

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

FORM 10-K

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

For the fiscal year ended September 30, 2016  
or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number : 001-35803

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

Ireland

(State or other jurisdiction of incorporation or organization)

98-1088325

(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

Ordinary shares, par value \$0.20 per share

Name of each exchange on which registered

New York Stock Exchange

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate 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  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer  Accelerated filer

Non-accelerated filer  (Do not check if smaller reporting company) Smaller reporting company

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant (assuming solely for the purposes of this calculation that all directors and executive officers of the Registrant are "affiliates") as of March 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)) ("Raplix") 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:

- 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") type 1, 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 FFDC"). 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 FFDC. 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 FFDCRA (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.)

**Available Information**

Our website address is [www.mallinckrodt.com](http://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](http://www.sec.gov).

We use our website at [www.mallinckrodt.com](http://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.

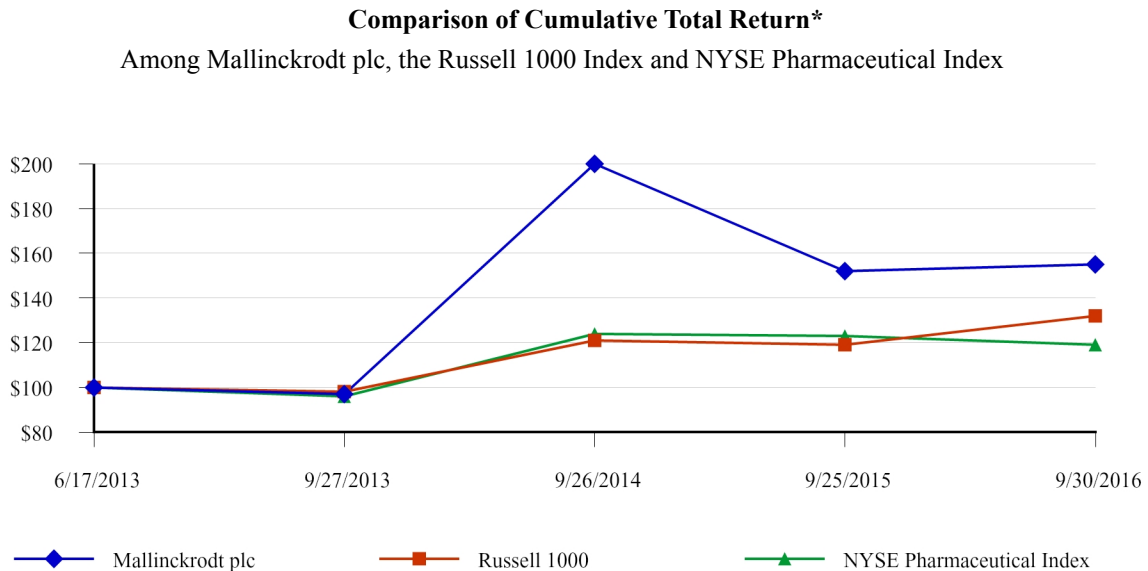
During the quarter ended September 30, 2016, we repurchased 687,103 of our ordinary shares related to both our \$500.0 million share repurchase program, announced on November 19, 2015, and the satisfaction of tax withholding obligations in connection with the vesting of restricted stock issued to employees 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.



\*\$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 <sup>(1)</sup>				
	2016	2015	2014	2013	2012
<b>Consolidated and Combined Statement of Income Data:</b>					
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 <sup>(2)</sup>	262.2	203.3	140.5	141.9	144.1
Operating income (loss) <sup>(3)(4)</sup>	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)
<b>Share Data <sup>(5)</sup>:</b>					
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
<b>Consolidated and Combined Balance Sheet Data:</b>					
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		Percentage Change
	2016	2015	
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.

## **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		Percentage Change
	2015	2014	
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		Percentage Change
	2016	2015	
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 <sup>(1)</sup>	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		Percentage Change
	2016	2015	
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		Percentage Change
	2016	2015	
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	<u>\$ 2,300.6</u>	<u>\$ 1,622.8</u>	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		Percentage Change
	2016	2015	
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	<u>\$ 1,025.2</u>	<u>\$ 1,251.6</u>	(18.1)

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

	Fiscal Year		Percentage Change
	2016	2015	
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	<u>\$ 1,025.2</u>	<u>\$ 1,251.6</u>	(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 <sup>(1)</sup>	(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		Percentage Change
	2015	2014	
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 <sup>(1)</sup>	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		Percentage Change
	2015	2014	
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		Percentage Change
	2015	2014	
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		Percentage Change
	2015	2014	
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	<u>\$ 1,251.6</u>	<u>\$ 1,199.4</u>	4.4

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

	Fiscal Year		Percentage Change
	2015	2014	
Hydrocodone (API) and hydrocodone-containing tablets	\$ 167.2	\$ 99.4	68.2%
Oxycodone (API) and oxycodone-containing tablets	154.6	155.2	(0.4)
Methylphenidate ER	136.5	209.6	(34.9)
Other controlled substances	572.2	584.5	(2.1)
Other	221.1	150.7	46.7
Specialty Generics	<u>\$ 1,251.6</u>	<u>\$ 1,199.4</u>	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 <sup>(1)</sup>	(45.3)		(68.2)	
Non-restructuring impairment charges	—		(27.1)	
Separation costs	—		(9.6)	
Total operating (loss) income	<u>\$ 353.8</u>		<u>\$ 43.4</u>	

(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 CMD5 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 CMD5 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 <sup>(1)</sup>	1,632.7	277.2	519.0	468.9	367.6
Capital lease obligations <sup>(1)</sup>	1.2	1.0	0.2	—	—
Operating lease obligations	135.7	26.5	39.1	25.2	44.9
Purchase obligations <sup>(2)</sup>	247.7	147.5	51.9	20.8	27.5
Total contractual obligations	<u>\$ 8,151.6</u>	<u>\$ 708.3</u>	<u>\$ 947.5</u>	<u>\$ 3,116.0</u>	<u>\$ 3,379.8</u>

- (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.**

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## 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
<b>Net sales</b>	\$ 3,380.8	\$ 2,923.1	\$ 1,650.3
Cost of sales	1,525.8	1,300.2	765.7
<b>Gross profit</b>	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)
<b>Operating income</b>	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
<b>Income (loss) from continuing operations before income taxes</b>	233.4	107.3	(34.6)
Benefit from income taxes	(255.6)	(129.3)	(12.6)
<b>Income (loss) from continuing operations</b>	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)
<b>Net income (loss)</b>	\$ 643.7	\$ 324.7	\$ (319.3)
<b>Basic earnings per share (Note 8):</b>			
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
<b>Diluted earnings per share (Note 8):</b>			
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.

**MALLINCKRODT PLC**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**  
*(in millions)*

	Fiscal Year		
	2016	2015	2014
<b>Net income (loss)</b>	\$ 643.7	\$ 324.7	\$ (319.3)
<b>Other comprehensive (loss), net of tax</b>			
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)
<b>Total other comprehensive (loss), net of tax</b>	(86.5)	(64.8)	(42.8)
<b>Comprehensive income (loss)</b>	\$ 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
<b>Assets</b>		
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
<b>Total current assets</b>	<b>1,506.6</b>	<b>1,846.1</b>
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
<b>Total Assets</b>	<b>\$ 15,498.7</b>	<b>\$ 16,404.1</b>
<b>Liabilities and Shareholders' Equity</b>		
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
<b>Total current liabilities</b>	<b>1,234.7</b>	<b>929.4</b>
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
<b>Total Liabilities</b>	<b>10,228.0</b>	<b>11,092.9</b>
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
<b>Total Shareholders' Equity</b>	<b>5,270.7</b>	<b>5,311.2</b>
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 15,498.7</b>	<b>\$ 16,404.1</b>

See Notes to Consolidated Financial Statements.

**MALLINCKRODT PLC**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
*(in millions)*

	Fiscal Year		
	2016	2015	2014
<b>Cash Flows From Operating Activities:</b>			
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	<u>1,184.6</u>	<u>896.4</u>	<u>373.4</u>
<b>Cash Flows From Investing Activities:</b>			
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	<u>(108.0)</u>	<u>(2,296.6)</u>	<u>(2,890.8)</u>
<b>Cash Flows From Financing Activities:</b>			
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	<u>(1,162.3)</u>	<u>1,069.9</u>	<u>2,953.9</u>
Effect of currency rate changes on cash	0.3	(11.6)	(4.2)
<b>Net (decrease) increase in cash and cash equivalents</b>	<u>(85.4)</u>	<u>(341.9)</u>	<u>432.3</u>
<b>Cash and cash equivalents at beginning of period</b>	<u>365.9</u>	<u>707.8</u>	<u>275.5</u>
<b>Cash and cash equivalents at end of period</b>	<u>\$ 280.5</u>	<u>\$ 365.9</u>	<u>\$ 707.8</u>
<b>Supplemental Disclosures of Cash Flow Information:</b>			
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				
<b>Balance at September 27, 2013</b>	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)
<b>Balance at September 26, 2014</b>	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)
<b>Balance at September 25, 2015</b>	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)
<b>Balance at September 30, 2016</b>	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, except 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:

Major line items constituting income (loss) from discontinued operations	Fiscal Year		
	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
<b>Income (loss) from discontinued operations</b>	<b>110.3</b>	<b>108.0</b>	<b>(119.3)</b>
Income tax expense	49.0	36.4	2.5
<b>Income (loss) from discontinued operations, net of income taxes</b>	<b>\$ 61.3</b>	<b>\$ 71.6</b>	<b>\$ (121.8)</b>

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
<b>Carrying amounts of major classes of assets included as part of discontinued operations</b>		
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
<b>Total assets classified as held for sale in the balance sheet</b>	<b>\$ 308.8</b>	<b>\$ 318.6</b>
<b>Carrying amounts of major classes of liabilities included as part of discontinued operations</b>		
Accounts payable	\$ 17.7	\$ 16.2
Other current and non-current liabilities	103.1	94.2
<b>Total liabilities classified as held for sale in the balance sheet</b>	<b>\$ 120.8</b>	<b>\$ 110.4</b>

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:

Major line items constituting income (loss) from discontinued operations	Fiscal Year		
	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	—	—
<b>Income from discontinued operations, before income taxes</b>	<b>87.9</b>	<b>4.9</b>	<b>(209.5)</b>
Income tax expense (benefit)	(2.5)	10.8	(34.7)
<b>Income (loss) from discontinued operations net of tax</b>	<b>\$ 90.4</b>	<b>\$ (5.9)</b>	<b>\$ (174.8)</b>

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
<b>Carrying amounts of major classes of assets included as part of discontinued operations</b>		
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
<b>Total assets classified as held for sale in the balance sheet</b>	<b>\$ —</b>	<b>\$ 299.9</b>
<b>Carrying amounts of major classes of liabilities included as part of discontinued operations</b>		
Accounts payable	\$ —	\$ 22.0
Other current and non-current liabilities	—	50.8
<b>Total liabilities classified as held for sale in the balance sheet</b>	<b>\$ —</b>	<b>\$ 72.8</b>

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.



*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:

	<b>Stratatech</b>	<b>Hemostasis</b>	<b>Therakos</b>	<b>Ikaria</b>	<b>Questcor</b>	<b>Cadence</b>
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 <sup>(1)</sup>	3.2	7.9	40.2	174.3	274.3	18.0
<b>Total assets acquired</b>	<b>160.5</b>	<b>241.8</b>	<b>1,704.9</b>	<b>3,043.9</b>	<b>8,177.8</b>	<b>1,700.3</b>
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	—	—	—	—
<b>Total debt</b>	<b>1.0</b>	<b>—</b>	<b>344.8</b>	<b>1,121.0</b>	<b>—</b>	<b>30.0</b>
<b>Total liabilities assumed</b>	<b>84.5</b>	<b>68.3</b>	<b>685.8</b>	<b>1,790.3</b>	<b>2,391.3</b>	<b>371.1</b>
<b>Net assets acquired</b>	<b>\$ 76.0</b>	<b>\$ 173.5</b>	<b>\$ 1,019.1</b>	<b>\$ 1,253.6</b>	<b>\$ 5,786.5</b>	<b>\$ 1,329.2</b>

- (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:

	<b>Stratatech</b>	<b>Hemostasis</b>	<b>Therakos</b>	<b>Ikaria</b>	<b>Questcor</b>	<b>Cadence</b>
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:

<b>Stratatech</b>	<b>Amount</b>	<b>Amortization Period</b>
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.

<b>Hemostasis Products</b>	<b>Amount</b>	<b>Amortization Period</b>
Raplixia - 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 Raplixia, Recothrom and PreveLeak, respectively. All assets acquired are included within the Company's Specialty Brands segment.

<b>Therakos</b>	<b>Amount</b>	<b>Amortization Period</b>
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.

<b>Ikaria</b>	<b>Amount</b>	<b>Amortization Period</b>
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.

<i>Questcor</i>	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
	<u>\$ 5,601.1</u>	

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.

<i>Cadence</i>	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:

	2016	2015	2014
<b>Net sales</b>			
Therakos	\$ 207.6	\$ —	\$ —
Ikaria	491.5	191.9	—
Questcor	1,218.4	1,125.9	129.2
Cadence	284.3	263.0	124.4
	<u>\$ 2,201.8</u>	<u>\$ 1,580.8</u>	<u>\$ 253.6</u>
<b>Operating income (loss)</b>			
Therakos	\$ 12.5	\$ —	\$ —
Ikaria	201.1	47.1	—
Questcor	371.5	223.3	17.4
Cadence	(84.5)	(97.3)	(66.9)
	<u>\$ 500.6</u>	<u>\$ 173.1</u>	<u>\$ (49.5)</u>

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

<b>Intangible asset amortization</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Therakos	\$ 78.0	\$ —	\$ —
Ikaria	124.5	57.1	—
Questcor	300.7	301.4	34.9
Cadence	162.5	162.5	85.9
	<u>\$ 665.7</u>	<u>\$ 521.0</u>	<u>\$ 120.8</u>

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:

<b>Acquisition-related costs</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Stratatech	\$ 3.7	\$ —	\$ —
Hemostasis Products	2.7	—	—
Therakos	0.3	22.5	—
Ikaria	0.2	30.9	—
Questcor	—	—	47.5
Cadence	—	—	17.6
	<u>\$ 6.9</u>	<u>\$ 53.4</u>	<u>\$ 65.1</u>

*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.

	<b>2016</b>	<b>2015</b>
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

## 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 <sup>(1)</sup>	—	(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 <sup>(1)</sup>	—	(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 <sup>(1)</sup>	—	(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.



## 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<sup>(1)</sup>:

	2016	2015	2014
Domestic	\$ (275.3)	\$ (107.5)	\$ (76.0)
International	508.7	214.8	41.4
Total	<u>\$ 233.4</u>	<u>\$ 107.3</u>	<u>\$ (34.6)</u>

(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<sup>(1)</sup>:

	2016	2015	2014
Current:			
Domestic	\$ 0.3	\$ 0.2	\$ 22.3
International	120.5	67.3	18.9
Current income tax provision	<u>120.8</u>	<u>67.5</u>	<u>41.2</u>
Deferred:			
Domestic	\$ 0.7	\$ (0.8)	\$ (41.9)
International	(377.1)	(196.0)	(11.9)
Deferred income tax (benefit)	<u>(376.4)</u>	<u>(196.8)</u>	<u>(53.8)</u>
	<u>\$ (255.6)</u>	<u>\$ (129.3)</u>	<u>\$ (12.6)</u>

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

The fiscal 2016 Domestic current income tax provision reflects a utilization of \$1.0 million of net operating losses. The Domestic net operating loss utilization is comprised of net operating losses carried forward from fiscal 2015. The fiscal 2016 International current income tax provision reflects a utilization of \$29.2 million of net operating losses and \$9.5 million of U.S. credits. The International net operating loss utilization is comprised of \$17.9 million of net operating losses acquired in conjunction with the Hemostasis Acquisition and the remainder of the utilization relates to net operating losses carried forward from fiscal 2015. The U.S. credit utilization is comprised of credits carried forward from fiscal 2015 and generated during fiscal 2016.

The fiscal 2015 International current income tax provision reflects a utilization of \$7.0 million of net operating losses (primarily in the U.S.) and \$14.3 million of U.S. credits. The net operating loss utilization is comprised of \$4.8 million of net operating losses acquired in conjunction with the Ikaria Acquisition and the remainder of the utilization relates to net operating losses carried forward from fiscal 2014. The U.S. credit utilization is comprised of \$7.2 million of credits acquired in conjunction with the Ikaria Acquisition and the remainder utilization relating to credits carried forward or generated during fiscal 2015.

The fiscal 2014 Domestic current income tax provision reflects a utilization of \$221.3 million of net operating losses (primarily in the U.S.) and \$8.6 million of U.S. credits. The net operating loss utilization is comprised of \$187.8 million of net operating losses acquired in conjunction with the Cadence Acquisition and the remainder utilization relating to net operating losses carried forward.

The Company has a provincial tax holiday in Canada that expires on April 1, 2017. The tax holiday reduced International tax expense by \$1.0 million, \$5.1 million and \$0.3 million for the fiscal years 2016, 2015 and 2014, respectively.

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

	2016	2015	2014
Provision for income taxes at Domestic statutory income tax rate <sup>(1)</sup>	\$ 46.6	\$ 21.4	\$ (12.1)
Adjustments to reconcile to income tax provision:			
U.S. state income tax provision, net <sup>(5)</sup>	—	—	(7.0)
Rate difference between Domestic and International jurisdictions <sup>(2)</sup>	(249.3)	(152.9)	(14.2)
U.S. manufacturing deduction <sup>(5)</sup>	—	—	(2.7)
Valuation allowances, nonrecurring	2.1	(2.1)	0.1
Adjustments to accrued income tax liabilities and uncertain tax positions	(14.9)	(7.0)	(0.4)
Interest and penalties on accrued income tax liabilities and uncertain tax positions	(16.4)	0.3	(7.7)
Investment in partnership	—	—	20.0
Credits, principally research and orphan drug <sup>(3) (4)</sup>	(33.7)	(8.1)	(0.7)
Permanently nondeductible and nontaxable items	7.9	14.7	13.4
Other	2.1	4.4	(1.3)
Provision for income taxes	<u>\$ (255.6)</u>	<u>\$ (129.3)</u>	<u>\$ (12.6)</u>

- (1) The statutory tax rate reflects the U.K. statutory tax rate of 20% for fiscal 2016 and 2015, and the U.S. federal statutory tax rate of 35% for fiscal 2014.
- (2) Includes the impact of certain recurring valuation allowances for Domestic and International jurisdictions.
- (3) Due to the December 31, 2013 Research Credit tax law expiration, fiscal 2014 includes \$0.7 million for the period September 28, 2013 through December 31, 2013. During fiscal 2015, the legislation was extended, with a retroactive effective date of January 1, 2014. As such, fiscal 2015 includes approximately \$3.6 million of credit related to the period January 1, 2014 through September 26, 2014.
- (4) The Company realized a tax benefit of \$27.4 million resulting from a U.K. tax credit on a dividend between affiliates.
- (5) For fiscal 2016, U.S. state income tax benefit of \$15.1 million was combined with the rate differences between Domestic and International jurisdictions. For fiscal 2015, U.S. state income tax benefit of \$34.9 million, and U.S. manufacturing deduction tax benefit of \$4.3 million were combined with the rate differences between Domestic and International jurisdictions. Fiscal 2014 includes U.S. state income tax benefit of \$4.4 million associated with fiscal 2014 acquisitions and integration thereof.

The rate difference between Domestic and International jurisdictions changed from \$152.9 million of tax benefit to \$249.3 million of tax benefit for fiscal 2015 to fiscal 2016, respectively. This change was predominately related to recent acquisitions, which resulted in more income in lower tax rate jurisdictions and less income in the higher tax rate U.S. jurisdiction relative to income in all jurisdictions. The change in the lower tax rate jurisdictions was predominately due to recent acquisitions, which resulted in more income in lower tax rate jurisdictions and less income in the higher tax rate U.S. jurisdiction relative to income in all jurisdictions. The change in the lower tax rate jurisdictions was primarily attributable to increased operating income partially offset by amortization. The change in the U.S. jurisdiction was primarily attributable to increased amortization and the cost of financing recent acquisitions. The \$96.4 million increase in the tax benefit included increases of \$146.3 million of tax benefit attributed to changes in operating income and \$32.0 million of tax benefit related to acquisition and other non-acquisition related items; partially offset by \$56.8 million of increased tax expense to the change in amortization and a \$25.1 million decrease to the U.S. state tax benefit associated with the impact of recent acquisitions, integration thereof, and legislative changes.

The rate difference between Domestic and International jurisdictions changed from \$14.2 million of tax benefit to \$152.9 million of tax benefit for fiscal 2014 to fiscal 2015, respectively. The rate difference between Domestic and International jurisdictions would have been \$19.0 million of tax benefit in fiscal 2014 if the referenced rate would have been the U.K. statutory rate of 21%. This change was predominately related to recent acquisitions, which resulted in more income in lower tax rate jurisdictions and less income in the higher tax rate U.S. jurisdiction relative to income in all jurisdictions. The change in the lower tax rate jurisdictions was predominately due to recent acquisitions, both of which resulted in more income in lower tax rate jurisdictions and less income in the higher tax rate U.S. jurisdiction relative to income in all jurisdictions. The change in the lower tax rate jurisdictions was primarily attributable to increased operating income partially offset by amortization. The change in the U.S. jurisdiction was primarily attributable to increased amortization and the cost of financing recent acquisitions. The \$138.7 million increase in the tax benefit included increases of \$62.4 million of tax benefit attributed to changes in operating income, \$62.2 million of tax benefit related to acquisition and other non-acquisition related items and \$31.8 million of tax benefit to the U.S. state tax benefit associated with the impact of recent acquisitions, integration thereof, and legislative changes, and \$4.8 million of tax benefit can be attributed to the change in the referenced rate from U.S. to U.K.; partially offset by \$22.5 million of increased tax expense to the change in amortization.

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

	2016	2015	2014
Balance at beginning of fiscal year	\$ 89.2	\$ 82.0	\$ 100.1
Additions related to current year tax positions	63.8	4.5	3.2
Additions related to prior period tax positions	10.8	19.9	30.6
Reductions related to prior period tax positions	(37.8)	(7.7)	(33.0)
Reductions related to disposition transactions	(6.6)	—	—
Settlements	(2.6)	(7.8)	(6.9)
Lapse of statute of limitations	(2.0)	(1.7)	(12.0)
Balance at end of fiscal year	<u>\$ 114.8</u>	<u>\$ 89.2</u>	<u>\$ 82.0</u>

During fiscal 2015, the Company made a payment of \$8.9 million (\$7.4 million of tax and \$1.5 million of interest) to the U.S. Internal Revenue Service ("IRS") in connection with the settlement of certain tax matters for 2008 and 2009. During fiscal 2014, the Company made a payment of \$35.9 million (\$27.3 million of tax and \$8.6 million of interest) to the IRS in connection with the settlement of certain tax matters for 2005 through 2007.

