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 December 29, 2017

or

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

For the transition period from _____ to _____

Commission File Number : 001-35803

Mallinckrodt public limited company

(Exact name of registrant as specified in its charter)

Ireland	**98-1088325**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

3 Lotus Park, The Causeway, Staines-Upon-Thames,
Surrey TW18 3AG, United Kingdom
(Address of principal executive offices) (Zip Code)
Telephone: +44 017 8463 6700
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Ordinary shares, par value $0.20 per share	New York Stock Exchange

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act

Large accelerated filer	☒	Accelerated filer	☐	Non-accelerated filer	☐	Smaller reporting company	☐	Emerging growth company	☐

(Do not check if smaller reporting company)

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 June 30, 2017, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $4,352.8 million (based upon the closing price of $44.81 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 February 23, 2018 was 86,350,357.

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 December 29, 2017, are incorporated by reference into Part III of this report.

MALLINCKRODT PLC
INDEX TO FORM 10-K

Presentation of Information

Unless the context requires otherwise, references to "Mallinckrodt plc," "Mallinckrodt," "we," "us," "our" and "the Company" refer to Mallinckrodt plc, an Irish public limited company, and its consolidated subsidiaries for periods subsequent to its separation from Covidien plc on June 28, 2013. For periods prior to June 28, 2013, these terms refer to the combined historical business and operations of Covidien plc's Pharmaceuticals business as it was historically managed as part of Covidien plc. Unless the context requires otherwise, references to "Covidien" refer to 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 specialty pharmaceutical products and therapies. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; analgesics and gastrointestinal products.

In the past few years, we have executed on Mallinckrodt's ongoing transformation to become an innovation-driven specialty pharmaceuticals growth company through a series of strategic acquisitions and divestitures, developing strong commercial platforms and an increasingly robust pipeline. In doing so, our emphasis has evolved to focus on a development portfolio of treatments for severe and critically ill infants and adults.

Through December 29, 2017, we operated our business in two reportable segments, which are further described below:

- *Specialty Brands* includes branded medicines; and
- *Specialty Generics* includes specialty generic drugs, active pharmaceutical ingredients ("APIs") and external manufacturing.

We completed the sale of our Nuclear Imaging ("Nuclear") business and our contrast media and delivery systems ("CMDS") business on January 27, 2017 and November 27, 2015, respectively. As a result, prior year balances have been recast to present the financial results of these businesses as discontinued operations.

In January 2018, we announced that we entered into a definitive agreement to sell our RECOTHROM® Thrombin topical (Recombinant) ("Recothrom") and PreveLeak™ Surgical Sealant ("PreveLeak") assets to Baxter International, Inc. In February 2018, we acquired Sucampo Pharmaceuticals, Inc., including AMITIZA® (lubiprostone), a leading global product in the branded gastrointestinal market.

To further execute upon our strategic vision, on February 22, 2018, our Board of Directors provided authorization to dispose of three areas of our business, which are referred to collectively as "the Specialty Generics Disposal Group" and include the following: (1) Our Specialty Generics business comprised of our Specialty Generics segment, with the exception of our external manufacturing operations; (2) certain of our non-promoted brands business, which is currently reflected in our Specialty Brands segment; and (3) our ongoing, post-divestiture supply agreement with the acquirer of the CMDS business, which is currently reflected in our Other non-operating segment. Given our shift in focus to patients with severe and critical conditions, the areas within the Specialty Generics Disposal Group no longer align with our strategic vision, as such, beginning in the first quarter of fiscal 2018, the historical financial results attributable to the Specialty Generics Disposal Group will be reflected in our consolidated financial statements as discontinued operations.

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

Fiscal Year

We historically reported our results based on a "52-53 week" year ending on the last Friday of September. On May 17, 2016, our Board of Directors approved a change in our fiscal year end to the last Friday in December from the last Friday in September. The change in fiscal year became effective for our 2017 fiscal year, which began on December 31, 2016 and ended on December 29, 2017. As a result of the change in fiscal year end, we filed a Transition Report on Form 10-Q on February 7, 2017 covering the period from October 1, 2016 through December 30, 2016 ("the three months ended December 30, 2016") with the comparable period from September 26, 2015 through December 25, 2015 ("the three months ended December 25, 2015"). Fiscal 2016 covers the period from September 26, 2015 through September 30, 2016.

