Mallinckrodt plc
Form 10-K
November 29, 2016
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 30, 2016
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 25, 2016, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $6,564.4 million (based upon the closing price of $60.06 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 22, 2016 was 105,858,223.

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 30, 2016, 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

We are a global business that develops, manufactures, markets and distributes branded and generic specialty pharmaceutical products and therapies. Therapeutic areas of focus include autoimmune and rare disease specialty areas (including neurology, rheumatology, nephrology, ophthalmology and pulmonology); immunotherapy and neonatal critical care respiratory therapies; analgesics and hemostasis products; and central nervous system drugs.

We operate our business in two reportable segments, which are further described below:

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

We completed the sale of our contrast media and delivery systems ("CMDS") business on November 27, 2015. The financial results of this business are presented as a discontinued operation.

On August 24, 2016, we announced that we had entered into a definitive agreement to sell our Nuclear Imaging business to IBA Molecular ("IBAM"), which is expected to be completed during the first half of calendar 2017. The Nuclear Imaging business is deemed to be held for sale and the financial results of this business are presented as a discontinued operation. As a result, prior year balances have been recast to present this business as a discontinued operation.

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

History and Development

Our Specialty 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.

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, we completed multiple acquisitions of specialty branded pharmaceutical businesses within our Specialty Brands segment. We believe these acquisitions have created a foundation and framework for future growth. In addition to these acquisitions, we also implemented significant actions under our restructuring programs intended to improve our long-term profit margins and yield efficiencies from selling, general and administrative expenses ("SG&A"). In November 2015, we completed the sale of our CMDS business and in August 2016 entered into a definitive agreement to sell our Nuclear Imaging business, in order to further increase our focus on specialty pharmaceuticals.

In May 2015, our Board of Directors 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 of specialty branded pharmaceutical companies and assets in recent years that created a framework for future organic volume growth and additional business development. We successfully completed the integration of these acquisitions and generated synergies from these transactions, primarily associated with SG&A. We expect to realize further synergies in SG&A expenses during fiscal 2017. 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.
- Diversified business model with increasing shift towards high-margin Specialty Brands business with significant cash flow generation. We have a diverse portfolio in both our Specialty Brands and Specialty Generics segments that generate significant cash flows. We have furthered our shift toward the Specialty Brands business with the completed divestiture of our CMDS business and agreement to divest our Nuclear Imaging business. In the fourth quarter of fiscal 2016, net sales from our Specialty Brands segment represented 72.5% of net sales from our reportable segments compared with 61.2% in the fourth quarter of fiscal 2015. We expect the Specialty Brands percentage to increase in fiscal 2017 due to the inclusion of full year results from our fiscal 2016 acquisitions, organic volume growth in Specialty Brands and increased competition in Specialty Generics. Specialty Brands segment operating income increased from 45.3% in the fourth quarter of fiscal 2015 to 52.8% in the fourth quarter of fiscal 2016. The increased revenues and segment operating income position us for strong cash flow generation, enabling us to potentially decrease net debt leverage over time. Net cash flows from operating activities in fiscal 2016 were $1,184.6 million compared with $896.4 million in fiscal 2015, both of which included operating cash flows from discontinued operations.
- Expertise in highly regulated raw materials. We have expertise in the acquisition and importation of highly regulated raw materials, such as opioids and other controlled substances in our Specialty Generics segment. For example, in calendar 2015, we estimated that we received approximately 25% 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 23% 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 collaboration with a wide variety of regulatory authorities including the DEA, U.S. Food and Drug Administration ("FDA") and U.S. Department of Agriculture ("USDA").
- 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.

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; 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 two reportable segments: Specialty Brands and Specialty Generics. Management measures and evaluates our operating segments based on segment net sales and operating income. Information regarding the product portfolios and business strategies of these segments is included in the following discussion. Financial information regarding each of our reportable segments, as well as other geographical information, is included in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and in Note 20 of the Notes to Consolidated 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 products for autoimmune and rare diseases (including in the specialty areas of neurology, rheumatology, nephrology, ophthalmology and pulmonology); immunotherapy and neonatal respiratory critical care therapies; analgesics and hemostasis products and central nervous system drugs. In fiscal 2016, our Specialty Brands segment accounted for 69.2% of net sales from our operating segments.

We started our Specialty Brands product portfolio in 2001 and shifted the focus of this portfolio 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"). In fiscal 2016, we further expanded our Specialty Brands business with the February 2016 acquisition of RECOTHROM® Thrombin topical (Recombinant) ("Recothrom"), PreveLeak™ Surgical Sealant ("PreveLeak"), and RAPLIXA™ (Fibrin Sealant (Human)) ("Raplixa") and the development product StrataGraft® regenerative skin tissue ("StrataGraft"). 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, pulmonologists, neonatologists, ophthalmologists, surgeons, and pharmacy directors) with our own direct sales force of over 500 sales representatives as of September 30, 2016. 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 ensure reimbursement for our products to patients that are prescribed our products by their physicians.

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

- Acthar is an injectable drug approved by the FDA for use in 19 indications. The product currently generates substantially all of its net sales from ten 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; the treatment of ophthalmic conditions related to severe acute and chronic allergic and inflammatory processes; 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.
- 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.
- 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.

- 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 an 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.

- Hemostasis products deliver innovation across the spectrum of surgical bleeding with a suite of products and services to help improve hemostasis management. Recothrom is a topical thrombin indicated to aid hemostasis whenever oozing blood and minor bleeding from capillaries and small venules is accessible and control of bleeding by standard surgical techniques (such as suture, ligature, or cautery) is ineffective or impractical in adults and pediatric populations greater than or equal to one month of age. PreveLeak is indicated for use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage. Raplixa is a fibrin sealant indicated as an adjunct to hemostasis for mild to moderate bleeding in adults undergoing surgery when control of bleeding by standard surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical. Raplixa is used in conjunction with an absorbable gelatin sponge (USP) and may be applied directly or using the RaplixaSpray™ device. Each of the acquired products is approved for use in the U.S. and certain European countries, with long-range market exclusivity through intellectual property protection – Recothrom to 2026, PreveLeak to 2028 and Raplixa to 2031. Only Recothrom and PreveLeak are currently marketed in the U.S.
- StrataGraft is a viable, full-thickness product being developed for regulatory approval for severe burns and other complex skin defects. It was designed to mimic natural human skin, with both dermal and fully differentiated epidermal layers. Unlike first generation products, this resorbable tissue is easily sutured or stapled and remains intact in the wound bed, providing critical barrier functionality during the wound healing process. StrataGraft is produced using unmodified NIKS® cells grown under standard operating procedures. Because the continuous NIKS skin cell line has been thoroughly characterized, StrataGraft products are virus-free, non-tumorigenic, and offer batch-to-batch genetic consistency.

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. 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 2016, our Specialty Generics segment accounted for 30.8% 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 2015 we estimated that we received approximately 25% 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 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.

Industry Overview and Trends

We believe our businesses are well positioned in attractive markets based on a global broadening of access to healthcare and increased demand for pharmaceutical products from emerging markets. With respect to specialty branded drugs, most disease states 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.

Competition

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 failed to provide positive outcomes or are not well tolerated by the patient. Similarly, Inomax is the only inhaled nitric oxide product approved by the FDA that is indicated for the treatment of term and near-term (>34 weeks) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension, where it improves oxygenation and reduces the need for extracorporeal membrane oxygenation. 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.

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, to 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. Several of the products in our Specialty Brands product portfolio benefit from these forms of regulatory and patent-conferred exclusivity.

Following the loss of regulatory and patent-conferred exclusivity, branded products often face increased competition from generic pharmaceuticals. 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, for example Acthar, that may not be prescribed unless a clear benefit in efficacy or safety is demonstrated or until alternatives have failed to provide positive patient outcomes or are not well tolerated by the patient.

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 Endo Health Solutions Inc., Johnson Matthey plc, Mylan N.V., Pfizer Inc., Purdue Pharma L.P. and Teva Pharmaceutical Industries Ltd., among others. We believe 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 pharmacies enable us to compete 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 operate in this highly competitive and regulated environment.

The Specialty Generics segment faces 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. Among the large generic controlled substance providers, we are the only generic manufacturer that has its own controlled substance API manufacturing capability. 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.

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.

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. Several of the other products in our Specialty Brands product portfolio currently benefit from these forms of regulatory and patent-conferred exclusivity.

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 $262.2 million, $203.3 million and $140.5 million in fiscal 2016, 2015 and 2014, respectively. We expect to continue to invest in R&D activities, both for existing products and the development of new portfolio assets. We intend to focus our R&D investments principally in the specialty pharmaceuticals area, specifically investments to support our Specialty Brands, where we believe there is the greatest opportunity for growth and profitability. Our Specialty Brands include medicines for pain management, acute and critical care, and autoimmune and rare diseases (“ARD”). Our primary focus for the latter includes the therapeutic areas of neurology, rheumatology, nephrology, ophthalmology and pulmonology.

Specialty Brands. We devote significant R&D resources for our branded products. Our R&D investments center on building a diverse, durable portfolio of innovative therapies that provide value to patients, physicians and payers. We are leveraging both organic development and acquiring late-stage development assets through the execution of our “acquire to invest” strategy to facilitate organic growth. Under this strategy, we look to acquire durable, but currently under-resourced assets for which we believe we can accelerate growth and expand reach to patients with substantial unmet medical needs.

Data generation is an important strategic driver for key products in order to extend evidence in approved uses, label enhancements and new indications. Our strategy is realized through investments in both clinical and health economic activities. We are committed to supporting research that helps advance the understanding and treatment of a variety of different disease states that will further the understanding and development of our currently marketed products, including Acthar®, Ofirmev®, Inomax, and Therakos immunotherapy.

Our "acquire to invest" strategy also includes the acquisition of early and late stage development products to meet the needs of underserved patient populations. Under our strategy we continue the development process and perform clinical trials to support FDA approval of new products. The most significant development products in our pipeline include Terlipressin, StrataGraft and Synacthen Depot in the U.S. Terlipressin is being investigated for the treatment of Hepatorenal Syndrome ("HRS") type1, an acute, rare and life-threatening condition requiring hospitalization, with no currently approved therapy in the U.S. or Canada. In July 2016, the Company enrolled the first patient in the company's Phase 3 clinical study to evaluate the efficacy and safety of terlipressin (for injection) in subjects with HRS type 1. StrataGraft is an investigational product in Phase 3 development for treatment of severe, deep partial thickness burns and Phase 2 development for treatment of severe, full thickness burns. In 2012, the FDA granted StrataGraft orphan product status, and the product is being developed as a biologic to be filed under a biologic license application that would confer regulatory protection until 2032. Synacthen Depot is a depot formulation of Synacthen (tetracosactide), a synthetic 24 amino acid melanocortin receptor agonist. In August 2016, we announced that the FDA has granted the company's request for a fast track designation for its Investigational New Drug ("IND") application for Synacthen Depot in the treatment of Duchenne muscular dystrophy ("DMD"). The FDA's fast track designation is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get potentially important new drugs to the patient earlier.

Specialty Generics. Specialty Generics development is focused on hard-to-manufacture pharmaceuticals with difficult-to-replicate pharmacokinetic profiles. Our Specialty Generics pipeline portfolio consists of several products in various stages of development. We currently do most of our development work at our Specialty Generics headquarters and technical development center in Webster Groves, Missouri.

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 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 2017, the user fee rate has been set at $2,038,100 for a 505(b)(1) NDA and $1,019,050 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, the 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 2017, the user fee rate is set at $70,480 for an ANDA and $35,240 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 2017 has a target of approving 90% of ANDA submissions within 10 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 2016, manufacturing and procurement quotas granted by the DEA have been sufficient to meet our sales and inventory requirements on most products. In October 2016, the DEA reduced the amount of almost every Schedule II opiate and opioid medication that may be manufactured in the United States in calendar year 2017 by 25 percent or more. A handful of medicines were reduced by more, such as hydrocodone, which will be 66 percent of calendar year 2016 level. A 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.

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. 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 $94.4 million, $82.3 million and $43.5 million in fiscal 2016, 2015, and 2014, respectively. The fiscal 2016 increase in provisions for Medicaid payments is primarily attributable to a $16.9 million increase associated with Acthar, due to double-digit net sales growth, which was partially offset by lower net sales of Specialty Generics. 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 Company was also impacted by the annual fee on branded prescription pharmaceutical manufacturers, which is not tax deductible, and recorded expense of $23.3 million, $20.0 million and $0.9 million in fiscal 2016, 2015, and 2014, respectively, within selling, general and administrative expenses. The fee significantly 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. Our compliance programs are facilitated by our 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 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 pursuant to either a centralized or decentralized procedure. The centralized procedure, which provides for a single marketing authorization valid for all E.U. member states, is mandatory for the approval of certain drug products and is optional for novel drug products that are in the interest of patient health. Under the centralized procedure, a single marketing authorization application is submitted for review to the European Medicines Agency, which makes a recommendation on the application to the European Commission, who determines whether or not to approve the application. The decentralized procedure provides for concurrent mutual recognition of national approval decisions, and is available for products that are not subject to the centralized procedure.
The E.U. has also adopted directives and other laws that govern the labeling, marketing, advertising, supply, distribution and drug safety monitoring and reporting of drug products. Such directives set regulatory standards throughout the E.U. and permit member states to supplement such standards with additional requirements.
European governments also regulate drug prices through the control of national healthcare systems that fund a large part of such costs to patients. Many regulate the pricing of a new drug product at launch through direct price controls or reference pricing and, recently, some have also imposed additional cost-containment measures on drug products. Such differences in national pricing regimes may create price differentials between E.U. member states. Many European governments also advocate generic substitution by requiring or permitting prescribers or pharmacists to

substitute a different company's generic version of a brand drug product that was prescribed, and patients are unlikely to take a drug product that is not reimbursed by their government.