On January 19, 2016, Tyco International plc ("Tyco International") announced it had entered into Stipulations of Settled Issues with the IRS to resolve certain disputes before the U.S. Tax Court. The disputes involved IRS audits of Tyco International for years in which companies that are now subsidiaries of Mallinckrodt were subsidiaries of Tyco International. On May 31, 2016, the U.S. Tax Court entered decisions consistent with the Stipulations of Settled Issues. As a result, all aspects of the disputes that were before the U.S. Tax court and Appeals Division of the IRS have been resolved for audit cycles from 1997-2007. Mallinckrodt is not a participant in the tax sharing agreement between Medtronic plc (as successor to Covidien plc), Tyco International and TE Connectivity and will not share in or be responsible for any payments to be made under the terms of the settlement.

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

	September 30, 2016	September 25, 2015
Accrued and other current liabilities	\$ —	\$ 1.3
Other income tax liabilities	55.4	80.0
Deferred income taxes (non-current liability)	59.4	7.9
	<u>\$ 114.8</u>	<u>\$ 89.2</u>

Included within total unrecognized tax benefits at September 30, 2016, September 25, 2015 and September 26, 2014, were \$113.1 million, \$87.4 million and \$82.0 million, respectively, of unrecognized tax benefits, which if favorably settled would benefit the effective tax rate. The remaining unrecognized tax benefits for each period would be offset by the write-off of related deferred and other tax assets, if recognized. During fiscal 2016, the Company recorded \$4.1 million of additional interest through tax provision and acquisition accounting and decreased accrued interest by \$32.1 million related to cash payments related to settlements as well as reductions related to prior periods and \$6.5 million related to disposition transactions. During fiscal 2015 and 2014, the Company accrued additional interest of \$5.7 million and \$7.0 million, respectively. The total amount of accrued interest related to uncertain tax positions was \$7.2 million, \$41.7 million and \$45.1 million, respectively.

It is reasonably possible that within the next twelve months, as a result of the resolution of various Domestic and International examinations and appeals and the expiration of various statutes of limitation, that the unrecognized tax benefits could decrease by up to \$14.6 million. Interest and penalties could decrease by up to \$6.1 million.

Income taxes payable, including uncertain tax positions and related interest accruals, is reported in the following consolidated balance sheet captions in the amounts shown:

	September 30, 2016	September 25, 2015
Accrued and other current liabilities	\$ 111.8	\$ 15.6
Other income tax liabilities	67.7	121.3
	<u>\$ 179.5</u>	<u>\$ 136.9</u>

At September 30, 2016, other assets included \$69.1 million of tax payments associated with non-current deferred intercompany transactions. Prepaid expenses and other current assets includes \$10.0 million of tax payments associated with current deferred intercompany transactions, and \$43.5 million of receivables associated with tax payments on account with the taxing authorities. At September 25, 2015, other assets includes \$51.7 million of tax payments associated with non-current deferred intercompany transactions. Prepaid expenses and other current assets includes a receivable of \$81.1 million and tax payments of \$8.7 million associated with current deferred intercompany transactions. All of the above items exclude amounts related to assets which are held for sale.

	September 30, 2016	September 25, 2015
Other assets	\$ 69.1	\$ 51.7
Prepaid expenses and other current assets	53.5	89.8
	<u>\$ 122.6</u>	<u>\$ 141.5</u>

Covidien continues to be examined by various taxing authorities for periods the Company was included within the consolidated results of Covidien. In connection with the Separation, the Company entered into a tax matters agreement ("the Tax Matters Agreement") with Covidien that generally governs Covidien's and Mallinckrodt's respective rights, responsibilities and obligations after the Separation with respect to certain taxes, including, but not limited to, ordinary course of business taxes. For further information on the Tax Matters Agreement, refer to Note 18.

As of September 30, 2016, the earliest open years for U.S. federal and state tax jurisdictions is 2010 and 2000, respectively. Additionally, a number of tax periods from 2009 to present are subject to examination by tax authorities in various jurisdictions, including Ireland, Luxembourg, Switzerland and the U.K.

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

	September 30, 2016	September 25, 2015
Deferred tax assets:		
Accrued liabilities and reserves	\$ 80.8	\$ 91.0
Inventories	35.4	21.4
Tax loss and credit carryforwards	332.3	159.5
Environmental liabilities	28.6	23.6
Rebate reserves	48.7	48.1
Expired product	12.2	26.3
Postretirement benefits	48.7	37.3
Federal and state benefit of uncertain tax positions and interest	17.4	33.6
Share-based compensation	22.1	17.6
Intangible assets	341.8	105.7
Other	14.9	8.7
	<u>982.9</u>	<u>572.8</u>
Deferred tax liabilities:		
Property, plant and equipment	(111.3)	(111.8)
Intangible assets	(775.1)	(1,550.7)
Installment sale	(1,902.9)	(1,465.3)
Investment in partnership	(186.0)	(187.9)
	<u>(2,975.3)</u>	<u>(3,315.7)</u>
Net deferred tax (liability) before valuation allowances	(1,992.4)	(2,742.9)
Valuation allowances	(564.9)	(233.0)
Net deferred tax (liability)	<u>\$ (2,557.3)</u>	<u>\$ (2,975.9)</u>

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

	September 30, 2016	September 25, 2015
Deferred income taxes (current asset)	\$ —	\$ 139.2
Other non-current assets	24.1	6.6
Accrued and other current liabilities	—	(4.2)
Deferred income taxes (non-current liability)	(2,581.4)	(3,117.5)
Net deferred tax (liability)	<u>\$ (2,557.3)</u>	<u>\$ (2,975.9)</u>

The above table reflects the reclassification of current deferred taxes to non-current upon the Company's adoption of ASU 2015-17, "Balance Sheet Reclassification of Deferred Taxes."

The Company's current deferred tax asset decreased from \$139.2 million at September 25, 2015 to zero at September 30, 2016 due to tax credit utilization of \$12.4 million in the current year, and the remainder primarily due to the adoption of ASU 2015-17, "Balance Sheet Reclassification of Deferred Taxes," whereby deferred taxes are reclassified as non-current. Non-current deferred tax liability decreased from \$3,117.5 million at September 25, 2015 to \$2,581.4 million at September 30, 2016, primarily due to \$322.8 million of decreases associated with the payment of internal installment sale obligations, \$122.6 million of decreases due to reclassification on the adoption of ASU 2015-17, \$66.4 million of decreases associated with the amortization of intangibles, and \$50.0 million of decreases related to other impacts of recent acquisitions and integration and normal operating activity. These factors were partially offset by a \$25.7 million increase from current year acquisitions.

The Hemostasis Acquisition resulted in a net deferred tax liability increase of \$1.4 million. Significant components of this increase include \$20.3 million of deferred tax liabilities associated with intangibles and \$4.1 million associated with inventory, partially offset by \$23.0 million of deferred tax assets associated with non U.K. net operating losses and tax credits.

The Stratatech Acquisition resulted in a net deferred tax liability increase of \$24.3 million. Significant components of this include \$35.5 million of deferred tax liabilities associated with intangibles partially offset by \$11.2 million of deferred tax assets associated with non U.K. net operating losses and tax credits.

As a part of the Ikaria integration, the Company entered into an internal installment sale transaction during fiscal 2016. The Ikaria internal installment sale transaction resulted in a decrease of \$535.1 million to the deferred tax liability associated with the completed technology and IPR&D intangible assets, a \$519.5 million increase to the deferred tax liability associated with an installment sale note receivable, a \$42.8 million increase to the current income tax liability, a \$23.8 million increase to deferred tax charges and a \$1.0 million increase to prepaid taxes.

As part of the Therakos integration, the Company entered into an internal installment sale transaction during fiscal 2016. The Therakos internal installment sale transaction resulted in a decrease of \$267.3 million to the deferred tax liability associated with the completed technology intangible asset, a \$250.4 million increase to the deferred tax liability associated with an installment sale note receivable, a \$17.3 million increase to the current income tax liability and a \$0.3 million increase to prepaid taxes.

At September 30, 2016, the Company had approximately \$246.1 million of net operating loss carryforwards in certain International jurisdictions, of which \$175.3 million have no expiration and the remaining \$70.8 million will expire in future years through 2036. As a result of the Company's disposition of its CMD5 business, as discussed in Note 4, the Company's International net operating losses increased by \$29.5 million. The Company had \$75.0 million of Domestic net operating loss carryforwards at September 30, 2016, which have no expiration date.

At September 30, 2016 the Company also had \$11.2 million of tax credits available to reduce future income taxes payable, primarily in jurisdictions within the U.S., of which \$4.0 million have no expiration and the remainder expire during fiscal 2017 through 2036.

The deferred tax asset valuation allowances of \$564.9 million and \$233.0 million at September 30, 2016 and September 25, 2015, respectively, relate principally to the uncertainty of the utilization of certain deferred tax assets, primarily International net operating losses and intangible assets. The Company believes that it will generate sufficient future taxable income to realize the tax benefits related to the remaining net deferred tax assets.

As of September 30, 2016, the cumulative amount of undistributed earnings of the Company's subsidiaries that may be subject to tax, but are considered to be indefinitely reinvested, was \$354.8 million. It is not practicable to determine the cumulative amount of tax liability that would arise if these indefinitely reinvested earnings were remitted due to a variety of factors including the complexity of the Company's global legal entity structure as well as the timing, extent, and nature of any hypothetical repatriation of unremitted earnings. The net decrease in such undistributed earnings as compared to the period ended September 25, 2015 was attributable to the removal of the earnings for the entities classified as held for sale, further adjusted by unrepatriated earnings associated with income and losses attributed to the current year activity.

As of September 25, 2015, the Company has also accrued a \$6.5 million deferred tax liability associated with approximately \$41.3 million of unrepatriated earnings that were not indefinitely reinvested related to assets held for sale, which was adjusted to \$3.9 million in 2016. As a result of the disposition of the CMD5 business, the Company satisfied this deferred tax liability. As of September 30, 2016, the Company has no deferred tax liabilities associated with unrepatriated earnings that are not indefinitely reinvested on assets from continuing operations or related to assets held for sale.

## 8. Earnings (Loss) per Share

In fiscal 2016, basic earnings (loss) per share was computed by dividing net income by the number of weighted-average shares outstanding during the period. Diluted earnings (loss) per share was computed using the weighted-average shares outstanding and, if dilutive, potential ordinary shares outstanding during the period. Potential ordinary shares represent the incremental ordinary shares issuable for restricted share units and share option exercises. The Company calculated the dilutive effect of outstanding restricted share units and share options on earnings (loss) per share by application of the treasury stock method.

In fiscal 2015 and 2014, basic and diluted earnings (loss) per share were computed using the two-class method. The two-class method is an earnings allocation that determines earnings per share for each class of common stock and participating securities according to dividends declared and participation rights in undistributed earnings. The Company's restricted stock awards, issued in conjunction with the Questcor Acquisition in August 2014, were considered participating securities as holders were entitled to receive non-forfeitable dividends during the vesting term. Diluted earnings per share included securities that could potentially dilute basic earnings per share during a reporting period, for which the Company includes all share-based compensation awards other than participating securities.

Dilutive securities, including participating securities, are not included in the computation of loss per share when the Company reports a net loss from continuing operations as the impact would be anti-dilutive.

	2016	2015	2014
<b>Earnings (loss) per share numerator:</b>			
Income (loss) from continuing operations attributable to common shareholders before allocation of earnings to participating securities	\$ 489.0	\$ 236.6	\$ (22.0)
Less: earnings allocated to participating securities	—	2.0	—
Income (loss) from continuing operations attributable to common shareholders, after earnings allocated to participating securities	489.0	234.6	(22.0)
Income (loss) from discontinued operations	154.7	88.1	(297.3)
Less: earnings from discontinued operations allocated to participating securities	—	0.7	—
Income (loss) from discontinued operations attributable to common shareholders, after allocation of earnings to participating securities	154.7	87.4	(297.3)
Net income (loss) attributable to common shareholders, after allocation of earnings to participating securities	<u>\$ 643.7</u>	<u>\$ 322.0</u>	<u>\$ (319.3)</u>
<b>Earnings (loss) per share denominator:</b>			
Weighted-average shares outstanding - basic	110.6	115.8	64.9
Impact of dilutive securities	0.9	1.4	—
Weighted-average shares outstanding - diluted	<u>111.5</u>	<u>117.2</u>	<u>64.9</u>
<b>Basic earnings (loss) per share attributable to common shareholders</b>			
Income (loss) from continuing operations	\$ 4.42	\$ 2.03	\$ (0.34)
Income (loss) from discontinued operations	1.40	0.75	(4.58)
Net income (loss) attributable to common shareholders	\$ 5.82	\$ 2.78	\$ (4.92)
<b>Diluted earnings (loss) per share attributable to common shareholders</b>			
Income (loss) from continuing operations	\$ 4.39	\$ 2.00	\$ (0.34)
Income (loss) from discontinued operations	1.39	0.75	(4.58)
Net income (loss) attributable to common shareholders	\$ 5.77	\$ 2.75	\$ (4.92)

The computation of diluted earnings per share for fiscal 2016, 2015 and 2014 excludes approximately 1.7 million, 0.1 million and 5.7 million, respectively, of equity awards because the effect would have been anti-dilutive. As the Company incurred a net loss in fiscal 2014, there was no allocation of the undistributed loss to participating securities because the effect would have been anti-dilutive to basic and diluted earnings per share.

## 9. Inventories

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

	September 30, 2016	September 25, 2015
Raw materials and supplies	\$ 62.0	\$ 52.9
Work in process	188.9	121.6
Finished goods	84.7	87.6
Inventories	<u>\$ 335.6</u>	<u>\$ 262.1</u>

## 10. Property, Plant and Equipment

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

	September 30, 2016	September 25, 2015
Land	\$ 46.8	\$ 47.1
Buildings	287.2	261.7
Capitalized software	85.3	85.4
Machinery and equipment	1,032.3	979.9
Construction in process	164.1	118.3
	<u>1,615.7</u>	<u>1,492.4</u>
Less: accumulated depreciation	(771.7)	(699.4)
Property, plant and equipment, net	<u>\$ 844.0</u>	<u>\$ 793.0</u>

Depreciation expense, including amounts related to capitalized leased assets, for continuing operations was \$113.3 million, \$90.8 million and \$76.7 million for fiscal 2016, 2015 and 2014, respectively.

### *Long-Lived Asset Impairment Analysis*

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

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

The Company's projections in the CMDS asset group included long-term net sales and operating income at lower than historical levels. The decrease in net sales and operating income was reflective of the notification of the loss of a significant customer, termination of a supply contract with a related party and increased competition in the marketplace. The Company utilized a WACC of

8.0%, which reflects the lower inherent risk with the decreasing revenue trends. These assumptions resulted in a fair value of the CMDS asset group that was less than its net book value. Therefore, the Company recorded impairment charges of \$65.9 million and \$52.4 million to the property, plant and equipment and long-lived amortizing intangible assets, respectively, included in the CMDS asset group. The Company sold its CMDS business and the financial results of this business are presented as a discontinued operation. The Company reclassified \$51.4 million of the impairment charge associated with property, plant and equipment to discontinued operations as certain of the assets were retained by the Company based upon the terms of the Company's agreement with Guerbet. The Company reclassified \$52.4 million of the impairment charge associated with intangible assets to discontinued operations.

## 11. Goodwill and Intangible Assets

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

	September 30, 2016	September 25, 2015
Specialty Brands	\$ 3,498.3	\$ 3,442.4
Specialty Generics	207.0	207.0
Total	<u>\$ 3,705.3</u>	<u>\$ 3,649.4</u>

During the fiscal year ended September 30, 2016, the gross carrying value of goodwill in the Specialty Brands segment increased by \$55.9 million, primarily attributable to \$57.3 million from the Stratatech Acquisition. The remaining change in goodwill is a result of the Hemostasis Acquisition, offset by purchase accounting adjustments for the Therakos Acquisition and Ikaria Acquisition primarily attributable to changes in deferred tax balances.

### *Goodwill Impairment Analysis*

As of the fiscal 2016 measurement date, the Company had identified the Specialty Brands, Specialty Generics and Nuclear Imaging businesses as representing the reporting units in our annual goodwill impairment analysis. For purposes of assessing impairment and the recoverability of goodwill for each reporting unit the Company makes various assumptions regarding estimated future cash flows, discount rates and other factors in determining the fair values of each reporting unit using the income approach. The Company's projections of future cash flows were then discounted based on a WACC determined from relevant market comparisons, adjusted upward for specific reporting unit risks (primarily the uncertainty of achieving projected operating cash flows). A terminal value growth rate was applied to the terminal year cash flows, both of which represent the Company's estimate of stable, sustainable growth. The fair value of the reporting unit represents the sum of the discounted cash flows from the discrete period and the terminal year cash flows. The fair values of the reporting units were assessed for reasonableness by aggregating the fair values and comparing this to the Company's market capitalization with a control premium.

The Company's projections in its Specialty Brands reporting unit include long-term revenue and operating income at levels higher than historical levels, which is primarily associated with the Therakos Acquisition, Hemostasis Acquisition and revenue growth for Acthar. The projections also reflect the potential impacts from the future loss of exclusivity related to Ofirmev. The Company utilized a WACC of 12.5%. These assumptions resulted in a fair value of the Specialty Brands reporting unit in excess of its net book value. Should the Specialty Brands reporting unit fail to experience growth in the aforementioned products, revise its long-term projections for these products downward or market conditions dictate utilization of higher discount rates, the Specialty Brands reporting unit could be subject to impairment in future periods.

The Company's projections in its Specialty Generics reporting unit include long-term revenue and operating income at lower than historical levels primarily attributable to increased competition. The Specialty Generics segment has and may continue to experience customer consolidation, which could result in further downward pressure to our long-term revenue and operating income projections. The Company utilized a WACC of 11.0%. These assumptions resulted in a fair value of the Specialty Generics reporting unit in excess of its net book value.

In October 2016, the Company was notified that the FDA was initiating Withdrawal Proceedings on the Company's Methylphenidate ER products, which could result in these products losing their FDA approval. The Specialty Generics segment includes cash flows from the sale of the Company's Methylphenidate ER products. The loss of FDA approval could have a material, negative impact to our Specialty Generics segment. It is possible that if the Specialty Generics segment experiences greater downward pressure than projected or the Company loses FDA approval of its Methylphenidate ER products, or a combination of these factors, it could result in impairment of goodwill and other long-lived assets associated with this segment.



In fiscal 2014, the Company recorded goodwill impairment charges related to its former Global Medical Imaging reporting unit (which included the CMDS and Nuclear Imaging businesses that are now included within discontinued operations). The Company recorded an impairment charge related to goodwill in fiscal 2014 of \$219.7 million, which eliminated all goodwill balances related to the Global Medical Imaging reporting unit. In fiscal 2016 and fiscal 2015, the Company announced that it had entered into definitive agreements to sell its Nuclear Imaging and CMDS businesses, respectively, therefore the businesses were each deemed to be held for sale and the financial results of each business are presented as discontinued operations. As a result, the Company reclassified the impairment charge to discontinued operations.

The gross carrying amount and accumulated amortization of intangible assets, excluding held for sale intangible assets, at the end of each period were as follows:

	September 30, 2016		September 25, 2015	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortizable:				
Completed technology	\$ 10,028.8	\$ 1,446.2	\$ 9,896.0	\$ 765.8
Licenses	185.1	112.3	185.1	99.8
Customer relationships	28.6	8.0	28.1	4.4
Trademarks	82.2	10.0	82.1	6.2
Other	6.7	6.7	6.7	6.7
Total	<u>\$ 10,331.4</u>	<u>\$ 1,583.2</u>	<u>\$ 10,198.0</u>	<u>\$ 882.9</u>
Non-Amortizable:				
Trademarks	\$ 35.0		\$ 35.0	
In-process research and development	399.1		316.2	
Total	<u>\$ 434.1</u>		<u>\$ 351.2</u>	

During fiscal 2016, the Company recorded impairment charges totaling \$16.9 million related to certain Specialty Brands in-process research and development intangible assets acquired as part of the CNS Therapeutics acquisition in fiscal 2013. The valuation method used to approximate fair value was based on the estimated discounted cash flows for the respective asset, and the impairment charges resulted from delays in anticipated FDA approval, higher than expected development costs and lower than previously anticipated commercial opportunities.

Finite-lived intangible asset amortization expense within continuing operations was \$700.1 million, \$550.3 million and \$154.8 million in fiscal 2016, 2015 and 2014, respectively. The estimated aggregate amortization expense on intangible assets owned by the Company, excluding held for sale intangible assets, is expected to be as follows:

Fiscal 2017	\$ 701.4
Fiscal 2018	692.4
Fiscal 2019	692.1
Fiscal 2020	691.9
Fiscal 2021	691.6

## 12. Debt

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

	September 30, 2016		September 25, 2015	
	Principal	Unamortized Discount and Debt Issuance Costs	Principal	Unamortized Discount and Debt Issuance Costs
<b>Current maturities of long-term debt:</b>				
Variable rate receivable securitization	\$ 235.0	\$ 0.4	\$ —	\$ —
Term loans due March 2021	20.0	0.4	20.0	—
4.00% term loan due February 2022	1.1	—	1.0	—
Capital lease obligation and vendor financing agreements	1.0	—	1.0	—
Total current debt	257.1	0.8	22.0	—
<b>Long-term debt:</b>				
Variable rate receivable securitization	—	—	153.0	0.8
3.50% notes due April 2018	300.0	1.1	300.0	1.7
4.875% notes due April 2020	700.0	8.8	700.0	11.3
Term loans due March 2021	1,933.5	35.4	1,958.5	44.1
4.00% term loan due February 2022	6.0	—	6.9	—
9.50% debentures due May 2022	10.4	—	10.4	—
5.75% notes due August 2022	884.0	12.1	900.0	14.4
8.00% debentures due March 2023	4.4	—	4.4	—
4.75% notes due April 2023	600.0	6.4	600.0	7.1
5.625% notes due October 2023	740.0	11.8	750.0	13.7
5.50% notes due April 2025	700.0	10.6	700.0	11.9
Revolving credit facility	—	3.6	500.0	4.9
Capital lease obligation and vendor financing agreements	0.2	—	1.0	—
Total long-term debt	5,878.5	89.8	6,584.2	109.9
Total debt	\$ 6,135.6	\$ 90.6	\$ 6,606.2	\$ 109.9

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

In April 2013, MIFSA issued \$300.0 million aggregate principal amount of 3.50% senior unsecured notes due April 2018 and \$600.0 million aggregate principal amount of 4.75% senior unsecured notes due April 2023 (collectively, "the Notes"). Mallinckrodt plc has fully and unconditionally guaranteed the Notes on an unsecured and unsubordinated basis. The Notes are subject to an indenture which contains covenants limiting the ability of MIFSA, its restricted subsidiaries (as defined in the Notes) and Mallinckrodt plc, as guarantor, to incur certain liens or enter into sale and lease-back transactions. It also restricts Mallinckrodt plc and MIFSA's ability to merge or consolidate with any other person or sell or convey all or substantially all of their assets to any one person. MIFSA may redeem all of the Notes at any time, and some of the Notes from time to time, at a redemption price equal to the principal amount of the Notes redeemed plus a make-whole premium. MIFSA will pay interest on the Notes semiannually in arrears on April 15<sup>th</sup> and October 15<sup>th</sup> of each year, which commenced on October 15, 2013.