History and Development

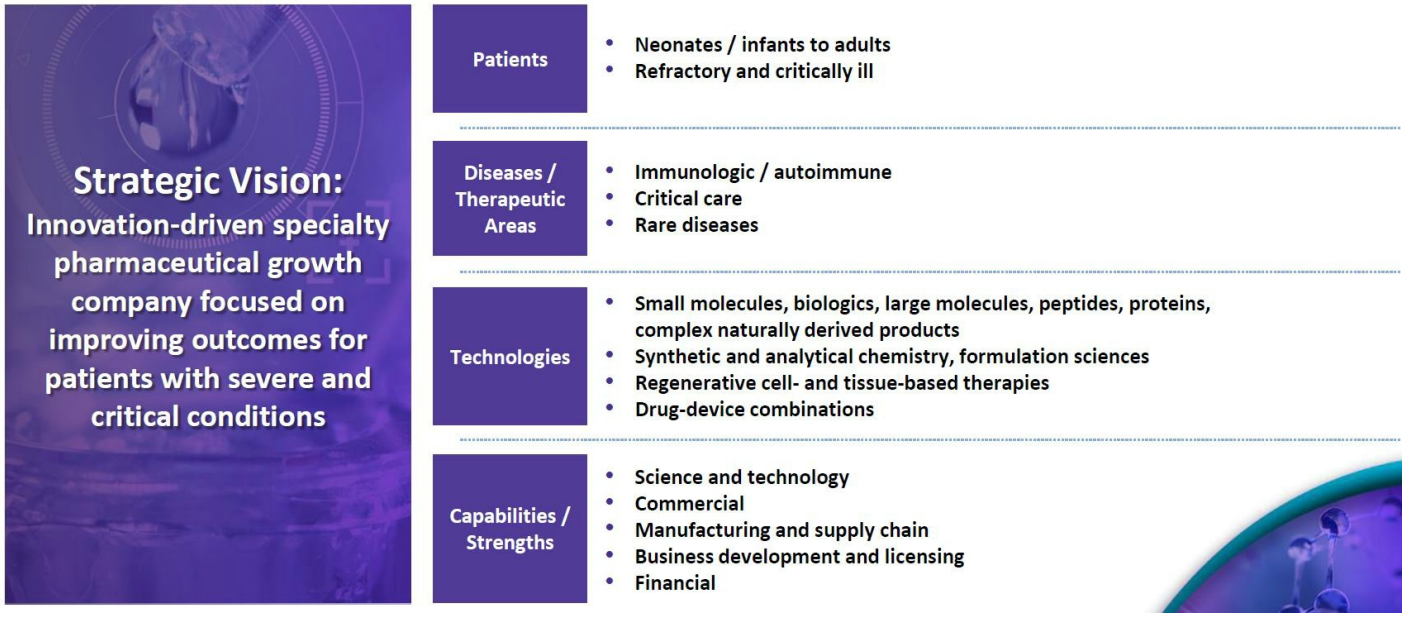
Our development can be traced to the founding of G. Mallinckrodt & Co. in 1867 (predecessor of today's API business). Over the past 150 years, Mallinckrodt has grown to become a global leader in specialty pharmaceuticals on a quest to improve the lives of patients around the world.

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").

In May 2015, our Board of Directors approved the migration of our principal executive offices to the United Kingdom ("U.K."), which is located at Three Lotus Park, The Causeway, Staines-upon-Thames, Surrey, TW18 3 AG. In addition, we have other locations in the United States ("U.S."), most notably our corporate shared services office in Hazelwood, Missouri, our Specialty Brands commercial headquarters in Bedminster, New Jersey and our Specialty Generics headquarters and technical development center in Webster Groves, Missouri.

Our Strategic Vision

Our Mission: Managing complexity. Improving lives. With this as our guide, our strategic vision is clear:



While we have set forth our strategic vision above, our business involves numerous risks and uncertainties which may prevent us from executing our strategies. 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 Products

Through December 29, 2017 and prior to the announcement of our plan to divest the Specialty Generics Disposal Group we managed 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 21 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 disease in the specialty areas of neurology, rheumatology, nephrology, ophthalmology and pulmonology; immunotherapy and neonatal respiratory critical care therapies, analgesics and gastrointestinal products. Our diversified, in-line portfolio of both marketed and development products is focused on patients with significant unmet medical needs. In the past few years, we have significantly expanded our Specialty Brands portfolio through our business development and licensing transactions as detailed below:

Product	Transaction Date	Product Status
Ofirmev®	March 2014	Marketed
H.P. Acthar® Gel	August 2014	Marketed
Inomax®	April 2015	Marketed
Therakos®	September 2015	Marketed
StrataGraft®	August 2016	In development
Stannsoporfin	September 2017	In development
Xenon gas for inhalation	October 2017	In development
MNK-6105 (previously OCR-002)	December 2017	In development
Amitiza® [(1)]	February 2018	Marketed
VTS-270 [(1)]	February 2018	In development
CPP-1X/sulindac [(1)]	February 2018	In development

[(1)] These products did not have any impact to fiscal 2017 results. Refer to Item 7. MD&A of Financial Conditions for discussion around the acquisition of these products in February 2018.

In addition to the products listed above, in fiscal 2016, we acquired Recothrom, PreveLeak and RAPLIXA™ (Fibrin Sealant (Human)) ("Raplixa") from The Medicines Company ("Hemostasis", "the Hemostasis Acquisition"). As our emphasis has evolved to focus on a development portfolio of treatments for seriously ill infants and adults, these products are now less strategic for us, and in January 2018 we announced plans to divest the products, which is covered in more detail below. We expect the sale of these products to close in the first quarter of 2018.

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 neurologists, rheumatologists, nephrologists, ophthalmologists, pulmonologists, neonatologists, surgeons, and pharmacy directors) with our own direct sales force of over 500 sales representatives as of December 29, 2017. 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.