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

Environmental

Our operations, like those of other pharmaceutical companies, involve the use of substances regulated under environmental laws, primarily in manufacturing processes and, as such, we are subject to numerous federal, state, local and non-U.S. environmental protection and health and safety laws and regulations. We cannot provide assurance that we have been or will be in full compliance with environmental, health and safety laws and regulations at all times. Certain environmental laws assess strict (i.e., can be imposed regardless of fault) and joint and several liability on current or previous owners of real property and current or previous owners or operators of facilities for the costs of investigation, removal or remediation of hazardous substances or materials at such properties or at properties at which parties have disposed of hazardous substances. We have, from time to time, received notification from the EPA and from state environmental agencies in the U.S. that conditions at a number of sites where the disposal of hazardous substances requires investigation, cleanup and other possible remedial actions. These agencies may require that we reimburse the government for costs incurred at these sites or otherwise pay for the cost of investigation and cleanup of these sites including compensation for damage to natural resources. We have projects underway at a number of current and former manufacturing facilities to investigate and remediate environmental contamination resulting from past operations, as further described in Item 3. Legal Proceedings and Note 18 to the Notes to Consolidated 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.

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.

Sales, Marketing and Customers

Sales and Marketing

We market our branded products to physicians (including rheumatologists, neurologists, nephrologists, pulmonologists, neonatologists, ophthalmologists and surgeons), pharmacists, pharmacy buyers, hospital procurement departments, ambulatory surgical centers, and specialty pharmacies. We distribute our branded and generic 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.

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 2016, 2015 and 2014 were as follows:

	Fiscal Year		
	2016	2015	2014
CuraScript	38%	35%	7 %
McKesson Corporation	12%	20%	25%
AmerisourceBergen Corporation	8 %	10%	15%
Cardinal Health, Inc.	7 %	11%	18%

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

Manufacturing and Distribution

We presently have ten manufacturing sites, including eight located in the U.S., as well as sites in Canada and Ireland, which handle production, assembly, quality assurance testing, packaging and sterilization of products for our Specialty Brands and Specialty Generics segments. Approximately, 93% and 7% of our manufacturing production (as measured by cost of production) was performed within the U.S. and Canada, respectively, in fiscal 2016.

We maintain distribution centers in 10 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 Specialty Brands products, including Acthar (for finish and filling of the product), Ofirmev, Recothrom and Therakos immunotherapy products.

Backlog

At September 30, 2016, the backlog of firm orders was less than 1% of net sales. We anticipate that substantially all of the backlog as of September 30, 2016 will be shipped during fiscal 2017.

Seasonality

We have historically experienced fluctuations in our business resulting from seasonality. Acthar has experienced lower net sales during the first calendar quarter, which we believe is partially attributable to certain medical conditions being exacerbated by warm temperatures and effects of annual insurance deductibles. 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. Lastly, we have experienced lower operating cash flows during the fourth calendar 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 30, 2016, we had approximately 4,500 employees, approximately 3,900 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, 2016, and current positions of our executive officers.

Name	Age	Title
Mark Trudeau	55	President, Chief Executive Officer and Director
Matthew Harbaugh	46	Executive Vice President and Chief Financial Officer
Meredith Fischer	63	Chief Public Affairs Officer
Raymond Furey	48	Chief Compliance Officer
Michael-Bryant Hicks	42	General Counsel
Ron Lloyd	56	Executive Vice President and President, Hospital Therapies
Hugh O'Neill	53	Executive Vice President and President, Autoimmune and Rare Diseases
Gary Phillips	50	Executive Vice President and Chief Strategy Officer
Steven Romano	57	Executive Vice President and Chief Scientific Officer
Frank Scholz	47	Executive Vice President of Global Operations and President, Specialty Generics
Ian Watkins	54	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 Bayer's 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 has served as a director of TE Connectivity Ltd. since March 2016.

Matthew Harbaugh is our Executive Vice President and Chief Financial Officer. He has executive responsibility for finance, procurement and information technology, as well as the Nuclear Imaging business. Mr. Harbaugh previously served as Vice President, Finance of Covidien’s Pharmaceuticals business, a position he 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., a New York-based private equity firm, from April 2007 until August 2007. Prior to that Mr. Harbaugh worked nearly ten years for Monsanto, where he held several positions, including corporate finance director, investor relations, and finance director/chief financial officer for Monsanto's southern Argentine/Chilean and Canadian operations via two expatriate assignments.

Meredith Fischer is our Chief Public Affairs Officer. 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 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 Senior Vice President since May 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.

Michael-Bryant Hicks is our General Counsel. Mr. Hicks joined Mallinckrodt in March 2016. Before joining Mallinckrodt, Mr. Hicks served as Senior Vice President, General Counsel, Chief Compliance Officer and Corporate Secretary of The Providence Service Corporation, a global provider of a range of healthcare services, from January 2014 to February 2016. Prior to that, he served as Assistant General Counsel at DaVita Healthcare Partners, Inc., a leading provider of dialysis services from February 2011 to December 2013. Mr. Hicks was lead attorney for DaVita's acquisition of HealthCare Partners, one of the country's largest operators of integrated medical groups and physician networks, and served as interim general counsel for the business. Additionally, he spent five years at Beckman Coulter, Inc., a provider of biomedical testing products, where he was associate general counsel and head of legal support for the company's Asia and Latin America operations, and was an associate in the corporate law practices of two international

law firms - Vinson & Elkins LLP and Mayer, Brown, Rowe & Maw LLP. He began his career as a law clerk for the Honorable James A. Beaty, Jr. of the U.S. District Court for the Middle District of North Carolina.

Ron Lloyd is our Executive Vice President and President, Hospital Therapies. Prior to joining Mallinckrodt in January 2016, Mr. Lloyd worked at Baxter Healthcare/Baxalta for 12 years, where he held various commercial leadership positions including: President of the Immunology Division of Baxalta from January to June 2015; Franchise Head, Immunology from January to December 2014; General Manager BioScience U.S. Region from March 2011 to December 2014; General Manager/Vice President - Generative Medicine, Bioscience Division from January 2007 to March 2011; and Vice President - Global Marketing, BioScience Division from April 2003 to December 2006. Mr. Lloyd previously served in a number of commercial and business development capacities at Abbott Laboratories.

Hugh O'Neill is our Executive 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 Executive 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 U.S. 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, M.D. is our Executive 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 with his role 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.

Dr. Frank Scholz is our Executive Vice President of Global Operations and President, Specialty Generics. His responsibilities include global manufacturing operations, quality and supply chain, as well as the Specialty Generics segment. He joined Mallinckrodt in March 2014 as Senior Vice President of Global Operations and assumed his current position in September 2016. 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 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.)

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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 regulations that govern and influence 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 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 $3,705.3 million and $9,182.3 million, respectively, at September 30, 2016. 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.

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 2041, 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, on inhaled nitric oxide gas delivery systems as well as methods

of using such systems, and on use of nitric oxide gas sensors, such patents that may have the effect of inhibiting development of competitive generic products.

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 any patents that are subsequently obtained. The latest expiring of the in-licensed patents expires in 2021.

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. Four patent applications were filed in 2016 relating to improvements to the CELLEX system, disposable kit and overall photopheresis method, that, if approved, may offer patent protection through approximately 2036.

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 18 of the Notes to Consolidated 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 2016, manufacturing and procurement quotas granted by the DEA have been sufficient to meet our sales and inventory requirements on most products. In October 2016, the DEA reduced the amount of almost every Schedule II opiate and opioid medication that may be manufactured in the United States in calendar year 2017 by 25 percent or more. A handful of medicines were reduced by more, such as hydrocodone, which will be 66 percent of calendar year 2016 level. 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, if these distributors were to experience difficulty in paying us on a timely basis, or if these distributors negotiate lower pricing terms, the occurrence of one or more of these factors 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 specialty branded and specialty generic pharmaceuticals, and API. However, our fiscal 2015 and 2014 acquisitions brought a small number of relatively significant products, most notably Acthar and to a lesser extent, Inomax, Ofirmev and Therakos, 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, for 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. An example of such a strategic alliance is the arrangement between McKesson Corporation and Wal-Mart Stores, Inc. that was announced in May 2016 for the sourcing of generic pharmaceuticals. McKesson represents our largest wholesale customer in the Specialty Generics segment. Failure to negotiate distribution arrangements having advantageous pricing and other terms of sale could cause us to lose market share to our competitors or result in lower pricing on volume we retain, both of which 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 maintain volume and pricing with historical or anticipated levels 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 governmental health administration authorities, private health coverage insurers and other third-party payers. 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.

We may experience pricing pressure on certain of our products due to legal changes or changes in insurers' reimbursement practices resulting from recent increased public scrutiny of healthcare and pharmaceutical costs, which could reduce our future revenue and profitability.

Recent public and governmental scrutiny of the cost of healthcare generally and pharmaceuticals in particular, especially in connection with price increases of certain products, could affect our ability to maintain or increase the prices of one or more of our products, which could negatively impact our future revenue and profitability. Certain press reports and other commentary have criticized the substantial increases in the price of Acthar that occurred prior to our acquisition of the product. Acthar represented 34% of our net sales for fiscal 2016. In addition, U.S. federal prosecutors recently issued subpoenas to another pharmaceutical company seeking information about its drug pricing practices, among other issues, and members of the U.S. Congress have sought

information from certain pharmaceutical companies (not including Mallinckrodt) relating to drug price increases. We cannot predict whether any particular legislative or regulatory changes or changes in insurers' reimbursement practices may result from any such public scrutiny, what the nature of any such changes might be or what impact they may have on us. If legislative or regulatory action were taken or insurers changed their reimbursement practices to limit our ability to maintain or increase the prices of our products, our future revenue and profitability could be negatively affected.

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 pharmaceutical 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. 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. In addition, it is unclear how market participants will react to price increases. For example, following pricing actions in our Specialty Generics segment in fiscal 2015, additional competitors entered the marketplace for several of these products and prices subsequently decreased. If customers do not maintain or increase existing sales volumes or market participants do not take similar actions after price increases are enacted, we may be unable to replace lost sales with orders from other customers, and 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 initiated such restructuring activities. 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, which we expect to decrease net sales in this segment compared with fiscal 2016 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, personal injury, antitrust matters, securities class action lawsuits, breach of contract, Medicare and Medicaid reimbursement claims, promotional practices and compliance with laws relating to the manufacture 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 $10.0 million per claim of the first $25.0 million of a loss in our primary liability policies and purchase an additional $150.0 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 found to be unlawful, we will 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 remediation 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. 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 30, 2016, it was probable that we would incur remediation costs in the range of $38.7 million to $121.3 million. We also concluded that, as of September 30, 2016, the best estimate within this range was $75.9 million. For further information on our environmental obligations, refer to Item 3. Legal Proceedings and Note 18 of the Notes to Consolidated 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.

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.

We are increasingly dependent on information technology and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. We are increasingly dependent on sophisticated information technology systems and infrastructure to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced significant elements of our operations to third parties, some of which are outside the U.S., including significant elements of our information technology infrastructure, and as a result we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of our third party vendors with whom we contract, make such systems potentially vulnerable to service interruptions. The size and complexity of our and our vendors' systems and the large amounts of confidential information that is present on them also makes them potentially vulnerable to security breaches from inadvertent or intentional actions by our employees, partners or vendors, or from attacks by malicious third parties. We and our vendors could be susceptible to third party attacks on our information security systems, which attacks are of ever increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including criminal groups, “hackers” and others. Maintaining the secrecy of this confidential, proprietary, and/or trade secret information is important to our competitive business position. However, such information can be difficult to protect. While we have taken steps to protect such information and invested heavily in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology

or information, and/or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information, could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

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 30, 2016, we had $6,135.6 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 30, 2016, we had $1,953.5 million outstanding variable-rate debt on our senior secured term loans and $235.0 million outstanding variable-rate debt on our receivables securitization. As of September 30, 2016, we had no outstanding borrowings on our revolving credit facility, but we would be subject to variable interest rate risk if we were to borrow in the future. 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

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. In April 2016, the U.S. Department of the Treasury issued Temporary Regulations promulgated under Internal Revenue Code Section 7874 to reduce the tax benefits of, or preclude entirely, certain inversion transactions. The Company does not believe these Temporary Regulations will have a material impact to the Company's status as a foreign corporation for U.S. federal tax purposes. However, other changes in tax law, such as additional 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, the President, U.S. Department of the Treasury, and Congress have issued recent proposals that would amend the inversion

rules. Although the proposals would generally apply to prospective transactions, no assurance can be given that such proposals will not be changed in the legislative process to apply to prior transactions.