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

equivalents, to (ii) the Company's adjusted consolidated EBITDA, as defined in the credit agreement. The Facilities bear interest at LIBOR plus a margin based on the Company's total net debt leverage ratio, and the Term Loan is subject to a minimum LIBOR level of 0.75%. Interest payment dates are variable based on the LIBOR rate utilized, but the Company generally expects interest to be payable every 90 days. The Term Loan requires quarterly principal amortization payments in an amount equal to 0.25% of the original principal amount of the Term Loan payable on the last day of each calendar quarter, which commenced on June 30, 2014, with the remaining balance payable on the due date, March 19, 2021. The Company incurred an original issue discount of 0.25%, or \$3.3 million, associated with the Term Loan. The Revolver contains a \$150.0 million letter of credit provision, of which none had been issued as of September 30, 2016. On August 28, 2015, in connection with the Therakos Acquisition, Mallinckrodt Enterprises LLC and Mallinckrodt plc, two wholly owned subsidiaries of Mallinckrodt plc, MIFSA and MCB, entered into a \$250.0 million replacement revolving credit facility (the "2015 Replacement Revolving Credit Facility"), which refinanced and replaced in full the existing revolving credit facility, and an additional \$250.0 million incremental revolving credit facility (the "2015 Incremental Revolving Credit Facility" and, together with the 2015 Replacement Revolving Credit Facility, the "2015 Revolving Credit Facility"), such that the 2015 Revolving Credit Facility has an aggregate facility size of \$500.0 million. Unused commitments on the 2015 Revolving Credit Facility are subject to an annual commitment fee, which was 0.275% as of September 30, 2016, and the fee applied to outstanding letters of credit is based on the interest rate applied to borrowings. As of September 30, 2016, there were no outstanding borrowings under the 2015 Revolving Credit Facility, the applicable interest rate was 3.10% as of September 30, 2016.

In July 2014, Mallinckrodt Securitization S.À.R.L. ("Mallinckrodt Securitization"), a wholly-owned special purpose subsidiary of the Company, entered into a \$160.0 million accounts receivable securitization facility that matures in July 2017 ("the Receivable Securitization"). In January 2015, Mallinckrodt Securitization amended the Receivable Securitization with third-party lenders to increase the borrowing limit from \$160.0 million to \$250.0 million. The terms of the Receivable Securitization, and the determination of interest rates, were largely unchanged. Mallinckrodt Securitization may, from time to time, obtain up to \$250.0 million in third-party borrowings secured by certain receivables, which may be increased to \$300.0 million upon approval of the third-party lenders, subject to certain conditions. The Receivable Securitization agreements contain customary representations, warranties and affirmative and negative covenants. The borrowings under the Receivable Securitization are to be repaid as the secured receivables are collected. Loans under the Receivable Securitization will bear interest (including facility fees) at a rate equal to the one month LIBOR rate plus a margin of 0.80%. Unused commitments on the Receivables Securitization are subject to an annual commitment fee of 0.35%. As of September 30, 2016, the applicable interest rate on outstanding borrowings under the Receivable Securitization was 1.33% and outstanding borrowings totaled \$235.0 million.

In August 2014, MIFSA and MCB issued \$900.0 million aggregate principal amount of 5.75% senior unsecured notes due August 1, 2022 ("the 2022 Notes"). The 2022 Notes are guaranteed on an unsecured basis by certain of MIFSA's subsidiaries. The 2022 Notes are subject to an indenture that contains certain customary covenants and events of default (subject in certain cases to customary grace and cure periods). The occurrence of an event of default under the indenture could result in the acceleration of the 2022 Notes and could cause a cross-default that could result in the acceleration of other indebtedness of Mallinckrodt plc and its subsidiaries. MIFSA may redeem some or all of the 2022 Notes prior to August 1, 2017 by paying a make-whole premium. MIFSA may redeem some or all of the 2022 Notes on or after August 1, 2017 at specified redemption prices. In addition, prior to August 1, 2017, MIFSA may redeem up to 40% of the aggregate principal amount of the 2022 Notes with the net proceeds of certain equity offerings. The Issuers are obligated to offer to repurchase the 2022 Notes at a price of (a) 101% of their principal amount plus accrued and unpaid interest, if any, as a result of certain change of control events and (b) 100% of their principal amount plus accrued and unpaid interest, if any, in the event of certain asset sales. These obligations are subject to certain qualifications and exceptions. MIFSA pays interest on the 2022 Notes semiannually in arrears on February 1<sup>st</sup> and August 1<sup>st</sup> of each year, which commenced on February 1, 2015.

In August 2014, MIFSA and MCB entered into a \$700.0 million senior secured term loan facility ("the New Term Loan"). The New Term Loan is an incremental tranche under the credit agreement governing our existing Term Loan and Revolver, entered into in March 2014, (collectively, with the New Term Loan, represent "the Senior Secured Credit Facilities"). New Term Loan has substantially similar terms to the Term Loan (other than pricing); including the determination of interest rates and quarterly principal amortization payments equal to 0.25% of the original principal amount of the New Term Loan. The quarterly principal payments commenced on December 31, 2014, with the remaining balance payable on the due date of March 19, 2021. Mallinckrodt plc and its subsidiaries (other than MIFSA, MCB and the subsidiaries of MIFSA that guarantee the Facilities) will not guarantee the New Term Loan, and the New Term Loan will not be secured by the assets of such entities. The August 2014 Term Loan bears interest under substantially similar terms of the March 2014 Term Loan, including the use of LIBOR rates with a minimum floor, except that the margin applied to LIBOR is not dependent upon the Company's total net debt leverage ratio.

On April 15, 2015, MIFSA and MCB issued \$700.0 million aggregate principal amount of 4.875% senior unsecured notes due April 15, 2020 ("the 2020 Notes") and \$700.0 million aggregate principal amount of 5.50% senior unsecured notes due April 15, 2025 ("the 2025 Notes", and together with the 2020 Notes, the "Ikaria Notes"). The Ikaria Notes are guaranteed by Mallinckrodt plc and each of its subsidiaries that guarantee the obligations under the Facilities, which following the Ikaria Acquisition includes Compound Holdings II, Inc. and its U.S. subsidiaries. The Ikaria Notes are subject to an indenture that contains certain customary covenants and events of default (subject in certain cases to customary grace and cure periods). The occurrence of an event of default under the indenture could result in the acceleration of the Ikaria Notes and could cause a cross-default that could result in the acceleration of

other indebtedness of the Company. The Issuers may redeem some or all of the (i) 2020 Notes prior to April 15, 2017 and (ii) 2025 Notes prior to April 15, 2020, in each case, by paying a “make-whole” premium. The Issuers may redeem some or all of the (i) 2020 Notes on or after April 15, 2017 and (ii) 2025 Notes on or after April 15, 2020, in each case, at specified redemption prices. In addition, prior to (i) April 15, 2017, in the case of the 2020 Notes, and (ii) April 15, 2018, in the case of the 2025 Notes, the Issuers may redeem up to 40% of the aggregate principal amount of the 2020 Notes or 2025 Notes, as the case may be, with the net proceeds of certain equity offerings. The Issuers are obligated to offer to repurchase (a) each series of Notes at a price of 101% of their principal amount plus accrued and unpaid interest, if any, as a result of certain change of control events and (b) the Notes at a price of 100% of their principal amount plus accrued and unpaid interest, if any, in the event of certain net asset sales. These obligations are subject to certain qualifications and exceptions. The Company pays interest on the Ikaria Notes semiannually on April 15<sup>th</sup> and October 15<sup>th</sup> of each year, which commenced on October 15, 2015.

On September 24, 2015, in connection with the Therakos Acquisition, MIFSA and MCB issued \$750.0 million aggregate principal amount of 5.625% senior unsecured notes due October 2023 (the “2023 Notes”). The Notes are guaranteed by Mallinckrodt plc and each of its subsidiaries under the Facilities, which following the Therakos Acquisition includes TGG Medical Solutions, Inc. and its U.S. subsidiaries. The 2023 Notes are subject to an indenture that contains certain customary covenants and events of default (subject in certain cases to customary grace and cure periods). The occurrence of an event of default under the indenture could result in the acceleration of the 2023 Notes and could cause a cross-default that could result in the acceleration of other indebtedness of the Company. The Issuers may redeem some or all of the 2023 Notes on or after October 15, 2018 at specified redemption prices. In addition, prior to October 15, 2018, the Issuers may redeem up to 40% of the aggregate principal amount of the 2023 Notes with the net proceeds of certain equity offerings. The Issuers may also redeem all, but not less than all, of the Notes at any time at a price of 100% of their principal amount, plus accrued and unpaid interest, if any, in the event the Issuers become obligated to pay additional amounts as a result of changes affecting certain withholding tax laws applicable to payments on the Notes. The Issuers are obligated to offer to repurchase the 2023 Notes (a) at a price of 101% of their principal amount plus accrued and unpaid interest, if any, as a result of certain change of control events and (b) the 2023 Notes at a price of 100% of their principal amount plus accrued and unpaid interest, if any, in the event of certain net asset sales. These obligations are subject to certain qualifications and exceptions. The Company pays interest on the 2023 Notes semiannually on April 15<sup>th</sup> and October 15<sup>th</sup> of each year, which commenced on April 15, 2016.

As of September 30, 2016, the weighted-average interest rate for the term loan due March 2021 was 3.43%, and outstanding principal under these agreements totaled approximately \$1,953.5 million.

The aggregate amounts of debt, including the capital lease obligation, maturing during the next five fiscal years are as follows:

Fiscal 2017	\$	257.1
Fiscal 2018		321.3
Fiscal 2019		16.2
Fiscal 2020		721.3
Fiscal 2021		1,879.8

### 13. Retirement Plans

#### *Pension Plan Termination*

On March 31, 2016, the Company terminated six of its previously frozen U.S. pension plans. The Company is evaluating alternatives to settle the outstanding obligations of these pension plans, and expects final settlement to occur during fiscal 2017, subject to customary regulatory approvals. The Company's ultimate settlement obligation will depend upon the nature of participant settlements and the prevailing market conditions. As a result, certain assumptions utilized in determining the obligations under these pension plans reflect those expected in the final settlement of the Company's obligations.

#### *Defined Benefit Plans*

The Company sponsors a number of defined benefit retirement plans covering certain of its U.S. employees and non-U.S. employees. As of September 30, 2016, U.S. plans represented 100% of the Company's total pension plan assets and 96% of the Company's projected benefit obligation. The Company generally does not provide postretirement benefits other than retirement plan benefits for its employees; however, certain of the Company's U.S. employees participate in postretirement benefit plans that provide medical benefits. These plans are unfunded.

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

	Pension Benefits			Postretirement Benefits		
	Fiscal Year			Fiscal Year		
	2016	2015	2014	2016	2015	2014
Service cost	\$ 1.8	\$ 2.4	\$ 2.7	\$ 0.1	\$ 0.1	\$ 0.1
Interest cost	13.2	14.5	15.4	2.0	1.9	2.1
Expected return on plan assets	(16.7)	(18.9)	(20.5)	—	—	—
Amortization of net actuarial loss	11.3	9.2	8.0	—	—	—
Amortization of prior service cost	—	—	—	(2.1)	(4.0)	(9.3)
Loss on plan settlements	8.1	5.9	3.8	—	—	—
Net periodic benefit cost (credit)	\$ 17.7	\$ 13.1	\$ 9.4	\$ —	\$ (2.0)	\$ (7.1)

The following table represents the changes in benefit obligations, plan assets and the net amounts recognized on the consolidated balance sheets for pension and postretirement benefit plans at the end of fiscal 2016 and 2015:

	Pension Benefits		Postretirement Benefits	
	2016	2015	2016	2015
<i>Change in benefit obligation:</i>				
Projected benefit obligations at beginning of year	\$ 375.5	\$ 400.8	\$ 52.2	\$ 52.0
Service cost	1.8	2.4	0.1	0.1
Interest cost	13.2	14.5	2.0	1.9
Actuarial (gain) loss	65.5	(0.8)	0.5	2.1
Benefits and administrative expenses paid	(20.1)	(17.8)	(4.0)	(3.9)
Plan settlements	(26.5)	(23.6)	—	—
Plan curtailments and amendments	(0.4)	—	—	—
Net transfer in/(out)	—	0.7	—	—
Currency translation	0.1	(0.7)	—	—
Projected benefit obligations at end of year	\$ 409.1	\$ 375.5	\$ 50.8	\$ 52.2

<i>Change in plan assets:</i>				
Fair value of plan assets at beginning of year	\$ 309.9	\$ 339.0	\$ —	\$ —
Actual return on plan assets	29.5	1.9	—	—
Employer contributions	16.7	10.4	4.0	3.9
Benefits and administrative expenses paid	(20.1)	(17.8)	(4.0)	(3.9)
Plan settlements	(26.5)	(23.6)	—	—
Currency translation	—	—	—	—
Fair value of plan assets at end of year	\$ 309.5	\$ 309.9	\$ —	\$ —
Funded status at end of year	\$ (99.6)	\$ (65.6)	\$ (50.8)	\$ (52.2)

	Pension Benefits		Postretirement Benefits	
	2016	2015	2016	2015
<i>Amounts recognized on the consolidated balance sheet:</i>				
Non-current assets	\$ 4.0	\$ 3.9	\$ —	\$ —
Current liabilities	(5.2)	(2.9)	(4.3)	(4.6)
Non-current liabilities	(98.4)	(66.6)	(46.5)	(47.6)
Net amount recognized on the consolidated balance sheet	\$ (99.6)	\$ (65.6)	\$ (50.8)	\$ (52.2)

<i>Amounts recognized in accumulated other comprehensive income consist of:</i>				
Net actuarial loss	\$ (141.2)	\$ (107.9)	\$ (5.6)	\$ (5.1)
Prior service credit	0.3	—	12.8	14.9
Net amount recognized in accumulated other comprehensive income	\$ (140.9)	\$ (107.9)	\$ 7.2	\$ 9.8

The estimated amounts that will be amortized from accumulated other comprehensive income into net periodic benefit cost (credit) in fiscal 2017 are as follows:

	<b>Pension Benefits</b>	<b>Postretirement Benefits</b>
Amortization of net actuarial loss	\$ 14.1	\$ 0.1
Amortization of prior service cost	0.3	(2.1)

The accumulated benefit obligation for all pension plans at the end of fiscal 2016 and 2015 was \$408.7 million and \$375.3 million, respectively. Additional information related to pension plans is as follows:

	<b>2016</b>	<b>2015</b>
<i>Pension plans with accumulated benefit obligations in excess of plan assets:</i>		
Accumulated benefit obligation	\$ 398.1	\$ 363.4
Fair value of plan assets	295.0	294.1

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

### **Actuarial Assumptions**

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

	<b>U.S. Plans</b>			<b>Non-U.S. Plans</b>		
	<b>2016</b>	<b>2015</b>	<b>2014</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Discount rate	3.9%	3.8%	4.2%	2.0%	2.4%	3.1%
Expected return on plan assets	5.8%	6.0%	6.5%	2.0%	2.0%	2.0%
Rate of compensation increase	—%	—%	—%	—%	—%	—%

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

	<b>U.S. Plans</b>			<b>Non-U.S. Plans</b>		
	<b>2016</b>	<b>2015</b>	<b>2014</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Discount rate	2.3%	3.9%	3.9%	1.3%	2.4%	2.4%
Rate of compensation increase	—%	—%	—%	—%	—%	—%

For the Company's funded U.S. plans, the discount rate is based on the estimated final settlement discount rates based on quotes received from a group of well-rated insurance carriers who are active in the single premium group annuity marketplace. The group of insurance carriers are rated A or better by AM best. For the Company's unfunded U.S. plans, the discount rate is based on the market rate for a broad population of AA-rated (Moody's or S&P) corporate bonds over \$250.0 million.

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

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

	<u>2016</u>	<u>2015</u>	<u>2014</u>
Net periodic benefit cost	4.0%	3.6%	4.0%
Benefit obligations	3.2%	3.9%	3.7%

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

	<u>2016</u>	<u>2015</u>
Healthcare cost trend rate assumed for next fiscal year	7.1%	7.1%
Rate to which the cost trend rate is assumed to decline	4.5%	4.5%
Fiscal year the ultimate trend rate is achieved	2029	2029

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

	<u>One-Percentage-Point Increase</u>	<u>One-Percentage-Point Decrease</u>
Effect on total of service and interest cost	\$ —	\$ —
Effect on postretirement benefit obligation	0.3	(0.2)

### ***Plan Assets***

In conjunction with the Company's decision to terminate and annuitize the defined benefit pension plans in fiscal 2016, the Company elected to change the asset allocation to shift substantially to debt securities, in an attempt to mitigate fluctuations in both interest rates and the equity markets.

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

	<u>U.S. Plans</u>	
	<u>2016</u>	<u>2015</u>
Equity securities	—%	27%
Debt securities	96	70
Cash and cash equivalents	4	3
Other	—	—
Total	<u>100%</u>	<u>100%</u>

The following tables provide a summary of plan assets held by the Company's pension plans that are measured at fair value on a recurring basis at the end of fiscal 2016 and 2015:

	Fiscal 2016	Basis of Fair Value Measurement		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Equity Securities:				
U.S. large cap	1.4	1.4	—	—
Debt securities:				
Diversified fixed income funds <sup>(1)</sup>	296.1	296.1	—	—
Other	12.0	12.0	—	—
Total	\$ 309.5	\$ 309.5	\$ —	\$ —

	Fiscal 2015	Basis of Fair Value Measurement		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Equity Securities:				
U.S. small mid cap	\$ 15.1	\$ 15.1	\$ —	\$ —
U.S. large cap	46.2	46.2	—	—
International	22.9	22.7	0.2	—
Debt securities:				
Diversified fixed income funds <sup>(1)</sup>	197.2	196.9	0.3	—
High yield bonds	11.3	11.3	—	—
Emerging market funds	7.4	7.4	—	—
Other	9.8	9.0	0.8	—
Total	\$ 309.9	\$ 308.6	\$ 1.3	\$ —

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

*Equity securities.* Equity securities primarily consist of mutual funds with underlying investments in foreign equity and domestic equity markets. The fair value of these investments is based on net asset value of the units held in the respective fund, which are determined by obtaining quoted prices on nationally recognized securities exchanges (level 1) or through net asset values provided by the fund administrators that can be corroborated by observable market data (level 2).

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

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

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

### Contributions

The Company's funding policy is to make contributions in accordance with the laws and customs of the various countries in which the Company operates, as well as to make discretionary voluntary contributions from time to time. In fiscal 2016 and 2015, the Company made \$16.7 million and \$10.4 million in contributions, respectively, to the Company's pension plans.



### ***Expected Future Benefit Payments***

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

	<b>Pension Benefits</b>	<b>Postretirement Benefits</b>
Fiscal 2017	\$ 113.2	\$ 4.3
Fiscal 2018	22.2	4.0
Fiscal 2019	21.8	3.7
Fiscal 2020	20.5	3.5
Fiscal 2021	19.2	3.3
Fiscal 2021 - 2025	85.9	14.9

The above table reflects increased lump sum disbursements in fiscal 2017 associated with the termination of the Company's six qualified U.S. pension plans. Disbursements associated with the settlement of the remaining obligations under these plans have not been reflected.

### ***Defined Contribution Retirement Plans***

The Company maintains one active tax-qualified 401(k) retirement plan and one active non-qualified deferred compensation plan in the U.S. The 401(k) retirement plan provides for an automatic Company contribution of three percent of an eligible employee's pay, with an additional Company matching contribution generally equal to 50% of each employee's elective contribution to the plan up to six percent of the employee's eligible pay. The deferred compensation plan permits eligible employees to defer a portion of their compensation. Total defined contribution expense related to continuing operations was \$25.3 million, \$22.1 million and \$19.0 million for fiscal 2016, 2015 and 2014, respectively.

### ***Rabbi Trusts and Other Investments***

The Company maintains several rabbi trusts, the assets of which are used to pay retirement benefits. The rabbi trust assets are subject to the claims of the Company's creditors in the event of the Company's insolvency. Plan participants are general creditors of the Company with respect to these benefits. The trusts primarily hold life insurance policies and debt and equity securities, the value of which is included in other assets on the consolidated balance sheets. Note 19 provides additional information regarding the debt and equity securities. The carrying value of the 134 life insurance contracts held by these trusts was \$59.2 million and \$57.9 million at September 30, 2016 and September 25, 2015, respectively. These contracts had a total death benefit of \$150.0 million and \$147.3 million at September 30, 2016 and September 25, 2015, respectively. However, there are outstanding loans against the policies amounting to \$43.4 million and \$40.4 million at September 30, 2016 and September 25, 2015, respectively.

The Company has insurance contracts which serve as collateral for certain of the Company's non-U.S. pension plan benefits, which totaled \$8.3 million and \$8.9 million at September 30, 2016 and September 25, 2015, respectively. These amounts were also included in other assets on the consolidated balance sheets.

## **14. Equity**

### ***Preferred Shares***

Mallinckrodt is authorized to issue 500,000,000 preferred shares, par value of \$0.20 per share, none of which were issued or outstanding at September 30, 2016. Rights as to dividends, return of capital, redemption, conversion, voting and otherwise with respect to these shares may be determined by Mallinckrodt's Board of Directors on or before the time of issuance. In the event of the liquidation of the Company, the holders of any preferred shares then outstanding would, if issued on such terms that they carry a preferential distribution entitlement on liquidation, be entitled to payment to them of the amount for which the preferred shares were subscribed and any unpaid dividends prior to any payment to the ordinary shareholders.

### Share Repurchases

On November 19, 2015, the 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 the Board of Directors on January 23, 2015 (the "January 2015 Program") was completed in the first fiscal quarter of 2016. On March 16, 2016, the 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.

	March 2016 Repurchase Program		November 2015 Repurchase Program		January 2015 Repurchase Program	
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount
Authorized repurchase amount		\$ 350.0		\$ 500.0		\$ 300.0
Repurchases:						
Fiscal 2015	—	—	—	—	823,592	75.0
Fiscal 2016	—	—	6,510,824	425.6	3,199,279	225.0
Remaining amount available		<u>\$ 350.0</u>		<u>\$ 74.4</u>		<u>\$ —</u>

The Company also repurchases shares from certain employees in order to satisfy employee tax withholding requirements in connection with the vesting of restricted shares. In addition, the Company repurchases shares to settle certain option exercises. The Company spent \$2.3 million and \$17.2 million to acquire shares in connection with equity-based awards in fiscal 2016 and 2015, respectively.

### 15. Share Plans

Total share-based compensation cost from continuing operations was \$41.4 million, \$115.0 million and \$64.9 million for fiscal 2016, 2015 and 2014, respectively. These amounts are generally included within selling, general and administrative expenses in the consolidated statements of income. In conjunction with the Questcor Acquisition, Questcor equity awards were converted to Mallinckrodt equity awards which resulted in post-combination expense of \$90.4 million in fiscal 2015, included in the above total share-based compensation, of which \$80.6 million is included within selling, general and administrative expenses and \$9.8 million is included within restructuring charges, net. The incremental fair value associated with the conversion of Covidien equity awards into Mallinckrodt equity awards is included in separation costs. The Company recognized a related tax benefit associated with this expense of \$13.1 million, \$41.3 million and \$23.4 million in fiscal 2016, 2015 and 2014, respectively.