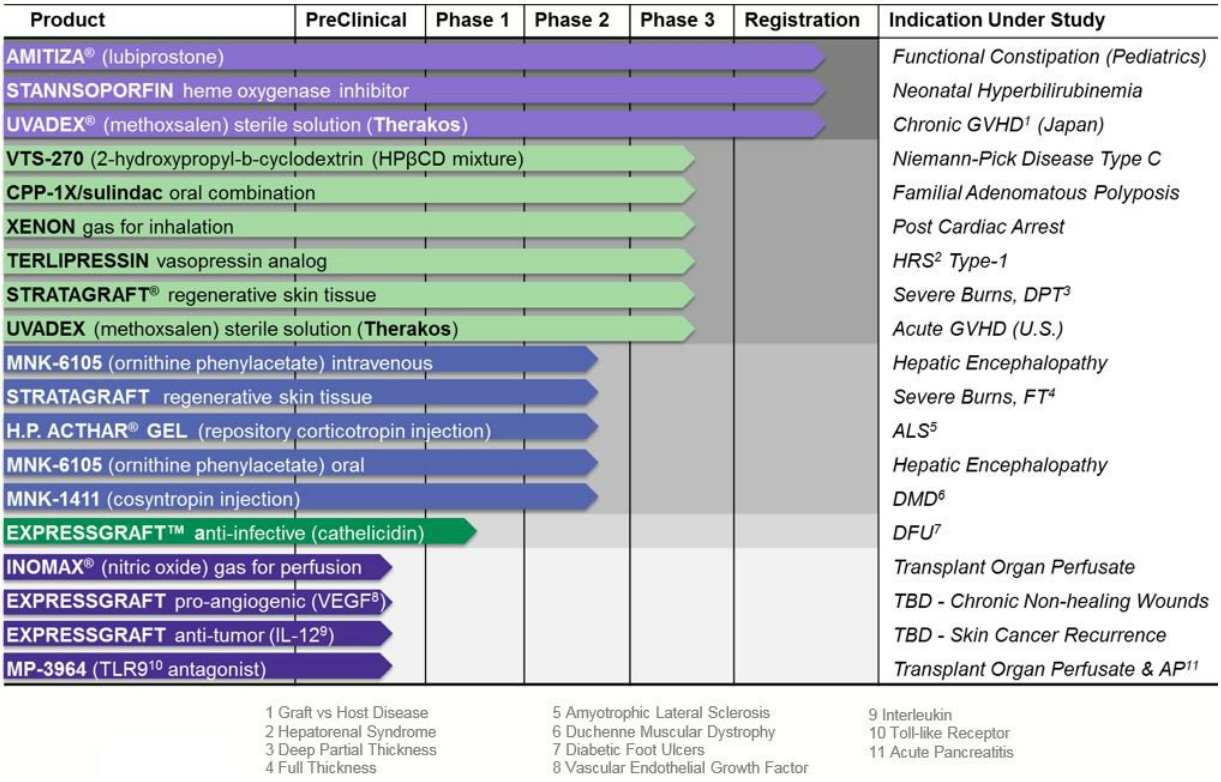
The following is a description of select products in our Specialty Brands product portfolio:

- *H.P. Acthar® Gel ("H.P. Acthar Gel")* is an injectable drug approved by the U.S. Federal Drug Administration ("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 H.P. Acthar Gel 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.

  Since acquiring H.P. Acthar Gel, we have initiated critical controlled trials in an effort to expand the product's evidence base and strengthen its clinical profile. For example, we are currently enrolling patients in a Phase 2 study to evaluate H.P. Acthar Gel for patients with Amyotrophic Lateral Sclerosis ("ALS") a progressive and fatal

neurodegenerative disorder. In addition, we continue our efforts to extend the value of the product through Phase 4 studies and product enhancements.

- *Inomax® ("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 2034, 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. There has been recent patent litigation related to the Inomax product, as further described in 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.
- *Ofirmev® ("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"), one of which expired in August 2017 and the other will expire in June 2021. 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® ("Therakos")* 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") and provides the only integrated ECP system in the world. ECP involves drawing 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 U.S., 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.
- *Amitiza®* ("*Amitiza")* is a leading global product in the branded constipation market. Amitiza is approved by the FDA for treatment of chronic idiopathic constipation in adults, irritable bowel syndrome with constipation in women 18 years of age and older, and opioid-induced constipation in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation. Amitiza is a chloride channel activator which increases fluid secretion and motility of the intestine, facilitating passage of stool. Roughly 40 million patients in the U.S. suffer from some form of chronic constipation. Of the branded products currently marketed, only Amitiza is approved for three constipation indications in the U.S. The FDA is currently reviewing a supplemental New Drug Application ("NDA") for Amitiza in children 6 to 17 years of age with pediatric functional constipation ("PFC"). The supplemental NDA received a Priority Review designation and has a user fee goal date of April 28, 2018. If approved, Amitiza would be the first and only approved prescription therapy available to treat children with PFC.
- *Pipeline products* - we have multiple products in various stages of development, which we believe will provide long-term organic growth and diversification. The status of each of these products is shown below. For a more detailed description of these pipeline products, refer to the Research and Development ("R&D") section in this Item 1. Business.



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 near-term pipeline in this segment is limited, we do have products in development longer-term. Within this segment, we provide 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 2017, our Specialty Generics segment accounted for 26.5% of net sales from our reportable 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 2017 we estimated that we received approximately 36% 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.

Research and Development

We devote significant resources to the research and development ("R&D") of products and proprietary drug technologies. We incurred R&D expenses from continuing operations of $277.3 million, $262.2 million, $203.3 million and $66.2 million in fiscal 2017, 2016 and 2015 and the three months ended December 30, 2016, 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 areas, specifically investments to support our Specialty Brands, where we believe there is the greatest opportunity for growth and profitability.

Specialty Brands. We devote significant R&D resources to 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. Our strategy focuses on growth and pipeline opportunities related to 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.

Data generation is an important strategic driver for our key products in development as they 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 H.P. Acthar Gel, Inomax, Ofirmev and Therakos.