Future changes to U.S. and foreign tax laws could adversely affect us.
The European Commission, U.S. Congress and Treasury Department, the Organization for Economic Co-operation and Development, and other government agencies in jurisdictions where we and our affiliates do business have had an extended focus on issues related to the taxation of multinational corporations, particularly payments made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. As a result, the tax laws in the European Union, 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.
Recent examples include the Organization for Economic Co-operation and Development's recommendations on base erosion and profit shifting, the European Commission's Anti-Tax Avoidance Directive and the Corporate Tax Package released in October 2016 which includes a Common Consolidated Corporate Tax Base and Switzerland's Corporate Tax Reform III. These initiatives include recommendations and proposals that, if enacted in countries in which we and our affiliates do business, could adversely affect us and our affiliates.

We may not be able to maintain a competitive worldwide effective corporate tax rate.
We cannot give any assurance as to what our effective tax rate will be in the future, because of, among other things, uncertainty regarding the tax policies of the jurisdictions where we operate. Our actual effective tax rate may vary from our expectation and that variance may be material. Additionally, the tax laws of 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 Taxation 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 obligations.
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. During the fiscal year ended September 30, 2016, the Company entered into similar transactions with certain intangible assets acquired in the Ikaria Acquisition and Therakos Acquisition. The installment sale transactions resulted in a taxable gain. In accordance with Internal Revenue Code Section 453A 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 30, 2016, the Company had an aggregate $1,883.7 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 differs 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, license rights or businesses;
- the operating and share price performance of comparable companies;
- actual or anticipated sales of our ordinary shares;

- allegations by third parties (even if unsubstantiated) regarding our products or business practices;
- publicity and media reports regarding actual or potential competitive or other developments in the markets we serve;
- new regulations or legislation in the U.S. relating to the development, sale or pricing of pharmaceuticals or medical devices;
- political pressure to reduce the pricing of pharmaceuticals;
- continued consolidation in pharmacy networks and among insurers that may further increase their competitive market power;
- changes to the regulatory and legal environment in which we operate; and
- U.S. and worldwide economic conditions.

Third parties, some of whom may have taken investment positions that would increase in value if our share price declines ("short sellers"), may make allegations related to our products or business practices. These short sellers make a profit when our shares decline in value, and their actions and public statements, and the resulting publicity, may cause further volatility in our share price. In November 2015, one short seller publicly made assertions regarding Acthar that were not substantiated in any way. In March 2016 the short seller reiterated, again without any substantiation, many of the same assertions. On both occasions, the unsubstantiated assertions attracted media attention and our share price fluctuated. This volatility may cause the value of a shareholder's investment to decline.

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 a 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.

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 30, 2016, we owned a total of eleven facilities in three countries. Our owned facilities consist of approximately 2.7 million square feet, and our leased facilities consist of approximately 1.6 million square feet. We have ten manufacturing sites, which are used by our Specialty Brands and Specialty Generics segments. We have one manufacturing site in Canada, one manufacturing site in Ireland and eight 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, personal injury, 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. For further information on pending legal proceedings, refer to Note 18 of the Notes to Consolidated 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.

	FY2016		FY2015	
	High	Low	High	Low
First Quarter	$76.66	$53.41	$99.73	$83.19
Second Quarter	75.88	53.42	132.51	93.89
Third Quarter	66.27	55.97	130.13	113.18
Fourth Quarter	83.06	54.05	126.51	68.45

There were approximately 3,055 shareholders of record of our ordinary shares as of November 22, 2016.

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 was 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 30, 2016, we repurchased 687,103 of our ordinary shares related to both our $500.0 million share repurchase program, announced on November 19, 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
6/25/2016 - 7/29/2016	3,845	$61.82	—	$ 474.8
7/30/2016 - 8/26/2016	3,083	75.31	—	474.8
8/27/2016 - 9/30/2016	680,175	74.22	679,666	424.3
6/25/2016 - 9/30/2016	687,103	74.16		

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 30, 2016.

Comparison of Cumulative Total Return*
Among Mallinckrodt plc, the Russell 1000 Index and NYSE Pharmaceutical Index
*$100 invested on June 17, 2013 in shares or index.

Performance Graph Data

	Mallinckrodt	Russell 1000 Index	NYSE Pharmaceutical Index
June 17, 2013	$ 100	$ 100	$ 100
September 27, 2013	97	104	100
September 26, 2014	200	121	124
September 25, 2015	152	119	123
September 30, 2016	155	132	119

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 30, 2016.

Item 6. Selected Financial Data.

The following table sets forth selected financial data as of and for the fiscal years ended September 30, 2016, September 25, 2015, September 26, 2014, September 27, 2013 and September 28, 2012. 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 2016, 2015, and 2014, and the consolidated balance sheet data as of September 30, 2016 and September 25, 2015 were derived from our consolidated and combined financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K. The September 26, 2014, September 27, 2013 and September 28, 2012 balance sheets were derived from our audited consolidated and combined financial statements that are not included in this Annual Report on Form 10-K. In fiscal 2016 and 2015, the Company announced that it had entered into a definitive agreement to sell its Nuclear Imaging and CMDS businesses to IBAM and Guerbet, respectively. Accordingly, the combined statement of income data for fiscal 2013 and 2012 are derived from our unaudited consolidated financial statements that are not included in this annual report.

This selected financial information should be read in conjunction with our consolidated 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]				
	2016	2015	2014	2013	2012
Consolidated and Combined Statement of Income Data:					
Net sales	$3,380.8	$ 2,923.1	$ 1,650.3	$ 1,274.7	$1,078.2
Gross profit	1,855.0	1,622.9	884.6	610.5	448.0
Research and development expenses [2]	262.2	203.3	140.5	141.9	144.1
Operating income (loss) [3] [4]	617.3	353.8	43.4	20.0	0.8
Income (loss) from continuing operations before income taxes	233.4	107.3	(34.6)	2.2	1.7
Income (loss) from continuing operations	489.0	236.6	(22.0)	(27.6)	(23.3)
Share Data [5]:					
Basic income (loss) from continuing operations per share	$4.42	$ 2.03	$ (0.34)	$ (0.48)	$(0.40)
Diluted income (loss) from continuing operations per share	4.39	2.00	(0.34)	(0.48)	(0.40)
Cash dividends per ordinary share	—	—	—	—	—
	September 30, 2016	September 25, 2015	September 26, 2014	September 27, 2013	September 28, 2012
Consolidated and Combined Balance Sheet Data:					
Total assets	$15,498.7	$ 16,404.1	$ 12,787.3	$ 3,556.6	$2,898.9
Long-term debt	5,788.7	6,474.3	3,874.0	918.3	8.9
Shareholders' equity	5,270.7	5,311.2	4,958.0	1,255.6	1,891.9

(1) Fiscal 2016 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 2016, 2015, 2014, 2013, and 2012 include restructuring charges, net, of $33.3 million, $45.0 million, $68.0 million, $16.8 million and $3.9 million, respectively. Fiscal 2016 includes $16.9 million of non-restructuring impairment charges. 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 $27.1 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, and 2012 include separation related costs of $9.6 million, $74.2 million and $25.5 million, respectively.

(4) Fiscal 2013 and 2012 include expense allocations from Covidien of $39.6 million and $49.2 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 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 business that develops, manufactures, markets and distributes branded and generic specialty pharmaceutical products and therapies. Therapeutic areas of focus include autoimmune and rare disease specialty areas (including neurology, rheumatology, nephrology, ophthalmology and pulmonology); immunotherapy and neonatal critical care respiratory therapies; analgesics and hemostasis products and central nervous system drugs.

We operate our business in two reportable segments, which are further described below:

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

We completed the sale of the contrast media and delivery systems ("CMDS") business on November 27, 2015. The financial results of this business are presented as a discontinued operation.

On August 24, 2016, we announced that we had entered into a definitive agreement to sell our Nuclear Imaging business to IBA Molecular ("IBAM"), which is expected to be completed during the first half of calendar 2017. The Nuclear Imaging business is deemed to be held for sale. As a result, prior year balances have been recast to present the financial results of this business as a discontinued operation.

Beginning in the first quarter of fiscal year 2016, we revised the presentation of certain medical affairs costs to better align with industry practice, which were previously included in selling, general and administrative ("SG&A") expenses and are now included in research and development ("R&D") expenses. As a result, $56.4 million and $22.5 million of expenses previously included in SG&A for the fiscal years ended September 25, 2015 and September 26, 2014, respectively, have been classified as R&D expenses to conform to this change. No other financial statement line items were impacted by this change in classification.

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

Significant Events

Acquisitions

In August 2016, we acquired Stratatech Corporation, through the acquisition of all outstanding common stock for upfront consideration of $76.0 million and contingent milestone payments, which are primarily regulatory, and royalty obligations that could result in up to $121.0 million of additional consideration ("the Stratatech Acquisition"). The acquisition was funded with cash on hand. Stratatech is a regenerative medicine company focused on the development of unique, proprietary skin substitute products. Developmental products include StrataGraft® regenerative skin tissue and a technology platform for genetically enhanced skin tissues.

In February 2016, we acquired three commercial stage topical hemostasis drugs from The Medicines Company ("the Hemostasis Acquisition") - RECOTHROM® Thrombin topical (Recombinant), PreveLeak™ Surgical Sealant, and RAPLIXA™ (Fibrin Sealant (Human)) - for upfront consideration of $173.5 million, inclusive of existing inventory, and contingent sales-based milestone payments that could result in up to $395.0 million of additional consideration. The acquisition was funded with cash on hand.

In September 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 product relates to the administering of extracorporeal photopheresis therapies through their UVAR XTS® and CELLEX™ Photopheresis Systems.

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® (nitric oxide) gas for inhalation ("Inomax"), a vital treatment option in neonatal critical care.

In August 2014, we acquired Questcor, a pharmaceutical 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, ophthalmology 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 pharmaceutical 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.

Divestitures

On August 24, 2016, we announced that we entered into a definitive agreement to sell our Nuclear Imaging business to IBAM for approximately $690.0 million, subject to working capital adjustments, which is expected to be completed during the first half of calendar 2017. The Nuclear Imaging business is deemed to be held for sale and the financial results of this business are presented as a discontinued operation. As a result, prior year balances have been recast to present the Nuclear Imaging business as a discontinued operation.

On November 27, 2015, we completed the sale of our CMDS business to Guerbet S.A. ("Guerbet") for cash consideration of approximately $270.0 million, subject to yet to be resolved net working capital adjustments. The financial results for the CMDS business are presented as a discontinued operation.

Business Factors Influencing the Results of Operations

Products

As a result of acquisitions in fiscal 2016, 2015 and 2014, we obtained the sales and marketing rights to three commercial stage topical hemostasis products on February 1, 2016; Therakos on September 25, 2015; 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 portfolio contributed to the net sales and operating income within this segment. The aggregate net sales of these products were $2,169.1 million, $1,485.5 million and $247.3 million during the fiscal years ended September 30, 2016, September 25, 2015 and September 26, 2014, respectively. Our cost of sales for fiscal 2016, 2015 and 2014 included $24.3 million, $44.1 million and $25.7 million, respectively, of expense recognition associated with the fair value adjustments of acquired inventory. Our cost of sales also included $665.0 million, $515.0 million and $120.3 million, respectively, of amortization associated with intangibles recognized from these

acquisitions. Included within SG&A in our consolidated statement of income, is $6.9 million, $53.4 million and $65.1 million of transaction costs, respectively, in fiscal 2016, 2015 and 2014 associated with our acquisitions.

In December 2012, we received approval from the FDA to manufacture Methylphenidate ER. 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 class BX-rated drugs. 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. We are subject to the FDA's Approval Withdrawal Proceedings, which could result in our Methylphenidate ER products losing their FDA approval. The loss of FDA approval could have a material, negative impact to our

Specialty Generics segment, which could result in impairment of goodwill and other long-lived assets associated with this segment. Net sales of Methylphenidate ER were $103.5 million, $136.5 million and $209.6 million in fiscal 2016, 2015 and 2014, respectively.

Our Therakos immunotherapy business has recently experienced temporary, third-party manufacturer production complications with kits supporting its first-generation UVAR XTS® photopheresis system. We are working diligently to mitigate the shortage. While it is possible the situation could continue into the second fiscal quarter of 2017, we believe our efforts will successfully resolve the issue sooner. Overall revenue impact is expected to be between $5 to $10 million in each of the transition period ending December 30, 2016 and the first fiscal quarter of 2017.

In May 2014, we launched an authorized generic version of Exalgo, and subsequently additional competitors entered the market. Net sales of Exalgo were $25.6 million, $39.4 million and $76.1 million in fiscal 2016, 2015 and 2014, respectively. Net sales across the branded and authorized generic products during fiscal 2016 and 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 30, 2016, we incurred restructuring charges of $125.4 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.