### Stock Compensation Plans

Prior to the Separation, the Company adopted the 2013 Mallinckrodt Pharmaceuticals Stock and Incentive Plan ("the 2013 Plan"). The 2013 Plan provides for the award of share options, share appreciation rights, annual performance bonuses, long-term performance awards, restricted units, restricted shares, deferred share units, promissory shares and other share-based awards (collectively, "Awards"). The 2013 Plan provided for a maximum of 5.7 million common shares to be issued as Awards, subject to adjustment as provided under the terms of the 2013 Plan. In fiscal 2015, the Company amended the 2013 Plan and adopted the 2015 Mallinckrodt Pharmaceuticals Stock and Incentive Plan ("the 2015 Plan"). The 2015 Plan provides for a maximum of 17.8 million common shares to be issued as Awards (an incremental 12.1 million Awards from the 2013 Plan subject to issuance), subject to adjustment as provided under the terms of the 2015 Plan. As of September 30, 2016, all equity awards held by the Company's employees were either converted from Covidien equity awards at the Separation, converted from Questcor equity awards, or granted under the 2013 Plan or 2015 Plan.

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

Share option activity and information is as follows:

	Share Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at September 26, 2014	3,526,789	\$ 36.84		
Granted	635,567	102.20		
Exercised	(1,132,778)	29.79		
Expired/Forfeited	(243,135)	58.00		
Outstanding at September 25, 2015	2,786,443	52.76		
Granted	1,248,828	72.44		
Exercised	(413,830)	32.76		
Expired/Forfeited	(199,585)	72.65		
Outstanding at September 30, 2016	3,421,856	61.17	7.3	\$ 49.6
Vested and unvested expected to vest as of September 30, 2016	2,997,502	61.60	7.5	\$ 42.6
Exercisable at September 30, 2016	1,388,805	45.55	5.3	38.2

As of September 30, 2016, there was \$35.5 million of total unrecognized compensation cost related to unvested share option awards, which is expected to be recognized over a weighted-average period of 2.7 years.

The grant date fair value of share options has been estimated using the Black-Scholes pricing model. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. The expected volatility assumption is based on the historical and implied volatility of the Company's peer group with similar business models. The expected life assumption is based on the contractual and vesting term of the share option, employee exercise patterns and employee post-vesting termination behavior. The expected annual dividend per share is based on the Company's current intentions regarding payment of cash dividends. The risk-free interest rate is based on U.S. Treasury zero-coupon issues with a remaining term equal to the expected life assumed at the date of grant. The weighted-average assumptions used in the Black-Scholes pricing model for shares granted in fiscal 2016, 2015 and 2014, along with the weighted-average grant-date fair value, were as follows:

	2016	2015	2014
Expected share price volatility	31%	29%	32%
Risk-free interest rate	1.74%	1.72%	1.96%
Expected annual dividend per share	—%	—%	—%
Expected life of options (in years)	5.3	5.3	5.5
Fair value per option	\$ 22.82	\$ 30.08	\$ 17.38

In fiscal 2016, 2015 and 2014, the total intrinsic value of options exercised was \$15.3 million, \$89.5 million and \$34.2 million, respectively, and the related tax benefit was \$5.7 million, \$33.1 million and \$12.0 million, respectively.

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

RSU activity is as follows:

	Shares	Weighted-Average Grant-Date Fair Value
Non-vested at September 26, 2014	589,222	\$ 47.88
Granted	273,733	105.68
Vested	(219,189)	49.84
Forfeited	(71,272)	68.15
Non-vested at September 25, 2015	572,494	73.45
Granted	615,074	70.10
Vested	(193,849)	69.27
Forfeited	(99,260)	79.95
Non-vested at September 30, 2016	894,459	70.40

The total fair value of Mallinckrodt restricted share unit awards granted during fiscal 2016 was \$43.1 million. The total vest date fair value of Mallinckrodt restricted share units vested during fiscal 2016 was \$13.4 million. As of September 30, 2016, there was \$47.2 million of total unrecognized compensation cost related to non-vested restricted share units granted. The cost is expected to be recognized over a weighted-average period of 2.7 years.

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

PSU activity is as follows <sup>(1)</sup>:

	Shares	Weighted-Average Grant-Date Fair Value
Non-vested at September 26, 2014	72,740	\$ 63.46
Granted	77,306	125.84
Forfeited	(19,072)	92.05
Non-vested at September 25, 2015	130,974	96.05
Granted	145,192	83.00
Forfeited	(9,521)	96.30
Non-vested at September 30, 2016	266,645	88.59

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

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

	2016	2015	2014
Expected stock price volatility	41%	27%	28%
Peer group stock price volatility	36%	32%	33%
Correlation of returns	24%	14%	17%

The weighted-average grant date fair value per share of PSUs granted was \$83.00 in fiscal 2016. As of September 30, 2016, there was \$13.7 million of unrecognized compensation cost related to PSUs, which is expected to be recognized over a weighted-average period of 1.7 years.

*Restricted stock awards.* Recipients of restricted stock awards ("RSAs") pertain solely to converted awards from the Questcor Acquisition, which were converted at identical terms to their original award. The converted RSAs maintain voting rights and a non-forfeitable right to receive dividends. RSAs are subject to accelerated vesting as prescribed by the terms of the original award based on a change in control, and substantially all of which vested over a thirteen month period of time from the date of the Questcor Acquisition. Restrictions on RSAs lapse upon normal retirement, death or disability of the employee. The grant-date fair value of RSAs, adjusted for estimated forfeitures, is recognized as expense on a straight-line basis over the service period.

	Shares	Weighted-Average Grant-Date Fair Value
Non-vested at September 26, 2014	1,432,031	\$ 70.88
Vested	(1,362,823)	70.88
Forfeited	(34,646)	70.88
Non-vested at September 25, 2015	34,562	70.88
Vested	(9,760)	70.88
Forfeited	(7,936)	70.88
Non-vested at September 30, 2016	16,866	70.88

The total vest date fair value of Mallinckrodt restricted share awards vested during fiscal 2016 was \$0.6 million.

### ***Employee Stock Purchase Plans***

Effective March 16, 2016, upon approval by the shareholders of Mallinckrodt, the Company adopted a new qualified Mallinckrodt Employee Stock Purchase Plan ("ESPP"). Substantially all full-time employees of the Company's U.S. subsidiaries and employees of certain qualified non-U.S. subsidiaries are eligible to participate in the ESPP. Eligible employees authorize payroll deductions to be made to purchase shares at 15% below the market price at the beginning or end of an offering period. Employees are eligible to authorize withholdings such that purchases of shares may amount to \$25,000 of fair market value for each calendar year as prescribed by IRC Section 423. Mallinckrodt has elected to deliver shares under the period by utilizing treasury stock accumulated by the Company.

Prior to the first offering period of the ESPP (July 1, 2016), the Company maintained a non-qualified employee stock purchase plan ("the Old ESPP"). Substantially all full-time employees of the Company's U.S. subsidiaries and employees of certain qualified non-U.S. subsidiaries were eligible to participate in the Old ESPP. Eligible employees authorized payroll deductions to be made for the purchase of shares. The Company matched a portion of the employee contribution by contributing an additional 15% (25% in fiscal 2014 and fiscal 2015) of the employee's payroll deduction up to a \$25,000 per employee contribution. All shares purchased under the Old ESPP were purchased on the open market by a designated broker.

## 16. Accumulated Other Comprehensive Income

The components of accumulated other comprehensive income are as follows:

	Currency Translation	Unrecognized Loss on Derivatives	Unrecognized Gain (Loss) on Benefit Plans	Accumulated Other Comprehensive Income
Balance at September 27, 2013	\$ 158.6	\$ (7.3)	\$ (42.8)	\$ 108.5
Other comprehensive income (loss), net	(27.6)	—	(17.1)	(44.7)
Reclassification from other comprehensive income (loss)	—	0.5	1.4	1.9
Balance at September 26, 2014	131.0	(6.8)	(58.5)	65.7
Other comprehensive income (loss), net	(70.8)	—	(1.1)	(71.9)
Reclassification from other comprehensive income (loss)	—	0.4	6.7	7.1
Balance at September 25, 2015	60.2	(6.4)	(52.9)	0.9
Other comprehensive income (loss), net	0.8	—	(39.5)	(38.7)
Reclassification from other comprehensive income (loss)	(59.4)	0.5	11.1	(47.8)
Balance at September 30, 2016	<u>\$ 1.6</u>	<u>\$ (5.9)</u>	<u>\$ (81.3)</u>	<u>\$ (85.6)</u>

The following summarizes reclassifications out of accumulated other comprehensive income for the 2016 and 2015 fiscal years:

	Amount Reclassified from Accumulated Other Comprehensive Income	Amount Reclassified from Accumulated Other Comprehensive Income	Line Item in the Condensed Consolidated Statement of Income
	September 30, 2016	September 25, 2015	
Amortization of unrealized loss on derivatives	\$ 0.7	\$ 0.6	Interest expense
Income tax provision	(0.2)	(0.2)	Provision for income taxes
Net of income taxes	0.5	0.4	
Amortization of pension and post-retirement benefit plans:			
Net actuarial loss	11.4	9.4	(1)
Prior service credit	(2.7)	(4.6)	(1)
Disposal of discontinued operations	0.8	—	
Plan settlements	8.1	6.0	(1)
Total before tax	17.6	10.8	
Income tax provision	(6.5)	(4.1)	Provision for income taxes
Net of income taxes	11.1	6.7	
Currency translation	(59.4)	—	
Total reclassifications for the period	<u>\$ (47.8)</u>	<u>\$ 7.1</u>	

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

## 17. Guarantees

In disposing of assets or businesses, the Company has historically provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to the assets, environmental risks involved in the sale of real estate, liability to investigate and remediate environmental contamination at waste disposal sites and manufacturing facilities, and unidentified tax liabilities related to periods prior to disposition. The Company assesses the probability of potential liabilities related to such representations, warranties and indemnities and adjusts potential liabilities as a result of changes in facts and circumstances. The Company believes, given the information currently available, that their ultimate resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

In connection with the sale of the Specialty Chemical business (formerly known as Mallinckrodt Baker) in fiscal 2010, the Company agreed to indemnify the purchaser with respect to various matters, including certain environmental, health, safety, tax and other matters. The indemnification obligations relating to certain environmental, health and safety matters have a term of 17 years from the sale, while some of the other indemnification obligations have an indefinite term. The amount of the liability relating to all of these indemnification obligations included in other liabilities on the Company's consolidated balance sheets at September 30, 2016 and September 25, 2015 was \$15.7 million, of which \$12.9 million and \$13.0 million, respectively, related to environmental, health and safety matters. The value of the environmental, health and safety indemnity was measured based on the probability-weighted present value of the costs expected to be incurred to address environmental, health and safety claims made under the indemnity. The aggregate fair value of these indemnification obligations did not differ significantly from their aggregate carrying value at September 30, 2016 and September 25, 2015. As of September 30, 2016, the maximum future payments the Company could be required to make under these indemnification obligations was \$71.0 million. The Company was required to pay \$30.0 million into an escrow account as collateral to the purchaser, of which \$19.0 million remained in other assets on the consolidated balance sheets at September 30, 2016 and September 25, 2015.

The Company has recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 18. In addition, the Company is liable for product performance; however the Company believes, given the information currently available, that their ultimate resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

The Company is required to provide the U.S. Nuclear Regulatory Commission financial assurance demonstrating its ability to fund the decommissioning of its Maryland Heights, Missouri radiopharmaceuticals production facility upon closure, though the Company does not intend to close this facility. The Company has provided this financial assurance in the form of surety bonds totaling \$30.2 million. As of September 30, 2016, the Company had various other letters of credit and guarantee and surety bonds totaling \$32.7 million. Upon closing the sale of the Nuclear Imaging business, these obligations will be transferred to the buyer.

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.

In addition, the separation and distribution agreement entered into with Covidien at the Separation provides for cross-indemnities principally designed to place financial responsibility of the obligations and liabilities of the Company's business with the Company and financial responsibility for the obligations and liabilities of Covidien's remaining business with Covidien, among other indemnities.

## 18. Commitments and Contingencies

The Company has purchase obligations related to commitments to purchase certain goods and services. At September 30, 2016, such obligations were as follows:

Fiscal 2017	\$	147.5
Fiscal 2018		31.6
Fiscal 2019		20.3
Fiscal 2020		14.1
Fiscal 2021		6.7

The Company is 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 below. The Company believes that these legal proceedings and claims likely will be resolved over an extended period of time. Although it is not feasible to predict the outcome of these matters, the Company believes, unless indicated below, given the information currently available, that their ultimate resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

### *Governmental Proceedings*

In November 2011 and October 2012, the Company received subpoenas from the U.S. Drug Enforcement Administration requesting production of documents relating to its suspicious order monitoring program for controlled substances. The United States Attorney's Office (the "USAO") for the Eastern District of Michigan is investigating the possibility that the Company failed to report suspicious orders of controlled substances during the period 2006-2011 in violation of the Controlled Substances Act and its related

regulations. The USAO for the Northern District of New York and Office of Chief Counsel for the U.S. Drug Enforcement Administration are investigating the possibility that the Company failed to maintain appropriate records and security measures with respect to manufacturing of certain controlled substances at its Hobart facility during the period 2012-2013. While it is not possible at this time to determine with certainty the ultimate outcome of this matter, the Company believes, given the information currently available, that the ultimate resolution, after taking into account amounts already accrued, could have a material adverse effect on its financial condition, results of operations and cash flows.

In September 2012, Questcor received a subpoena from the USAO for the Eastern District of Pennsylvania for information relating to its promotional practices related to Acthar. Questcor has also been informed by the USAO for the Eastern District of Pennsylvania that the USAO for the Southern District of New York and the SEC are participating in the investigation to review Questcor's promotional practices and related matters related to Acthar. On March 9, 2015, the Company received a "No Action" letter from the SEC regarding its review of the Company's promotional practices related to Acthar.

In June 2014, Questcor received a subpoena and Civil Investigative Demand ("CID") from the Federal Trade Commission ("FTC") seeking documentary materials and information regarding the FTC's investigation into whether Questcor's acquisition of certain rights to develop, market, manufacture, distribute, sell and commercialize Synacthen Depot® from Novartis AG and Novartis Pharma AG (collectively, "Novartis") violates antitrust laws. Subsequently, a small number of states commenced similar investigations focused on whether the transaction violates state antitrust laws. The Company is not aware of any existing or pending litigation in connection with these investigations. While it is not possible at this time to determine with certainty the ultimate outcome of this matter, the Company believes, given the information currently available, that the ultimate resolution, after taking into account amounts already accrued, could have a material adverse effect on its financial condition, results of operations and cash flows.

In March 2014, the USAO for the Eastern District of Pennsylvania requested the production of documents related to an investigation of the U.S. promotion of Therakos' immunotherapy drug/device system UVADEX/UVAR XTS and UVADEX/CELLEX (collectively, the "Therakos System"), for indications not approved by the FDA, including treatment of patients with graft versus host disease ("GvHD") and solid organ transplant patients, including pediatric patients. The investigation also includes Therakos' efforts to secure FDA approval for additional uses of, and alleged quality issues relating to, UVADEX/UVAR. In August 2015, the USAO for the Eastern District of Pennsylvania sent Therakos a subsequent request for documents related to the investigation and has since made certain related requests. We are in the process of responding to those requests.

In November 2014, the Company received a CID from the Civil Medicaid Fraud Division of the Texas Attorney General's Office. According to the CID, the Attorney General's office is investigating the possibility of false reporting of information by the Company regarding the prices of certain of its drugs used by Texas Medicaid to establish reimbursement rates for pharmacies that dispensed the Company's drugs to Texas Medicaid recipients.

We have responded to or are in the process of responding to each of the subpoenas and the CIDs and we intend to cooperate fully in each such investigation.

*Mallinckrodt Inc. v. U.S. Food and Drug Administration and United States of America.* The Company filed a Complaint for Declaratory and Injunctive Relief ("the Complaint") in the U.S. District Court for the District of Maryland Greenbelt Division against the FDA and the United States of America in November 2014 for judicial review of what the Company believes is the FDA's inappropriate and unlawful reclassification of the Company's Methylphenidate HCl Extended-Release tablets USP (CII) ("Methylphenidate ER") in the Orange Book: Approved Drug Products with Therapeutic Equivalence ("Orange Book") on November 13, 2014. In its Complaint, the Company asked the court to: issue an injunction to (a) set aside the FDA's reclassification of the Company's Methylphenidate ER products from freely substitutable at the pharmacy level (class AB) to presumed to be therapeutically inequivalent (class BX) in the Orange Book and (b) prohibit the FDA from reclassifying the Company's Methylphenidate ER products in the future without following applicable legal requirements; and issue a declaratory judgment that the FDA's action reclassifying the Company's Methylphenidate ER products in the Orange Book is unlawful. The Company concurrently filed a motion with the same court requesting an expedited hearing to issue a temporary restraining order ("TRO") directing the FDA to reinstate the Orange Book AB rating for the Company's Methylphenidate ER products on a temporary basis. The court denied the Company's motion for a TRO. In December 2014, the FDA filed a motion to dismiss the Complaint with the district court. The Company filed its opposition to the motion to dismiss in January 2015, and concurrently filed a motion for summary judgment. In July 2015, the court granted the FDA's motion to dismiss with respect to three of the five counts in the Complaint and granted summary judgment in favor of the FDA with respect to the two remaining counts. The Company appealed the court's decision to the U.S. Court of Appeals for the Fourth Circuit. On October 18, 2016, the FDA initiated proceedings, proposing to withdraw approval of Mallinckrodt's Abbreviated New Drug Application for Methylphenidate ER. On October 21, 2016, the United States Court of Appeals for the Fourth Circuit issued an Order removing Company's pending litigation with the FDA from the Court's oral argument calendar and placing that litigation in abeyance pending the outcome of the withdrawal proceedings. The Company concurrently submitted to the FDA requests for a hearing in the withdrawal proceeding and for a 90-day extension of the deadline for submitting documentation supporting the necessity of a hearing. The FDA has granted the Company's extension request, with a new deadline of March 19, 2017, and the Company is preparing the supporting documentation for the March submission. The Company plans to vigorously set forth its position in the withdrawal proceedings.



## ***Patent/Antitrust Litigation***

*Tyco Healthcare Group LP, et al. v. Mutual Pharmaceutical Company, Inc.* In March 2007, the Company filed a patent infringement suit in the U.S. District Court for the District of New Jersey against Mutual Pharmaceutical Co., Inc., et al. (collectively, "Mutual") after Mutual submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking to sell a generic version of the Company's 7.5 mg RESTORIL™ sleep aid product. Mutual also filed antitrust and unfair competition counterclaims. The patents at issue have since expired or been found invalid. The trial court issued an opinion and order granting the Company's motion for summary judgment regarding Mutual's antitrust and unfair competition counterclaims. Mutual appealed this decision to the U.S. Court of Appeals for the Federal Circuit and the Federal Circuit issued a split decision, affirming the trial court in part and remanding to the trial court certain counterclaims for further proceedings. The Company filed a motion for summary judgment with the U.S. District Court regarding the remanded issues. In May 2015, the trial court issued an opinion granting-in-part and denying-in-part the Company's motion for summary judgment.

*'222 and '218 Patent Litigation: InnoPharma Licensing LLC and InnoPharma, Inc.* In September 2014, Cadence and Mallinckrodt IP, subsidiaries of the Company, and Pharmatop, the owner of the two U.S. patents licensed exclusively by the Company, filed suit in the U.S. District Court for the District of Delaware against InnoPharma Licensing LLC and InnoPharma, Inc. (collectively "InnoPharma") alleging that InnoPharma infringed U.S. Patent Nos. 6,028,222 ("the '222 patent") and 6,992,218 ("the '218 patent") following receipt of an August 2014 notice from InnoPharma concerning its submission of a New Drug Application ("NDA"), containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev.

*'222 and '218 Patent Litigation: Agila Specialties Private Limited, Inc. and Agila Specialties Inc. (a Mylan Inc. Company), (collectively "Agila").* In December 2014, Cadence and Mallinckrodt IP, subsidiaries of the Company, and Pharmatop, the owner of the two U.S. patents licensed exclusively by the Company, filed suit in the U.S. District Court for the District of Delaware against Agila alleging that Agila infringed the '222 and the '218 patents following receipt of a November 2014 notice from Agila concerning its submission of a NDA containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev.

The Company has successfully asserted the '222 and '218 patents and maintained their validity in both litigation and proceedings at the U.S. Patent and Trademark Office ("USPTO"). The Company will continue to vigorously enforce its intellectual property rights relating to Ofirmev to prevent the marketing of infringing generic or competing products prior to December 6, 2020, which, if unsuccessful, could adversely affect the Company's ability to successfully maximize the value of Ofirmev and have an adverse effect on its financial condition, results of operations and cash flows.

*Inomax Patents: Inter Partes Review ("IPR") Proceedings.* In February 2015 and March 2015, the USPTO issued Notices of Filing Dates Accorded to Petitions for IPR petitions filed by Praxair Distribution, Inc. concerning ten patents covering Inomax (i.e., five patents expiring in 2029 and five patents expiring in 2031).

In July 2015 the USPTO Patent Trial and Appeal Board ("PTAB") issued rulings denying the institution of four of the five IPR petitions challenging the five patents expiring in 2029. The PTAB also issued a ruling in July 2015 that instituted the IPR proceeding in the fifth of this group of patents and the PTAB ruled in July 2016 that one claim of this patent survived review and is valid while the remaining claims were unpatentable. The Company believes the valid claim describes and encompasses the manner in which Inomax is distributed in conjunction with its approved labeling and that Praxair infringes that claim. Praxair filed an appeal and Mallinckrodt filed a cross-appeal of this decision to the Court of Appeals for the Federal Circuit. In March 2016, Praxair Distribution, Inc. submitted additional IPR petitions for the five patents expiring in 2029. The PTAB issued non-appealable rulings in August and September 2016 denying institution of all five of these additional IPR petitions.

In September 2015 the USPTO PTAB issued rulings that instituted the IPR proceedings in each of the second set of five patents that expire in 2031. In September 2016 the PTAB ruled that all claims in the five patents expiring in 2031 are patentable.

*Inomax Patent Litigation: Praxair Distribution, Inc. and Praxair, Inc. (collectively "Praxair").* In February 2015, INO Therapeutics LLC and Ikaria, Inc., subsidiaries of the Company, filed suit in the U.S. District Court for the District of Delaware against Praxair following receipt of a January 2015 notice from Praxair concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of Inomax. In July 2016, the Company filed a second suit against Praxair in the U.S. District Court for the District of Delaware following receipt of a Paragraph IV notice concerning three additional patents recently added to the FDA Orange Book that was submitted by Praxair regarding its ANDA for a generic version of Inomax. The infringement claims in the second suit have been added to the original suit. In September 2016, the Company filed a third suit against Praxair in the U.S. District Court for the District of Delaware following receipt of a Paragraph IV notice concerning a fourth patent recently added to the FDA Orange Book that was submitted by Praxair regarding its ANDA for a generic version of Inomax.

The Company intends to vigorously enforce its intellectual property rights relating to Inomax in both the IPR and Praxair litigation proceedings to prevent the marketing of infringing generic products prior to the expiration of the patents covering Inomax. An adverse outcome in either the IPRs or the Praxair litigation ultimately could result in the launch of a generic version of Inomax before the expiration of the last of the listed patents on February 19, 2034 (August 19, 2034 including pediatric exclusivity), which could adversely affect the Company's ability to successfully maximize the value of Inomax and have an adverse effect on its financial condition, results of operations and cash flows.