The most significant development products in our pipeline are:

- *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 2017, we announced the enrollment of the 75th subject in our ongoing Phase 3 clinical study to evaluate the efficacy and safety of terlipressin (for injection) in subjects with HRS type 1. This marked the achievement of one quarter of our target enrollment for this trial and we continue to make progress on this clinical study.
- *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. In June 2017, we announced the enrollment of the first patient in our Phase 3 clinical study to evaluate the efficacy and safety of StrataGraft regenerative skin tissue in the promotion of autologous skin regeneration of complex skin defects due to thermal burns that contain intact dermal elements. In July 2017, we announced that StrataGraft is among the first products to be designated as a Regenerative Medicine Advanced Therapy ("RMAT") by the FDA under the provisions of the 21st Century Cures Act. The RMAT designation allows for earlier and increased interactions with the FDA, including discussions of whether priority review and/or accelerated approval would be appropriate based on surrogate or intermediate endpoints that would be reasonably likely to predict long-term clinical benefit; or reliance upon data obtained from a meaningful number of sites. Building upon the science of StrataGraft, we also maintain ExpressGraft-C9T1 skin tissue, a biologically-active skin tissue with a fully stratified epithelial compartment comprised of human keratinocytes and a dermal compartment containing fibroblasts. This tissue has been genetically modified to up-regulate production of a naturally occurring antimicrobial. It is being evaluated in a first-in-human prospective, open-label trial focused on assessing the safety and tolerability in the treatment of patients with diabetic foot ulcers, a type of wound that is often difficult to heal.
- *MNK-1411* (the product formerly described as 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 granted our request for fast track designation for its Investigational New Drug ("IND") application for MNK-1411 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 that fill an unmet medical need. Then in fiscal 2017, the FDA granted orphan drug designation to MNK-1411 for the treatment of DMD. The Phase 1 study for MNK-1411 in healthy volunteers has been completed and the information derived was used to determine optimal dosing in our Phase 2 trial, which is expected to commence in 2018.
- *Stannsoporfin*, a heme oxygenase inhibitor, is under investigation for its potential to reduce the production of bilirubin. If approved, stannsoporfin is expected to be a highly effective therapy used for near- and full-term infants at risk of developing complications associated with severe jaundice. This new treatment option may reduce the number of newborns advancing to bilirubin levels requiring more intrusive, less specific therapies, most often blood exchange transfusion and less frequently intravenous immunoglobululin infusions, both of which have a more complex and lengthy administration than stannsoporfin's single injection. Stannsoporfin, if approved, may also decrease the risks associated with other treatments (i.e., bilirubin rebound) and the risk of prolonged and/or severe bilirubin elevation, which can impact central nervous system development. In December 2016, stannsoporfin was granted fast track designation by the FDA and a NDA has been submitted.
- *Xenon gas for inhalation* is a noble gas that has been used safely as an inhaled therapy in several studies to date. Following cardiac arrest, calcium channels in the brain can get over-activated, causing neuronal damage and cell death. When inhaled, xenon binds to N-methyl-D-aspartate receptors through a unique glycine-binding mechanism and can help regulate the flow of ions through the calcium channels. By mitigating neuronal damage and cell death following a cardiac arrest, inhaled xenon may be able to reduce time in coma, lower mortality rates and improve cognitive and motor functions. The Phase 3 trial will be conducted under an FDA Special Protocol Agreement and is currently expected to begin in early 2018.

- *MNK-6105*, an ammonia scavenger, is being studied for treatment of hepatic encephalopathy ("HE"), a neuropsychiatric syndrome associated with hyperammonemia, a complication of acute or chronic liver disease. If approved, MNK-6105 is expected to be an effective therapy that rapidly eliminates ammonia in the bloodstream, excreting it through the kidneys, a more effective and less burdensome method of addressing HE than existing treatment options. The intravenous ("IV") formulation of MNK-6105, if approved, is expected to provide rapid reduction in symptoms of acute HE, and potentially reduce hospitalization stay. MNK-6105's oral formulation, if approved, is expected to provide post-discharge continuity of care for the HE patient, reducing the risk of recurrent HE episodes and rehospitalization. It is also anticipated that patients may transition from the IV to the oral formulation prior to discharge from the hospital setting. The FDA and European Medicines Agency ("EMA") have granted orphan drug designation to MNK-6105. The FDA also granted fast track designation to MNK-6105.
- *VTS-270* is in Phase 3 development for Niemann-Pick Type C ("NPC"). NPC is a rare, neurodegenerative, and ultimately fatal disease that can present at any age. NPC is caused by mutations in either the NPC1 or NPC2 genes, resulting in the disruption of the trafficking of intracellular cholesterol, leading to intracellular lipid accumulation in various tissues, including the brain, liver, and spleen. NPC presents with neurologic and visceral features that overlap with other diseases often leading to a missed or delayed diagnosis. Neurodegenerative presentation in NPC is a major driver of morbidity and mortality. There are four main types of the disease – types A, B, C1 and C2; NPC encompasses types C1 and C2, which causes accumulation of cholesterol and other lipids in cells, resulting in severe neurological, systemic or psychiatric disorders. Manifestations of the genetic disorder typically occur in childhood with occasional late onset. NPC is usually fatal, and the majority of cases lead to death. The FDA granted VTS-270 its orphan drug designation, and the resulting seven years exclusivity would be applied upon approval of the drug. The EMA also granted VTS-270 orphan drug status. In addition, the FDA granted the compound its Breakthrough Designation, indicating the drug is (1) intended to treat a serious or life-threatening disease or condition alone or combined with one or more other drugs, and (2) preliminary clinical evidence indicates it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The Breakthrough Designation status results in expedited review by the agency.
- *CPP-1X/sulindac* is in Phase 3 development for Familial Adenomatous Polyposis ("FAP") under a collaborative agreement with Cancer Prevention Pharmaceuticals and Sucampo. FAP results from a genetic mutation leading to uncontrolled growth of hundreds to thousands of polyps in the lower digestive tract. Left untreated, there is a high liklihood of developing colorectal cancer. The disease typically progresses without clear warning signs until reaching advanced stages. It can also lead to abnormal manifestations in other organs including bone, skin, retina, teeth and other malignant lesions. The FDA granted CPP-1X/sulindac its orphan drug designation, as well as its Fast Track designation, a process designed to facilitate development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. Orphan drug status was also granted to the therapy by the EMA. CPP-1X/sulindac, if approved, will target the underlying disease mechanism, preventing polyp growth and delaying disease progression.