In July 2016, the Company's Board of Directors approved a $100.0 million to $125.0 million restructuring program ("the 2016 Mallinckrodt Program") designed to further improve its cost structure, as the Company continues to transform its business. The 2016 Mallinckrodt Program is expected to include actions across both the Specialty Brands and Specialty Generics segments, as well as within corporate functions. There is no specified time period associated with the 2016 Mallinckrodt Program. Through September 30, 2016, we incurred restructuring charges of $8.3 million under the 2016 Mallinckrodt Program, which are expected to generate savings, substantially within our SG&A expenses.

Results of Operations

Fiscal Year Ended September 30, 2016 Compared with Fiscal Year Ended September 25, 2015

Net Sales

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

	Fiscal Year		
	2016	2015	Percentage Change
U.S.	$3,095.4	$2,647.0	16.9 %
Europe, Middle East and Africa	211.8	159.0	33.2
Other	73.6	117.1	(37.1)
Net sales	$3,380.8	$2,923.1	15.7

Net sales in fiscal 2016 increased $457.7 million, or 15.7%, to $3,380.8 million, compared with $2,923.1 million in fiscal 2015. This increase was primarily driven by the full year inclusion of Inomax and Therakos immunotherapy net sales along with Acthar net sales growth within the Specialty Brands segment. These increases were partially offset by decreased sales in all Specialty Generics categories due to increased competition. 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.

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Operating Income

Gross profit. Gross profit for fiscal 2016 increased $232.1 million, or 14.3%, to $1,855.0 million, compared with $1,622.9 million in fiscal 2015. The increase in gross profit primarily resulted from a shift in the mix of net sales toward the higher-margin Specialty Brands segment, due to the inclusion of Inomax and Therakos immunotherapy. These increases were partially offset by a $148.8 million increase in amortization, primarily associated with Inomax and Therakos immunotherapy intangibles, and a $178.4 million decrease in gross profit from the Specialty Generics segment. During fiscal 2016 and 2015, gross profit included $24.3 million and $44.1 million, respectively, of expense associated with fair value adjustments of acquired inventory. Overall, gross profit margin was 54.9% during fiscal 2016, compared with 55.5% during fiscal 2015.

Selling, general and administrative expenses. SG&A expenses for fiscal 2016 were $925.3 million, compared with $1,023.8 million for fiscal 2015, a decrease of $98.5 million, or 9.6%. The decrease was primarily attributable to fiscal 2015 charges of $73.0 million of legal settlements (including Questcor and Synacthen related litigation), $80.6 million of share-based compensation associated with Questcor equity awards that were converted into Mallinckrodt awards at the date of the Questcor Acquisition, that subsequently vested in September 2015, $53.4 million of transaction costs, primarily related to the Ikaria Acquisition, and a $13.3 million environmental charge. Fiscal 2016 included $14.5 million of legal reserve charges. The remaining change resulted from the addition of $65.8 million of SG&A expenses associated with the Ikaria and Therakos acquisitions and higher stock compensation expense. SG&A expenses were 27.4% of net sales for fiscal 2016 and 35.0% of net sales for fiscal 2015.

Research and development expenses. R&D expenses increased $58.9 million, or 29.0%, to $262.2 million in fiscal 2016, compared with $203.3 million in fiscal 2015. 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 7.8% and 7.0% in fiscal 2016 and 2015, respectively.

Restructuring and related charges, net. During fiscal 2016, we recorded $38.2 million of restructuring and related charges, net, of which $4.9 million related to accelerated depreciation and was included in cost of sales. The remaining $33.3 million primarily related to employee severance and benefits across the Specialty Brands segment and corporate functions. During fiscal 2015, we recorded restructuring and related charges, net, of $45.3 million, of which $0.3 million related to accelerated depreciation and was included in cost of sales. The remaining $45.0 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.

Non-restructuring impairment charges. Non-restructuring impairment charges were $16.9 million for fiscal 2016. The impairments related to in-process research and development intangible assets associated with the CNS Therapeutics acquisition in fiscal 2013. The impairments resulted from delays in anticipated FDA approval, higher than expected development costs and lower than previously anticipated commercial opportunities.

Non-Operating Items

Interest expense and interest income. During fiscal 2016 and fiscal 2015, net interest expense was $383.3 million and $254.6 million, respectively. The increase in net interest expense was primarily related to the issuance of approximately $1.4 billion of debt associated with the Ikaria Acquisition, approximately $1.3 billion of debt associated with the Therakos Acquisition and a $37.3 million increase in interest accrued on deferred tax liabilities associated with outstanding installment notes. Interest expense during fiscal 2016 and 2015 included $26.4 million and $23.4 million, respectively, of non-cash interest expense.

Other income, net. During fiscal 2016 and 2015, we recorded other loss of $0.6 million and income of $8.1 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 2016, we recognized an income tax benefit of $255.6 million on income from continuing operations before income taxes of $233.4 million. In fiscal 2015, income tax benefit was $129.3 million on income from continuing operations before income taxes of $107.3 million. Our effective tax rate

was negative 109.5% and negative 120.5% for fiscal 2016 and 2015, respectively. Our effective tax rate for fiscal 2016 was impacted by receiving $7.6 million of tax benefit associated with $40.4 million of restructuring costs, $6.2 million of tax benefit associated with $16.9 million of impairments, $31.3 million of tax benefit associated with accrued income tax liabilities and uncertain tax positions, $33.7 million of tax benefit associated with primarily U.K. and U.S. tax credits, and $249.3 million of tax benefit associated with the rate difference between U.K. and non-U.K. jurisdictions. Our effective tax rate for fiscal 2015 was impacted by receiving a $10.4 million tax benefit on $53.4 million of transaction costs, $15.5 million of tax benefit associated with $45.3 million of restructuring costs, $6.7 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 $152.9 million of tax benefit associated with the rate difference between U.K. and non-U.K. jurisdictions.

Income (loss) from discontinued operations, net of income taxes. We recorded income of $154.7 million and $88.1 million on discontinued operations, net of income taxes, during fiscal 2016 and 2015, respectively. During fiscal 2016, the income from discontinued operations included a $95.3 million gain on disposal of the CMDS business and income, net of tax, for the Nuclear Imaging business of $61.3 million. The fiscal 2015 income from discontinued operations reflects income, net of tax, for the Nuclear Imaging business of $71.6 million and a benefit from the release of a $22.5 million tax indemnification obligation associated with a business that was disposed of in fiscal 1997. The remaining amounts in both periods primarily related to the results of operations for the CMDS business.

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.	$2,647.0	$1,485.0	78.2	%
Europe, Middle East and Africa	159.0	140.8	12.9	
Other	117.1	24.5	378.0	
Net sales	$2,923.1	$1,650.3	77.1	

Net sales in fiscal 2015 increased $1,272.8 million, or 77.1%, to $2,923.1 million, compared with $1,650.3 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. 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 $738.3 million, or 83.5%, to $1,622.9 million, compared with $884.6 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. Overall, gross profit margin was 55.5% in fiscal 2015, compared with 53.6% in fiscal 2014.

Selling, general and administrative expenses. SG&A expenses for fiscal 2015 were $1,023.8 million, compared with $611.0 million for fiscal 2014, an increase of $412.8 million, or 67.6%. 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 37.0% of net sales for fiscal 2014.

Research and development expenses. R&D expenses increased $62.8 million, or 44.7%, to $203.3 million in fiscal 2015, compared with $140.5 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 7.0% and 8.5% for 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 restructuring and related charges, net, of $45.3 million, of which $0.3 million related to accelerated depreciation and was included in cost of sales. The remaining $45.0 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 $68.2 million, of which $0.2 million related to accelerated depreciation and was included in cost of sales. The remaining $68.0 million primarily related to $35.1 million of accelerated share-based compensation associated with Questcor employees, employee severance and benefits incurred across both the Specialty Brands and Specialty Generics segments and a $2.3 million asset impairment.

Non-restructuring impairment charges. During fiscal 2014, we recorded $27.1 million of non-restructuring impairment charges. The charges consisted of $14.2 million of property, plant and equipment impairments and $12.8 million of intangible asset impairments, primarily related to Pennsaid intangibles upon the return of our product rights to Nuvo as part of a legal settlement.

Gain on divestitures. During fiscal 2015 and 2014, we recorded gains on divestiture and license of $3.0 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 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 $129.3 million on income from continuing operations before income taxes of $107.3 million. In fiscal 2014, income tax benefit was $12.6 million on a loss from continuing operations before income taxes of $34.6 million. Our effective tax rate was negative 120.5% and 36.4% 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, $15.5 million of tax benefit associated with $45.3 million of restructuring costs, $6.7 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 $152.9 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, $21.4 million of tax benefit associated with $68.2 million of restructuring costs, $8.1 million of tax benefit associated with accrued income tax liabilities and uncertain tax positions, $2.7 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, $10.0 million of tax benefit associated with the $27.1 million impairment of tangible and intangible assets, and $14.2 million of tax benefit associated with the rate difference between U.S. and non-U.S. jurisdictions.

Income (loss) from discontinued operations, net of income taxes. We recorded income of $88.1 million and a loss of $297.3 million from discontinued operations, net of income taxes, during fiscal 2015 and 2014, respectively. The fiscal 2015 income from discontinued operations reflects income, net of tax, for the Nuclear Imaging business of $71.6 million and a benefit from the release of a $22.5 million tax indemnification obligation associated with a business that was disposed of in fiscal 1997, partially offset by a $5.9 million loss from our CMDS business. Fiscal 2014 primarily reflects a $174.8 million loss from our CMDS business and a $121.8 million loss from our Nuclear Imaging business. The CMDS business loss primarily related to $204.0 million of goodwill, intangible and property, plant and equipment impairment charges and $47.2 million of restructuring charges. The Nuclear Imaging business loss primarily related to $124.5 million of goodwill, intangible and property, plant and equipment impairment charges and $13.4 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.

Business Segment Results

The businesses included within our reportable segments are described below:

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

Management measures and evaluates our 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, but are not limited to, net sales and expenses associated with net sales of products to the acquirer of the CMDS business under an ongoing supply agreement, 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 operating income and in the reconciliations presented below. Selected information by business segment is as follows:

Fiscal Year Ended September 30, 2016 Compared with Fiscal Year Ended September 25, 2015

Net Sales

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

	Fiscal Year		
	2016	2015	Percentage Change
Specialty Brands	$2,300.6	$1,622.8	41.8 %
Specialty Generics	1,025.2	1,251.6	(18.1)
Net sales of operating segments	3,325.8	2,874.4	15.7
Other [(1)]	55.0	48.7	12.9
Net sales	$3,380.8	$2,923.1	15.7

(1) Following the disposition of the CMDS business, this represents transactions under an ongoing supply agreement with the acquirer of the CMDS business. Prior to the disposition of the CMDS business, this 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 2016 increased $677.8 million, or 41.8%, to $2,300.6 million, compared with $1,622.8 million for fiscal 2015. The increased net sales were primarily driven by the acquisition and growth of Inomax and the acquisition of Therakos immunotherapy, which increased net sales by $289.1 million and $207.6 million, respectively. In addition, net sales of Acthar increased by $123.1 million or 11.9% compared with fiscal 2015 primarily due to increased volume.

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

	Fiscal Year		
	2016	2015	Percentage Change
U.S.	$2,224.9	$1,610.3	38.2 %
Europe, Middle East and Africa	69.8	9.9	605.1

Other	5.9	2.6	126.9
Net sales	$2,300.6	$1,622.8	41.8

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

	Fiscal Year		
	2016	2015	Percentage Change
Acthar	$1,160.4	$1,037.3	11.9 %
Inomax	474.3	185.2	156.1
Ofirmev	284.3	263.0	8.1
Therakos immunotherapy	207.6	—	—
Hemostasis products	42.5	—	—
Other	131.5	137.3	(4.2)
Specialty Brands	$2,300.6	$1,622.8	41.8

Specialty Generics. Net sales for fiscal 2016 decreased $226.4 million, or 18.1%, to $1,025.2 million, compared with $1,251.6 million for fiscal 2015. The decrease in net sales was driven by decreases of $104.1 million, $33.0 million, $28.4 million and $20.7 million in net sales of other controlled substances, Methylphenidate ER, oxycodone-related products, and hydrocodone-related products, respectively. The decrease in other controlled substances, oxycodone-related products, and hydrocodone-related products net sales were related to increased market competition. The decrease in Methylphenidate ER net sales was primarily attributable to the FDA reclassification of these products to therapeutically inequivalent status. We expect decreased net sales in this segment in fiscal 2017.

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

	Fiscal Year		
	2016	2015	Percentage Change
U.S.	$870.5	$1,036.7	(16.0)%
Europe, Middle East and Africa	87.0	100.5	(13.4)
Other	67.7	114.4	(40.8)
Net sales	$1,025.2	$1,251.6	(18.1)

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

	Fiscal Year		
	2016	2015	Percentage Change
Hydrocodone (API) and hydrocodone-containing tablets	$146.5	$167.2	(12.4)%
Oxycodone (API) and oxycodone-containing tablets	126.2	154.6	(18.4)
Methylphenidate ER	103.5	136.5	(24.2)
Other controlled substances	468.1	572.2	(18.2)
Other	180.9	221.1	(18.2)
Specialty Generics	$1,025.2	$1,251.6	(18.1)

Operating Income

Operating income by segment and as a percentage of segment net sales for fiscal 2016 and 2015 is shown in the following table (dollars in millions):

	Fiscal Year			
	2016		2015	
Specialty Brands	$1,166.2	50.7%	$637.6	39.3%
Specialty Generics	376.1	36.7	594.4	47.5
Segment operating income	1,542.3	46.4	1,232.0	42.9
Unallocated amounts:				
Corporate and allocated expenses	(169.8)		(282.6)	
Intangible asset amortization	(700.1)		(550.3)	
Restructuring and related charges, net [(1)]	(38.2)		(45.3)	
Non-restructuring impairment charges	(16.9)		—	
Total operating income (loss)	$617.3		$353.8	

(1) Includes restructuring-related accelerated depreciation.