### ***Commercial and Securities Litigation***

*Retrophin Litigation.* In January 2014, Retrophin, Inc. ("Retrophin") filed a lawsuit against Questcor in the U.S. District Court for the Central District of California, alleging a variety of federal and state antitrust violations based on Questcor's acquisition from Novartis of certain rights to develop, market, manufacture, distribute, sell and commercialize Synacthen. In June 2015, the parties entered into a binding settlement agreement, under the terms of which Retrophin agreed to dismiss the litigation with prejudice and Questcor agreed to make a one-time cash payment to Retrophin in the amount of \$15.5 million.

*Glenridge Litigation.* In June 2011, Glenridge Pharmaceuticals LLC ("Glenridge"), filed a lawsuit against Questcor in the Superior Court of California, Santa Clara County, alleging that Questcor had underpaid royalties to Glenridge under a royalty agreement related to net sales of Acthar. In August 2012, Questcor filed a separate lawsuit against the three principals of Glenridge, as well as Glenridge, challenging the enforceability of the royalty agreement. In August 2013, the two lawsuits were consolidated into one case in the Superior Court of California, Santa Clara County. In October 2014, the parties entered into a binding term sheet settling the lawsuit. Under the terms of the settlement, the royalty rate payable by Questcor was reduced, royalties were capped instead of being payable for so long as Acthar was sold and Questcor agreed to pay Glenridge a reduced amount in satisfaction of royalties Questcor had previously accrued but not paid during the course of the lawsuit. In February 2015, the settlement agreement was finalized, with terms consistent with the October 2014 term sheet.

*Putative Class Action Securities Litigation.* In September 2012, a putative class action lawsuit was filed against Questcor and certain of its officers and directors in the U.S. District Court for the Central District of California, captioned *John K. Norton v. Questcor Pharmaceuticals, et al.*, No. SACv12-1623 DMG (FMOx). The complaint purported to be brought on behalf of shareholders who purchased Questcor common stock between April 26, 2011 and September 21, 2012. The complaint generally alleged that Questcor and certain of its officers and directors engaged in various acts to artificially inflate the price of Questcor stock and enable insiders to profit through stock sales. The complaint asserted that Questcor and certain of its officers and directors violated sections 10 (b) and/or 20(a) of the Securities Exchange Act of 1934, as amended ("the Exchange Act"), by making allegedly false and/or misleading statements concerning the clinical evidence to support the use of Acthar for indications other than infantile spasms, the promotion of the sale and use of Acthar in the treatment of multiple sclerosis and nephrotic syndrome, reimbursement for Acthar from third-party insurers, and Questcor's outlook and potential market growth for Acthar. The complaint sought damages in an unspecified amount and equitable relief against the defendants. This lawsuit was consolidated with four subsequently-filed actions asserting similar claims under the caption: *In re Questcor Securities Litigation*, No. CV 12-01623 DMG (FMOx). In October 2013, the District Court granted in part and denied in part Questcor's motion to dismiss the consolidated amended complaint. In October 2013, Questcor filed an answer to the consolidated amended complaint and fact discovery was concluded in January 2015. In April 2015, the parties executed a long-form settlement agreement, under the terms of which Questcor agreed to pay \$38.0 million to resolve the plaintiff claims, inclusive of all fees and costs. Questcor and the individual defendants maintain that the plaintiffs' claims are without merit, and have entered into the settlement to eliminate the uncertainties, burden and expense of further protracted litigation. During fiscal 2015, the Company established a \$38.0 million reserve for this settlement, which was subsequently paid to a settlement fund. The court issued its final approval of the settlement on September 18, 2015.

*Federal Shareholder Derivative Litigation.* On October 4, 2012, another alleged shareholder filed a derivative lawsuit in the United States District Court for the Central District of California captioned *Gerald Easton v. Don M Bailey, et al.*, No. SACV12-01716 DOC (JPRx). The suit asserted claims substantially identical to those asserted in the *do Valle* derivative action described below against the same defendants. This lawsuit was consolidated with five subsequently-filed actions asserting similar claims under the caption: *In re Questcor Shareholder Derivative Litigation*, CV 12- 01716 DMG (FMOx). Following the resolution of the motion to dismiss in the consolidated putative securities class action, the court issued an order staying the federal derivative action until the earlier of: (a) 60 days after the resolution of any motion for summary judgment filed in the putative class action lawsuit, (b) 60 days after the deadline to file a motion for summary judgment in the putative class action lawsuit, if none is filed, or (c) the execution of any settlement agreement (including any partial settlement agreement) to resolve the putative class action lawsuit. In July 2015, the parties stipulated to a dismissal of the derivative case and Questcor agreed to make a one-time cash payment to plaintiffs in the form of a mootness fee.

*State Shareholder Derivative Litigation.* In October 2012, an alleged shareholder filed a derivative lawsuit purportedly on behalf of Questcor against certain of its officers and directors in the Superior Court of the State of California, Orange County, captioned *Monika do Valle v. Virgil D. Thompson, et al.*, No. 30-2012-00602258-CU-SL-CXC. The complaint asserted claims for breach of fiduciary duty, abuse of control, mismanagement and waste of corporate assets arising from substantially similar allegations as those

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

*Put Options Securities Action.* In March 2013, individual traders of put options filed a securities complaint in the United States District Court for the Central District of California captioned *David Taban, et al. v. Questcor Pharmaceuticals, Inc.*, No. SACV13-0425. The complaint generally asserted claims against Questcor and certain of its officers and directors for violations of the Exchange Act and for state law fraud and fraudulent concealment based on allegations similar to those asserted in the putative securities class action described above. The complaint sought compensatory and punitive damages of an unspecified amount. Following the resolution of the motion to dismiss in the consolidated putative securities class action, the court issued an order staying this action until the earlier of: (a) sixty (60) days after the resolution of any motion for summary judgment filed in the putative class action lawsuit, (b) sixty (60) days after the deadline to file a motion for summary judgment in the putative class action lawsuit, if none is filed, or (c) the execution of any settlement agreement (including any partial settlement agreement) to resolve the putative class action lawsuit. In May 2015, the parties entered into a binding settlement agreement, under the terms of which plaintiffs agreed to dismiss the litigation with prejudice and Questcor agreed to make a one-time cash payment to plaintiffs.

### ***Pricing Litigation***

*State of Utah v. Apotex Corp., et al.* The Company, along with several other pharmaceutical companies, was a defendant in this matter which was filed in May 2008, in the Third Judicial Circuit of Salt Lake County, Utah. The State of Utah alleged, generally, that the defendants reported false pricing information in connection with certain drugs that were reimbursable under Utah Medicaid, resulting in overpayment by Utah Medicaid for those drugs, and sought monetary damages and attorneys' fees. The Company believes that it had meritorious defenses to these claims and vigorously defended against them. In December 2015, the parties entered into a binding settlement agreement, under the terms of which the State of Utah agreed to dismiss the litigation with prejudice and the Company agreed to make a one-time cash payment to the State of Utah within the reserve established for this matter.

### ***Environmental Remediation and Litigation Proceedings***

The Company is involved in various stages of investigation and cleanup related to environmental remediation matters at a number of sites, including those described below. The ultimate cost of site cleanup and timing of future cash outlays is difficult to predict, given the uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations and alternative cleanup methods. The Company concluded that, as of September 30, 2016, it was probable that it would incur remediation costs in the range of \$38.7 million to \$121.3 million. The Company also concluded that, as of September 30, 2016, the best estimate within this range was \$75.9 million, of which \$2.6 million was included in accrued and other current liabilities and the remainder was included in environmental liabilities on the consolidated balance sheet at September 30, 2016. While it is not possible at this time to determine with certainty the ultimate outcome of these matters, the Company believes, given the information currently available, that the final resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on its financial condition, results of operations and cash flows.

*Crab Orchard National Wildlife Refuge Superfund Site, near Marion, Illinois.* The Company is a successor in interest to International Minerals and Chemicals Corporation ("IMC"). Between 1967 and 1982, IMC leased portions of the Additional and Uncharacterized Sites ("AUS") Operable Unit at the Crab Orchard Superfund Site ("the Site") from the government and manufactured various explosives for use in mining and other operations. In March 2002, the Department of Justice, the U.S. Department of the Interior and the U.S. Environmental Protection Agency ("EPA") (together, "the Government Agencies") issued a special notice letter to General Dynamics Ordnance and Tactical Systems, Inc. ("General Dynamics"), one of the other potentially responsible parties ("PRPs") at the Site, to compel General Dynamics to perform the remedial investigation and feasibility study ("RI/FS") for the AUS Operable Unit. General Dynamics negotiated an Administrative Order on Consent ("AOC") with the Government Agencies to conduct an extensive RI/FS at the Site under the direction of the U.S. Fish and Wildlife Service. General Dynamics asserted in August 2004 that the Company is jointly and severally liable, along with approximately eight other lessees and operators at the AUS Operable Unit, for alleged contamination of soils and groundwater resulting from historic operations, and has threatened to file a contribution claim against the Company and other parties for recovery of its costs incurred in connection with the RI/FS activities being conducted at the AUS Operable Unit. The Company and other PRPs who received demand letters from General Dynamics have explored settlement alternatives, but have not reached settlement to date. General Dynamics has completed the RI and initiated the FS, and the PRPs agreed to enter into non-binding mediation. While it is not possible at this time to determine with certainty the ultimate outcome of this case, the Company believes, given the information currently available, that the final resolution of all known claims, after taking

into account amounts already accrued, will not have a material adverse effect on its financial condition, results of operations and cash flows.

*Mallinckrodt Veterinary, Inc., Millsboro, Delaware.* The Company previously operated a plant in Millsboro, Delaware ("the Millsboro Site") that manufactured various animal healthcare products. In 2005, the Delaware Department of Natural Resources and Environmental Control found trichloroethylene ("TCE") in the Millsboro public water supply at levels that exceeded the federal drinking water standards. Further investigation to identify the TCE plume in the ground water indicated that the plume has extended to property owned by a third party near the Millsboro Site. The Company, and another former owner, assumed responsibility for the Millsboro Site cleanup under the Alternative Superfund Program administered by the EPA. The Company and another PRP have entered into two AOCs with the EPA to perform investigations to abate, mitigate or eliminate the release or threat of release of hazardous substances at the Millsboro Site and to conduct an Engineering Evaluation/Cost Analysis to characterize the nature and extent of the contamination. The Company, along with the other party, continues to conduct the studies and prepare remediation plans in accordance with the AOCs. While it is not possible at this time to determine with certainty the ultimate outcome of this matter, the Company believes, given the information currently available, that the ultimate resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on its financial condition, results of operations and cash flows.

*Coldwater Creek, Saint Louis County, Missouri.* The Company is named as a defendant in numerous tort complaints filed in and subsequent to February 2012 with numerous plaintiffs pending in the U.S. District Court for the Eastern District of Missouri. These cases allege personal injury for alleged exposure to radiological substances, including in Coldwater Creek in Missouri, and in the air. Plaintiffs allegedly lived and/or worked in various locations in Saint Louis County, Missouri near Coldwater Creek. Radiological residues which may have been present in the creek have previously been remediated by the U.S. Army Corps of Engineers ("USACE"). The USACE continues to study and remediate the creek and surrounding areas. The Company believes that it has meritorious defenses to these complaints and is vigorously defending against them. The Company is unable to estimate a range of reasonably possible losses for the following reasons: (i) the proceedings are in intermediate stages; (ii) the Company has not received and reviewed complete information regarding the plaintiffs and their medical conditions; and (iii) there are significant factual and scientific issues to be resolved. An initial group of bellwether plaintiffs have been selected by the court and discovery is ongoing. While it is not possible at this time to determine with certainty the ultimate outcome of this case, the Company believes, given the information currently available, that the final resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on its financial condition, results of operations and cash flows.

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

In April 2014, the EPA issued its revised FFS, with remedial alternatives to address cleanup of the lower 8-mile stretch of the River, which also included a "no action" option. The EPA estimates the cost for the alternatives range from \$365.0 million to \$3.2 billion. The EPA's preferred approach would involve bank-to-bank dredging of the lower 8-mile stretch of the River and installing an engineered cap at a discounted, estimated cost of \$1.7 billion. Based on the issuance of the EPA's revised FFS, the Company recorded a \$23.1 million accrual in fiscal 2014 representing the estimate of its allocable share of the joint and several remediation liability resulting from this matter.

In April 2015, the CPG presented a draft of the RI/FS of the River to the EPA. The CPG's RI/FS included alternatives that ranged from "no action," targeted remediation of the entire 17-mile stretch of the River to remedial actions consistent with the EPA's preferred approach for the lower 8-mile stretch of the River and also included remediation alternatives for the upper 9-mile stretch of the River. The discounted cost estimates for the CPG remediation alternatives ranged from \$483.4 million to \$2.7 billion. The Company recorded an additional charge of \$13.3 million in the second quarter of fiscal 2014 based on the Company's estimate of its allocable share of the joint and several remediation liability resulting from this matter.

On March 4, 2016, the EPA issued the Record of Decision ("ROD") for the lower 8 miles of the River. The EPA's selected remedy for this stretch of the River was a slight modification of the preferred approach it identified in the revised FFS issued in April 2014. The new discounted, estimated cost is \$1.38 billion. By letter dated March 31, 2016, EPA notified the Company, and approximately 98 other parties, of the Company's potential liability for the lower 8 miles of the River. The letter also announced the EPA's intent to seek to determine whether one company, Occidental Chemicals Corporation ("OCC"), will voluntarily enter into an agreement to perform the remedial design for the remedy selected in the ROD. The letter states that, after execution of such an agreement, EPA plans to begin negotiation of an agreement under which OCC and the other major PRPs would implement and/or pay for the EPA's selected remedy for the lower 8 miles of the River. Finally, the letter announced EPA's intent to provide a separate notice to unspecified parties of the opportunity to discuss a cash out settlement for the lower 8 miles of the River at a later date. On October 5, 2016, EPA announced that OCC had entered into an agreement to develop the remedial design.

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

### ***Products Liability Litigation***

Beginning with lawsuits brought in July 1976, the Company is also named as a defendant in personal injury lawsuits based on alleged exposure to asbestos-containing materials. A majority of the cases involve product liability claims based principally on allegations of past distribution of products containing asbestos. A limited number of the cases allege premises liability based on claims that individuals were exposed to asbestos while on the Company's property. Each case typically names dozens of corporate defendants in addition to the Company. The complaints generally seek monetary damages for personal injury or bodily injury resulting from alleged exposure to products containing asbestos. The Company's involvement in asbestos cases has been limited because it did not mine or produce asbestos. Furthermore, in the Company's experience, a large percentage of these claims have never been substantiated and have been dismissed by the courts. The Company has not suffered an adverse verdict in a trial court proceeding related to asbestos claims and intends to continue to defend these lawsuits. When appropriate, the Company settles claims; however, amounts paid to settle and defend all asbestos claims have been immaterial. As of September 30, 2016, there were approximately 11,700 asbestos-related cases pending against the Company.

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

### ***Industrial Revenue Bonds***

Through September 30, 2016, the Company exchanged title to \$88.0 million of its plant assets in return for an equal amount of Industrial Revenue Bonds ("IRB") issued by Saint Louis County. The Company also simultaneously leased such assets back from Saint Louis County under capital leases expiring through December 2025, the terms of which provide it with the right of offset against the IRBs. The lease also provides an option for the Company to repurchase the assets at the end of the lease for nominal consideration. These transactions collectively result in a ten-year property tax abatement from the date the property is placed in service. Due to the 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.

### ***Interest Bearing Deferred Tax Obligation***

As part of the integration of Questcor, the Company entered into an internal installment sale transaction related to certain Acthar intangible assets during the three months ended December 26, 2014. During the three months ended December 25, 2015, 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 ("Section 453A") the gain is considered taxable in the period in which installment payments are received. 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. The GAAP calculation of interest associated with these deferred tax liabilities is subject to variable interest rates. The Company recognized interest expense associated with the Section 453A deferred tax liabilities of \$73.8 million and \$36.5 million for fiscal 2016 and 2015, respectively.

The Company has reported Section 453A interest on its tax returns on the basis of its interpretation of the U.S. Internal Revenue Code and Regulations. Alternative interpretations of these provisions could result in additional interest payable on the deferred tax liability. Due to the inherent uncertainty in these interpretations, the Company has deferred the recognition of the benefit associated with the Company's interpretation and maintains a corresponding liability. During the year ended September 30, 2016, the Company reclassified \$25.7 million of previously established payables from accrued and other current liabilities to other liabilities in the

condensed consolidated balance sheet. This balance is expected to increase over future periods until such uncertainty is resolved. Favorable resolution of this uncertainty would likely result in a material reversal of this liability and a benefit being recorded to interest expense within the consolidated statements of income.

### **Leases**

The Company has facility, vehicle and equipment leases that expire at various dates. Rental expense under facility, vehicle and equipment operating leases related to continuing operations was \$23.9 million, \$22.2 million and \$12.2 million for fiscal 2016, 2015 and 2014, respectively. The Company also has facility and equipment commitments under capital leases.

The following is a schedule of minimum lease payments for non-cancelable leases as of September 30, 2016:

	Operating Leases	Capital Leases
Fiscal 2017	\$ 26.5	\$ 1.0
Fiscal 2018	20.1	0.2
Fiscal 2019	19.0	—
Fiscal 2020	13.7	—
Fiscal 2021	11.5	—
Thereafter	44.9	—
Total minimum lease payments	<u>\$ 135.7</u>	<u>1.2</u>
Less: interest portion of payments		—
Present value of minimum lease payments		<u>\$ 1.2</u>

### **Tax Matters**

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

On January 19, 2016, Tyco International plc ("Tyco International") announced it had entered into Stipulations of Settled Issues with the IRS to resolve certain disputes before the U.S. Tax Court. The disputes involved IRS audits of Tyco International for years in which companies that are now subsidiaries of Mallinckrodt were subsidiaries of Tyco International. On May 31, 2016 the U.S. Tax Court entered decisions consistent with the Stipulations of Settled Issues. As a result, all aspects of the controversy that were before the U.S. Tax Court and Appeals Division of the IRS have been resolved for audit cycles from 1997-2007. Mallinckrodt is not a participant in the tax sharing agreement between Medtronic plc (as successor to Covidien plc), Tyco International and TE Connectivity and will not share in or be responsible for any payments to be made under the terms of the settlement.

The IRS is examining tax years 2010-2012 with respect to certain tax returns filed by Covidien. Taxes for periods prior to September 29, 2012 are subject to the Company's \$200.0 million liability limitation, as prescribed in the Tax Matters Agreement. The Company believes that it is adequately reserved for taxes related to these years.

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.

### **Acquisition-Related Litigation**

Several putative class actions were filed by purported holders of Questcor common stock in connection with the Questcor Acquisition (*Hansen v. Thompson, et al.*, *Heng v. Questcor Pharmaceuticals, Inc., et al.*, *Buck v. Questcor Pharmaceuticals, Inc., et al.*, *Ellerbeck v. Questcor Pharmaceuticals, Inc., et al.*, *Yokem v. Questcor Pharmaceuticals, Inc., et al.*, *Richter v. Questcor Pharmaceuticals, Inc., et al.*, *Tramantano v. Questcor Pharmaceuticals, Inc., et al.*, *Crippen v. Questcor Pharmaceuticals, Inc., et al.*, *Patel v. Questcor Pharmaceuticals, Inc., et al.*, and *Postow v. Questcor Pharmaceuticals, Inc., et al.*). The actions were consolidated on June 3, 2014. The consolidated complaint named as defendants, and generally alleged that, the directors of Questcor breached their fiduciary duties in connection with the acquisition by, among other things, agreeing to sell Questcor for inadequate consideration and

pursuant to an inadequate process. The consolidated complaint also alleged that the Questcor directors breached their fiduciary duties by failing to disclose purportedly material information to shareholders in connection with the merger. The consolidated complaint also alleged, among other things, that the Company aided and abetted the purported breaches of fiduciary duty. The lawsuits sought various forms of relief, including but not limited to, rescission of the transaction, damages and attorneys' fees and costs.

On July 29, 2014, the defendants reached an agreement in principle with the plaintiffs in the consolidated actions, and that agreement was reflected in a Memorandum of Understanding ("MOU"). In connection with the settlement contemplated by the MOU, Questcor agreed to make certain additional disclosures related to the proposed transaction with the Company, which are contained in the Company's Current Report on Form 8-K filed with the SEC on July 30, 2014. Additionally, as part of the settlement and pursuant to the MOU, the Company agreed to forbear from exercising certain rights under the merger agreement with Questcor, as follows: the four business day period referenced in Section 5.3(e) of the merger agreement with Questcor was reduced to three business days. Consistent with the terms of the MOU, the parties entered into a formal stipulation of settlement in February 2015 and re-executed the stipulation of settlement on May 7, 2015 (collectively the "Stipulation of Settlement").

The Stipulation of Settlement was subject to customary conditions, including court approval. On May 8, 2015, the California Court denied plaintiffs' Motion for Preliminary Approval of Settlement. On October 23, 2015, the parties submitted a proposed Stipulation and Order re Dismissal With Prejudice dismissing the action with prejudice as to each of the named plaintiffs and without prejudice as to the remainder of the class and, on October 30, 2015, the California Court entered that Order.

### **Other Matters**

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

## **19. Financial Instruments and Fair Value Measurements**

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

- Level 1— observable inputs such as quoted prices in active markets for identical assets or liabilities;
- Level 2— significant other observable inputs that are observable either directly or indirectly; and
- Level 3— significant unobservable inputs in which there is little or no market data, which requires the Company to develop its own assumptions.

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

	September 30, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Debt and equity securities held in rabbi trusts	\$ 34.6	\$ 23.1	\$ 11.5	\$ —
Foreign exchange forward and option contracts	\$ 0.2	\$ 0.2	\$ —	\$ —
	<u>\$ 34.8</u>	<u>\$ 23.3</u>	<u>\$ 11.5</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Deferred compensation liabilities	\$ 26.8	\$ —	\$ 26.8	\$ —
Contingent consideration and acquired contingent liabilities	247.8	—	—	247.8
Foreign exchange forward and option contracts	1.6	1.6	—	—
	<u>\$ 276.2</u>	<u>\$ 1.6</u>	<u>\$ 26.8</u>	<u>\$ 247.8</u>

	September 25, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Debt and equity securities held in rabbi trusts	\$ 34.6	\$ 24.2	\$ 10.4	\$ —
	<u>\$ 34.6</u>	<u>\$ 24.2</u>	<u>\$ 10.4</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Deferred compensation liabilities	\$ 20.0	\$ —	\$ 20.0	\$ —
Contingent consideration and acquired contingent liabilities	174.6	—	—	174.6
Foreign exchange forward and option contracts	3.3	3.3	—	—
	<u>\$ 197.9</u>	<u>\$ 3.3</u>	<u>\$ 20.0</u>	<u>\$ 174.6</u>

*Debt and equity securities held in rabbi trust.* Debt securities held in the rabbi trust primarily consist of U.S. government and agency securities and corporate bonds. When quoted prices are available in an active market, the investments are classified as level 1. When quoted market prices for a security are not available in an active market, they are classified as level 2. Equity securities held in the rabbi trust primarily consist of U.S. common stocks, which are valued using quoted market prices reported on nationally recognized securities exchanges.