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

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, H.P. Acthar Gel 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.

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 targeted for niche patient populations with unmet medical needs, for example H.P. Acthar Gel, 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, as well as our ability 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 those and 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 reputation of the product name, which typically benefits from trademark protection or is based on the difficulties associated with replicating the product formulation or bioavailability. H.P. Acthar Gel is not subject to patent or other exclusivity, with the exception of IS which was granted orphan drug status from the FDA upon its approval in October 2010. H.P. Acthar Gel'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.

Regulatory Matters

Quality Assurance Requirements

The FDA enforces regulations to ensure that the methods used in, and the facilities and controls used for, the manufacture, processing, packaging and holding of drugs and medical devices conform to current good manufacturing practice ("cGMP"). The cGMP regulations that the FDA enforces are comprehensive and cover all aspects of manufacturing operations, from receipt of raw materials to finished product distribution, and are designed to ensure that the finished products meet all the required identity, strength, quality and purity characteristics. The cGMP regulations for devices, called the Quality System Regulations, are also comprehensive and cover all aspects of device manufacture, from pre-production design validation to installation and servicing, insofar as they bear upon the safe and effective use of the device and whether the device otherwise meets the requirements of the U.S. Federal Food, Drug and Cosmetic Act ("the FFDCA"). Other regulatory authorities have their own cGMP rules. Ensuring compliance requires a continuous commitment of time, money and effort in all operational areas.

The FDA conducts pre-approval inspections of facilities engaged in the development, manufacture, processing, packaging, testing and holding of the drugs subject to NDAs and Abbreviated New Drug Applications ("ANDA"). If the FDA concludes that the facilities to be used do not or did not meet cGMP, good laboratory practice ("GLP") or good clinical practice ("GCP") requirements, it will not approve the application. Corrective actions to remedy the deficiencies must be performed and are usually verified in a subsequent inspection. In addition, manufacturers of both pharmaceutical products and API used to formulate the drug also ordinarily undergo a pre-approval inspection, although the inspection can be waived when the manufacturer has had a passing cGMP inspection in the

immediate past. Failure of any facility to pass a pre-approval inspection will result in delayed approval and could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The FDA also conducts periodic inspections of drug and device facilities to assess their cGMP status. If the FDA were to find serious cGMP non-compliance during such an inspection, it could take regulatory actions that could materially adversely affect our business, results of operations, financial condition and cash flows. Additionally, imported API and other components needed to manufacture products could be rejected by U.S. Customs and Border Protection, usually after conferring with the FDA. In the case of domestic facilities, the FDA could initiate product seizures or, in some instances, require product recalls and seek to enjoin a product's manufacture and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with cGMP requirements, sanctions may be imposed that include preventing that company from receiving the necessary licenses to export its products and classifying that company as an "unacceptable supplier," thereby disqualifying that company from selling products to federal agencies.

United States

In general, drug manufacturers operate in a highly regulated environment. In the U.S., we must comply with laws, regulations, guidance documents and standards promulgated by the FDA, the Department of Health and Human Services ("DHHS"), the DEA, the Environmental Protection Agency ("EPA"), the Customs Service and state boards of pharmacy.

The FDA's authority to regulate the safety and efficacy of pharmaceuticals comes from the FFDCA. In addition to reviewing NDAs, for branded drugs, and ANDAs, for generic drugs, the FDA has the authority to ensure that pharmaceutical products introduced into interstate commerce are neither "adulterated" or "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 or 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 ("DOJ").

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 and laboratory 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 an FDA Advisory Committee meeting in which the FDA 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 2018, the user fee rate has been set at $2,421,500 for a 505(b)(1) NDA and $1,210,740 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. Under the Generic Drug User Fee Amendments of 2017, the fiscal 2018 user fee rate is set at $171,820 for an ANDA and the prior approval supplement to an ANDA fee was removed. 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 2018 has a target of approving 90% of ANDA submissions within 10 months of submission.

Aside from the backlog described above, the timing of FDA approval of ANDAs depends on other factors, including whether an ANDA holder has challenged any listed patents to the RLD and whether the RLD is entitled to one or more periods of marketing exclusivity under the FFDCA (such as pediatric exclusivity under the BPCA). In general, the FDA will not approve (but will continue to review) an ANDA in which the RLD holder has sued, within 45 days of receiving notice of the ANDA filing, the ANDA holder for patent infringement until either the litigation has been resolved or 30 months has elapsed, whichever is later.

