In making this determination, we consider applicable deductibles, policy limits and the historical payment experience of the insurance carriers. Receivables are not netted against the related liabilities for financial statement presentation.

Income Taxes

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

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

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

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

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

Recently Issued Accounting Standards

Refer to Note 3 of Notes to Consolidated and Combined Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K for a discussion regarding recently issued accounting standards and their estimated impact on our financial condition, results of operations and cash flows.

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

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

Interest Rate Risk

Our exposure to interest rate risk relates primarily to our variable-rate debt instruments, which bear interest based on LIBOR plus margin. As of September 25, 2015, our outstanding debt included $1,978.5 million variable-rate debt on our senior secured term loan, $500.0 million on our senior unsecured revolving credit facility and $153.0 million variable-rate debt on our receivables securitization program. Assuming a one percent increase in the applicable interest rates, in excess of applicable minimum floors, annual interest expense would increase by approximately $26.3 million.

The remaining outstanding debt as of September 25, 2015 is fixed-rate debt. Changes in market interest rates generally affect the fair value of fixed-rate debt, but do not impact earnings or cash flows.

Currency Risk

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

The consolidated statement of income is exposed to currency risk from intercompany financing arrangements, which primarily consist of intercompany debt and intercompany cash pooling, where the denominated currency of the transaction differs from the functional currency of one or more of our subsidiaries. We performed a sensitivity analysis for these arrangements as of September 25, 2015 that measures the potential unfavorable impact to income from continuing operations before income taxes from a hypothetical 10% adverse movement in foreign exchange rates relative to the U.S. dollar, with all other variables held constant. The aggregate potential unfavorable impact from a hypothetical 10% adverse change in foreign exchange rates was $20.0 million as of September 25, 2015. This hypothetical loss does not reflect any hypothetical benefits that would be derived from hedging activities, including cash holdings in similar foreign currencies, that we have historically utilized to mitigate our exposure to movements in foreign exchange rates.

The financial results of our non-U.S. operations are translated into U.S. dollars, further exposing us to currency exchange rate fluctuations. We have performed a sensitivity analysis as of September 25, 2015 that measures the change in the net financial position arising from a hypothetical 10% adverse movement in the exchange rates of the Euro, the Mexican Peso and the Canadian Dollar, our most widely used foreign currencies, relative to the U.S. dollar, with all other variables held constant. The aggregate potential change in net financial position from a hypothetical 10% adverse change in the above currencies was $41.6 million as of September 25, 2015. The change in the net financial position associated with the translation of these currencies is generally recorded as an unrealized gain or loss on foreign currency translation within accumulated other comprehensive income in shareholders' equity of our consolidated balance sheets.

Item 8. Financial Statements and Supplementary Data.

INDEX TO FINANCIAL STATEMENTS

Consolidated and Combined Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Mallinckrodt plc:

We have audited the accompanying consolidated balance sheets of Mallinckrodt plc and subsidiaries (the "Company") as of September 25, 2015 and September 26, 2014, and the related consolidated and combined statements of income, comprehensive income, changes in shareholders' equity, and cash flows for each of the three fiscal years in the period ended September 25, 2015. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedule based on our audits.

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

In our opinion, such consolidated and combined financial statements present fairly, in all material respects, the financial position of Mallinckrodt plc and subsidiaries as of September 25, 2015 and September 26, 2014, and the results of their operations and their cash flows for each of the three years in the period ended September 25, 2015, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

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

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of September 25, 2015, based on the criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated November 24, 2015 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP
St. Louis, Missouri
November 24, 2015

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

	Fiscal Year		
	2015	2014	2013
Net sales	$3,346.9	$2,082.0	$1,712.3
Cost of sales	1,493.3	1,021.8	890.0
Gross profit	1,853.6	1,060.2	822.3
Selling, general and administrative expenses	1,169.8	745.0	495.9
Research and development expenses	185.1	163.5	157.9
Restructuring charges, net	40.4	81.4	23.7
Separation costs	—	9.6	74.2
Non-restructuring impairment charges	—	151.6	—
Gain on divestiture and license	(3.5)	(15.0)	(2.9)
Operating income (loss)	461.8	(75.9)	73.5
Interest expense	(255.6)	(82.6)	(19.5)
Interest income	1.0	1.5	0.3
Other income, net	8.1	3.1	1.4
Income (loss) from continuing operations before income taxes	215.3	(153.9)	55.7
Provision for (benefit from) income taxes	(92.9)	(10.1)	47.5
Income (loss) from continuing operations	308.2	(143.8)	8.2
Income (loss) from discontinued operations, net of tax expense (benefit) of $11.5, $(34.7), and $21.1	16.5	(175.5)	50.6
Net income (loss)	$324.7	$(319.3)	$58.8
Basic earnings per share (Note 8):			
Income (loss) from continuing operations	$2.64	$(2.22)	$0.14
Income (loss) from discontinued operations, net of income taxes	0.14	(2.70)	0.88
Net income (loss)	$2.78	$(4.92)	$1.02
Basic weighted-average shares outstanding	115.8	64.9	57.7
Diluted earnings per share (Note 8):			
Income (loss) from continuing operations	$2.61	$(2.22)	$0.14
Income (loss) from discontinued operations, net of income taxes	0.14	(2.70)	0.88
Net income (loss)	$2.75	$(4.92)	$1.02
Diluted weighted-average shares outstanding	117.2	64.9	57.8

See Notes to Consolidated and Combined Financial Statements.

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

	Fiscal Year		
	2015	2014	2013
Net income (loss)	$324.7	$(319.3)	$58.8
Other comprehensive income (loss), net of tax			
Currency translation adjustments	(70.8)	(27.6)	1.5
Unrecognized gain (loss) on derivatives, net of tax (benefit) expense of $0.2, $0.2 and $-	0.4	0.5	(7.3)
Unrecognized gain (loss) on benefit plans, net of tax (benefit) expense of $(2.1), $(7.3) and $23.9	5.6	(15.7)	34.2
Total other comprehensive income (loss), net of tax	(64.8)	(42.8)	28.4
Comprehensive income (loss)	$259.9	$(362.1)	$87.2

See Notes to Consolidated and Combined Financial Statements.