Specialty Brands. Operating income for fiscal 2016 increased $528.6 million to $1,166.2 million, compared with $637.6 million for fiscal 2015. Operating margin increased to 50.7% for fiscal 2016, compared with 39.3% for fiscal 2015. The increase in operating income and margin was impacted by the $677.8 million increase in net sales, primarily attributable to the acquisitions of Inomax and Therakos immunotherapy. These higher net sales were partially offset by a net $16.4 million increase in SG&A expenses. The net increase was attributable to increased shared services allocations and $65.8 million of incremental costs from acquisitions; these factors were partially offset by $80.6 million of share-based compensation expense associated with Questcor Acquisition equity awards during fiscal 2015 that did not recur in the current year. Increased R&D expenses reduced operating income by $14.0 million.

Specialty Generics. Operating income for fiscal 2016 decreased $218.3 million to $376.1 million, compared with $594.4 million for fiscal 2015. Operating margin decreased to 36.7% for fiscal 2016, compared with 47.5% for fiscal 2015. The decrease in operating income and margin was impacted by the $226.4 million decrease in net sales, which resulted in a $178.4 million unfavorable gross profit impact, due to increased competition in several product categories. Increased R&D expenses reduced operating income by $48.2 million.

Corporate and allocated expenses. Corporate and allocated expenses were $169.8 million and $282.6 million for fiscal 2016 and 2015, respectively. Fiscal 2016 included $14.5 million of provisions for legal matters, $6.9 million of transaction costs and $4.4 million of expense from changes in fair value of contingent consideration liabilities. Fiscal 2015 included $73.0 million of legal settlements (including Questcor and Synacthen related litigation), a $13.3 million environmental remediation charge and $53.4 million of transaction costs, primarily related to the Ikaria Acquisition. Excluding the aforementioned items, corporate and allocated expenses remained reasonably consistent.

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
Net sales of operating segments	2,874.4	1,612.9	78.2
Other [(1)]	48.7	37.4	30.2
Net sales	$2,923.1	$1,650.3	77.1

(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 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)
Methylphendiate 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

Operating Income

Operating income (loss) 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	$637.6	39.3%	$(68.6)	(16.6)%
Specialty Generics	594.4	47.5	599.4	50.0
Segment operating income	1,232.0	42.9	530.8	32.9
Unallocated amounts:				
Corporate and allocated expenses	(282.6)		(227.7)	
Intangible asset amortization	(550.3)		(154.8)	
Restructuring and related charges, net [1]	(45.3)		(68.2)	
Non-restructuring impairment charges	—		(27.1)	
Separation costs	—		(9.6)	
Total operating (loss) income	$353.8		$43.4	

(1) Includes restructuring-related accelerated depreciation.

Specialty Brands. Operating income for fiscal 2015 increased $706.2 million to $637.6 million, compared with a $68.6 million loss for fiscal 2014. Our operating margin increased to 39.3% for fiscal 2015, compared with negative 16.6% 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 $335.2 million increase in SG&A 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 $62.6 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 decreased $5.0 million to $594.4 million, compared with $599.4 million for fiscal 2014. Our operating margin decreased to 47.5% for fiscal 2015, compared with 50.0% for fiscal 2014. The decrease in operating income was attributable to higher SG&A expenses and a non-recurring $11.7 million gain in fiscal 2014 from the license of extended-release oxymorphone intellectual property. These factors were partially offset by the higher gross profit from the $52.2 million increase in net sales. The decrease in the operating margin was primarily attributable to lower net sales of high-margin Methylphenidate ER in fiscal 2015.

Corporate and allocated expenses. Corporate and allocated expenses were $282.6 million and $227.7 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.

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.

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 2017, we intend to fund capital expenditures with cash generated from operations. At September 30, 2016, we had capital expenditure commitments of $25.5 million.

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

	Fiscal Year		
	2016	2015	2014
Net cash (used in) provided by:			
Operating activities	$ 1,184.6	$ 896.4	$ 373.4
Investing activities	(108.0)	(2,296.6)	(2,890.8)
Financing activities	(1,162.3)	1,069.9	2,953.9
Effect of currency exchange rate changes on cash and cash equivalents	0.3	(11.6)	(4.2)
Net (decrease) increase in cash and cash equivalents	$ (85.4)	$ (341.9)	$ 432.3

Operating Activities

Net cash provided by operating activities of $1,184.6 million for fiscal 2016 was primarily attributable to income from continuing operations, as adjusted for non-cash items, and a $116.0 million inflow from net investment in working capital. The working capital inflow was primarily driven by a $93.9 million inflow from net tax related balances, a $31.2 million decrease in accounts receivable, net, and a $17.9 million net inflow related to other assets and liabilities, primarily related to increases in accrued payroll and accrued interest. These were offset by a $17.3 million outflow related to inventory balances and a $9.7 million decrease in accounts payable.

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.

The aforementioned cash flows from operating activities include cash flows from the ongoing operations of the Nuclear Imaging and CMDS businesses that are included within discontinued operations. Subsequent to the completion of these transactions, we will no longer generate cash flows from these businesses. See further discussion of our discontinued operations in Note 18 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Investing Activities

Net cash used in investing activities decreased $2,188.6 million to $108.0 million for fiscal 2016, compared with $2,296.6 million for fiscal 2015. The decrease primarily resulted from fiscal 2016 payments, net of cash acquired, of $170.2 million and $75.8 million related to the acquisitions of Hemostasis and Stratatech, respectively; compared with 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. The decrease further resulted from the $267.0 million cash inflow related to the disposal of the CMDS business and a $44.2 million increase in cash inflows associated with restricted cash, which primarily resulted from the release of balances previously restricted for payment of Synacthen contingent consideration. These decreases were partially offset by a $34.9 million increase in capital expenditures in fiscal 2016 compared with fiscal 2015.

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.

Financing Activities

Net cash used in financing activities was $1,162.3 million for fiscal 2016, compared with $1,069.9 million provided by financing activities for fiscal 2015. The change largely resulted from a $2,911.7 million decrease in cash inflows from the issuance of external debt in fiscal 2016 compared with fiscal 2015, when external debt was issued to fund the Ikaria and Therakos acquisitions and increases in the accounts receivable securitization facility. The change in net cash used in financing activities was further impacted by the ongoing share repurchase programs, which resulted in $652.9 million of cash outflows related to share repurchases in fiscal 2016, compared with $92.2 million during fiscal 2015, as well as a $54.5 million decrease in cash inflows from the excess tax benefit derived from share-based compensation and proceeds from stock option exercises. These were partially offset by a decrease in repayment of debt, with $568.6 million of payments made in fiscal 2016 compared with $1,848.4 million during fiscal 2015.

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.

Inflation

Inflationary pressures have had an adverse effect on us through higher raw material and fuel costs. 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 30, 2016, total debt principal was $6,135.6 million compared with total debt principal at September 25, 2015 of $6,606.2 million. The decrease in total debt principal resulted primarily from the repayment of our revolving credit facility. Total debt principal at September 30, 2016 is comprised of $1,953.5 million of variable rate term loans, $3,945.9 million of fixed rate instruments, $235.0 million of borrowings under a variable rate receivable securitization program and $1.2 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 30, 2016 our fixed-rate instruments had a weighted-average interest rate of 5.29% and pay interest at various dates throughout the fiscal year. As of September 30, 2016, the applicable interest rate on outstanding borrowings under the Receivable Securitization was 1.3%, 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 30, 2016, $257.1 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 30, 2016, we were not utilizing our revolving credit facility. As such there was $500.0 million of borrowing capacity under our revolving credit facility. Under the terms of one of our lease agreements, if we do not maintain $25.0 million of borrowing capacity under our credit facilities, we are required to maintain cash and cash equivalents to cover any shortfall to this amount of borrowing capacity.

As of September 30, 2016, 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. During fiscal 2016, we repurchased $26.0 million of face value of our debt.

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

Capitalization

Shareholders' equity was $5,270.7 million, at September 30, 2016, compared with $5,311.2 million, at September 25, 2015. The decrease in shareholders' equity is primarily attributed to the repurchases of common shares and changes in

accumulated other comprehensive income.

On November 19, 2015, our Board of Directors authorized a $500.0 million share repurchase program (the “November 2015 Program”). The November 2015 Program commenced after the $300.0 million share repurchase program authorized by our Board of Directors on January 23, 2015 (the “January 2015 Program”) was completed in the first fiscal quarter of 2016. On March 16, 2016, our Board of Directors authorized an additional $350.0 million share repurchase program (the “March 2016 Program”) which will commence upon the completion of the November 2015 Program. These programs have no time limit or expiration date, and the Company currently expects to fully utilize each program.

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 30, 2016 (dollars 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	$6,134.3	$256.1	$337.3	$2,601.1	$2,939.8
Interest on long-term debt obligations [1]	1,632.7	277.2	519.0	468.9	367.6
Capital lease obligations [1]	1.2	1.0	0.2	—	—
Operating lease obligations	135.7	26.5	39.1	25.2	44.9
Purchase obligations [2]	247.7	147.5	51.9	20.8	27.5
Total contractual obligations	$8,151.6	$708.3	$947.5	$3,116.0	$3,379.8

(1) Interest on debt and capital lease obligations are projected for future periods using interest rates in effect as of September 30, 2016. 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 $623.2 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.

As part of our acquisitions, we are subject to contractual arrangements to pay contingent consideration to former owners of these businesses. The payment of obligations under these arrangements are uncertain, and even if payments are expected to be made the timing of these payments may be uncertain as well. As of September 30, 2016, we have accrued $247.8 million for these potential payments, of which $219.0 million is considered to be long-term. For further information on our contingent consideration arrangements, refer to Note 19 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Non-current income taxes payable, primarily related to unrecognized tax benefits, is included within other income tax liabilities on the consolidated balance sheet and, as of September 30, 2016, was $67.7 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 the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

As of September 30, 2016, we had net unfunded pension and postretirement benefit obligations of $99.6 million and $50.8 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 2017, but may elect to make voluntary contributions to its defined pension plans or its postretirement benefit plans during fiscal 2017. Should the Company settle all outstanding obligations associated with their six U.S. qualified pension plans, it is expected that contributions will be needed associated with the unfunded portion of these obligations. The Company expects this final settlement to occur during the first half of calendar 2017.

We are involved in various stages of investigation and cleanup related to environmental remediation matters at a number of sites. 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 30, 2016, we believe that it is probable that we will incur investigation and remediation costs of approximately $75.9 million, of which $2.6 million is included in accrued and other current liabilities on our consolidated balance sheet at September 30, 2016. Note 18 of the Notes to

Consolidated 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.

Legal Proceedings

We are subject to various legal proceedings and claims, including patent infringement claims, product liability matters, personal injury, environmental matters, employment disputes, contractual disputes and other commercial disputes, including those described in Note 18 of the Notes to Consolidated 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 17 of the Notes to Consolidated 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 $30.2 million. Upon closing the sale of our Nuclear Imaging business, these obligations will be transferred to the buyer. As of September 30, 2016, we had various other letters of credit and guarantee and surety bonds totaling $32.7 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. In February 2016, following completion of the decommissioning efforts, the trustee returned the cash on deposit and it was available for general use.

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. During the third quarter of fiscal 2016, the Company and St. Louis County agreed on a change in valuation of the plant assets and IRBs and a sale of additional assets to St. Louis County. The net effect of the agreements between the Company and St. Louis County during the quarter resulted in a new valuation of plant assets of $73.7 million, a decrease of $14.3 million.

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 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 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 27, 2013	$ 220.5	$ 48.6	$ 15.1	$ 284.2
Provisions	1,535.9	86.0	88.7	1,710.6
Payments or credits	(1,499.2)	(33.0)	(91.0)	(1,623.2)
Acquisitions	30.1	0.5	—	30.6
Balance at September 26, 2014	287.3	102.1	12.8	402.2
Provisions	2,072.7	12.9	91.8	2,177.4
Payments or credits	(2,052.2)	(43.5)	(88.8)	(2,184.5)
Acquisitions	0.2	1.1	—	1.3
Balance at September 25, 2015	308.0	72.6	15.8	396.4
Provisions	1,937.9	14.3	78.6	2,030.8
Payments or credits	(1,920.1)	(47.9)	(81.2)	(2,049.2)
Balance at September 30, 2016	$ 325.8	$ 39.0	$ 13.2	$ 378.0

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

Total provisions for fiscal 2016 decreased $146.6 million compared with fiscal 2015. The decrease in rebates and chargebacks of $134.8 million primarily related to a $206.8 million decrease in Specialty Generics as increased

competition resulted in lower customer volume, partially offset by a $72.0 million increase in Specialty Brands. The Specialty Brands increase was due to an increase in Acthar volume, a greater percentage of Acthar prescriptions being covered under managed care contracts and the impact from acquisitions. Provisions for returns were relatively consistent across periods, due to of $8.7 million and $9.0 million of favorable changes in estimate associated with the Exalgo returns reserve within the Specialty Brands segment, in fiscal 2016 and 2015, respectively. Other sales deductions decreased by $13.2 million, primarily attributable to increased competition within the Specialty Generics segment.