Patent and Non-Patent Exclusivity Periods. A sponsor of a NDA is required to identify in its application any patent that claims the drug or a use of the drug subject to the application. Upon NDA approval, the FDA lists these patents in the Orange Book. Any person that files a Section 505(b)(2) NDA, the type of NDA that relies upon the data in the application for which the patents are listed, or an ANDA to secure approval of a generic version of a previous drug, must make a certification in respect to listed patents. The FDA may not approve such an application for the drug until expiration of the listed patents unless the generic applicant certifies that the listed patents are invalid, unenforceable or not infringed by the proposed generic drug and gives notice to the holder of the NDA for the

RLD of the bases upon which the patents are challenged, and the holder of the RLD does not sue the later applicant for patent infringement within 45 days of receipt of notice. If an infringement suit is filed, the FDA may not approve the later application until the earliest of: (a) 30 months after receipt of the notice by the holder of the NDA for the RLD; (b) entry of an appellate court judgment holding the patent invalid, unenforceable or not infringed; (c) such time as the court may order; or (d) the expiration of the patent.

One of the key motivators for challenging patents is the 180-day market exclusivity period ("generic exclusivity") granted to the developer of a generic version of a product that is the first to make a Paragraph IV certification and that prevails in litigation with the manufacturer of the branded product over the applicable patent(s) or is not sued. For a variety of reasons, there are situations in which a company may not be able to take advantage of an award of generic exclusivity. The determination of when generic exclusivity begins and ends is very complicated.

The holder of the NDA for the RLD may also be entitled to certain non-patent exclusivity during which the FDA cannot approve an application for a competing generic product or 505(b)(2) NDA product. Generally, if the RLD is a new chemical entity, the FDA may not accept for filing any application that references the innovator's NDA for five years from the approval of the innovator's NDA. However, this five-year period is shortened to four years where a filer's ANDA includes a Paragraph IV certification. In other cases, where the innovator has provided certain clinical study information, the FDA may accept for filing, but may not approve, an application that references the innovator's NDA for a period of three years from the approval of the innovator's NDA.

Certain additional periods of exclusivity may be available if the RLD is indicated for use in a rare disease or condition or is studied for pediatric indications.

Risk Evaluation and Mitigation Strategies. For certain drug products or classes, such as transmucosal immediate-release fentanyl ("TIRF") 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 program 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 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, "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. In calendar 2017, manufacturing and procurement quotas granted by the DEA were sufficient to meet our sales and inventory requirements on most products. In November

2017, the DEA reduced the amount of almost every Schedule II opiate and opioid medication that may be manufactured in the U.S. in calendar year 2018 by 20 percent. 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 of 2010, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (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. 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 $91.6 million, $94.4 million, $82.3 million and $18.0 million in fiscal 2017, 2016, 2015 and the three months ended December 30, 2016, respectively. The fiscal 2017 decrease in provisions for Medicaid payments is primarily attributable to an $8.5 million decrease associated with Specialty Generics, due to lower net sales in fiscal 2017, which was partially offset by $4.9 million increase associated with H.P. Acthar Gel because of increased net sales during fiscal 2017. The fiscal 2016 increase in provisions for Medicaid payments is primarily attributable to a $16.9 million increase associated with H.P. Acthar Gel, due to double-digit net sales growth, which was partially offset by lower net sales of Specialty Generics. The Company was also impacted by the annual fee on branded prescription pharmaceutical manufacturers, which is not tax deductible, and recorded expense of $21.8 million, $23.3 million, $20.0 million and $8.3 million in fiscal 2017, 2016, 2015 and the three months ended December 30, 2016, respectively, within SG&A.

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 ("FCPA") of 1977 and similar worldwide anti-bribery laws in non-U.S. jurisdictions, such as the 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 robust compliance programs 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 programs, 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 programs 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 has taken place requires investigation, cleanup and other possible remedial actions. These agencies may require that we reimburse the government for costs incurred at these sites or otherwise pay for the cost of investigation and cleanup of these sites including compensation for damage to natural resources. We have projects underway at a number of current and former manufacturing facilities to investigate and remediate environmental contamination resulting from past operations, as further described in Item 3. Legal Proceedings and Note 19 to 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 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 the Company'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 neurologists, rheumatologists, nephrologists, pulmonologists, ophthalmologists, neonatologists 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 2017, 2016, 2015 and the three months ended December 30, 2016 were as follows:

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	December 30, 2016	December 25, 2015	December 30, 2016
CuraScript, Inc.	40%	38%	35%	43%
McKesson Corporation	*	12%	20%	10%
AmerisourceBergen Corporation	*	*	10%	*
Cardinal Health, Inc.	*	*	11%	*

* - Net sales to these distributors were less than 10% of our total net sales during the respective periods presented above.

No other customer accounted for 10% or more of our net sales in the above periods presented.

Manufacturing and Distribution

As of December 29, 2017, we had nine manufacturing sites, including seven 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 2017.

As of December 29, 2017, we maintained distribution centers in 9 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 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 H.P. Acthar Gel (for finish and filling of the product), Ofirmev, Recothrom and Therakos products.

Backlog

At December 29, 2017, the backlog of firm orders was less than 1% of net sales. We anticipate that substantially all of the backlog as of December 29, 2017 will be shipped during fiscal 2018.

Seasonality

We have historically experienced fluctuations in our business resulting from seasonality. For example, H.P. Acthar Gel has typically experienced lower net sales during the first calendar quarter compared to other calendar quarters, which we believe is partially attributable to effects of annual insurance deductibles and certain medical conditions being exacerbated by warm temperatures. In addition, we have historically experienced lower operating cash flows during the period in which we pay annual employee compensation. In previous years, annual employee compensation was paid during the fourth calendar quarter; however, given the change in our fiscal year end to the last Friday in December from the last Friday in September, we now expect to pay annual employee compensation during the first calendar quarter. 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, and we have experienced lower net sales in DEA controlled products during the fourth calendar quarter. While we have experienced these fluctuations in the past, they may not be indicative of what we will experience in the future.