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

	September 25, 2015	September 26, 2014
Assets		
Current Assets:		
Cash and cash equivalents	$ 365.9	$ 707.8
Accounts receivable, less allowance for doubtful accounts of $4.7 and $3.7	548.5	476.6
Inventories	281.8	306.4
Deferred income taxes	142.7	152.3
Prepaid expenses and other current assets	207.3	227.1
Current assets held for sale	299.9	200.8
Total current assets	1,846.1	2,071.0
Property, plant and equipment, net	991.3	886.8
Goodwill	3,649.4	2,401.9
Intangible assets, net	9,666.3	7,082.2
Long-term assets held for sale	—	111.2
Other assets	251.0	234.2
Total Assets	$ 16,404.1	$ 12,787.3
Liabilities and Shareholders' Equity		
Current Liabilities:		
Current maturities of long-term debt	$ 22.3	$ 21.2
Accounts payable	133.0	110.7
Accrued payroll and payroll-related costs	103.7	116.3
Accrued royalties	29.3	67.7
Accrued and other current liabilities	568.3	529.9
Current liabilities held for sale	72.8	59.0
Total current liabilities	929.4	904.8
Long-term debt	6,474.3	3,874.0
Pension and postretirement benefits	116.7	116.2
Environmental liabilities	73.3	59.2
Deferred income taxes	3,132.4	2,399.6
Other income tax liabilities	121.3	122.6
Long-term liabilities held for sale	—	9.7
Other liabilities	245.5	343.2
Total Liabilities	11,092.9	7,829.3
Commitments and contingencies (Note 19)		
Shareholders' Equity:		
Preferred shares, $0.20 par value, 500,000,000 authorized; none issued or outstanding	—	—
Ordinary A shares, €1.00 par value, 40,000 authorized; none issued or outstanding	—	—
Ordinary shares, $0.20 par value, 500,000,000 authorized; 117,513,370 and 116,160,353 issued; 116,283,149 and 115,929,588 outstanding	23.5	23.2
Ordinary shares held in treasury at cost, 1,230,221 and 230,765	(109.7)	(17.5)
Additional paid-in capital	5,357.6	5,172.4
Retained earnings (deficit)	38.9	(285.8)

Accumulated other comprehensive income	0.9	65.7
Total Shareholders' Equity	5,311.2	4,958.0
Total Liabilities and Shareholders' Equity	$ 16,404.1	$ 12,787.3

See Notes to Consolidated and Combined Financial Statements.

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

	Fiscal Year		
	2015	2014	2013
Cash Flows From Operating Activities:			
Net income (loss)	$324.7	$(319.3)	$58.8
Adjustments to reconcile net cash provided by operating activities:			
Depreciation and amortization	672.5	275.9	139.6
Share-based compensation	117.0	67.7	16.2
Deferred income taxes	(191.6)	(107.5)	(9.0)
Non-cash impairment charges	—	381.2	—
Inventory provisions	—	32.1	15.5
Other non-cash items	(59.6)	(23.6)	(6.2)
Changes in assets and liabilities, net of the effects of acquisitions:			
Accounts receivable, net	0.7	(51.3)	(181.2)
Inventories	61.3	56.0	27.7
Accounts payable	20.4	(32.9)	7.2
Income taxes	30.2	(54.8)	60.7
Other	(79.2)	149.9	6.6
Net cash provided by operating activities	896.4	373.4	135.9
Cash Flows From Investing Activities:			
Capital expenditures	(148.0)	(127.8)	(147.9)
Acquisitions and intangibles, net of cash acquired	(2,154.7)	(2,793.8)	(88.1)
Restricted cash	3.1	4.1	—
Other	3.0	26.7	1.3
Net cash used in investing activities	(2,296.6)	(2,890.8)	(234.7)
Cash Flows From Financing Activities:			
Issuance of external debt	3,010.0	3,043.2	898.1
Repayment of external debt and capital leases	(1,848.4)	(34.8)	(1.3)
Excess tax benefit from share-based compensation	34.1	8.9	3.4
Debt financing costs	(39.9)	(71.7)	(12.0)
Net transfers to parent	—	—	(515.9)
Proceeds from exercise of share options	34.4	25.8	0.6
Repurchase of shares	(92.2)	(17.5)	—
Other	(28.1)	—	0.1
Net cash provided by financing activities	1,069.9	2,953.9	373.0
Effect of currency rate changes on cash	(11.6)	(4.2)	1.3
Net (decrease) increase in cash and cash equivalents	(341.9)	432.3	275.5
Cash and cash equivalents at beginning of period	707.8	275.5	—
Cash and cash equivalents at end of period	$365.9	$707.8	$275.5
Supplemental Disclosures of Cash Flow Information:			
Cash paid for interest	$200.5	$57.2	$0.8
Cash paid for income taxes, net	123.8	128.0	15.0

See Notes to Consolidated and Combined Financial Statements.

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

	Ordinary Shares		Treasury Shares		Additional Paid-In Capital	Retained Earnings	Contributed Surplus	Parent Company Investment	Accumulated Other Comprehensive Income	Total Shareholders' Equity
	Number	Par Value	Number	Amount						
Balance at September 28, 2012	—	$—	—	$—	$—	$—	$ —	$ 1,807.0	$ 84.9	$ 1,891.9
Net income	—	—	—	—	—	33.5	—	25.3	—	58.8
Currency translation adjustments	—	—	—	—	—	—	—	—	1.5	1.5
Change in derivatives, net of tax	—	—	—	—	—	—	—	—	(7.3)	(7.3)
Minimum pension liability, net of tax	—	—	—	—	—	—	—	—	34.2	34.2
Net transfers to parent	—	—	—	—	—	—	—	(515.9)	—	(515.9)
Separation related adjustments	—	—	—	—	—	—	—	(209.9)	(4.8)	(214.7)
Transfer of parent company investment to contributed surplus	—	—	—	—	—	—	1,106.5	(1,106.5)	—	—
Transfer of contributed surplus to distributable reserves	—	—	—	—	1,095.0	—	(1,095.0)	—	—	—
Share options exercised	—	—	—	—	0.6	—	—	—	—	0.6
Share-based compensation	—	—	—	—	6.5	—	—	—	—	6.5
Issuance of ordinary shares	57.7	11.5	—	—	—	—	(11.5)	—	—	—
Balance at September 27, 2013	57.7	$11.5	—	$—	$1,102.1	$33.5	$ —	$—	$ 108.5	$ 1,255.6
Net loss	—	—	—	—	—	(319.3)	—	—	—	(319.3)
Currency translation	—	—	—	—	—	—	—	—	(27.6)	(27.6)