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

*Deferred compensation liabilities.* The Company maintains a non-qualified deferred compensation plan in the U.S., which permits eligible employees of the Company to defer a portion of their compensation. A recordkeeping account is set up for each participant and the participant chooses from a variety of funds for the deemed investment of their accounts. The recordkeeping accounts generally correspond to the funds offered in the Company's U.S. tax-qualified defined contribution retirement plan and the account balance fluctuates with the investment returns on those funds.

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

*Contingent consideration and acquired contingent liabilities.* In October 2012, the Company recorded contingent consideration of \$6.9 million upon the acquisition of CNS Therapeutics. This contingent consideration, which could potentially total a maximum of \$9.0 million, is primarily based on whether the FDA approves another concentration of Gablofen on or before December 31, 2016. The fair value of the contingent payments was measured based on the probability-weighted present value of the consideration expected to be transferred using a discount rate of 1.0%. At September 30, 2016, the fair value of this contingent consideration was \$0.9 million.

In August 2014, the Company recorded acquired contingent liabilities of \$195.4 million from the Questcor Acquisition. The contingent liabilities relate to Questcor's contingent obligations associated with their acquisition of an exclusive, perpetual and irrevocable license to develop, market, manufacture, distribute, sell and commercialize Synacthen and Synacthen Depot (collectively "Synacthen") from Novartis AG and Novartis Pharma AG (collectively "Novartis") and their acquisition of BioVectra. The fair value of these contingent consideration obligations at September 30, 2016 were \$123.4 million.

Under the terms of the license agreement with Novartis, the Company made a \$25.0 million payment in fiscal 2016, and is obligated to make annual payments of \$25.0 million subsequent to fiscal 2016 until such time that the Company obtains FDA approval of Synacthen and makes a \$25.0 million payment upon obtaining FDA approval of Synacthen. If FDA approval is obtained, the Company will pay an annual royalty to Novartis based on a percentage of net sales in the U.S. market. As of September 30, 2016, the total remaining payments under the license agreement shall not exceed \$165.0 million. The terms of the license agreement do allow the Company to terminate the license agreement at its discretion following the fiscal 2018 payment or upon the occurrence of certain events following the fiscal 2016 payment. The Company measured the fair value of the contingent payments based on a probability-weighted present value of the consideration expected to be transferred using a discount rate of 4.7%.



Based on the terms of the acquisition agreement with the former shareholders of BioVectra, the Company was obligated to pay additional cash consideration of \$50.0 million CAD based on BioVectra's financial results from January 2013 through a portion of fiscal 2016. During fiscal 2015 and 2014, the Company made \$5.0 million CAD payments. During fiscal 2016, the Company paid the remaining obligation of \$40.0 million CAD to the former owners of BioVectra to reach the maximum cumulative payment of \$50.0 million CAD. At September 30, 2016, there are no further contingent liabilities associated with BioVectra.

As part of the Hemostasis Acquisition, the Company provided contingent consideration to The Medicines Company in the form of sales based milestones associated with Raplixa and PreveLeak, and acquired contingent liabilities associated with The Medicines Company's prior acquisitions of the aforementioned products. The Company determined the fair value of the contingent consideration and acquired contingent liabilities based on an option pricing model to be \$57.7 million and \$11.0 million, respectively, at September 30, 2016.

As part of the Stratatech Acquisition, the Company provided contingent consideration to the Stratatech Corporation, primarily in the form of regulatory filing and approval milestones associated with the deep partial thickness and full thickness indications associated with the StrataGraft product. The Company assesses the likelihood of and timing of making such payments. The Company determined the fair value of the contingent consideration associated with the Stratatech Acquisition to be \$54.9 million at September 30, 2016.

Balance at September 25, 2015	\$	174.6
Acquisition date fair value of contingent consideration		106.9
Acquisition date fair value of acquired contingent consideration		10.6
Payments		(55.0)
Accretion expense		6.3
Fair value adjustment		4.4
Balance at September 30, 2016	\$	<u>247.8</u>

#### ***Financial Instruments Not Measured at Fair Value***

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and the majority of other current assets and liabilities approximate fair value because of their short-term nature. The Company classifies cash on hand and deposits in banks, including commercial paper, money market accounts and other investments it may hold from time to time, with an original maturity to the Company of three months or less, as cash and cash equivalents (level 1). The fair value of restricted cash is equivalent to its carrying value of \$19.1 million and \$66.3 million as of September 30, 2016 and September 25, 2015, respectively (level 1), substantially all of which is included in other assets on the consolidated balance sheets. The Company's life insurance contracts are carried at cash surrender value, which is based on the present value of future cash flows under the terms of the contracts (level 3). Significant assumptions used in determining the cash surrender value include the amount and timing of future cash flows, interest rates and mortality charges. The fair value of these contracts approximates the carrying value of \$67.6 million and \$66.8 million at September 30, 2016 and September 25, 2015, respectively. These contracts are included in other assets on the consolidated balances sheets.

The carrying values of the Company's revolving credit facility and variable rate receivable securitization approximate the fair values due to the short-term nature of these instruments. The carrying value of the 4.00% term loan approximates the fair value of this instrument, as calculated using the discounted exit price for the instrument, and is therefore classified as level 3. Since the quoted market prices for the Company's term loans and 8.00% and 9.50% debentures are not available in an active market, they are classified as level 2 for purposes of developing an estimate of fair value. The Company's 3.50%, 4.75%, 4.875%, 5.50%, 5.625% and 5.75% notes are classified as level 1, as quoted prices are available in an active market for these notes. The following table presents the carrying values and estimated fair values of the Company's long-term debt, excluding capital leases, as of the end of each period:

	September 30, 2016		September 25, 2015	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Variable rate receivable securitization	\$ 235.0	\$ 235.0	\$ 153.0	\$ 153.0
3.50% notes due April 2018	300.0	299.6	300.0	294.3
4.875% notes due April 2020	700.0	712.4	700.0	684.1
Term loans due March 2021	1,953.5	1,951.8	1,978.5	1,966.5
4.00% term loan due February 2022	7.1	7.1	7.9	7.9
9.50% debentures due May 2022	10.4	12.1	10.4	13.0
5.75% notes due August 2022	884.0	869.3	900.0	876.1
8.00% debentures due March 2023	4.4	4.9	4.4	5.3
4.75% notes due April 2023	600.0	539.5	600.0	539.6
5.625% notes due October 2023	740.0	710.2	750.0	705.2
5.50% notes due April 2025	700.0	663.6	700.0	646.0
Revolving credit facility	—	—	500.0	500.0

### Concentration of Credit and Other Risks

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

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

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

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

	September 30, 2016	September 25, 2015
McKesson Corporation	30%	26%
AmerisourceBergen Corporation	15%	13%
CuraScript, Inc.	14%	18%
Cardinal Health, Inc.	10%	13%

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

	Fiscal Year		
	2016	2015	2014
Acthar	34%	35%	7%
Inomax	14%	6%	—%
Acetaminophen products (API)	5%	7%	12%
Methylphenidate ER	3%	5%	13%

## 20. Segment and Geographical Data

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

On November 27, 2015, the Company completed the sale of the CMDS business to Guerbet. As a result, the CMDS business was eliminated from the Global Medical Imaging segment, which was renamed 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 is deemed to be held for sale and the financial results of this business are presented as a discontinued operation.

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

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 API consisting of biologics, medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients.

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

Management manages assets on a total company basis, not by operating segment. The chief operating decision maker does not regularly review any asset information by operating segment and, accordingly, the Company does not report asset information by operating segment. Total assets were approximately \$15.5 billion and \$16.4 billion at September 30, 2016 and September 25, 2015, respectively.

Selected information by business segment is as follows:

	Fiscal Year		
	2016	2015	2014
<b>Net sales:</b>			
Specialty Brands	\$ 2,300.6	\$ 1,622.8	\$ 413.5
Specialty Generics	1,025.2	1,251.6	1,199.4
Net sales of operating segments <sup>(1)</sup>	3,325.8	2,874.4	1,612.9
Other <sup>(2)</sup>	55.0	48.7	37.4
Net sales	<u>\$ 3,380.8</u>	<u>\$ 2,923.1</u>	<u>\$ 1,650.3</u>
<b>Operating income:</b>			
Specialty Brands	\$ 1,166.2	\$ 637.6	\$ (68.6)
Specialty Generics	376.1	594.4	599.4
Segment operating income	1,542.3	1,232.0	530.8
<b>Unallocated amounts:</b>			
Corporate and allocated expenses <sup>(3)</sup>	(169.8)	(282.6)	(227.7)
Intangible asset amortization	(700.1)	(550.3)	(154.8)
Restructuring and related charges, net <sup>(4)</sup>	(38.2)	(45.3)	(68.2)
Non-restructuring impairments	(16.9)	—	(27.1)
Separation costs	—	—	(9.6)
Operating income	<u>\$ 617.3</u>	<u>\$ 353.8</u>	<u>\$ 43.4</u>
<b>Depreciation and amortization <sup>(5)</sup>:</b>			
Specialty Brands	\$ 716.6	\$ 559.5	\$ 153.3
Specialty Generics	96.8	81.6	78.2
	<u>\$ 813.4</u>	<u>\$ 641.1</u>	<u>\$ 231.5</u>

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

(2) Represents net sales from an ongoing, post-divestiture supply agreement with the acquirer of the CMDS business. Amounts for periods prior to the divestiture represent the reclassification of intercompany sales to third-party sales to conform with the expected presentation of the ongoing supply agreement.

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

(4) Includes restructuring-related accelerated depreciation.

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

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

	Fiscal Year		
	2016	2015	2014
Acthar	\$ 1,160.4	\$ 1,037.3	\$ 122.9
Inomax	474.3	185.2	—
Ofirmev	284.3	263.0	124.4
Therakos immunotherapy	207.6	—	—
Hemostasis products	42.5	—	—
Other	131.5	137.3	166.2
Specialty Brands	<u>2,300.6</u>	<u>1,622.8</u>	<u>413.5</u>
Hydrocodone (API) and hydrocodone-containing tablets	146.5	167.2	99.4
Oxycodone (API) and oxycodone-containing tablets	126.2	154.6	155.2
Methylphenidate ER	103.5	136.5	209.6
Other controlled substances	468.1	572.2	584.5
Other	180.9	221.1	150.7
Specialty Generics	<u>1,025.2</u>	<u>1,251.6</u>	<u>1,199.4</u>
Other <sup>(1)</sup>	55.0	48.7	37.4
Net sales	<u>\$ 3,380.8</u>	<u>\$ 2,923.1</u>	<u>\$ 1,650.3</u>

- (1) Represents net sales from an ongoing, post-divestiture supply agreement with the acquirer of the CMDS business. Amounts for periods prior to the divestiture represent the reclassification of intercompany sales to third-party sales to conform with the expected presentation of the ongoing supply agreement.

Selected information by geographic area excluding assets held for sale is as follows:

	Fiscal Year		
	2016	2015	2014
Net sales <sup>(1)</sup> :			
U.S.	\$ 3,095.4	\$ 2,647.0	\$ 1,485.0
Europe, Middle East and Africa	211.8	159.0	140.8
Other	73.6	117.1	24.5
	<u>\$ 3,380.8</u>	<u>\$ 2,923.1</u>	<u>\$ 1,650.3</u>
Long-lived assets <sup>(2)</sup> :			
U.S.	\$ 742.4	\$ 747.8	
Europe, Middle East and Africa <sup>(3)</sup>	61.2	13.4	
Other	52.5	44.5	
	<u>\$ 856.1</u>	<u>\$ 805.7</u>	

- (1) Net sales are attributed to regions based on the location of the entity that records the transaction, none of which relate to the country of Ireland.  
(2) Long-lived assets are primarily composed of property, plant and equipment.  
(3) Includes long-lived assets located in Ireland of \$59.3 million, and \$10.7 million at the end of fiscal 2016 and 2015, respectively.

## 21. Selected Quarterly Financial Data (Unaudited)

	Fiscal 2016 (by quarter)			
	Q1	Q2	Q3	Q4
Net sales	\$ 811.2	\$ 815.8	\$ 866.6	\$ 887.2
Gross profit	450.9	425.1	488.8	490.2
Income from continuing operations	103.8	98.5	176.7	110.0
Income from discontinued operations	107.3	19.8	22.6	5.0
Net income	211.1	118.3	199.3	115.0
Basic earnings per share from continuing operations <sup>(1)</sup>	\$ 0.90	\$ 0.89	\$ 1.63	\$ 1.02
Diluted earnings per share from continuing operations <sup>(1)</sup>	0.89	0.88	1.62	1.01

	Fiscal 2015 (by quarter)			
	Q1	Q2	Q3	Q4
Net sales	\$ 666.3	\$ 709.5	\$ 768.5	\$ 778.8
Gross profit	355.7	399.7	441.7	425.8
Income from continuing operations	73.6	55.3	34.6	73.1
Income from discontinued operations	19.1	43.5	23.4	2.1
Net income	92.7	98.8	58.0	75.2
Basic earnings per share from continuing operations <sup>(1)</sup>	\$ 0.63	\$ 0.47	\$ 0.30	\$ 0.62
Diluted earnings per share from continuing operations <sup>(1)</sup>	0.63	0.47	0.29	0.62

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

## 22. Condensed Consolidating Financial Statements

MIFSA is a holding company established to own, directly or indirectly, substantially all of the operating subsidiaries of the Company, to issue debt securities and to perform treasury operations.

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

Set forth below are the condensed consolidating balance sheets as of September 30, 2016 and September 25, 2015 and condensed consolidating statements of comprehensive income and cash flows for the three years ended September 30, 2016. Eliminations represent adjustments to eliminate investments in subsidiaries and intercompany balances and transactions between or among Mallinckrodt plc, MIFSA and the other subsidiaries. Condensed consolidating and combining financial information for Mallinckrodt plc and MIFSA, on a standalone basis, has been presented using the equity method of accounting for subsidiaries.

**MALLINCKRODT PLC**  
**CONDENSED CONSOLIDATING BALANCE SHEET**  
As of September 30, 2016  
*(in millions)*

	<u>Mallinckrodt plc</u>	<u>Mallinckrodt International Finance S.A.</u>	<u>Other Subsidiaries</u>	<u>Eliminations</u>	<u>Consolidated</u>
<b>Assets</b>					
Current Assets:					
Cash and cash equivalents	\$ 0.3	\$ 25.0	\$ 255.2	\$ —	\$ 280.5
Accounts receivable, net	—	—	465.8	—	465.8
Inventories	—	—	335.6	—	335.6
Deferred income taxes	—	—	—	—	—
Prepaid expenses and other current assets	1.4	0.1	114.4	—	115.9
Current assets held for sale	—	—	308.8	—	308.8
Intercompany receivable	88.9	473.8	1,081.4	(1,644.1)	—
<b>Total current assets</b>	<u>90.6</u>	<u>498.9</u>	<u>2,561.2</u>	<u>(1,644.1)</u>	<u>1,506.6</u>
Property, plant and equipment, net	—	—	844.0	—	844.0
Goodwill	—	—	3,705.3	—	3,705.3
Intangible assets, net	—	—	9,182.3	—	9,182.3
Long-term assets held for sale	—	—	—	—	—
Investment in subsidiaries	5,657.8	20,168.4	11,020.0	(36,846.2)	—
Intercompany loan receivable	143.5	—	3,159.4	(3,302.9)	—
Other assets	—	—	260.5	—	260.5
<b>Total Assets</b>	<u>\$ 5,891.9</u>	<u>\$ 20,667.3</u>	<u>\$ 30,732.7</u>	<u>\$ (41,793.2)</u>	<u>\$ 15,498.7</u>
<b>Liabilities and Shareholders' Equity</b>					
Current Liabilities:					
Current maturities of long-term debt	\$ —	\$ 19.8	\$ 236.5	\$ —	\$ 256.3
Accounts payable	0.2	—	109.9	—	110.1
Accrued payroll and payroll-related costs	—	—	116.0	—	116.0
Accrued interest	—	79.3	1.3	—	80.6
Accrued and other current liabilities	2.2	7.5	541.2	—	550.9
Current liabilities held for sale	—	—	120.8	—	120.8
Intercompany payable	618.8	462.6	562.7	(1,644.1)	—
<b>Total current liabilities</b>	<u>621.2</u>	<u>569.2</u>	<u>1,688.4</u>	<u>(1,644.1)</u>	<u>1,234.7</u>
Long-term debt	—	5,767.8	20.9	—	5,788.7
Pension and postretirement benefits	—	—	144.9	—	144.9
Environmental liabilities	—	—	73.4	—	73.4
Deferred income taxes	—	—	2,581.4	—	2,581.4
Other income tax liabilities	—	—	67.7	—	67.7
Long-term liabilities held for sale	—	—	—	—	—
Intercompany loans payable	—	3,302.9	—	(3,302.9)	—
Other liabilities	—	7.4	329.8	—	337.2
<b>Total liabilities</b>	<u>621.2</u>	<u>9,647.3</u>	<u>4,906.5</u>	<u>(4,947.0)</u>	<u>10,228.0</u>
Shareholders' equity	5,270.7	11,020.0	25,826.2	(36,846.2)	5,270.7
<b>Total Liabilities and Shareholders' Equity</b>	<u>\$ 5,891.9</u>	<u>\$ 20,667.3</u>	<u>\$ 30,732.7</u>	<u>\$ (41,793.2)</u>	<u>\$ 15,498.7</u>

**MALLINCKRODT PLC**  
**CONDENSED CONSOLIDATING BALANCE SHEET**  
As of September 25, 2015  
*(in millions)*

	<u>Mallinckrodt plc</u>	<u>Mallinckrodt International Finance S.A.</u>	<u>Other Subsidiaries</u>	<u>Eliminations</u>	<u>Consolidated</u>
<b>Assets</b>					
Current Assets:					
Cash and cash equivalents	\$ 0.1	\$ 152.1	\$ 213.7	\$ —	\$ 365.9
Accounts receivable, net	—	—	489.6	—	489.6
Inventories	—	—	262.1	—	262.1
Deferred income taxes	—	—	139.2	—	139.2
Prepaid expenses and other current assets	1.3	0.2	192.9	—	194.4
Current assets held for sale	—	—	394.9	—	394.9
Intercompany receivable	39.1	128.6	9,699.5	(9,867.2)	—
Total current assets	<u>40.5</u>	<u>280.9</u>	<u>11,391.9</u>	<u>(9,867.2)</u>	<u>1,846.1</u>
Property, plant and equipment, net	—	—	793.0	—	793.0
Goodwill	—	—	3,649.4	—	3,649.4
Intangible assets, net	—	—	9,666.3	—	9,666.3
Long-term assets held for sale	—	—	223.6	—	223.6
Investment in subsidiaries	14,797.7	18,838.6	10,050.0	(43,686.3)	—
Intercompany loan receivable	174.4	—	2,498.2	(2,672.6)	—
Other assets	—	0.1	225.6	—	225.7
<b>Total Assets</b>	<u>\$ 15,012.6</u>	<u>\$ 19,119.6</u>	<u>\$ 38,498.0</u>	<u>\$ (56,226.1)</u>	<u>\$ 16,404.1</u>
<b>Liabilities and Shareholders' Equity</b>					
Current Liabilities:					
Current maturities of long-term debt	\$ —	\$ 20.0	\$ 2.0	\$ —	\$ 22.0
Accounts payable	—	0.2	116.6	—	116.8
Accrued payroll and payroll-related costs	0.1	—	94.9	—	95.0
Accrued interest	—	77.1	3.1	—	80.2
Accrued and other current liabilities	1.8	0.3	484.0	—	486.1
Current liabilities held for sale	—	—	129.3	—	129.3
Intercompany payable	9,699.5	—	167.7	(9,867.2)	—
Total current liabilities	<u>9,701.4</u>	<u>97.6</u>	<u>997.6</u>	<u>(9,867.2)</u>	<u>929.4</u>
Long-term debt	—	6,299.4	174.9	—	6,474.3
Pension and postretirement benefits	—	—	114.2	—	114.2
Environmental liabilities	—	—	73.3	—	73.3
Deferred income taxes	—	—	3,117.5	—	3,117.5
Other income tax liabilities	—	—	121.3	—	121.3
Long-term liabilities held for sale	—	—	53.9	—	53.9
Intercompany loans payable	—	2,672.6	—	(2,672.6)	—
Other liabilities	—	—	209.0	—	209.0
<b>Total liabilities</b>	<u>9,701.4</u>	<u>9,069.6</u>	<u>4,861.7</u>	<u>(12,539.8)</u>	<u>11,092.9</u>
Shareholders' equity	5,311.2	10,050.0	33,636.3	(43,686.3)	5,311.2
<b>Total Liabilities and Shareholders' Equity</b>	<u>\$ 15,012.6</u>	<u>\$ 19,119.6</u>	<u>\$ 38,498.0</u>	<u>\$ (56,226.1)</u>	<u>\$ 16,404.1</u>



**MALLINCKRODT PLC**  
**CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME**  
Fiscal year ended September 30, 2016  
*(in millions)*

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
<b>Net sales</b>	\$ —	\$ —	\$ 3,380.8	\$ —	\$ 3,380.8
Cost of sales	—	—	1,525.8	—	1,525.8
<b>Gross profit</b>	—	—	1,855.0	—	1,855.0
Selling, general and administrative expenses	51.3	0.8	873.2	—	925.3
Research and development expenses	—	—	262.2	—	262.2
Restructuring charges, net	—	—	33.3	—	33.3
Non-restructuring impairment charges	—	—	16.9	—	16.9
Separation costs	—	—	—	—	—
Gains on divestiture and license	—	—	—	—	—
<b>Operating income (loss)</b>	(51.3)	(0.8)	669.4	—	617.3
Interest expense	(230.3)	(327.0)	(82.4)	255.1	(384.6)
Interest income	—	0.5	255.9	(255.1)	1.3
Other income (expense), net	90.0	1.7	(92.3)	—	(0.6)
Intercompany interest and fees	(16.1)	—	16.1	—	—
Equity in net income of subsidiaries	820.8	1,327.2	1,057.9	(3,205.9)	—
<b>Income from continuing operations before income taxes</b>	613.1	1,001.6	1,824.6	(3,205.9)	233.4
Benefit from income taxes	(30.6)	(18.1)	(206.9)	—	(255.6)
<b>Income from continuing operations</b>	643.7	1,019.7	2,031.5	(3,205.9)	489.0
Income from discontinued operations, net of income taxes	—	38.2	116.5	—	154.7
<b>Net income</b>	643.7	1,057.9	2,148.0	(3,205.9)	643.7
Other comprehensive loss, net of tax	(86.5)	(86.5)	(173.5)	260.0	(86.5)
<b>Comprehensive income</b>	\$ 557.2	\$ 971.4	\$ 1,974.5	\$ (2,945.9)	\$ 557.2

**MALLINCKRODT PLC**  
**CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME**  
Fiscal year ended September 25, 2015  
*(in millions)*