Employees

At December 29, 2017, we had approximately 3,900 employees, approximately 3,400 of which are based in the U.S. Certain of these employees are represented by unions or work councils. We believe that we generally have a good relationship with our employees, and with the unions and work councils that represent certain employees.

Executive Officers

Set forth below are the names, ages as of February 1, 2018, and current positions of our executive officers.

Name	Age	Title
Mark Trudeau	56	President, Chief Executive Officer and Director
Matthew Harbaugh	47	Executive Vice President and Chief Financial Officer
Meredith Fischer	65	Chief Public Affairs Officer
Mark Casey	54	General Counsel
Ron Lloyd	57	Executive Vice President and President, Hospital Therapies
Hugh O'Neill	54	Executive Vice President and President, Autoimmune and Rare Diseases
Gary Phillips, MD	51	Executive Vice President and Chief Strategy Officer
Steven Romano, MD	58	Executive Vice President and Chief Scientific Officer
Frank Scholz	49	Executive Vice President of Global Operations and President, Specialty Generics
Karen Sheehy	56	Chief Compliance Officer
Ian Watkins	55	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. 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 Argentine/Chilean and Canadian operations via two expatriate assignments.

Mark Casey is our General Counsel. Mr. Casey joined Mallinckrodt in February 2018. Before joining Mallinckrodt, Mr. Casey served as Senior Vice President, General Counsel, and Secretary of Idera Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company, from June 2015 to January 2018. Prior to that, Mr. Casey served as Senior Vice President, Chief Administrative Officer, General Counsel, and Secretary at Hologic, Inc., a global medical device and diagnostics company, from March 2012 to December 2014 and as Senior Vice President, General Counsel, and Secretary from October 2007 to March 2012, following Hologic's acquisition of Cytyc Corporation. Prior to the acquisition, Mr. Casey served as Vice President, Deputy General Counsel, and Chief Patent Counsel of Cytyc from 2002 to 2007. Prior to joining Cytyc, Mr. Casey held roles of increasing responsibility at Boston Scientific Corporation and EMC Corporation.

Meredith Fischer is our Chief Public Affairs Officer. In anticipation of the Separation, 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.

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, 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.

Karen Sheehy is our Chief Compliance Officer, a role she assumed in January 2017. Ms. Sheehy joined Mallinckrodt from Sanofi where she worked for more than 15 years, serving most recently as Head of Compliance for North America. Prior to joining Sanofi, Ms. Sheehy worked at Daiichi Pharmaceuticals and was an attorney in private practice at Riker, Danzig, Scherer, Hyland & Perretti LLP where she focused on complex commercial litigation. She began her career as a judicial law clerk for the Honorable Maurice J. Gallipoli, Presiding Judge, Superior Court, Civil Division, Hudson County, New Jersey.

Ian Watkins is our Chief Human Resources Officer. He has executive responsibility for organizational development, effectiveness and sustainability, talent acquisition, total rewards, and human resources systems and service delivery. He is also responsible for supporting the Board of Directors in their governance activities related to executive compensation, talent and succession management. 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 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 sec.gov.

We use our website at 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. We are also required to track and report adverse events and product quality problems associated with our products to the FDA and other regulatory authorities. Failure to comply with the requirements of FDA or other regulatory authorities, including a failed inspection or a failure in our adverse event reporting system, or any other unexpected or serious health or safety concerns associated with our products, including opioid pain products and H.P. Acthar Gel, could result in adverse inspection reports, warning letters, product recalls or seizures, product liability claims, labeling changes, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. Any of these actions could cause a loss of customer confidence in our products, which could adversely affect our sales, or otherwise have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. In addition, the requirements of regulatory authorities, including interpretative guidance, are subject to change and compliance with additional or changing requirements or interpretative guidance may subject the company to further review, result in product delays or otherwise increase our costs, and thus have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Furthermore, 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, in the U.S. 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 governmental 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. We have compliance programs in place, including policies, training and various forms of monitoring, designed to address these risks. Nonetheless, these programs and policies may not always protect us from conduct by individual employees that violate these laws. If the FDA or any other governmental agency initiates an enforcement action against us 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 business, financial condition, results of operations and cash flows.

If our business development activities are unsuccessful, it may adversely affect us.

Part of our business strategy includes evaluating potential business development opportunities to grow the business through merger, acquisition, licensing agreements or other strategic transactions. The process to evaluate potential opportunities may be complex, time-consuming and expensive. Once a potential opportunity 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.

Once an acquisition or licensing transaction is consummated, there are further potential risks related to integration activities, including with regard to 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.

In addition, we intend to continue to explore opportunities to enter into strategic collaborations with other parties, which may include other pharmaceutical companies, academic and research institutions, government agencies and other public and private research organizations. These third-party collaborators are often directly responsible for clinical development under these types of arrangements, and we may not have the same level of decision-making capabilities for the prioritization and management of development-related activities as we would for our internal research and development activities. Failures by these partners to meet their contractual, regulatory, or other obligations to us, or any disruption in the relationships with these partners, could have a material adverse effect on our pipeline and business. In addition, these collaborative relationships for research and development could extend for many years and may give rise to disputes regarding the relative rights, obligations and revenues of us versus our partners, including the ownership of intellectual property and associated rights and obligations. These could result in the loss of intellectual property rights or other intellectual property protections, delay the development and sale of potential products, and lead to lengthy and expensive litigation or arbitration.