Total provisions for fiscal 2015 increased $466.8 million compared with fiscal 2014. The increase in rebates and chargebacks of $536.8 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 $3.1 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 2016 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 and Nuclear Imaging business that are now presented as discontinued operations). For further information on our goodwill impairment analysis, refer to Notes 2 and 11 of the Notes to Consolidated 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. Impairments of Specialty Brands in-process research and development intangible assets acquired as part of the CNS Therapeutics acquisition were recorded during fiscal 2016. No impairments of intangible assets were recorded in fiscal 2015. Impairments of 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 Consolidated 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.

Contingent Consideration

As part of certain acquisitions, we are subject to contractual arrangements to pay contingent consideration to former owners of these businesses. The payment of obligations under these arrangements are uncertain, and even if payments are expected to be made the timing of these payments may be uncertain as well. These contingent consideration obligations are required to be recorded at fair value within the consolidated balance sheet and adjusted at each respective balance sheet date, with changes in the fair value being recognized in the consolidated statement of income. The determination of fair value is dependent upon a number of factors, which include projections of future revenues, the probability of success of achieving certain regulatory milestones, competitive entrants into the marketplace, the timing association the aforementioned criteria, and market place data (e.g., interest rates). Several of these assumptions require projections several years into the future. Due to these inherent uncertainties, there is risk that the contingent consideration liabilities may be overstated or understated. Changes in economic and operating conditions impacting these assumptions are expected to impact future operating results, with the magnitude of the impact tied to the significance in the change in assumptions.

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 18 of Notes to Consolidated 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 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 30, 2016, our outstanding debt included $1,953.5 million variable-rate debt on our senior secured term loan and $235.0 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 $21.9 million.

The remaining outstanding debt as of September 30, 2016 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 30, 2016 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 $17.3 million as of September 30, 2016. 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 30, 2016 that measures the change in the net financial position arising from a hypothetical 10% adverse movement in the exchange rates of the Euro 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 $34.6 million as of September 30, 2016. 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 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 30, 2016 and September 25, 2015, and the related consolidated statements of income, comprehensive income, changes in shareholders' equity, and cash flows for each of the three fiscal years in the period ended September 30, 2016. 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 financial statements present fairly, in all material respects, the financial position of Mallinckrodt plc and subsidiaries as of September 30, 2016 and September 25, 2015, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2016, 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.

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 30, 2016, 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 29, 2016 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP
St. Louis, Missouri
November 29, 2016

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

	Fiscal Year		
	2016	2015	2014
Net sales	$3,380.8	$2,923.1	$1,650.3
Cost of sales	1,525.8	1,300.2	765.7
Gross profit	1,855.0	1,622.9	884.6
Selling, general and administrative expenses	925.3	1,023.8	611.0
Research and development expenses	262.2	203.3	140.5
Restructuring charges, net	33.3	45.0	68.0
Separation costs	—	—	9.6
Non-restructuring impairment charges	16.9	—	27.1
Gain on divestiture and license	—	(3.0)	(15.0)
Operating income	617.3	353.8	43.4
Interest expense	(384.6)	(255.6)	(82.6)
Interest income	1.3	1.0	1.5
Other (expense) income, net	(0.6)	8.1	3.1
Income (loss) from continuing operations before income taxes	233.4	107.3	(34.6)
Benefit from income taxes	(255.6)	(129.3)	(12.6)
Income (loss) from continuing operations	489.0	236.6	(22.0)
Income (loss) from discontinued operations, net of tax expense (benefit) of $43.5, $47.9 and $(32.2)	154.7	88.1	(297.3)
Net income (loss)	$643.7	$324.7	$(319.3)
Basic earnings per share (Note 8):			
Income (loss) from continuing operations	$4.42	$2.03	$(0.34)
Income (loss) from discontinued operations, net of income taxes	1.40	0.75	(4.58)
Net income (loss)	$5.82	$2.78	$(4.92)
Basic weighted-average shares outstanding	110.6	115.8	64.9
Diluted earnings per share (Note 8):			
Income (loss) from continuing operations	$4.39	$2.00	$(0.34)
Income (loss) from discontinued operations, net of income taxes	1.39	0.75	(4.58)
Net income (loss)	$5.77	$2.75	$(4.92)
Diluted weighted-average shares outstanding	111.5	117.2	64.9

See Notes to Consolidated Financial Statements.

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MALLINCKRODT PLC
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(in millions)

	Fiscal Year		
	2016	2015	2014
Net income (loss)	$643.7	$324.7	$(319.3)
Other comprehensive (loss), net of tax			
Currency translation adjustments	(58.6)	(70.8)	(27.6)
Unrecognized gain on derivatives, net of tax expense of $0.2, $0.2 and $0.2	0.5	0.4	0.5
Unrecognized gain (loss) on benefit plans, net of tax (benefit) expense of $(15.0), $(2.1) and $(7.3)	(28.4)	5.6	(15.7)
Total other comprehensive (loss), net of tax	(86.5)	(64.8)	(42.8)
Comprehensive income (loss)	$557.2	$259.9	$(362.1)

See Notes to Consolidated Financial Statements.

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

	September 30, 2016	September 25, 2015
Assets		
Current Assets:		
Cash and cash equivalents	$ 280.5	$ 365.9
Accounts receivable, less allowance for doubtful accounts of $4.0 and $3.6	465.8	489.6
Inventories	335.6	262.1
Deferred income taxes	—	139.2
Prepaid expenses and other current assets	115.9	194.4
Current assets held for sale	308.8	394.9
Total current assets	1,506.6	1,846.1
Property, plant and equipment, net	844.0	793.0
Goodwill	3,705.3	3,649.4
Intangible assets, net	9,182.3	9,666.3
Other assets	260.5	225.7
Long-term assets held for sale	—	223.6
Total Assets	$ 15,498.7	$ 16,404.1
Liabilities and Shareholders' Equity		
Current Liabilities:		
Current maturities of long-term debt	$ 256.3	$ 22.0
Accounts payable	110.1	116.8
Accrued payroll and payroll-related costs	116.0	95.0
Accrued interest	80.6	80.2
Accrued and other current liabilities	550.9	486.1
Current liabilities held for sale	120.8	129.3
Total current liabilities	1,234.7	929.4
Long-term debt	5,788.7	6,474.3
Pension and postretirement benefits	144.9	114.2
Environmental liabilities	73.4	73.3
Deferred income taxes	2,581.4	3,117.5
Other income tax liabilities	67.7	121.3
Other liabilities	337.2	209.0
Long-term liabilities held for sale	—	53.9
Total Liabilities	10,228.0	11,092.9
Commitments and contingencies (Note 18)		
Shareholders' Equity:		
Preferred shares, $0.20 par value, 500,000,000 authorized; none issued or outstanding	—	—
Ordinary A shares, €1.00 par value, 40,000 authorized; none issued or outstanding	—	—
Ordinary shares, $0.20 par value, 500,000,000 authorized; 118,137,297 and 117,513,370 issued; 107,167,693 and 116,283,149 outstanding	23.6	23.5
Ordinary shares held in treasury at cost, 10,969,604 and 1,230,221	(762.6)	(109.7)
Additional paid-in capital	5,412.7	5,357.6
Retained earnings	682.6	38.9

Accumulated other comprehensive income	(85.6	) 0.9
Total Shareholders' Equity	5,270.7	5,311.2
Total Liabilities and Shareholders' Equity	$ 15,498.7	$ 16,404.1

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in millions)

	Fiscal Year		
	2016	2015	2014
Cash Flows From Operating Activities:			
Net income (loss)	$643.7	$324.7	$(319.3)
Adjustments to reconcile net cash provided by operating activities:			
Depreciation and amortization	834.5	672.5	275.9
Share-based compensation	42.9	117.0	67.7
Deferred income taxes	(432.9)	(191.6)	(107.5)
Non-cash impairment charges	16.9	—	381.2
Inventory provisions	29.2	—	32.1
Gain on disposal of discontinued operations	(95.3)	—	—
Other non-cash items	29.6	(59.6)	(23.6)
Changes in assets and liabilities, net of the effects of acquisitions:			
Accounts receivable, net	31.2	0.7	(51.3)
Inventories	(17.3)	61.3	56.0
Accounts payable	(9.7)	20.4	(32.9)
Income taxes	93.9	30.2	(54.8)
Other	17.9	(79.2)	149.9
Net cash provided by operating activities	1,184.6	896.4	373.4
Cash Flows From Investing Activities:			
Capital expenditures	(182.9)	(148.0)	(127.8)
Acquisitions and intangibles, net of cash acquired	(245.4)	(2,154.7)	(2,793.8)
Proceeds from disposal of discontinued operations, net of cash	267.0	—	—
Restricted cash	47.3	3.1	4.1
Other	6.0	3.0	26.7
Net cash used in investing activities	(108.0)	(2,296.6)	(2,890.8)
Cash Flows From Financing Activities:			
Issuance of external debt	98.3	3,010.0	3,043.2
Repayment of external debt and capital leases	(568.6)	(1,848.4)	(34.8)
Excess tax benefit from share-based compensation	—	34.1	8.9
Debt financing costs	(0.1)	(39.9)	(71.7)
Proceeds from exercise of share options	14.0	34.4	25.8
Repurchase of shares	(652.9)	(92.2)	(17.5)
Other	(53.0)	(28.1)	—
Net cash (used in) provided by financing activities	(1,162.3)	1,069.9	2,953.9
Effect of currency rate changes on cash	0.3	(11.6)	(4.2)
Net (decrease) increase in cash and cash equivalents	(85.4)	(341.9)	432.3
Cash and cash equivalents at beginning of period	365.9	707.8	275.5
Cash and cash equivalents at end of period	$280.5	$365.9	$707.8
Supplemental Disclosures of Cash Flow Information:			
Cash paid for interest	$332.4	$200.5	$57.2
Cash paid for income taxes, net	165.4	123.8	128.0

See Notes to Consolidated Financial Statements.

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

	Ordinary Shares		Treasury Shares		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total Shareholders' Equity
	Number	Par Value	Number	Amount				
Balance at September 27, 2013	57.7	$11.5	—	$—	$1,102.1	$33.5	$ 108.5	$ 1,255.6
Net loss	—	—	—	—	—	(319.3)	—	(319.3)
Currency translation adjustments	—	—	—	—	—	—	(27.6)	(27.6)
Change in derivatives, net of tax	—	—	—	—	—	—	0.5	0.5
Minimum pension liability, net of tax	—	—	—	—	—	—	(15.7)	(15.7)
Ordinary shares issued in connection with the Questcor Acquisition	57.3	11.4	—	—	3,968.2	—	—	3,979.6
Share options exercised	0.8	0.2	—	—	25.6	—	—	25.8
Vesting of restricted shares	0.4	0.1	—	—	(0.1)	—	—	—
Excess tax benefit from share-based compensation	—	—	—	—	8.9	—	—	8.9
Share-based compensation	—	—	—	—	67.7	—	—	67.7
Repurchase of ordinary shares	—	—	0.2	(17.5)	—	—	—	(17.5)
Balance at September 26, 2014	116.2	$23.2	0.2	$(17.5)	$5,172.4	$(285.8)	$ 65.7	$ 4,958.0
Net income	—	—	—	—	—	324.7	—	324.7
Currency translation	—	—	—	—	—	—	(70.8)	(70.8)
Change in derivatives, net of tax	—	—	—	—	—	—	0.4	0.4
Minimum pension liability, net of taxes	—	—	—	—	—	—	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 shares	—	—	1.0	(92.2)	—	—	—	(92.2)
Balance at September 25, 2015	117.5	$23.5	1.2	$(109.7)	$5,357.6	$38.9	$ 0.9	$ 5,311.2
Net income	—	—	—	—	—	643.7	—	643.7
Currency translation adjustments	—	—	—	—	—	—	(58.6)	(58.6)
Change in derivatives, net of tax	—	—	—	—	—	—	0.5	0.5
Minimum pension liability, net of tax	—	—	—	—	—	—	(28.4)	(28.4)
Share options exercised	0.4	0.1	—	—	13.9	—	—	14.0
Vesting of restricted shares	0.2	—	—	—	—	—	—	—
Excess tax benefit from share-based compensation	—	—	—	—	(1.7)	—	—	(1.7)
Share-based compensation	—	—	—	—	42.9	—	—	42.9
Repurchase of ordinary shares	—	—	9.8	(652.9)	—	—	—	(652.9)
Balance at September 30, 2016	118.1	$23.6	11.0	$(762.6)	$5,412.7	$682.6	$ (85.6)	$ 5,270.7

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
NOTES TO CONSOLIDATED 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 business that develops, manufactures, markets and distributes specialty pharmaceutical products and therapies. Therapeutic areas of focus include autoimmune and rare disease specialty areas (including neurology, rheumatology, nephrology, ophthalmology and pulmonology); immunotherapy and neonatal respiratory critical care therapies; analgesics and hemostasis products and central nervous system drugs.