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
<b>Net sales</b>	\$ —	\$ —	\$ 2,923.1	\$ —	\$ 2,923.1
Cost of sales	—	—	1,300.2	—	1,300.2
<b>Gross profit</b>	—	—	1,622.9	—	1,622.9
Selling, general and administrative expenses	116.3	15.7	891.8	—	1,023.8
Research and development expenses	—	—	203.3	—	203.3
Restructuring charges, net	9.8	—	35.2	—	45.0
Non-restructuring impairments	—	—	—	—	—
Separation costs	—	—	—	—	—
Gains on divestiture and license	—	—	(3.0)	—	(3.0)
<b>Operating income (loss)</b>	(126.1)	(15.7)	495.6	—	353.8
Interest expense	(96.4)	(230.2)	(25.2)	96.2	(255.6)
Interest income	—	0.1	97.1	(96.2)	1.0
Other income (expense), net	216.3	—	(208.2)	—	8.1
Intercompany interest and fees	(14.7)	—	14.7	—	—
Equity in net income of subsidiaries	330.6	496.3	250.5	(1,077.4)	—
<b>Income from continuing operations before income taxes</b>	309.7	250.5	624.5	(1,077.4)	107.3
Benefit from income taxes	(15.9)	—	(113.4)	—	(129.3)
<b>Income from continuing operations</b>	325.6	250.5	737.9	(1,077.4)	236.6
Income (loss) from discontinued operations, net of income taxes	(0.9)	—	89.0	—	88.1
<b>Net income</b>	324.7	250.5	826.9	(1,077.4)	324.7
Other comprehensive loss, net of tax	(64.8)	(64.8)	(69.9)	134.7	(64.8)
<b>Comprehensive income</b>	\$ 259.9	\$ 185.7	\$ 757.0	\$ (942.7)	\$ 259.9

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

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
<b>Net sales</b>	\$ —	\$ —	\$ 1,650.3	\$ —	\$ 1,650.3
Cost of sales	—	—	765.7	—	765.7
<b>Gross profit</b>	—	—	884.6	—	884.6
Selling, general and administrative expenses	37.7	7.3	566.0	—	611.0
Research and development expenses	—	—	140.5	—	140.5
Restructuring charges, net	35.3	—	32.7	—	68.0
Non-restructuring impairments	—	—	27.1	—	27.1
Separation costs	2.5	—	7.1	—	9.6
Gains on divestiture and license	—	—	(15.0)	—	(15.0)
<b>Operating income (loss)</b>	(75.5)	(7.3)	126.2	—	43.4
Interest expense	—	(86.3)	—	3.7	(82.6)
Interest income	—	—	5.2	(3.7)	1.5
Other income (expense), net	30.9	—	(27.8)	—	3.1
Intercompany interest and fees	(9.0)	—	9.0	—	—
Equity in net income of subsidiaries	(264.8)	(171.2)	(300.2)	736.2	—
<b>Loss from continuing operations before income taxes</b>	(318.4)	(264.8)	(187.6)	736.2	(34.6)
benefit from income taxes	—	—	(12.6)	—	(12.6)
<b>Loss from continuing operations</b>	(318.4)	(264.8)	(175.0)	736.2	(22.0)
Loss from discontinued operations, net of income taxes	(0.9)	—	(296.4)	—	(297.3)
<b>Net loss</b>	(319.3)	(264.8)	(471.4)	736.2	(319.3)
Other comprehensive loss, net of tax	(42.8)	(42.8)	(84.1)	126.9	(42.8)
<b>Comprehensive loss</b>	\$ (362.1)	\$ (307.6)	\$ (555.5)	\$ 863.1	\$ (362.1)

**MALLINCKRODT PLC**  
**CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS**  
Fiscal year ended September 30, 2016  
*(in millions)*

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
<b>Cash Flows From Operating Activities:</b>					
Net cash provided by (used in) operating activities	\$ 17.9	\$ (47.4)	\$ 1,214.1	\$ —	\$ 1,184.6
<b>Cash Flows From Investing Activities:</b>					
Capital expenditures	—	—	(182.9)	—	(182.9)
Acquisitions and intangibles, net of cash acquired	—	—	(245.4)	—	(245.4)
Proceeds from disposal of discontinued operations, net of cash	—	234.0	33.0	—	267.0
Intercompany loan investment	—	(175.2)	(1,714.5)	1,889.7	—
Investment in subsidiary	—	(861.2)	—	861.2	—
Proceeds from sale of subsidiary	3.4	—	—	(3.4)	—
Acquisition of subsidiary	—	—	(3.4)	3.4	—
Restricted cash	—	—	47.3	—	47.3
Other	—	—	6.0	—	6.0
Net cash used in investing activities	3.4	(802.4)	(2,059.9)	2,750.9	(108.0)
<b>Cash Flows From Financing Activities:</b>					
Issuance of external debt	—	—	98.3	—	98.3
Repayment of external debt and capital leases	—	(549.2)	(19.4)	—	(568.6)
Excess tax benefit from share-based compensation	—	—	—	—	—
Debt financing costs	—	—	(0.1)	—	(0.1)
Proceeds from exercise of share options	14.0	—	—	—	14.0
Intercompany loan borrowings	617.8	1,271.9	—	(1,889.7)	—
Capital contribution	—	—	861.2	(861.2)	—
Repurchase of shares	(652.9)	—	—	—	(652.9)
Other	—	—	(53.0)	—	(53.0)
Net cash provided by financing activities	(21.1)	722.7	887.0	(2,750.9)	(1,162.3)
Effect of currency rate changes on cash	—	—	0.3	—	0.3
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>0.2</b>	<b>(127.1)</b>	<b>41.5</b>	<b>—</b>	<b>(85.4)</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>0.1</b>	<b>152.1</b>	<b>213.7</b>	<b>—</b>	<b>365.9</b>
<b>Cash and cash equivalents at end of period</b>	<b>0.3</b>	<b>25.0</b>	<b>255.2</b>	<b>—</b>	<b>280.5</b>

**MALLINCKRODT PLC**  
**CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS**  
Fiscal year ended September 25, 2015  
*(in millions)*

	<b>Mallinckrodt plc</b>	<b>Mallinckrodt International Finance S.A.</b>	<b>Other Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
<b>Cash Flows From Operating Activities:</b>					
Net cash provided by (used in) operating activities	\$ 207.0	\$ (148.2)	\$ 837.6	\$ —	\$ 896.4
<b>Cash Flows From Investing Activities:</b>					
Capital expenditures	—	—	(148.0)	—	(148.0)
Acquisitions and intangibles, net of cash acquired	—	—	(2,154.7)	—	(2,154.7)
Intercompany loan investment	(149.4)	—	(554.2)	703.6	—
Investment in subsidiary	—	(3,014.4)	—	3,014.4	—
Restricted Cash	—	—	3.1	—	3.1
Other	—	—	3.0	—	3.0
Net cash used in investing activities	(149.4)	(3,014.4)	(2,850.8)	3,718.0	(2,296.6)
<b>Cash Flows From Financing Activities:</b>					
Issuance of external debt	—	2,890.0	120.0	—	3,010.0
Repayment of external debt and capital leases	—	(258.3)	(1,590.1)	—	(1,848.4)
Excess tax benefit from share-based compensation	—	—	34.1	—	34.1
Debt financing costs	—	(39.1)	(0.8)	—	(39.9)
Proceeds from exercise of share options	34.4	—	—	—	34.4
Intercompany loan borrowings	—	703.6	—	(703.6)	—
Capital contribution	—	—	3,014.4	(3,014.4)	—
Repurchase of shares	(92.2)	—	—	—	(92.2)
Other	—	—	(28.1)	—	(28.1)
Net cash provided by financing activities	(57.8)	3,296.2	1,549.5	(3,718.0)	1,069.9
Effect of currency rate changes on cash	—	—	(11.6)	—	(11.6)
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(0.2)</b>	<b>133.6</b>	<b>(475.3)</b>	<b>—</b>	<b>(341.9)</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>0.3</b>	<b>18.5</b>	<b>689.0</b>	<b>—</b>	<b>707.8</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 0.1</b>	<b>\$ 152.1</b>	<b>\$ 213.7</b>	<b>\$ —</b>	<b>\$ 365.9</b>

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

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

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

None.

**Item 9A. Controls and Procedures.**

***Evaluation of Disclosure Controls and Procedures***

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

Our management, with the participation of our CEO and CFO, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15 and 15d-15 under the Exchange Act) as of September 30, 2016. Based on that evaluation, our CEO and CFO concluded that, as of that date, our disclosure controls and procedures were effective.

***Management's Report on Internal Control Over Financial Reporting***

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

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

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

Management assessed the effectiveness of our internal control over financial reporting as of September 30, 2016. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control—Integrated Framework (2013)*. Management's assessment included an evaluation of the design of the Company's internal control over financial reporting and testing of the operational effectiveness of its internal control over financial reporting. Based on our assessment, we believe that our internal controls over financial reporting were effective as of September 30, 2016.

Management's assessment of internal control over financial reporting, as discussed above, excluded Stratatech Corporation, acquired by the Company in fiscal 2016, which represented less than 1% of our total net sales and approximately 1% of our total assets as of and for the period ended September 30, 2016, respectively. Because management's assessment of internal control over financial reporting included the accounting for goodwill and intangible assets from these acquisitions, the percentage of total assets as of September 30, 2016 that was excluded from management's assessment of internal control over financial reporting was less than 1%.

Our internal control over financial reporting as of September 30, 2016 has been audited by Deloitte & Touche LLP, the independent registered public accounting firm that audited and reported on the consolidated financial statements included in this annual report on Form 10-K. This report is included below.

***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2016 that have materially affected, or are likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Mallinckrodt plc:

We have audited the internal control over financial reporting of Mallinckrodt plc and subsidiaries (the "Company") as of September 30, 2016, based on the criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. As described in Management's Report on Internal Control over Financial Reporting, management excluded from its assessment the internal control over financial reporting at Stratatech Corporation ("Stratatech"), which was acquired on August 31, 2016 and whose financial statements constitute approximately less than 1% of total net sales and approximately 1% of total assets of the consolidated financial statement amounts as of and for the year ended September 30, 2016. Accordingly, our audit did not include the internal control over financial reporting at Stratatech. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2016, based on the criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended September 30, 2016 of the Company and our report dated November 29, 2016 expressed an unqualified opinion on those financial statements and financial statement schedule.

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



**Item 9B. Other Information.**

None

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance.**

Information regarding our directors required under this Item 10. Directors, Executive Officers and Corporate Governance will be included in our definitive proxy statement for our annual general meeting of shareholders, which will be filed with the United States Securities and Exchange Commission within 120 days after September 30, 2016.

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

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

**Item 11. Executive Compensation.**

Information regarding the compensation of our named executive officers and directors required under this Item 11. Executive Compensation will be included in our definitive proxy statement for our annual general meeting of shareholders, which will be filed with the United States Securities and Exchange Commission within 120 days after September 30, 2016.

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

Information regarding individuals or groups which own more than 5% of our ordinary shares, as well as information regarding the security ownership of our executive officers and directors, and other shareholder matters required under this Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters will be included in our definitive proxy statement for our annual general meeting of shareholders, which will be filed with the United States Securities and Exchange Commission within 120 days after September 30, 2016.

	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
	(a) <sup>(1)(2)</sup>	(b) <sup>(3)</sup>	(c) <sup>(4)</sup>
Equity compensation plans approved by security holders	3,556,200	\$71.64	16,613,244
Equity compensation plans not approved by security holders	—	—	—
<b>TOTAL</b>	<b>3,556,200</b>	<b>\$71.64</b>	<b>16,613,244</b>

- (1) As of September 30, 2016, there were 2,422,357 ordinary shares to be issued upon exercise of outstanding options with a weighted-average exercise price of \$71.64, and 1,133,843 ordinary shares to be issued upon settlement of restricted units and performance units granted pursuant to our Stock and Incentive Plan.
- (2) This table does not include information regarding:
- \* Options and restricted units converted from Covidien awards in connection with our separation from Covidien in June 2013. We did not assume any equity compensation plans from Covidien, and no grants of Mallinckrodt equity may be made pursuant to any Covidien plans. As of September 30, 2016, there were 856,871 ordinary shares to be issued upon exercise of these converted options with a weighted-average exercise price of \$37.16 and 26,432 ordinary shares to be issued upon settlement of converted restricted units.
  - \* Options, RSAs and RSUs converted from Questcor awards in connection with our acquisition of Questcor in August 2014. We did not assume any equity compensation plans from Questcor, and no grants of Mallinckrodt equity may be made pursuant to any Questcor plans. As of September 30, 2016, there were 142,705 ordinary shares to be issued upon exercise of these converted options with a weighted-average exercise price of \$28.25 and 17,792 ordinary shares to be issued upon settlement of converted RSA and RSU awards.
- (3) Does not take into account restricted units and performance units, which do not have an exercise price.
- (4) As of September 30, 2016, there were 11,636,864 ordinary shares available for issuance pursuant to our Stock and Incentive Plan and 4,976,380 ordinary shares subject to purchase pursuant to the Mallinckrodt Employee Stock Purchase Plan. Ordinary shares subject to the Mallinckrodt Employee Stock Purchase Plan may be unissued shares or reacquired shares.

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

Information regarding transactions with related parties and director independence required under this Item 13. Certain Relationships and Related Transactions, and Director Independence will be included in our definitive proxy statement for our annual general meeting of shareholders, which will be filed with the United States Securities and Exchange Commission within 120 days after September 30, 2016.

**Item 14. Principal Accounting Fees and Services.**

Information regarding the services provided by and the fees paid to Deloitte & Touche LLP, our independent auditors, required under this Item 14. Principal Accounting Fees and Services will be included in our definitive proxy statement for our annual general meeting of shareholders, which will be filed with the United States Securities and Exchange Commission within 120 days after September 30, 2016.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules.

Documents filed as part of this report:

- 1) *Financial Statements.* The following are included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.
  - Report of Independent Registered Public Accounting Firm
  - Consolidated Statement of Income for the fiscal year ended September 30, 2016, September 25, 2015 and September 26, 2014
  - Consolidated Statement of Comprehensive Income for the fiscal year ended September 30, 2016, September 25, 2015 and September 26, 2014
  - Consolidated Balance Sheets as of September 30, 2016 and September 25, 2015
  - Consolidated Statement of Cash Flows for the fiscal year ended September 30, 2016, September 25, 2015 and September 26, 2014
  - Consolidated Statement of Changes in Shareholders' Equity for the period from September 27, 2013 to September 30, 2016
  - Notes to Consolidated Financial Statements
- 2) *Financial Statement Schedules.* The financial statement schedule is included below. All other schedules have been omitted because they are not applicable, not required or the information is included in the financial statements or notes thereto.

#### Schedule II - Valuation and Qualifying Accounts

(in millions)

Description	Balance at Beginning of Period	Charged to Income	Additions and Other	Deductions	Balance at End of Period
<b>Allowance for doubtful accounts:</b>					
Fiscal year ended September 30, 2016	\$ 3.6	\$ 0.3	\$ —	\$ 0.1	\$ 4.0
Fiscal year ended September 25, 2015	2.2	1.2	—	0.2	3.6
Fiscal year ended September 26, 2014	2.4	—	—	(0.2)	2.2
<b>Sales reserve accounts:</b>					
Fiscal year ended September 30, 2016	\$ 396.4	\$ 2,030.8	\$ —	\$ (2,049.2)	\$ 378.0
Fiscal year ended September 25, 2015	402.2	2,177.4	1.3	(2,184.5)	396.4
Fiscal year ended September 26, 2014	284.2	1,710.6	30.6	(1,623.2)	402.2
<b>Tax valuation allowance:</b>					
Fiscal year ended September 30, 2016	\$ 233.0	\$ 315.7	\$ 15.8	\$ 0.4	\$ 564.9
Fiscal year ended September 25, 2015	76.9	155.4	0.2	0.5	233.0
Fiscal year ended September 26, 2014	28.3	33.9	14.7	—	76.9

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

### Item 16. Form 10-K Summary

None.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### MALLINCKRODT PUBLIC LIMITED COMPANY

November 29, 2016

By:           /s/ Matthew K. Harbaugh          

Matthew K. Harbaugh  
*Executive Vice President and Chief Financial Officer*  
*(principal financial officer)*

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>          /s/ Mark C. Trudeau          </u> Mark C. Trudeau	President, Chief Executive Officer and Director <i>(principal executive officer)</i>	November 29, 2016
<u>          /s/ Matthew K. Harbaugh          </u> Matthew K. Harbaugh	Executive Vice President and Chief Financial Officer <i>(principal financial officer)</i>	November 29, 2016
<u>          /s/ Kathleen A. Schaefer          </u> Kathleen A. Schaefer	Senior Vice President and Corporate Controller <i>(principal accounting officer)</i>	November 29, 2016
<u>          *          </u> Melvin D. Booth	Chairman of the Board of Directors	November 29, 2016
<u>          *          </u> David R. Carlucci	Director	November 29, 2016
<u>          *          </u> J. Martin Carroll	Director	November 29, 2016
<u>          *          </u> Diane H. Gulyas	Director	November 29, 2016
<u>          *          </u> JoAnn A. Reed	Director	November 29, 2016
<u>          *          </u> Angus C. Russell	Director	November 29, 2016
<u>          *          </u> Virgil D. Thompson	Director	November 29, 2016
<u>          *          </u> Kneeland C. Youngblood, M.D.	Director	November 29, 2016
<u>          *          </u> Joseph A. Zaccagnino	Director	November 29, 2016

\* Kenneth L. Wagner, by signing his name hereto, does sign this document on behalf of the above noted individuals, pursuant to powers of attorney duly executed by such individuals which have been filed as an Exhibit to this Annual Report on Form 10-K.

          /s/ Kenneth L. Wagner          

Kenneth L. Wagner, Attorney-in-fact

## EXHIBIT INDEX

<b>Exhibit Number</b>	<b>Exhibit</b>
2.1	Separation and Distribution Agreement between Covidien plc and Mallinckrodt plc, dated June 28, 2013 (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed July 1, 2013).
2.2	Agreement and Plan of Merger, dated as of February 10, 2014, by and among Mallinckrodt plc, Madison Merger Sub, Inc. and Cadence Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed February 11, 2014).
2.3	Agreement and Plan of Merger, dated as of April 5, 2014, by and among Mallinckrodt plc, Quincy merger Sub, Inc. and Questcor Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed April 7, 2014).
2.4	Stock Purchase Agreement, dated March 5, 2015, by and among Compound Holdings I, LLC, Compound Holdings II, Inc., Mallinckrodt Enterprises LLC and Mallinckrodt plc (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed March 5, 2015).
2.5	Stock Purchase Agreement, dated as of July 27, 2015, by and between Mallinckrodt Group S.à r.l., Mallinckrodt U.S. Holdings Inc., Mallinckrodt Netherlands Holdings B.V., Mallinckrodt Finance GmbH, Ludlow Corporation, Mallinckrodt Holdings GmbH, Mallinckrodt International Finance S.A. and Guerbet S.A. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed July 28, 2015).
2.6	First Amendment to Stock Purchase Agreement, dated as of November 27, 2015, by and between Mallinckrodt Group S.à r.l., Mallinckrodt U.S. Holdings Inc., Mallinckrodt Netherlands Holdings B.V., Mallinckrodt Finance GmbH, Ludlow Corporation, Mallinckrodt Holdings GmbH, Mallinckrodt International Finance S.A. and Guerbet S.A. (incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K filed November 27, 2015).
2.7	Stock Purchase Agreement, dated August 9, 2015, by and among TGG Medical Holdings, LLC, TGG Medical Solutions, Inc., Mallinckrodt Enterprises LLC and Mallinckrodt plc (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed August 10, 2015).
2.8	Share Purchase Agreement, dated as of August 24, 2016, by and among Mallinckrodt Chemical Holdings (U.K.) Limited, Mallinckrodt Netherlands Holdings B.V., GLO Dutch Bidco B.V. and GLO US Bidco, LLC (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed August 24, 2016).
3.1	Certificate of Incorporation of Mallinckrodt plc (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed July 1, 2013).
3.2	Amended and Restated Memorandum and Articles of Association of Mallinckrodt plc (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed July 1, 2013).
4.1	Indenture, dated as of April 11, 2013, by and among Mallinckrodt International Finance S.A., Covidien International Finance S.A. and Deutsche Bank Trust Company Americas, as trustee (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed July 1, 2013).
4.2	Supplemental Indenture, dated as of June 28, 2013, by and among Mallinckrodt plc, Mallinckrodt International Finance S.A. and Deutsche Bank Trust Company Americas, as trustee (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed July 1, 2013).
4.3	Indenture, dated as of August 13, 2014, among Mallinckrodt International Finance, S.A., Mallinckrodt CB LLC, the Guarantors party thereto from time to time and Deutsche Bank Trust Company Americas, as trustee (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed August 14, 2014).
4.4	Indenture, dated as of April 15, 2015, among Mallinckrodt International Finance S.A., Mallinckrodt CB LLC, the Guarantors party thereto from time to time and Deutsche Bank Trust Company Americas, as trustee (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed April 17, 2015).
4.5	Indenture, dated as of September 24, 2015, among Mallinckrodt International Finance S.A., Mallinckrodt CB LLC, the Guarantors party thereto from time to time and Deutsche Bank Trust Company Americas, as trustee (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed September 28, 2015).
10.1	Tax Matters Agreement between Covidien plc and Mallinckrodt plc, dated June 28, 2013 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 1, 2013).
10.2	Employee Matters Agreement between Covidien plc and Mallinckrodt plc, dated June 28, 2013 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 1, 2013).
10.3	Transition Services Agreement between Covidien plc and Mallinckrodt plc, dated June 28, 2013 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed July 1, 2013).
10.4	Credit Agreement, dated as of March 19, 2014, among Mallinckrodt plc, Mallinckrodt International Finance S.A., Mallinckrodt CB LLC, the lenders party thereto from time to time and Deutsche Bank AG New York Branch, as Administrative Agent (incorporated herein by reference to Exhibit (b)(3) of the Schedule TO/A filed by Mallinckrodt plc and Madison Merger Sub, Inc. on March 19, 2014).