adjustments										
Change in derivatives, net of tax	—	—	—	—	—	—	—	—	0.5	0.5
Minimum pension liability, net of tax	—	—	—	—	—	—	—	—	(15.7)	(15.7)
Ordinary shares issued in connection with the Questcor acquisition	57.3	11.4	—	—	3,968.2	—	—	—	—	3,979.6
Share options exercised	0.8	0.2	—	—	25.6	—	—	—	—	25.8
Vesting of restricted shares	0.4	0.1	—	—	(0.1)	—	—	—	—	—
Excess tax benefit from share-based compensation	—	—	—	—	8.9	—	—	—	—	8.9
Share-based compensation	—	—	—	—	67.7	—	—	—	—	67.7
Repurchase of ordinary shares	—	—	0.2	(17.5)	—	—	—	—	—	(17.5)
Balance at September 26, 2014	116.2	$23.2	0.2	$(17.5)	$5,172.4	$(285.8)	$—	$—	$ 65.7	$ 4,958.0
Net income	—	—	—	—	—	324.7	—	—	—	324.7
Currency translation adjustments	—	—	—	—	—	—	—	—	(70.8)	(70.8)
Change in derivatives, net of tax	—	—	—	—	—	—	—	—	0.4	0.4
Minimum pension liability, net of tax	—	—	—	—	—	—	—	—	5.6	5.6
Share options exercised	1.2	0.2	—	—	34.2	—	—	—	—	34.4
Vesting of restricted shares	1.3	0.3	—	—	(0.3)	—	—	—	—	—
Shares canceled	(1.2)	(0.2)	—	—	0.2	—	—	—	—	—
Excess tax benefit from share-based compensation	—	—	—	—	34.1	—	—	—	—	34.1
Share-based compensation	—	—	—	—	117.0	—	—	—	—	117.0
Repurchase of ordinary shares	—	—	1.0	(92.2)	—	—	—	—	—	(92.2)
	117.5	$23.5	1.2	$(109.7)	$5,357.6	$38.9	$—	$—	$ 0.9	$ 5,311.2

Balance at September 25, 2015	

See Notes to Consolidated and Combined Financial Statements.

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

1. Background and Basis of Presentation

Background

Mallinckrodt plc and its subsidiaries (collectively, "Mallinckrodt" or "the Company"), is a global specialty biopharmaceutical and nuclear imaging business that develops, manufactures, markets and distributes specialty pharmaceutical and biopharmaceutical products and nuclear imaging agents. Therapeutic areas of focus include autoimmune and rare disease specialty areas (including neurology, rheumatology, nephrology and pulmonology); immunotherapy and neonatal respiratory critical care therapies; and central nervous system drugs. The Company also supports the diagnosis of disease with nuclear medicine imaging agents.

During the first quarter of fiscal 2015, the Company changed its reportable segments to present the Specialty Brands and Specialty Generics businesses as reportable segments. The Company historically presented the Specialty Brands and Specialty Generics businesses within the Specialty Pharmaceuticals segment.

During the fourth quarter of fiscal 2015, the Company announced that it had entered into a definitive agreement to sell its global contrast media and delivery systems ("CMDS") business to Guerbet S.A. ("Guerbet"), which is expected to be completed during the first quarter of fiscal 2016. The CMDS business is deemed to be held for sale and the financial results of this business are presented as a discontinued operation. The CMDS business has been eliminated from the Global Medical Imaging segment, which has been renamed Nuclear Imaging.

Prior year amounts have been recast to conform to current presentation.

The three reportable segments are further described below:

- Specialty Brands produces and markets branded pharmaceuticals and biopharmaceuticals;
- Specialty Generics produces specialty generic pharmaceuticals and active pharmaceutical ingredients ("API") consisting of biologics, medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients; and
- Nuclear Imaging manufactures and markets radiopharmaceuticals (nuclear medicine).

In May 2015, the Board of Directors of Mallinckrodt plc approved the migration of the Company’s principal executive offices from Ireland to the United Kingdom. The Company remains incorporated in Ireland and continues to be subject to U.S. Securities and Exchange Commission ("SEC") reporting requirements and the applicable corporate governance rules of the New York Stock Exchange.

Mallinckrodt plc was incorporated in Ireland on January 9, 2013 for the purpose of holding the Pharmaceuticals business of Covidien plc ("Covidien"), which was subsequently acquired by Medtronic plc. On June 28, 2013, Covidien shareholders of record received one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien held as of the record date, June 19, 2013, and the Pharmaceuticals business of Covidien was transferred to Mallinckrodt plc, thereby completing its legal separation from Covidien ("the Separation").

Basis of Presentation

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

The consolidated and combined financial statements have been prepared in U.S. dollars and in accordance with accounting principles generally accepted in the U.S. ("GAAP"). The preparation of the consolidated and combined financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses. Actual results may differ from those estimates. The consolidated and combined financial statements include the accounts of the Company, its wholly-owned subsidiaries and entities in which they own or

control more than fifty percent of the voting shares, or have the ability to control through similar rights. The results of entities disposed of are included in the consolidated and combined financial statements up to the date of disposal and, where appropriate, these operations have been reflected as discontinued operations. Divestitures of product lines not representing businesses have been reflected in operating income. All intercompany balances and transactions have been eliminated in consolidation and, in the opinion of management, all normal recurring adjustments necessary for a fair presentation have been included in the results reported.

As a result of the Company's classification of the CMDS business as held for sale and the change in reportable segments, certain amounts from prior years have been revised to conform to the current year presentation,.

The Company's combined financial statements for periods prior to June 28, 2013, including the nine months ended June 28, 2013 that is included within the Company's fiscal 2013 results, may not be indicative of its future performance and do not necessarily reflect the results of operations, financial position and cash flows that would have been had it operated as an independent, publicly-traded company for the entirety of the periods presented, including as a result of changes in the Company's capitalization in connection with the Separation. The combined financial statements for periods prior to June 28, 2013 include expense allocations for certain functions provided by Covidien, including, but not limited to, general corporate expenses related to finance, legal, information technology, human resources, communications, employee benefits and incentives, insurance and share-based compensation. These expenses were allocated to the Company on the basis of direct usage when identifiable, with the remainder allocated on the basis of operating expenses, headcount or other measures. The amounts allocated were $39.6 million for fiscal 2013 and were included within selling, general and administrative expenses. Management considers the bases on which the expenses have been allocated to reasonably reflect the utilization of services provided to, or the benefit received by, the Company during the periods presented; however, the allocations may not reflect the expense the Company would have incurred as an independent, publicly-traded company. Actual costs that may have been incurred if the Company had been a standalone company would depend on a number of factors, including organizational structure, what functions were outsourced or performed by employees, and strategic decisions made in areas such as information technology and infrastructure. The Company is unable to determine what those costs would have been had the Company been independent during the applicable periods. Following the Separation, the Company has performed these functions using its own resources or purchased services, certain of which are being provided by Covidien during a transitional period pursuant to a transition services agreement dated June 28, 2013, between Mallinckrodt and Covidien, particularly in relation to areas outside the U.S. The terms and prices on which such services were rendered may not have been as favorable as those that were allocated to the Company by Covidien. The Company terminated the transition services agreement during the first quarter of fiscal 2015.