On August 24, 2016, the Company announced that it had entered into a definitive agreement to sell its Nuclear Imaging business to IBA Molecular ("IBAM"), which is expected to be completed during the first half of calendar 2017. The Nuclear Imaging business was deemed to be held for sale. As a result, prior year balances have been recast to present the financial results of the Nuclear Imaging business as a discontinued operation.

The Company completed the sale of the contrast media and delivery systems ("CMDS") business on November 27, 2015. The financial results of this business are presented as a discontinued operation.

The two reportable segments are further described below:

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

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 consolidated 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 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 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 financial statements up to the date of disposal and, where appropriate, these operations have been reflected as discontinued operations. Divestitures of product lines not meeting the criteria for discontinued operations 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.

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 reserves 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 was 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.

Beginning in the first quarter of fiscal year 2016, we revised the presentation of certain medical affairs costs to better align with industry practice, which were previously included in selling, general and administrative ("SG&A") expenses and are now included in research and development ("R&D") expenses. As a result, $56.4 million and $22.5 million of expenses previously included in SG&A for the fiscal years ended September 25, 2015 and September 26, 2014, respectively, have been classified as R&D expenses to conform to this change. No other financial statement line items were impacted by this change in classification.

Fiscal Year

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

On May 17, 2016, the Board of Directors of the Company approved a change in the Company’s fiscal year end to the last Friday in December from the last Friday in September. The change in fiscal year will become effective for the Company’s 2017 fiscal year, which will commence on December 31, 2016 and end on December 29, 2017. As a result, the Company will have a transition period which commenced on October 1, 2016 and will end on December 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, 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 $12.4 million, $11.6 million and $11.8 million in fiscal 2016, 2015 and 2014, 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, medical affairs 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 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 2016, the Company had $3.6 million of foreign currency losses, and during fiscal 2015 and 2014, the Company had $31.6 million and $6.0 million of foreign currency gains, respectively, 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 $0.2 million gain in fiscal 2016, a $24.8 million loss in fiscal 2015, and a $5.8 million loss in fiscal 2014 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

Deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been reflected in the consolidated 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.

3. Recently Issued Accounting Standards

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 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 year 2018 (following the change in fiscal year). The FASB subsequently issued additional ASUs to clarify the guidance of ASU 2014-09. The ASUs issued include ASU 2016-08, "Revenue from Contracts with Customers;" ASU

2016-10 "Revenue from Contracts with Customers, Identifying Performance Obligations and Licensing;" and ASU 2016-12, "Narrow-Scope Improvements and Practical Expedients." The Company is assessing the transition approach it will utilize and potential impact of adoption.

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 (following the change in fiscal year). The Company does not anticipate the adoption of this update to have a material impact.

FASB issued ASU 2015-16, "Simplifying the Accounting for Measurement-Period Adjustments," in September 2015. This update requires an acquirer to recognize adjustments to the provisional amounts that are identified during the measurement period in the reporting period in which the adjusting amounts are determined. The amendments in this update require an entity to present separately on the face of the income statement or disclose in the notes the portion of the amount recorded in current period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date. This guidance is effective for the Company in the first quarter of fiscal 2017 (following the change in fiscal year). The update is not expected to have a material impact for historical acquisitions.

The FASB issued ASU 2015-17, "Balance Sheet Reclassification of Deferred Taxes," in November 2015. This update requires all deferred tax assets and liabilities, along with any related valuation allowance, to be classified as noncurrent on the consolidated balance sheets. Each jurisdiction will now only have one net noncurrent deferred tax asset or liability. The Company elected to early adopt this guidance as of September 30, 2016 on a prospective basis. As such, the Company reclassified $122.6 million of current deferred income taxes to noncurrent as of September 30, 2016.

The FASB issued ASU 2016-02, "Leases," in February 2016. This update was issued to increase transparency and comparability among organizations by recognizing all lease transactions (with terms in excess of 12 months) on the balance sheet as a lease liability and a right-of-use asset (as defined). This guidance is effective for the Company in the first quarter of fiscal 2019 (following the change in fiscal year). Upon adoption, the lessee will apply the new standard using a modified retrospective approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. The Company is assessing the potential impact of this guidance.

The FASB issued ASU 2016-09, "Stock Compensation," in March 2016. This update simplifies several aspects of the accounting for share-based payment award transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification of certain tax effects within the statement of cash flows. This guidance is effective for the Company in the first quarter of fiscal 2017 (following the change in fiscal year). Upon adoption, the Company will recognize the incremental income tax expense or benefit related to share option exercises and restricted share unit vesting in the statement of income, whereas these tax effects are presently recognized directly in shareholders' equity. In addition, the incremental tax benefit associated with these events will be classified as a cash inflow from operating activity as compared with a financing activity, as required under current guidance.

The FASB issued ASU 2016-15, “Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments,” in August 2016 and ASU 2016-18 "Statement of Cash Flows (Topic 230): Restricted Cash," in November 2016. This update provides guidance for nine targeted clarifications with respect to how cash receipts and cash payments are classified in the statements of cash flows, with the objective of reducing diversity in practice. The guidance is effective for the Company in the first quarter of fiscal 2018 (following the change in fiscal year), with early adoption permitted. The Company is assessing the potential impact of this guidance.

The FASB issued ASU 2016-16, "Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory," in October 2016. This update simplifies the practice in how income tax consequences of an intra-entity transfer of an asset other than inventory should be recognized. Upon adoption, the entity must recognize such income tax consequences when

the intra-entity transfer occurs rather than waiting until such time as the asset has been sold to an outside party. The guidance is effective for the Company in the first quarter of fiscal 2018 (following the change in fiscal year). The Company is assessing the potential impact of this guidance.

4. Discontinued Operations and Divestitures

Discontinued Operations

Nuclear Imaging: During the fourth quarter of fiscal 2016, the Company announced that it had entered into a definitive agreement to sell its Nuclear Imaging business to IBAM, which is expected to be completed during the first half of calendar 2017. The Nuclear Imaging business was deemed to be held for sale and the financial results of this business are presented as a discontinued operation.

The following table summarizes the financial results of the Nuclear Imaging business for fiscal years 2016, 2015 and 2014 as presented in the consolidated statements of income:

	Fiscal Year		
Major line items constituting income (loss) from discontinued operations	2016	2015	2014
Net sales	$418.6	$423.8	$431.7
Cost of sales	216.6	193.1	256.1
Selling, general and administrative	83.7	89.6	111.5
Restructuring charges, net	2.3	(4.6)	13.4
Non-restructuring impairment charges	—	—	124.5
Other	5.7	37.7	45.5
Income (loss) from discontinued operations	110.3	108.0	(119.3)
Income tax expense	49.0	36.4	2.5
Income (loss) from discontinued operations, net of income taxes	$61.3	$71.6	$(121.8)

The fiscal 2014 non-restructuring impairment charge of $124.5 million includes charges of $119.5 million associated with goodwill. Further discussion of this impairment charge is included within Note 11.

The fiscal 2016 income tax expense of $49.0 million was impacted by tax expense of $11.7 million associated with the rate difference between Domestic and International jurisdictions, $14.4 million of tax expense associated with accrued income tax liabilities and uncertain tax positions, and $0.9 million of tax expense associated with permanently nondeductible, nontaxable, and other items. The fiscal 2015 income tax expense of $36.4 million was impacted by $14.3 million of tax expense associated with the rate difference between Domestic and International jurisdictions and $0.4 million of tax expense associated with permanently nondeductible, nontaxable, and other items. The fiscal 2014 income tax expense of $2.5 million was impacted by receiving no tax benefit on an impairment of $119.5 million, by $3.1 million of tax expense associated with the rate difference between Domestic and International jurisdictions, by a $1.3 million of tax benefit associated with accrued income tax liabilities and uncertain tax positions, and $0.7 million of tax expense associated with permanently nondeductible, nontaxable, and other items. Fiscal 2016 reflects $0.1 million of Domestic current income tax expense, $52.5 million of International current income tax expense, and $3.6 million of International deferred income tax benefit. Fiscal 2015 reflects $0.1 million of Domestic current income tax expense, $27.8 million of International current income tax expense, and $8.6 million of International deferred income tax expense. Fiscal 2014 reflects $18.6 million of Domestic current income tax expense, $1.0 million of International current income tax benefit, $7.8 million of Domestic deferred income tax benefit, and $7.4 million of International deferred income tax benefit. Domestic reflects U.K. in fiscal 2016 and 2015, and U.S. federal and state in fiscal 2014.

The following table summarizes the assets and liabilities of the Nuclear Imaging business that are classified as held for sale on the consolidated balance sheets as of September 30, 2016 and September 25, 2015:

	September 30, 2016	September 25, 2015
Carrying amounts of major classes of assets included as part of discontinued operations		
Accounts receivable	$ 53.7	$ 58.9
Inventories	19.0	19.7
Property, plant and equipment, net	189.0	198.3
Other current and non-current assets	47.1	41.7
Total assets classified as held for sale in the balance sheet	$ 308.8	$ 318.6
Carrying amounts of major classes of liabilities included as part of discontinued operations		
Accounts payable	$ 17.7	$ 16.2
Other current and non-current liabilities	103.1	94.2
Total liabilities classified as held for sale in the balance sheet	$ 120.8	$ 110.4

The following table summarizes significant cash and non-cash transactions of the Nuclear Imaging business that are included within the consolidated statements of cash flows for the fiscal years 2016, 2015 and 2014:

	Fiscal Year		
	2016	2015	2014
Depreciation	$20.9	$13.1	$17.9
Capital expenditures	9.7	7.6	8.1
Non-cash impairment charges	—	—	124.5

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

CMDS: On November 27, 2015, the Company completed the sale of the CMDS business to Guerbet S.A. ("Guerbet") for cash consideration of approximately $270.0 million, subject to net working capital adjustments.
Subsequent to the sale of the CMDS business, the Company continues to supply certain products under a supply agreement with Guerbet.
The following table summarizes the financial results of the CMDS business for fiscal 2016, 2015 and 2014 as presented in the consolidated statements of income:

	Fiscal Year		
Major line items constituting income (loss) from discontinued operations	2016	2015	2014
Net sales	$61.0	$413.8	$495.8
Cost of sales	46.9	306.4	352.9
Selling, general and administrative	20.3	97.5	97.1
Restructuring charges, net	—	0.3	47.2
Non-restructuring impairment charges	—	—	204.0
Other	1.2	4.7	4.1
(Loss) income from discontinued operations	(7.4)	4.9	(209.5)
Gain on disposal of discontinued operations	95.3	—	—
Income from discontinued operations, before income taxes	87.9	4.9	(209.5)
Income tax expense (benefit)	(2.5)	10.8	(34.7)
Income (loss) from discontinued operations net of tax	$90.4	$(5.9)	$(174.8)

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 2016 income tax benefit of $2.5 million impacted by a $0.4 million benefit related to adjust the fiscal 2015 accrual for taxes paid in connection with the $95.3 million gain on the disposition and a $2.1 million benefit related to the $7.4 million loss from discontinued operations. 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. Fiscal 2016 reflects $0.9 million of International current income tax expense, $3.4 million of International deferred income tax benefit, and none being allocable to the Domestic income tax provision. 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. Domestic reflects U.K. in fiscal 2016 and 2015, and U.S. federal and state in fiscal 2014.

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 30, 2016 and September 25, 2015:

	September 30, 2016	September 25, 2015
Carrying amounts of major classes of assets included as part of discontinued operations		
Accounts receivable	$ —	$ 68.5
Inventories	—	86.3
Property, plant and equipment, net	—	60.3
Intangible assets, net	—	27.7
Other current and non-current assets	—	57.1
Total assets classified as held for sale in the balance sheet	$ —	$ 299.9
Carrying amounts of major classes of liabilities included as part of discontinued operations		
Accounts payable	$ —	$ 22.0
Other current and non-current liabilities	—	50.8
Total liabilities classified as held for sale in the balance sheet	$ —	$ 72.8

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 2016, 2015 and 2014:

	Fiscal Year		
	2016	2015	2014
Depreciation	$ —	$ 15.5	$ 18.9
Amortization	—	2.3	7.5
Capital expenditures	1.6	9.5	12.3
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.

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Mallinckrodt Baker: During fiscal 2010, the Specialty Chemicals business (formerly known as "Mallinckrodt Baker") 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 2016, 2015, and 2014, the Company recorded a gain, net of tax, of $3.0 million, and losses, net of tax, of $0.1 million, and $0.7 million, respectively. The gains and losses were primarily related to the indemnification obligations to the purchaser, which are discussed in Note 17.
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 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.