- 10.5 Incremental Assumption Agreement No. 1, dated as of August 14, 2014, among Mallinckrodt International Finance, S.A., Mallinckrodt CB LLC, the subsidiaries of MIFSA party thereto and Deutsche Bank AG New York Branch, as administrative agent, as acknowledged by and consented to by Mallinckrodt plc and Mallinckrodt Quincy S.à r.l. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 14, 2014).
- 10.6 Refinancing Amendment No. 1 and Incremental Assumption Agreement No. 2, dated as of August 28, 2015, among Mallinckrodt plc, Mallinckrodt International Finance, S.A., Mallinckrodt CB LLC, the other subsidiaries of Mallinckrodt plc party thereto, the lenders party thereto and Deutsche Bank AG New York Branch, as administrative agent (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 28, 2015).
- 10.7 Letter Agreement dated September 30, 2016 between Mallinckrodt International Finance, S.A. and Deutsche Bank AG New York Branch, as administrative agent.
- 10.8 Note Purchase Agreement, dated as of July 28, 2014, among Mallinckrodt Securitization S.À R.L., the persons from time to time party thereto as purchasers, PNC Bank, National Association, as administrative agent, and Mallinckrodt LLC, as initial servicer (incorporated by reference to Exhibit 10.1 to the Company's Current Report filed July 30, 2014).
- 10.9 First Amendment to the Note Purchase Agreement, dated as of January 20, 2015, among Mallinckrodt Securitization S.A R.L., the persons from time to time party thereto as purchasers, PNC Bank, National Association, as administrative agent, and Mallinckrodt LLC, as initial servicer (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 27, 2015).
- 10.10 Purchase and Sale Agreement, dated as of July 28, 2014, among the various entities party thereto from time to time as originators, Mallinckrodt LLC, as initial servicer, and Mallinckrodt Securitization S.A R.L., as buyer (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 30, 2014).
- 10.11 First Amendment to the Purchase and Sale Agreement, dated as of January 20, 2015, among the various entities party thereto from time to time as originators, Mallinckrodt LLC, as initial servicer, and Mallinckrodt Securitization S.A R.L., as buyer (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 27, 2015).
- 10.12 Sale Agreement, dated as of July 28, 2014, between Liebel-Flarsheim Company LLC and Mallinckrodt LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed July 30, 2014).
- 10.13 Performance Guaranty, dated as of January 20, 2015, by Mallinckrodt International Finance S.A. in favor of PNC Bank, National Association, as administrative agent (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 27, 2015).
- 10.14 Incremental Assumption Agreement No. 1, dated as of August 14, 2014, among Mallinckrodt International Finance, S.A., Mallinckrodt CB LLC, the subsidiaries of MIFSA party thereto and Deutsche Bank AG New York Branch, as administrative agent, as acknowledged by and consented to by Mallinckrodt plc and Mallinckrodt Quincy S.à r.l. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 14, 2014).
- 10.15 Form of Deed of Indemnification by and between Mallinckrodt plc and Directors and Secretary (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed July 1, 2013).
- 10.16 Form of Indemnification Agreement by and between Mallinckrodt Brand Pharmaceuticals, Inc. and Directors and Secretary (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed July 1, 2013).
- 10.17 IV APAP Agreement (U.S. and Canada), dated as of February 21, 2006, by and between Cadence Pharmaceuticals, Inc. and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.11 to Amendment No. 2 of Cadence Pharmaceuticals, Inc.'s Registration Statement on Form S-1 filed September 25, 2006).
- 10.18 License Agreement, dated as of December 23, 2002, by and among SCR Pharmatop and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.12 to Amendment No. 2 of Cadence Pharmaceuticals, Inc.'s Registration Statement on Form S-1 filed September 25, 2006).
- 10.19\* Mallinckrodt Pharmaceuticals Severance Plan for U.S. Officers and Executives dated May 1, 2014 (incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K for the year ended September 26, 2014).
- 10.20\* Mallinckrodt Pharmaceuticals Change in Control Severance Plan for Certain U.S. Officers and Executives dated as of May 1, 2014 (incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K for the year ended September 26, 2014).
- 10.21\* Mallinckrodt Pharmaceuticals Stock and Incentive Plan (incorporated by reference to Exhibit 10.10 to the Company's Amendment No. 3 to Registration Statement on Form 10 filed on May 31, 2013).
- 10.22\* Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Restricted Unit Award for Chief Executive Officer (incorporated by reference to Exhibit 10.8 to the Company's Current Report on Form 8-K filed July 1, 2013).
- 10.23\* Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Restricted Unit Award (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed May 8, 2014).

- 10.24\* Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Option Award (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed May 8, 2014).
- 10.25\* Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Performance Unit Award FY14-FY16 Performance Cycle (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed May 8, 2014).
- 10.26\* Mallinckrodt Pharmaceuticals Stock and Incentive Plan (incorporated by reference to Appendix B to the Company's Proxy Statement filed on January 23, 2015).
- 10.27\* Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Restricted Unit Award to Non-Employee Directors (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 27, 2015).
- 10.28\* Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Restricted Unit Award (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 25, 2016).
- 10.29\* Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Restricted Unit Award (Cash Bonus for Stock Exchange - Bonus Exchange) (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 25, 2016).
- 10.30\* Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Restricted Unit Award (Cash Bonus for Stock Exchange - Match Amounts) (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 25, 2016).
- 10.31\* Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Option Award (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 25, 2016).
- 10.32\* Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Performance Unit Award FY16-FY18 Performance Cycle (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 25, 2016).
- 10.33\* Letter Agreement dated as of August 27, 2013 by and between Mallinckrodt LLC and Frank Scholz (incorporated by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K for the year ended September 26, 2014).
- 21.1 Subsidiaries of Mallinckrodt plc.
- 23.1 Consent of Deloitte & Touche LLP.
- 24.1 Powers of Attorney
- 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
- 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
- 32.1 Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101 The following materials from the Mallinckrodt plc Annual Report on Form 10-K for the fiscal year ended September 30, 2016 formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Statements of Income, (ii) the Consolidated Statements of Comprehensive Income, (iii) the Consolidated Balance Sheets, (iv) the Consolidated Statements of Cash Flows, (v) the Consolidated Statements of Shareholders' Equity and (vi) related notes.

\*Compensation plans or arrangements.

The agreements and other documents filed as exhibits to this report are not intended to provide factual information or other disclosure other than with respect to the terms of the agreements or other documents themselves, and you should not rely on them for that purpose. In particular, any representations and warranties made by us in these agreements or other documents were made solely within the specific context of the relevant agreement or document and may not describe the actual state of affairs as of the date they were made or at any other time.

MALLINCKRODT INTERNATIONAL FINANCE S.A.  
675 McDonnell Boulevard  
Hazelwood, MO 63042

September 30, 2016

Deutsche Bank AG New York Branch, as Administrative Agent  
60 Wall Street  
New York, NY 10005

Reference is made to that certain Credit Agreement, dated as of March 19, 2014 (as amended, supplemented, restated or otherwise modified from time to time, the "Credit Agreement"), by and among Mallinckrodt PLC, a public limited company incorporated in Ireland ("Parent"), Mallinckrodt International Finance S.A., a public limited liability company (*société anonyme*) incorporated under the laws of the Grand Duchy of Luxembourg (the "Lux Borrower"), Mallinckrodt CB LLC, a Delaware limited liability company (the "Co-Borrower"), the Lenders and Issuing Banks from time to time party thereto and Deutsche Bank AG New York Branch, as administrative agent (in such capacity, the "Administrative Agent"). All capitalized terms used herein (this "Agreement") and not otherwise defined herein shall have the meanings ascribed thereto in the Credit Agreement.

The Lux Borrower hereby gives notice that, beginning with the Parent's 2017 fiscal year, which will begin on December 31, 2016 and end on December 29, 2017 (the "2017 Fiscal Year"), the fiscal year of the Parent shall end on the last Friday in December of each calendar year. Pursuant to Section 6.11 of the Credit Agreement, each of the Lux Borrower and the Administrative Agent hereby acknowledge and agree that, beginning with the 2017 Fiscal Year, for all purposes of the Credit Agreement and each other Loan Document, any reference in the Credit Agreement or any other Loan Document to the "fiscal year" of the Parent shall mean any period ending on the last Friday in December of the applicable calendar year and beginning on the day immediately following the last Friday in December of the preceding calendar year. As a result of the foregoing: (a) in satisfaction of the obligations of the Parent and the Borrowers under Sections 5.04(a) and 5.04(b) of the Credit Agreement with respect to (x) the period beginning on September 26, 2015 and ending on September 30, 2016 (the "Existing 2016 Fiscal Year") and (y) the period beginning on October 1, 2016 and ending on December 30, 2016 (the "Transition Period"), the Parent and the Borrowers shall deliver (i) the financial statements and related information required by Section 5.04(a) of the Credit Agreement for the Existing 2016 Fiscal Year within 90 days after the end of the Existing 2016 Fiscal Year, (ii) the financial statements and related information required by Section 5.04(b) of the Credit Agreement (which financial statements and related information may, but are not required to, take the form of a transition report on Form 10-Q of the Parent and its consolidated Subsidiaries instead of the forms specified in Section 5.04(b) of the Credit Agreement) for the Transition Period within 45 days after the end of the Transition Period and (iii) concurrently with the delivery of financial statements under and in accordance with Section 5.04(a) of the Credit Agreement for the 2017 Fiscal Year, an opinion of independent public accountants of recognized national standing pertaining to financial statements for a period including the Transition Period and otherwise complying with the requirements of Section 5.04(a) of the Credit Agreement with respect to such an opinion; (b) the certificate of the applicable accounting firm required by Section 5.04(c)(y) of the Credit Agreement shall be delivered (i) with respect to the financial statements for the Existing 2016 Fiscal Year, concurrently with the financial statements described in clause (a)(i) hereof, (ii) with respect to the financial statements for the Transition Period, concurrently with the opinion described in clause (a)(iii) hereof and (iii) with respect to any subsequent fiscal year, in accordance with the requirements of such Section; (c) the Parent and the Borrowers shall deliver a Budget (i) for the 2017 Fiscal Year pursuant to Section 5.04(e) of the Credit Agreement within 90 days after the beginning of the 2017 Fiscal Year and shall not be required to deliver a Budget for the Transition Period or otherwise prior to such date under Section 5.04(e) of the Credit Agreement and (ii) for any subsequent fiscal year, in accordance with the requirements of Section 5.04(e) of the Credit Agreement; (d) the Parent and the Borrowers shall deliver an updated Perfection Certificate pursuant to Section 5.04(f) of the Credit Agreement (i) concurrently with the financial statements described in clause (a)(ii) hereof and shall not be required to do so with respect to the financial statements described in clause (a)(i) hereof and (ii) for any subsequent fiscal year, in accordance with the requirements of such Section; and (e) (i) the Excess Cash Flow Period that commenced on October 1, 2015 shall consist of both the Existing 2016 Fiscal Year and the Transition Period and shall end on December 30, 2016, (ii) the certificate and mandatory prepayment, if any, required by Section 2.11(c) of the Credit Agreement with respect to such Excess Cash Flow Period shall be delivered and/or paid (as applicable) no later than 5 Business Days following the date on which the financial statements described in clause (a)(ii) hereof are, or are required to be, delivered (and shall not be required to be delivered and/or paid (as applicable) at any time prior thereto), (iii) with respect to such Excess Cash Flow Period only, an Excess Cash Flow Interim Period may be a four-quarter period otherwise



satisfying the definition thereof and (iv) each subsequent Excess Cash Flow Period shall consist of the corresponding fiscal year of the Parent.

This Agreement shall not constitute an amendment or waiver of or consent to any provision of the Credit Agreement and the other Loan Documents except as expressly stated herein and shall not be construed as an amendment, waiver or consent to any action on the part of the Loan Parties that would require an amendment, waiver or consent of the Administrative Agent or the Lenders except as expressly stated herein. Except as expressly waived hereby, the provisions of the Credit Agreement and the other Loan Documents are and shall remain in full force and effect in accordance with their terms. This Agreement shall constitute a "Loan Document" for all purposes of the Credit Agreement and the other Loan Documents.

This Agreement may be executed in any number of separate counterparts by the parties hereto (including by telecopy or via electronic mail), each of which counterparts when so executed shall be an original, but all the counterparts shall together constitute one and the same instrument.

THIS AGREEMENT AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSES OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS AGREEMENT SHALL BE CONSTRUED IN ACCORDANCE WITH AND GOVERNED BY THE LAWS OF THE STATE OF NEW YORK.

On and after the date hereof, each reference in the Credit Agreement to "this Agreement," "hereunder," "hereof" or words of like import referring to the Credit Agreement, and each reference in the Notes and each of the other Loan Documents to "the Credit Agreement," "thereunder," "thereof" or words of like import referring to the Credit Agreement, shall mean and be a reference to the Credit Agreement, as amended by this Agreement.

IN WITNESS WHEREOF, as of the date first above written, each of the undersigned has executed this Letter Agreement.

MALLINCKRODT INTERNATIONAL FINANCE S.A.

/s/ John Einwalter

By: \_\_\_\_\_

Name: John Einwalter

Title: Vice President & Treasurer

## SUBSIDIARIES OF MALLINCKRODT PLC

Name of Subsidiary	Jurisdiction of Formation
101610 P.E.I., Inc.	Prince Edward Island
Acthar IP	Ireland
BioVectra Inc.	Prince Edward Island
Cache Holdings Limited	Bermuda
Carnforth Limited	Bermuda
CNS Therapeutics, Inc.	Delaware
Dritte CORSA Verwaltungsgesellschaft GmbH	Germany
DT Merger Sub, Inc.	Delaware
Enterprises Holdings, Inc.	Delaware
Ikaria Australia Pty Ltd	Australia
Ikaria Canada Inc.	Canada
Ikaria Japan K.K.	Japan
IMC Exploration Company	Maryland
INO Therapeutics LLC	Delaware
Ludlow Corporation	Massachusetts
Mallinckrodt APAP LLC	Delaware
Mallinckrodt ARD Finance, Inc.	Delaware
Mallinckrodt ARD Holdings Inc.	Delaware
Mallinckrodt ARD Holdings Limited	United Kingdom
Mallinckrodt ARD Inc.	California
Mallinckrodt ARD IP Limited	Ireland
Mallinckrodt Belgium BVBA	Belgium
Mallinckrodt Brand Pharmaceuticals, Inc.	Delaware
Mallinckrodt Buckingham	Ireland
Mallinckrodt Canada Cooperatie U.A.	Netherlands
Mallinckrodt Canada ULC	Alberta
Mallinckrodt CB LLC	Delaware
Mallinckrodt Chemical Holdings (U.K.) Ltd.	United Kingdom
Mallinckrodt Chemical Limited	United Kingdom
Mallinckrodt Critical Care Finance Inc.	Delaware
Mallinckrodt Enterprises Holdings, Inc.	California
Mallinckrodt Enterprises LLC	Delaware
Mallinckrodt Enterprises UK Limited	United Kingdom
Mallinckrodt Equinox Limited	United Kingdom
Mallinckrodt Finance GmbH	Switzerland
Mallinckrodt Finance Management Ireland Limited	Ireland
Mallinckrodt France Sarl	France
Mallinckrodt Group Sarl	Luxembourg
Mallinckrodt Group Sarl, Luxembourg (LU) Schaffhausen Branch	Switzerland
Mallinckrodt Holdings GmbH	Switzerland
Mallinckrodt Hospital Products Inc.	Delaware
Mallinckrodt Hospital Products IP Limited	Ireland
Mallinckrodt Inc.	Delaware
Mallinckrodt International Finance SA	Luxembourg
Mallinckrodt International Holdings S.a r.l.	Luxembourg
Mallinckrodt IP	Ireland
Mallinckrodt Japan Co. Ltd	Japan
Mallinckrodt LLC	Delaware

Mallinckrodt Lux IP S.a r.l.	Luxembourg
Mallinckrodt Manufacturing LLC	Delaware
Mallinckrodt Medical B.V.	Netherlands
Mallinckrodt Medical Holdings (UK) Limited	United Kingdom
Mallinckrodt MFC LLC	Delaware
Mallinckrodt Nederland B.V.	Netherlands
Mallinckrodt Netherlands Holdings B.V. (Finland Branch)	Finland
Mallinckrodt Netherlands Holdings B.V. Holland (Denmark Branch)	Denmark
Mallinckrodt Netherlands Holdings B.V., organizační složka	Czech Republic
Mallinckrodt Netherlands Holdings BV	Netherlands
Mallinckrodt Nuclear LLC	Delaware
Mallinckrodt Nuclear Medicine LLC	Delaware
Mallinckrodt PEI Inc	Quebec
Mallinckrodt Petten Holdings B.V.	Netherlands
Mallinckrodt Pharma IP Trading D.A.C.	Ireland
Mallinckrodt Pharmaceuticals India Private Limited	India
Mallinckrodt Pharmaceuticals Ireland Limited	Ireland
Mallinckrodt Pharmaceuticals Limited	United Kingdom
Mallinckrodt plc	Ireland
Mallinckrodt Quincy S.a r.l.	Luxembourg
Mallinckrodt Radioisotopes B.V.	Netherlands
Mallinckrodt Radiopharmaceuticals Deutschland GmbH	Germany
Mallinckrodt Radiopharmaceuticals Italia SpA	Italy
Mallinckrodt Radiopharmaceuticals Spain SL	Spain
Mallinckrodt Radiopharmaceuticals Sverige AB	Sweden
Mallinckrodt RP Canada Inc.	Ontario
Mallinckrodt RP UK Ltd	United Kingdom
Mallinckrodt Securitization Sarl	Luxembourg
Mallinckrodt Specialty Pharmaceuticals Ireland Limited	Ireland
Mallinckrodt Switzerland Limited	Switzerland
Mallinckrodt UK Finance LLP	United Kingdom
Mallinckrodt UK Ltd	United Kingdom
Mallinckrodt US Holdings Inc.	Nevada
Mallinckrodt US Holdings LLC	Delaware
Mallinckrodt US Pool LLC	Nevada
Mallinckrodt Veterinary, Inc.	Delaware
Mallinckrodt Windsor Ireland Finance	Ireland
Mallinckrodt Windsor Sarl	Luxembourg
MEH, Inc.	Nevada
MHP Finance, Inc.	Delaware
MKG Medical UK Ltd	United Kingdom
Montjeu Limited	Ireland
MUSHI UK Holdings Limited	United Kingdom
Phoenixglade Limited	Ireland
Profibrix B.V.	Netherlands
Questcor International Ltd.	Ireland
Representative Office of private limited liability company Mallinckrodt Netherlands Holdings B.V.	Russia
Roogen, Inc.	Delaware
Stratatech Corporation	Delaware
Therakos (Belgium) SPRL	Belgium
Therakos (Canada) Company	Canada
Therakos (France) SAS	France
Therakos (Italia) S.r.l	Italy
Therakos (UK), Limited Dutch Branch	Netherlands

Therakos (UK), Limited, Sucursal en Espana	Spain
Therakos (UK), Ltd	United Kingdom
Therakos (UK), Ltd Sweden Filial	Sweden
Therakos Germany GmbH	Germany
Therakos, Inc.	Florida
Viking Project Company, LLC	Delaware

<b>Name of Subsidiary</b>	<b>Jurisdiction of Formation</b>
Mallinckrodt Switzerland Limited	Switzerland
Mallinckrodt ARD Holdings Limited (FKA MIFSA UK Limited)	UK
Mallinckrodt Chemical Holdings (UK) Ltd.	UK
Mallinckrodt Chemical Limited	UK
Mallinckrodt Enterprises UK Limited	UK
Mallinckrodt Medical Argentina Ltd.	UK
Mallinckrodt Medical Holdings (UK) Limited	UK
Mallinckrodt UK Commercial Ltd	UK
Mallinckrodt UK Ltd	UK
MKG Medical UK Ltd	UK
MUSHI UK Holdings Limited	UK
BioVectra, Inc. USA	North Carolina
Cadence Pharmaceuticals, Inc.	Delaware
CNS Therapeutics, Inc.	Delaware
Enterprises Holdings, Inc.	Delaware
IMC Exploration Company	Maryland
Lafayette Pharmaceuticals LLC	Delaware
Ludlow Corporation	Massachusetts
Mallinckrodt APAP LLC	Delaware
Mallinckrodt ARD Holdings Inc.	Delaware
Mallinckrodt Brand Pharmaceuticals, Inc. (DE)	Delaware
Mallinckrodt CB LLC	Delaware
Mallinckrodt Enterprises Holdings, Inc.	California
Mallinckrodt Enterprises LLC	Delaware
Mallinckrodt Inc. (DE)	Delaware
Mallinckrodt LLC	Delaware
Mallinckrodt MFC LLC	Delaware
Mallinckrodt Nuclear LLC	Delaware
Mallinckrodt Nuclear Medicine LLC	Delaware
Mallinckrodt US Holdings, Inc. (FKA Kendall Holding Corp.)	Nevada
Mallinckrodt US Holdings LLC	Delaware
Mallinckrodt US Pool LLC	Nevada
Mallinckrodt Veterinary, Inc.	Delaware
MEH, Inc.	Nevada
Questcor Pharmaceuticals Inc.	California
Ribogene, Inc.	Delaware
Viking Project Company, LLC	Delaware

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-189711, 333-189712, 333-189716, 333-196054, 333-203912 and 333-211117 on Form S-8 of our reports dated November 29, 2016, relating to the consolidated financial statements and financial statement schedule of Mallinckrodt plc, and the effectiveness of Mallinckrodt plc's internal control over financial reporting, appearing in this Annual Report on Form 10-K of Mallinckrodt plc for the fiscal year ended September 30, 2016.

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

## POWER OF ATTORNEY

We, the undersigned officers and directors of Mallinckrodt plc, hereby severally constitute and appoint Kenneth L. Wagner to sign for us and in our names in the capacities indicated below, any and all amendments to the report on Form 10-K filed herewith, and to file the same, with all exhibits thereto and other documents in connection therewith, in each case, with the Securities and Exchange Commission, and generally to do all such things in our names and on our behalf in our capacities consistent with the provisions of the Securities Act of 1934, as amended, and all requirements of the Securities and Exchange Commission.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ Mark C. Trudeau</u> Mark C. Trudeau	President, Chief Executive Officer and Director <i>(principal executive officer)</i>	November 29, 2016
<u>/s/ Matthew K. Harbaugh</u> Matthew K. Harbaugh	Senior Vice President and Chief Financial Officer <i>(principal financial officer)</i>	November 29, 2016
<u>/s/ Kathleen A. Schaefer</u> Kathleen A. Schaefer	Vice President Controller <i>(principal accounting officer)</i>	November 29, 2016
<u>/s/ Melvin D. Booth</u> Melvin D. Booth	Chairman of the Board of Directors	November 29, 2016
<u>/s/ Don M. Bailey</u> Don M. Bailey	Director	November 29, 2016
<u>/s/ David R. Carlucci</u> David R. Carlucci	Director	November 29, 2016
<u>/s/ J. Martin Carroll</u> J. Martin Carroll	Director	November 29, 2016
<u>/s/ Diane H. Gulyas</u> Diane H. Gulyas	Director	November 29, 2016
<u>/s/ Nancy S. Lurker</u> Nancy S. Lurker	Director	November 29, 2016
<u>/s/ JoAnn A. Reed</u> JoAnn A. Reed	Director	November 29, 2016
<u>/s/ Angus C. Russell</u> Angus C. Russell	Director	November 29, 2016
<u>/s/ Virgil D. Thompson</u> Virgil D. Thompson	Director	November 29, 2016
<u>/s/ Kneeland C. Youngblood</u> Kneeland C. Youngblood	Director	November 29, 2016
<u>/s/ Joseph A. Zaccagnino</u> Joseph A. Zaccagnino	Director	November 29, 2016

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO RULE 13A-14(A) OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Mark C. Trudeau, certify that:

1. I have reviewed this annual report on Form 10-K of Mallinckrodt plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in the Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 29, 2016

By: /s/ Mark C. Trudeau

**Mark C. Trudeau**  
*President and Chief Executive Officer and  
Director*  
*(principal executive officer)*

**CERTIFICATION OF CHIEF FINANCIAL OFFICER  
PURSUANT TO RULE 13A-14(A) OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Matthew K. Harbaugh, certify that:

1. I have reviewed this annual report on Form 10-K of Mallinckrodt plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in the Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 29, 2016

By: /s/ Matthew K. Harbaugh

**Matthew K. Harbaugh**

*Executive Vice President and Chief Financial  
Officer  
(principal financial officer)*



**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

The undersigned officers of Mallinckrodt plc ("the Company") hereby certify to their knowledge that the Company's annual report on Form 10-K for the annual period ended September 30, 2016 ("the Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**By: /s/ Mark C. Trudeau**

**Mark C. Trudeau**

*President and Chief Executive Officer and  
Director*

November 29, 2016

**By: /s/ Matthew K. Harbaugh**

**Matthew K. Harbaugh**

*Executive Vice President and Chief Financial  
Officer*

November 29, 2016