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

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

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

consolidated balance sheet. Net income subsequent to the Separation has been included in retained earnings and is included in distributable reserves.

Fiscal Year

The Company reports its results based on a "52-53 week" year ending on the last Friday of September. Fiscal 2015, 2014 and 2013 each consisted of 52 weeks. Unless otherwise indicated, fiscal 2015, 2014 and 2013 refer to the Company's fiscal years ended September 25, 2015, September 26, 2014 and September 27, 2013, respectively. Fiscal 2016 will consist of 53 weeks and will end on September 30, 2016.

2. Summary of Significant Accounting Policies

Revenue Recognition

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

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

Shipping and Handling Costs

Shipping costs, which are costs incurred to physically move product from the Company's premises to the customer's premises, are classified as selling, general and administrative expenses. Handling costs, which are costs incurred to store, move and prepare product for shipment, are classified as cost of sales. Shipping costs included in selling, general and administrative expenses in continuing operations were $42.3 million, $47.8 million and $46.9 million in fiscal 2015, 2014 and 2013, respectively.

Research and Development

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

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

Currency Translation

For the Company's non-U.S. subsidiaries that transact in a functional currency other than U.S. dollars, assets and liabilities are translated into U.S. dollars using fiscal year-end exchange rates. Revenues and expenses are translated at the average exchange rates in effect during the related month. The net effect of these translation adjustments is shown in the consolidated and combined financial statements as a component of accumulated other comprehensive income. For subsidiaries operating in highly inflationary environments or where the functional currency is different from the local currency, non-monetary assets and liabilities are translated at the rate of exchange in effect on the date the assets and liabilities were acquired or assumed, while monetary assets and liabilities are translated at fiscal year-end exchange rates. Translation adjustments of these subsidiaries are included in net income. Gains and losses resulting from foreign currency transactions are included in net income. During fiscal 2015 and 2014, $30.7 million and $3.8 million of foreign currency gains, respectively, were included within net income from continuing operations. During fiscal 2013, $12.8 million of foreign currency losses were included within net income from continuing operations. The

Company entered into derivative instruments to mitigate the exposure of movements in certain of these foreign currency transactions and recognized a $24.8 million loss in fiscal 2015, a $6.3 million loss in fiscal 2014, and a $10.1 million gain in fiscal 2013 within net income from continuing operations.

Cash and Cash Equivalents

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

Accounts Receivable and Allowance for Doubtful Accounts

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

Inventories

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

Property, Plant and Equipment

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

Buildings	10	to	45 years
Leasehold improvements	1	to	20 years
Capitalized software	1	to	10 years
Machinery and equipment	1	to	20 years

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

Upon retirement or other disposal of property, plant and equipment, the cost and related amount of accumulated depreciation are eliminated from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds is included in net income.

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

Acquisitions

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

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

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

is then accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is abandoned, the indefinite-lived intangible asset is charged to expense.

Goodwill and Other Intangible Assets

Goodwill represents the excess of the purchase price of an acquired entity over the amounts assigned to assets and liabilities assumed in a business combination. The Company tests goodwill for impairment during the fourth quarter of each fiscal year, or more frequently if impairment indicators arise. The impairment test is comprised of a two-step approach. The first step requires a comparison of the carrying value of the reporting units to the fair value of these units. The Company estimates the fair value of its reporting units through internal analyses and valuation, utilizing an income approach (a level three measurement technique) based on the present value of future cash flows. If the carrying value of a reporting unit exceeds its fair value, the Company will perform the second step of the goodwill impairment test to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compares the implied fair value of a reporting unit's goodwill with its carrying value. The implied fair value of goodwill is determined in the same manner that the amount of goodwill recognized in a business combination is determined, with the Company allocating the fair value of a reporting unit to all of the assets and liabilities of that unit, including intangible assets, as if the reporting unit had been acquired in a business combination. Any excess of the value of a reporting unit over the amounts assigned to its assets and liabilities is the implied fair value of goodwill. Intangible assets acquired in a business combination are recorded at fair value, while intangible assets acquired in other transactions are recorded at cost. Intangible assets with finite useful lives are subsequently amortized generally using the straight-line method over the following estimated useful lives of the assets, except for customer relationships which are amortized over the estimated pattern of benefit from these relationships:

Completed technology	5	to	25 years
License agreements	8	to	30 years
Trademarks	13	to	30 years
Customer relationships			12 years

Amortization expense related to completed technology and certain other intangible assets is included in cost of sales, while amortization expense related to intangible assets that contribute to the Company's ability to sell, market and distribute products is included in selling, general and administrative expenses.

When a triggering event occurs, we evaluate potential impairment of finite-lived intangible assets by first comparing undiscounted cash flows associated with the asset, or the asset group they are part of, to its carrying value. If the carrying value is greater than the undiscounted cash flows, the amount of potential impairment is measured by comparing the fair value of the assets, or the asset group they are part of, with their carrying value. The fair value of the intangible asset, or the asset group they are part of, is estimated using an income approach. If the fair value is less than the carrying value of the intangible asset, or the asset group they are part of, the amount recognized for impairment is equal to the difference between the carrying value of the asset and the fair value of the asset. The Company assesses the remaining useful life and the recoverability of finite-lived intangible assets whenever events or circumstances indicate that the carrying value of an asset may not be recoverable. The Company annually tests the indefinite-lived intangible assets for impairment by comparing the fair value of the assets, estimated using an income approach, with their carrying value and records an impairment when the carrying value exceeds the fair value.

Contingencies

The Company is subject to various patent, product liability, government investigations, environmental liability and other legal proceedings in the ordinary course of business. The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. The Company discounts environmental liabilities using a risk-free rate of return when the obligation is fixed or reasonably determinable. The

impact of the discount in the consolidated balance sheets was not material in any period presented. Legal fees, other than those pertaining to environmental and asbestos matters, are expensed as incurred. Insurance recoveries related to potential claims are recognized up to the amount of the recorded liability when coverage is confirmed and the estimated recoveries are probable of payment. Assets and liabilities are not netted for financial statement presentation.

Share-Based Compensation

The Company recognizes the cost of employee services received in exchange for awards of equity instruments based on the grant-date fair value of those awards. That cost is recognized over the period during which an employee is required to provide service in exchange for the award, the requisite service period (generally the vesting period). For more information about our share-based awards, refer to Note 15.