5. Acquisitions and License Agreements
Business Acquisitions
Stratatech
On August 31, 2016, the Company acquired a developmental program from Stratatech Corporation - which includes StrataGraft®, a regenerative skin tissue and a technology platform for genetically enhanced skin tissues - for upfront consideration of $76.0 million, and contingent milestone payments, which are primarily regulatory, and royalty obligations that could result in up to $121.0 million of additional consideration ("the Stratatech Acquisition"). Stratatech is a regenerative medicine company focused on the development of unique, proprietary skin substitute products. Developmental products include StrataGraft® regenerative skin tissue ("StrataGraft") and a technology platform for genetically enhanced skin tissues. The Stratatech Acquisition was funded through cash on hand.

Hemostasis Products
On February 1, 2016, the Company acquired three commercial stage topical hemostasis drugs from The Medicines Company ("the Hemostasis Acquisition") - RECOTHROM® Thrombin topical (Recombinant) ("Recothrom"), PreveLeak™ Surgical Sealant ("PreveLeak"), and RAPLIXA™ (Fibrin Sealant (Human)) ("Raplixa") - for upfront consideration of $173.5 million, inclusive of existing inventory, and contingent sales-based milestone payments that could result in up to $395.0 million of additional consideration. The fair value of the contingent consideration and acquired contingent liabilities associated with the transaction were $52.0 million and $10.6 million, respectively, at February 1, 2016. The Hemostasis Acquisition was funded through cash on hand.

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.

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 ("Inomax"), 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 pharmaceutical 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 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, ophthalmology and pulmonology. Questcor also supplied 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 pharmaceutical company focused on commercializing products principally for use in the hospital setting, for total consideration of 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® (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.

Fair Value Allocation

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

	Stratatech	Hemostasis	Therakos	Ikaria	Questcor	Cadence
Cash	$ 0.2	$ 3.3	$41.3	$77.3	$445.1	$43.2
Inventory	—	94.6	23.5	26.3	67.9	21.0
Intangible assets	99.8	132.7	1,170.0	1,971.0	5,601.1	1,300.0
Goodwill (non-tax deductible)	57.3	3.3	429.9	795.0	1,789.4	318.1
Other assets, current and non-current [1]	3.2	7.9	40.2	174.3	274.3	18.0
Total assets acquired	160.5	241.8	1,704.9	3,043.9	8,177.8	1,700.3
Current liabilities	4.3	3.6	24.7	33.0	168.9	48.8
Unpaid purchase consideration (current)	—	—	—	—	128.8	—

Other liabilities (non-current)	—	10.6	0.6	15.8	186.8	—
Deferred tax liabilities, net (non-current)	24.3	2.1	315.7	620.5	1,906.8	292.3
Contingent consideration (non-current)	54.9	52.0	—	—	—	—
Total debt	1.0	—	344.8	1,121.0	—	30.0
Total liabilities assumed	84.5	68.3	685.8	1,790.3	2,391.3	371.1
Net assets acquired	$ 76.0	$ 173.5	$1,019.1	$1,253.6	$5,786.5	$1,329.2

(1) This amount includes $1.3 million, zero, $22.0 million, $73.8 million, $87.3 million, and $14.7 million of accounts receivable for the Stratatech Acquisition, Hemostasis Acquisition, Therakos Acquisition, Ikaria Acquisition, Questcor Acquisition and Cadence Acquisition, respectively, which is also the gross contractual value.

The following reconciles the total consideration to net assets acquired:

	Stratatech	Hemostasis	Therakos	Ikaria	Questcor	Cadence
Total consideration, net of cash	$ 130.7	$ 222.2	$977.8	$1,176.3	$5,470.2	$1,286.0
Plus: cash assumed in acquisition	0.2	3.3	41.3	77.3	445.1	43.2
Total consideration	130.9	225.5	1,019.1	1,253.6	5,915.3	1,329.2
Less: unpaid purchase consideration	—	—	—	—	(128.8)	—
Less: non-cash contingent consideration	(54.9)	(52.0)	—	—	—	—
Net assets acquired	$ 76.0	$ 173.5	$1,019.1	$1,253.6	$5,786.5	$1,329.2

Intangible assets acquired consist of the following:

Stratatech	Amount	Amortization Period
In-process research and development - StrataGraft	$ 99.8	Non-Amortizable

The IPR&D intangible asset relates to StrataGraft. The fair value of the IPR&D was determined using the income approach, which is a valuation technique that provides an estimate of fair value of the assets based on the market participant expectations of cash flows the asset would generate. The cash flows were discounted at a rate of 16.5%. The IPR&D discount rate for StrataGraft 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 future product development, the assembled workforce, 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.

Hemostasis Products	Amount	Amortization Period
Raplixa - Completed technology	$ 73.0	15 years
Recothrom - Completed technology	42.7	13 years
PreveLeak - Completed technology	17.0	13 years
	$ 132.7	

The completed technology intangible assets relate to each of the acquired drugs. The fair value of the intangible assets were determined using the income approach. The cash flows were discounted commensurate with the level of risk associated with each asset or its projected cash flows. The completed technology intangible assets utilized a discount rate of 17.0%, 16.0% and 17.0% for Raplixa, Recothrom and PreveLeak, respectively. All assets acquired are included within the Company's Specialty Brands segment.

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. The completed technology intangible asset utilized a discount rate of 17.0%. 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. Completed technology, trademark and 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. 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. The IPR&D 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. 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. 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.

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

Net sales	2016	2015	2014
Therakos	$207.6	$—	$—
Ikaria	491.5	191.9	—
Questcor	1,218.4	1,125.9	129.2
Cadence	284.3	263.0	124.4
	$2,201.8	$1,580.8	$253.6
Operating income (loss)			
Therakos	$12.5	$—	$—
Ikaria	201.1	47.1	—
Questcor	371.5	223.3	17.4
Cadence	(84.5)	(97.3)	(66.9)
	$500.6	$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	2016	2015	2014
Therakos	$78.0	$—	$—
Ikaria	124.5	57.1	—
Questcor	300.7	301.4	34.9
Cadence	162.5	162.5	85.9
	$665.7	$521.0	$120.8

During fiscal 2016, 2015 and 2014, the Company recognized $24.3 million, $44.1 million and $25.7 million, respectively, of expense 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 2016, 2015 and 2014 for each of the acquisitions discussed above were as follows:

Acquisition-related costs	2016	2015	2014
Stratatech	$3.7	$—	$—
Hemostasis Products	2.7	—	—
Therakos	0.3	22.5	—
Ikaria	0.2	30.9	—
Questcor	—	—	47.5
Cadence	—	—	17.6
	$6.9	$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, Therakos and Ikaria, 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 2.58%) entered into in connection with the Therakos Acquisition and 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), 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 acquisitions occurred on the assumed dates, 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 acquisitions or revenue growth that may be anticipated.

	2016	2015
Net sales	$3,380.8	$3,332.0
Income from continuing operations	499.4	288.9
Basic earnings per share from continuing operations	$4.52	$2.49
Diluted earnings from per share continuing operations	4.48	2.47

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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 2016, 2015 and 2014, the Company paid royalties of $46.3 million, $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 2016, $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 2016, 2015 and 2014, the Company paid royalties of $0.9 million, $3.2 million and $22.0 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 2016, 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, of which $15.0 million of these payments were made, which were capitalized as an intangible asset. 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 included actions across the Specialty Brands, Specialty Generics and former Global Imaging segments, as well as within corporate functions. The Company expected to incur charges of $100.0 million to $125.0 million under this program as the specific actions required to execute on these

initiatives were identified and approved. As of September 30, 2016, the Company has substantially completed the 2013 Mallinckrodt Program.

In July 2016, the Company's Board of Directors approved a $100.0 million to $125.0 million restructuring program ("the 2016 Mallinckrodt Program") designed to further improve its cost structure, as the Company continues to transform its business. The 2016 Mallinckrodt Program is expected to include actions across the Specialty Brands and Specialty Generics segments, as well as within corporate functions. There is no specified time period associated with the 2016 Mallinckrodt Program.

In addition to the 2016 Mallinckrodt Program and the 2013 Mallinckrodt Program, the Company has taken restructuring actions to generate synergies from its acquisitions.

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

	Fiscal Year		
	2016	2015	2014
Specialty Brands	$23.3	$36.5	$57.0
Specialty Generics	3.4	4.5	9.8
Corporate	11.5	4.3	1.4
Restructuring and related charges, net	38.2	45.3	68.2
Less: accelerated depreciation	(4.9)	(0.3)	(0.2)
Restructuring charges, net	$33.3	$45.0	$68.0

Net restructuring and related charges by program from continuing operations are comprised of the following:

	Fiscal Year		
	2016	2015	2014
2016 Mallinckrodt Program	$8.3	$—	$—
2013 Mallinckrodt Program	26.2	12.0	13.6
Acquisition programs	3.7	33.6	56.4
Other programs	—	(0.3)	(1.8)
Total programs	38.2	45.3	68.2
Less: non-cash charges, including impairments and accelerated share based compensation expense	(4.9)	(10.1)	(37.7)
Total charges expected to be settled in cash	$33.3	$35.2	$30.5

Non-cash charges in fiscal 2015 and 2014 include $9.8 million and $35.1 million, respectively, of accelerated share based compensation expense related to employee terminations, primarily related to the Questcor acquisition, and fiscal 2014 includes $2.3 million of property, plant and equipment asset impairments.

The following table summarizes cash activity for restructuring reserves, substantially all of which related to employee severance and benefits, with the exception of $8.5 million in fiscal 2014 related to consulting costs associated with restructuring initiatives related to the CMDS business:

	2016 Mallinckrodt Program	2013 Mallinckrodt Program	Acquisition Programs	Other Programs	Total
Balance at September 27, 2013	$ —	$ 14.9	$ —	$ 10.6	$25.5
Charges from continuing operations	—	19.2	22.9	1.4	43.5
Charges from discontinued operations	—	39.0	—	1.1	40.1
Changes in estimate from continuing operations	—	(7.3)	(1.6)	(4.1)	(13.0)
Changes in estimate from discontinued operations	—	(2.1)	—	(0.7)	(2.8)
Cash payments	—	(34.8)	(13.4)	(6.8)	(55.0)
Reclassifications [1]	—	(1.3)	—	(1.0)	(2.3)
Currency translation	—	(1.0)	—	(0.1)	(1.1)
Balance at September 26, 2014	—	26.6	7.9	0.4	34.9
Charges from continuing operations	—	11.7	25.3	—	37.0
Charges from discontinued operations	—	4.7	—	—	4.7
Changes in estimate from continuing operations	—	—	(1.5)	(0.3)	(1.8)
Changes in estimate from discontinued operations	—	(8.9)	—	—	(8.9)
Cash payments	—	(22.5)	(21.7)	(0.1)	(44.3)
Reclassifications [1]	—	(3.0)	—	—	(3.0)
Currency translation	—	(0.6)	—	—	(0.6)
Balance at September 25, 2015	—	8.0	10.0	—	18.0
Charges from continuing operations	6.4	24.6	5.0	—	36.0
Charges from discontinued operations	—	2.5	—	—	2.5
Changes in estimate from continuing operations	—	(1.4)	(1.3)	—	(2.7)
Changes in estimate from discontinued operations	—	(0.3)	—	—	(0.3)
Cash payments	(0.2)	(20.3)	(13.2)	—	(33.7)
Reclassifications [1]	—	(1.3)	—	—	(1.3)
Balance at September 30, 2016	$ 6.2	$ 11.8	$ 0.5	$ —	$18.5

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

Net restructuring and related charges, including associated asset impairments, incurred cumulative to date related to the 2016 and 2013 Mallinckrodt Programs are as follows:

	2016 Mallinckrodt Program	2013 Mallinckrodt Program
Specialty Brands	$ 4.7	$ 18.8
Specialty Generics	0.5	18.3
Discontinued Operations (including Nuclear and CMDS)	—	69.9
Corporate	3.1	18.4
	$ 8.3	$ 125.4

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

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7. Income Taxes

In May 2015, the activities of the Company's principal executive offices were relocated from Ireland to the U.K. which resulted in a change in the Company's tax residence to the U.K. Mallinckrodt plc remains incorporated in Ireland. The tax regime applicable to holding companies resident in the U.K. allows Mallinckrodt plc to continue to have flexibility in structuring its subsidiary operations and enhanced global cash management. The Company continues to be subject to taxation in various tax jurisdictions worldwide. As a result of the integration of acquired intellectual property, the Company's income and assets are no longer concentrated in a single tax jurisdiction. Accordingly, beginning in 2015, the Company reports the U.K. tax jurisdiction as its Domestic jurisdiction and the International jurisdiction represents areas outside the U.K. tax jurisdiction.

The Domestic and International components of income from continuing operations before income taxes were as follows[(1)]:

	2016	2015	2014
Domestic	$(275.3)	$(107.5)	$(76.0)
International	508.7	214.8	41.4
Total	$233.4	$107.3	$(34.6)

(1) Domestic reflects U.K. in fiscal 2016 and 2015, and U.S. federal and state in fiscal 2014.

Significant components of income taxes related to continuing operations are as follows[(1)]:

	2016	2015	2014
Current:			
Domestic	$ 0.3	$ 0.2	$ 22.3
International	120.5	67.3	18.9
Current income tax provision	120.8	67.5	41.2
Deferred:			
Domestic	$		