Income Taxes

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

Deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been reflected in the consolidated and combined financial statements. Deferred tax assets and liabilities are determined based on the differences between the book and tax bases of assets and liabilities and operating loss carryforwards, using tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided to reduce net deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Deferred tax liabilities are also recorded for deferred tax obligations related to installment sale arrangements. The deferral of tax payments to the IRS are subject to interest, which is accrued and included within interest expense.

The Company determines whether it is more likely than not that a tax position will be sustained upon examination. The tax benefit of any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the uncertainty. To the extent a full benefit is not expected to be realized on the uncertain tax position, an income tax liability is established. Interest and penalties on income tax obligations, associated with uncertain tax positions, are included in the provision for income taxes.

The calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations in a multitude of jurisdictions across the Company's global operations. Due to the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from current estimates of the tax liabilities. If the Company's estimate of tax liabilities proves to be less than the ultimate assessment, an additional charge to expense would result. If payment of these amounts ultimately proves to be less than the recorded amounts, the reversal of the liabilities may result in income tax benefits being recognized in the period when it is determined that the liabilities are no longer necessary. A significant portion of these potential tax liabilities are recorded in other income tax liabilities on the consolidated balance sheets as payment is not expected within one year.

Parent Company Investment

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

3. Recently Issued Accounting Standards

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

FASB issued ASU 2013-02, "Reporting Amounts Classified out of Accumulated Other Comprehensive Income," in February 2013. This guidance requires an entity to present, either on the face of the statement of income or separately in the notes to the financial statements, the effects on net income of significant amounts reclassified out of each

component of accumulated other comprehensive income, if those amounts are required to be reclassified to net income in their entirety in the same reporting period. The guidance was effective for the Company in the first quarter of fiscal 2014. The adoption did not have a material impact on the Company's financial condition, results of operations and cash flows.

FASB issued ASU 2013-04, "Obligations Resulting from Joint and Several Liability Arrangements for Which the Total Amount of the Obligation Is Fixed at the Reporting Date," in February 2013. This update provides guidance for the recognition, measurement and disclosure of obligations resulting from joint and several liability arrangements for which the total amount of the obligation is fixed at the reporting date, except for obligations addressed within existing guidance. An entity is required to measure those obligations as the sum of the amount the entity has agreed to pay on the basis of its arrangement among its co-obligors, and any additional amounts it

expects to pay on behalf of its co-obligors. The guidance also requires the entity to disclose the nature and amount of those obligations. The guidance was effective for the Company in the first quarter of fiscal 2015. The adoption did not have a material impact to the Company's financial condition, results of operations and cash flows.

FASB issued ASU 2013-11, "Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists," in July 2013. This update provides guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss or a tax credit carryforward exists, to eliminate diversity in practice in the presentation of unrecognized tax benefits in those instances. This guidance was effective for the Company in the first quarter of fiscal 2015. The adoption did not have a material impact to the Company's financial condition, results of operations and cash flows.

FASB issued ASU 2014-08, "Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity," in April 2014. Under the new guidance, only disposals representing a strategic shift in a company's operations and financial results should be reported as discontinued operations, with expanded disclosures. In addition, disclosure of the pre-tax income attributable to a disposal of a significant part of an organization that does not qualify as a discontinued operation is required. This guidance is effective for the Company in the first quarter of fiscal 2016, with early adoption permitted. The Company early adopted the guidance during the fourth quarter of fiscal 2015 with the classification of the CMDS business as held for sale.

FASB issued ASU 2014-09, "Revenue from Contracts with Customers," in May 2014. The issuance of ASU 2014-09 and International Financial Reporting Standards ("IFRS") 15, "Revenue from Contracts with Customers," completes the joint effort by FASB and the International Accounting Standards Board to clarify the principles for recognizing revenue and develop a common revenue standard for U.S. GAAP and IFRS. Under the new guidance, an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services, applying the following steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. The guidance is effective for the Company in the first quarter of fiscal 2019. Early adoption is permitted in the first quarter of fiscal 2018. The Company continues to assess the potential impact of the guidance.

FASB issued ASU 2015-03, "Interest - Imputation of Interest," in April 2015. The issuance of ASU 2015-03 is part of the FASB's initiative to simplify the presentation of debt issuance costs. Under the new guidance, debt issuance costs related to a recognized debt liability must be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The amortization of such costs should continue to be calculated using the interest method and be reported as interest expense. The guidance is effective for the Company in the first quarter of fiscal 2016, with early adoption permitted. The Company early adopted the guidance during the fourth quarter of fiscal 2015 and reclassified debt issuance costs, of $103.1 million at September 25, 2015, and expanded disclosure.

FASB issued ASU 2015-11, "Simplifying the Measurement of Inventory," in July 2015. The issuance of ASU 2015-11 is part of the FASB's initiative to more closely align the measurement of inventory between GAAP and IFRS. Under the new guidance, inventory must be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for the Company in the first quarter of fiscal 2017. The Company is assessing the potential impact of the guidance.

FASB issued ASU 2015-16, "Simplifying the Accounting for Measurement-Period Adjustments," in September 2015. Under the new guidance, the requirement to restate prior period financial statements for measurement period adjustments following a business combination is eliminated. The cumulative impact of a measurement period adjustment (including the impact on prior periods) should be recognized in the reporting period in which the adjustment is identified. The guidance is effective for the Company in the first quarter of fiscal 2017. The Company is assessing the potential impact of the guidance.

4. Discontinued Operations and Divestitures

Discontinued Operations

CMDS: During the fourth quarter of fiscal 2015, the Company announced that it had entered into a definitive agreement to sell its CMDS business to Guerbet in a transaction valued at approximately $270.0 million, which is expected to be completed during the first quarter of fiscal 2016. As of September 25, 2015, the CMDS business is deemed to be held for sale and the financial results of this business are presented as a discontinued operation. The CMDS business has been eliminated from the Global Medical Imaging segment, which has been renamed Nuclear Imaging.

Subsequent to the sale of the CMDS business, the Company will continue to supply certain products under a supply agreement with Guerbet.

The following table summarizes the financial results of the CMDS discontinued operations for the fiscal years ended September 25, 2015, September 26, 2014 and September 27, 2013 as presented in the consolidated statements of operations and comprehensive income:

	Fiscal Year		
Major line items constituting income (loss) from discontinued operations	2015	2014	2013
Net sales	$413.8	$495.8	$549.3
Cost of sales	306.4	352.9	346.7
Selling, general and administrative	97.5	97.1	114.0
Restructuring charges, net	0.3	47.2	9.5
Non-restructuring impairment charges	—	204.0	—
Other	4.7	4.1	8.4
Income (loss) from discontinued operations	4.9	(209.5)	70.7
Income tax expense (benefit)	10.8	(34.7)	21.1
Income (loss) from discontinued operations net of tax	$(5.9)	$(174.8)	$49.6

The fiscal 2014 non-restructuring impairment charge of $204.0 million includes charges of $51.4 million associated with property, plant and equipment, $52.4 million associated with intangible assets and $100.2 million associated with goodwill. Further discussion of these impairment charges are included within Notes 10 and 11.

The fiscal 2015 income tax expense of $10.8 million was impacted by approximately $10.0 million of tax expense related to taxes paid, or anticipated to be paid, in connection with the disposition. The fiscal 2014 income tax benefit of $34.7 million was impacted by receiving a tax benefit of $36.2 million on impairment of $204.0 million, by $3.0 million of tax expense associated with the rate difference between U.S. and non-U.S. jurisdictions, $2.5 million of tax benefit associated with nonrecurring valuation allowances, $0.9 million of tax expense associated with accrued income tax liabilities and uncertain tax positions, and $2.0 million of tax expense associated with permanently nondeductible, nontaxable, and other items. The fiscal 2013 income tax expense of $21.1 million was impacted by $0.7 million of tax benefit associated with the rate difference between U.S. and non-U.S. jurisdictions and $2.9 million of tax benefit associated with permanently nondeductible, nontaxable, and other items. Fiscal 2015 reflects $14.9 million of International current income tax expense, $4.4 million of International deferred income tax benefit, and none being allocable to the Domestic income tax provision. Fiscal 2014 reflects $10.4 million of Domestic current income tax expense, $6.6 million of International current income tax benefit, $35.6 million of Domestic deferred income tax benefit, and $3.0 million of International deferred income tax benefit. Fiscal 2013 reflects $5.6 million of Domestic current income tax expense, $10.7 million of International current income tax expense, $5.4 million of Domestic deferred income tax expense, and $0.5 million of International deferred income tax benefit. Domestic reflects U.K. in fiscal 2015, and U.S. federal and state in fiscal 2014 and 2013.

The following table summarizes the assets and liabilities of the CMDS business that are classified as held for sale on the consolidated balance sheets as of September 25, 2015 and September 26, 2014:

	September 25, 2015	September 26, 2014
Carrying amounts of major classes of assets included as part of discontinued operations		
Accounts receivable	$68.5	$68.9
Inventories	86.3	90.2
Property, plant and equipment, net	60.3	62.4
Intangible assets, net	27.7	30.0
Other current and non-current assets	57.1	60.5
Total assets classified as held for sale in the balance sheet	$299.9	$312.0
Carrying amounts of major classes of liabilities included as part of discontinued operations		
Accounts payable	$22.0	$18.0
Other current and non-current liabilities	50.8	50.7
Total liabilities classified as held for sale in the balance sheet	$72.8	$68.7

The following table summarizes significant cash and non-cash transactions of the CMDS business that are included within the consolidated statements of cash flows for the fiscal years ended September 25, 2015, September 26, 2014 and September 27, 2013:

	Fiscal Year		
	2015	2014	2013
Depreciation	$15.5	$18.9	$16.0
Amortization	2.3	7.5	7.5
Capital expenditures	9.5	12.3	17.4
Non-cash impairment charges	—	204.0	—

All other notes to the consolidated financial statements that were impacted by this discontinued operation have been reclassified accordingly.

Mallinckrodt Baker: During fiscal 2010, the Specialty Chemicals business (formerly known as "Mallinckrodt Baker"), which was part of the Company's Specialty Pharmaceuticals segment, was sold because its products and customer bases were not aligned with the Company's long-term strategic objectives. This business met the discontinued operations criteria and, accordingly, was included in discontinued operations for all periods presented. During fiscal 2015, 2014 and 2013, the Company recorded a loss, net of tax, of $0.1 million, a loss of $0.7 million, and a gain of $1.0 million, respectively. These gains and losses were primarily related to the indemnification obligations to the purchaser, which are discussed in Note 18.

Other: Prior to the Separation, the Company provided and accrued for an indemnification, to the purchaser of a certain legal entity, to indemnify it for tax obligations should the tax basis of certain assets not be recognized. The Company believes that, under the terms of the agreement between the parties, this indemnification obligation has expired. As such, the Company eliminated this liability and recorded a $22.5 million benefit, during fiscal 2015, in discontinued operations within the consolidated and combined statement of income.

License of Intellectual Property

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

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5. Acquisitions and License Agreements

Business Acquisitions

Therakos, Inc.

On September 25, 2015, the Company acquired Therakos, Inc. ("Therakos") through the acquisition of all the outstanding common stock of TGG Medical Solutions, Inc., the parent holding company of Therakos, in a transaction valued at approximately $1.3 billion, net of cash acquired ("the Therakos Acquisition"). Consideration for the transaction consisted of approximately $1.0 billion in cash paid to TGG Medical Solutions, Inc. shareholders and the assumption of approximately $0.3 billion of Therakos third-party debt, which was repaid in conjunction with the Therakos Acquisition. The acquisition and repayment of debt was funded through the issuance of $750.0 million aggregate principal amount of senior unsecured notes, a $500.0 million borrowing under a revolving credit facility and cash on hand. Therakos' primary immunotherapy products relate to the administering of extracorporeal photopheresis therapies through its UVAR XTS® and Cellex™ Photopheresis Systems, which accelerates the Company's growth in its Specialty Brands segment.

Ikaria, Inc.

On April 16, 2015, the Company acquired Ikaria, Inc. ("Ikaria") through the acquisition of all the outstanding common stock of Compound Holdings II, Inc., the parent holding company of Ikaria, in a transaction valued at approximately $2.3 billion, net of cash acquired ("the Ikaria Acquisition"). Consideration for the transaction consisted of approximately $1.2 billion in cash paid to Compound Holdings II, Inc. shareholders and the assumption of approximately $1.1 billion of Ikaria third-party debt, which was repaid in conjunction with the Ikaria Acquisition. The acquisition and repayment of debt was funded through the issuance of $1.4 billion aggregate principal amount of senior unsecured notes, a $240.0 million borrowing under the Revolver, which was repaid subsequent to the transaction, and cash on hand. Ikaria's primary product is INOMAX® (nitric oxide) for inhalation, a vital treatment option in neonatal critical care.

Questcor Pharmaceuticals

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

Cadence Pharmaceuticals

On March 19, 2014, the Company acquired all of the outstanding common stock of Cadence Pharmaceuticals, Inc. ("Cadence"), a biopharmaceutical company focused on commercializing products principally for use in the hospital setting, for total consideration of $14.00 per share in cash, or approximately $1.3 billion ("the Cadence Acquisition"). The acquisition was primarily funded through a $1.3 billion senior secured term loan credit facility, as further discussed in Note 12. Cadence's sole product, OFIRMEV® (acetaminophen) injection ("Ofirmev"), is a proprietary intravenous formulation of acetaminophen for the management of mild to moderate pain, the management of

moderate to severe pain with adjunctive opioid analgesics and the reduction of fever. The Cadence Acquisition added a growth product to the Specialty Brands product portfolio and provided us the opportunity to expand our reach into the hospital market, in which Cadence had an established presence.

CNS Therapeutics

On October 1, 2012, the Company acquired all the outstanding equity of CNS Therapeutics, Inc. ("CNS Therapeutics"), a specialty pharmaceuticals company focused on developing and commercializing intrathecal products for site-specific administration to the central nervous system to treat neurological disorders and intractable chronic pain, for total consideration, net of cash acquired, of

$95.0 million. The total consideration was comprised of an upfront cash payment of $88.1 million (net of cash acquired of $3.6 million) and the fair value of contingent consideration of $6.9 million. This contingent consideration, which could potentially total a maximum of $9.0 million, is discussed further in Note 20.

Fair Value Allocation

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

	Therakos	Ikaria	Questcor	Cadence	CNS Therapeutics
Cash	$41.3	$77.3	$445.1	$43.2	$3.6
Inventory	23.5	26.3	67.9	21.0	—
Intangible assets	1,170.0	1,971.0	5,601.1	1,300.0	91.9
Goodwill (non-tax deductible)	437.2	792.4	1,789.4	318.1	24.5
Other assets, current and non-current [1]	42.1	172.9	274.3	18.0	9.7
Total assets acquired	1,714.1	3,039.9	8,177.8	1,700.3	129.7
Current liabilities	24.7	32.6	168.9	48.8	4.0
Unpaid purchase consideration (current)	—	—	128.8	—	—
Other liabilities (non-current)	0.6	9.1	186.8	—	—
Deferred tax liabilities, net (non-current)	324.3	623.6	1,906.8	292.3	27.1
Contingent consideration (non-current)	—	—	—	—	6.9
Total debt	344.8	1,121.0	—	30.0	—
Total liabilities assumed	694.4	1,786.3	2,391.3	371.1	38.0
Net assets acquired	$1,019.7	$1,253.6	$5,786.5	$1,329.2	$91.7

(1) This amount includes $22.0 million, $73.8 million, $87.3 million, $14.7 million and $3.3 million of accounts receivable for the Therakos Acquisition, Ikaria Acquisition, Questcor Acquisition, Cadence Acquisition, and CNS Therapeutics, respectively, which is also the gross contractual value.

The following reconciles the total consideration to net assets acquired:

	Therakos	Ikaria	Questcor	Cadence	CNS Therapeutics
Total consideration, net of cash	$978.4	$1,176.3	$5,470.2	$1,286.0	$95.0
Plus: cash assumed in acquisition	41.3	77.3	445.1	43.2	3.6
Total consideration	1,019.7	1,253.6	5,915.3	1,329.2	98.6
Less: unpaid purchase consideration	—	—	(128.8)	—	—
Less: contingent consideration	—	—	—	—	(6.9)
Net assets acquired	$1,019.7	$1,253.6	$5,786.5	$1,329.2	$91.7

Intangible assets acquired consist of the following:

Therakos	Amount	Amortization Period
Completed technology	$1,170.0	15 years

The completed technology intangible asset relates to extracorporeal photopheresis treatment therapies. The fair value of the intangible asset was determined using the income approach, which is a valuation technique that provides an estimate of the fair value of the asset based on market participant expectations of cash flows the asset would generate. The cash flows were discounted commensurate with the level of risk associated with each asset or its projected cash

flows. The completed technology intangible asset utilized a discount rate of 17.0%. Based on the Company's preliminary estimate, the excess of purchase price over net tangible and intangible assets acquired resulted in goodwill, which represents the assembled workforce, future product and device development, anticipated synergies and the tax status of the transaction. The goodwill is not deductible for U.S. income tax purposes. All assets acquired are included within the Company's Specialty Brands segment.

Ikaria	Amount	Amortization Period
Completed technology	$1,820.0	15 years
Trademark	70.0	22 years
In-process research and development - terlipressin	81.0	Non-Amortizable
	$1,971.0	

The completed technology and trademark intangible assets relate to Inomax. The fair value of the intangible assets were determined using the income approach. The cash flows were discounted at various discount rates commensurate with the level of risk associated with each asset or its projected cash flows. Completed technology, trademark and in-process research and development ("IPR&D") terlipressin intangibles utilized discount rates of 14.5%, 14.5%, and 17.0%, respectively. The IPR&D discount rate for terlipressin was developed after assigning a probability of success to achieving the projected cash flows based on the current stage of development, inherent uncertainty in the FDA approval process and risks associated with commercialization of a new product. Based on the Company's preliminary estimate, the excess of purchase price over net tangible and intangible assets acquired resulted in goodwill, which represents the assembled workforce, future product and device development, anticipated synergies and the tax status of the transaction. The goodwill is not deductible for U.S. income tax purposes. All assets acquired are included within the Company's Specialty Brands segment.

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

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

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

The completed technology intangible asset relates to Ofirmev, the rights to which have been in-licensed from Bristol-Myers Squibb Company ("BMS"). The fair value of the intangible asset was determined using the income approach. The cash flows were discounted at a 13.0% rate. For more information on the BMS license agreement, refer to "License Agreement" below. The excess of purchase price over net tangible and intangible assets acquired resulted

in goodwill, which represents the assembled workforce, anticipated synergies and the tax status of the transaction. The goodwill is not deductible for U.S. income tax purposes. All assets acquired are included within the Company's Specialty Brands segment.

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

The in-process research and development projects primarily relate to certain investigational intrathecal pain products. As of the date of acquisition, these pain products were in various stages of development, with further development, testing, clinical trials and regulatory submission required in order to bring them to market. At the acquisition date, the total cost to complete these products was estimated to be approximately $18.0 million. The Company expects that regulatory approvals will occur between 2016 and 2019. The valuation of the in-process research and development was determined using, among other factors, appraisals primarily based on the discounted cash flow method. The cash flows were discounted at a 35% rate, which was considered commensurate with the risks and stages of development of the pain products. Future residual cash flows that could be generated from the products were determined based upon management's estimate of future revenue and expected profitability of the products. These projected cash flows were then discounted to their present values taking into account management's estimate of future expenses that would be necessary to bring the products to completion. The goodwill is not deductible for U.S. income tax purposes. All assets acquired are included within the Company's Specialty Brands segment.

Financial Results - The amount of net sales and earnings included in the Company's results for the periods presented were as follows:

Net sales	2015	2014
Ikaria	$191.9	$—
Questcor	1,125.9	129.2
Cadence	263.0	124.4
	$1,580.8	$253.6
Operating income (loss)		
Ikaria	$47.1	$—
Questcor	223.3	17.4
Cadence	(97.3)	(66.9)
	$173.1	$(49.5)

The amount of amortization on acquired intangible assets included within operating income (loss) for the periods presented was as follows:

Intangible asset amortization	2015	2014
Ikaria	$57.1	$—
Questcor	301.4	34.9
Cadence	162.5	85.9
	$521.0	$120.8

During fiscal 2015 and 2014, the Company recognized $44.1 million and $25.7 million, respectively, of expense primarily associated with fair value adjustments of acquired inventory. This expense was included within cost of sales.

Acquisition-Related Costs - Acquisition-related costs incurred in fiscal 2015 and 2014 for each of the fiscal 2015 and 2014 acquisitions discussed above were as follows:

Acquisition-related costs	2015	2014
Therakos	$22.5	$—
Ikaria	30.9	—

Questcor	—	47.5
Cadence	—	17.6
	$53.4	$65.1

Unaudited Pro Forma Financial Information - The following unaudited pro forma information presents a summary of the results of operations for the periods indicated as if the Questcor Acquisition and Cadence Acquisition had been completed as of September 29, 2012 and the Ikaria Acquisition and Therakos Acquisition as of September 28, 2013. The pro forma financial information is based on the historical financial information for the Company, Ikaria, Questcor and Cadence, along with certain pro forma adjustments. These pro forma adjustments consist primarily of:

- non-recurring costs related to the step-up in fair value of acquired inventory and transaction costs related to the acquisitions;
- increased amortization expense related to the intangible assets acquired in the acquisitions;
- elimination of direct acquisition transaction costs from the period of acquisition;
- increased interest expense to reflect the fixed rate unsecured notes and revolving credit facility (utilizing the interest rate in effect at the date of the acquisition of 2.6%) entered into in connection with the Therakos Acquisition, the fixed rate unsecured notes entered into in connection with the Ikaria Acquisition (assuming no interest related to the revolving credit facility which was paid down subsequent to the Ikaria Acquisition), the fixed-rate senior unsecured notes and variable-rate term loan entered into in connection with the acquisition of Questcor (utilizing the interest rate in effect at the date of acquisition of 3.50%), and the variable-rate term loan and revolving credit facility entered into in connection with the Cadence Acquisition (utilizing the interest rate in effect at the date of acquisition of 3.50%) including interest and amortization of deferred financing costs and original issue discount; and
- the related income tax effects.

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

	2015	2014
Net sales	$3,755.8	$3,598.1
Income (loss) from continuing operations	359.9	(63.1)
Basic earnings (loss) per share from continuing operations	$3.11	$(0.55)
Diluted earnings (loss) from per share continuing operations	3.07	(0.55)

License Agreements

Ofirmev

As part of the Cadence Acquisition, the Company acquired the exclusive development and commercialization rights to Ofirmev in the U.S. and Canada, as well as the rights to the patents and technology, which were originally in-licensed by Cadence from BMS in March 2006. BMS sublicensed these rights to Cadence under a license agreement with SCR Pharmatop S.A. ("Pharmatop"), and the Company has the right to grant sublicenses to third parties. Under this license agreement, the Company may be obligated to make future milestone payments of up to $25.0 million upon the achievement of certain levels of net sales, of which $10.0 million was paid during fiscal 2015. In addition, the Company is obligated to pay royalties on sales of the product. During fiscal 2015 and 2014, the Company paid royalties of $43.9 million and $13.2 million respectively.

Exalgo

In 2009, the Company's Specialty Brands segment acquired the rights to market and distribute the pain management drug EXALGO® (hydromorphone HCl) extended-release tablets (CII) ("Exalgo") in the U.S. Under the license agreement, the Company is obligated to make additional payments of up to $73.0 million based on the successful completion of specified development and regulatory milestones. Through fiscal 2015, $65.0 million of additional payments had been made, with $55.0 million being capitalized as an intangible asset. The Company is also required to pay royalties on sales of the product. During fiscal 2015, 2014 and 2013, the Company paid royalties of $3.2 million,

$22.0 million and $24.0 million, respectively.

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

Depomed

In 2009, the Company's Specialty Brands segment licensed worldwide rights to utilize Depomed, Inc.'s ("Depomed") Acuform gastric retentive drug delivery technology for the exclusive development of four products. Under this license agreement, the Company may be obligated to pay up to $64.0 million in development milestone payments. Through fiscal 2015, approximately $22.0 million of these payments have been made by the Company. During fiscal 2014, upon approval by the FDA for XARTEMIS™ XR (oxycodone HCl and acetaminophen) extended release tablets CII ("Xartemis XR"), the Company made a milestone payment of $10.0 million, which has been capitalized as an intangible asset.

Pennsaid

In 2009, the Company's Specialty Brands segment entered into a licensing agreement which granted it rights to market and distribute Pennsaid and Pennsaid 2%, a formulation of diclofenac sodium topical solution which was approved in February 2014 by the FDA and indicated for the treatment of pain associated with osteoarthritis of the knee. The Company was responsible for 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 2015, $15.0 million of these payments were made, all of which were capitalized as an intangible asset. The Company is also required to pay royalties on sales of the products under this agreement. During fiscal 2015, 2014 and 2013, the Company paid royalties of $1.8 million, $4.3 million and $3.9 million, respectively.

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

6. Restructuring and Related Charges

During fiscal 2013, the Company launched a restructuring program designed to improve its cost structure ("the 2013 Mallinckrodt Program"). The 2013 Mallinckrodt Program includes actions across all segments, as well as within corporate functions. The Company expects to incur charges of $100.0 million to $125.0 million under this program as the specific actions required to execute on these initiatives are identified and approved, most of which are expected to be incurred by the end of fiscal 2016.

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

Net restructuring and related charges by segment within continuing operations are as follows:

	Fiscal Year	
	2015	2014