Furthermore, the due diligence that we conduct in conjunction with an acquisition or other strategic collaboration may not sufficiently discover risks and contingent liabilities associated with the other party and, consequently, we may consummate an acquisition or otherwise enter into a strategic collaboration for which the risks and contingent liabilities are greater than were projected. In addition, in connection with acquisitions or other strategic collaborations, 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 or otherwise collaborate on may seek employment elsewhere, including with our competitors. Furthermore, there may be overlap between our products or customers and the companies which we acquire or enter into strategic collaborations with that may create conflicts in relationships or other commitments detrimental to the integrated businesses or impacted products. 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, results of operations and cash flows.

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.

Our recent acquisitions have significantly increased goodwill and intangible assets, which were $3,482.7 million and $8,375.0 million, respectively, at December 29, 2017. 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 legislative and 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 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, commercialize or launch new products or expand commercial opportunities for existing products or adapt to a changing technology and, as a result, our business may suffer.

Our future results of operations will depend, to a significant extent, upon our ability to successfully develop, commercialize and launch new products or expand commercial opportunities for existing products in a timely manner. There are numerous difficulties in developing, commercializing and launching new products or expanding commercial opportunities for existing products, including:

- developing, testing and manufacturing products in compliance with regulatory and quality standards in a timely manner;
- our ability to successfully engage with the FDA or other regulatory authorities as part of the approval process and to receive 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, commercializing and launching 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, commercialization and/or launch 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;
- effective execution of the product launches in a manner that is consistent with expected timelines and anticipated costs; and
- identifying appropriate partners for distribution of our products, including for any future over-the-counter commercialization opportunities, and negotiating contractual arrangements in a timely manner with commercially reasonable terms.

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. 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 with regulatory standards. 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.

Furthermore, the market perception and reputation of our products are important to our business and the continued acceptance of our products. Any negative press reports or other commentary about our products, whether accurate or not, could have a material adverse effect on our business, reputation, financial condition, cash flows or results of operation or could cause the market value of our common shares and/or debt securities to decline.

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, 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 approved timely, or if we are unable to obtain and realize the full benefits of the respective market exclusivity period for our products, or if our products cannot be successfully manufactured or commercialized timely, 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 H.P. Acthar Gel, Ofirmev, Inomax and Therakos 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, or if there is a change in the way courts and regulators interpret the laws, rules and regulations applicable to our intellectual property, our competitiveness could be impacted, which could adversely affect our competitive position, business, financial condition, results of operations and cash flows.

The composition patent for H.P. Acthar Gel 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 H.P. Acthar Gel. 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, we depended, in part, upon these patents to provide us with exclusive marketing rights for our product for some period of time. Since then, we have obtained new patents, which expire at various dates through 2036, on methods of identifying patients at risk of serious adverse events when nitric oxide is administered to patients with particular heart conditions. Such methods have been approved by the FDA 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. The Paragraph IV patent litigation trial against Praxair to prevent the marketing of potential infringing generic products prior to the expiration of the patents covering Inomax was held in March 2017 and a decision was rendered September 5, 2017 that ruled five patents invalid and six patents not infringed. We have appealed the decision to the Court of Appeals for the Federal Circuit. An adverse outcome in the appeal of the Praxair litigation decision ultimately could result in the launch of a generic version of Inomax before the expiration of the last of the patents listed in the FDA Orange Book, which could adversely affect our ability to successfully maximize the value of Inomax and have an adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

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 we have in-licensed from Bristol-Myers Squibb Company ("BMS") and its licensor, New Pharmatop LLC ("Pharmatop") and any method-of-use patents that we subsequently obtained. The latest expiration date of the in-licensed patents is 2021 whereas the latest expiration date of the subsequently obtained Company-owned patents is 2032. Settlement agreements have been reached in association with certain challenges to the in-licensed patents, which allow for generic competition to Ofirmev in December 2020, or earlier under certain circumstances.

Our Therakos products focus on extracorporeal photopheresis, which is an autologous immune cell therapy that is indicated in the U.S. for skin manifestations of CTCL and is available for several additional indications in markets outside the U.S. In the ECP process, blood is drawn from the patient, separating white blood cells from plasma and red blood cells (which are immediately returned to the patient). The separated white blood cells are treated with an Ultraviolet-A ("UVA") light activated drug, UVADEX® (methoxsalen) Sterile Solution, followed by UVA radiation in the photopheresis instrument, prior to being returned to the patient. Patents related to the methoxsalen composition have expired. Therakos manufactures two photopheresis 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. 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, including by coupling separate technologies to replicate what our products accomplish through a single system. Competitors may diminish the value of our trade secrets by reverse engineering or by independent invention. Additionally, current or former employees may improperly disclose such trade secrets to competitors or other third parties. We may not become aware of any such improper disclosure, and, in the event we do become aware, we may not have an adequate remedy available to us.

We operate in an industry characterized by extensive patent litigation, and we may from time to time be a party to such litigation. Such litigation and related matters are described in Note 19 of the Notes to Consolidated 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. Through the end of calendar 2017, manufacturing and procurement quotas granted by the DEA were sufficient to meet our sales and inventory requirements on most products. In November 2017, 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 2018 by 20 percent. 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 business.

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 business.

We sell a wide variety of products including specialty branded and specialty generic pharmaceuticals, as well as API. However, a small number of relatively significant products, most notably H.P. Acthar Gel and to a lesser extent, Inomax, Ofirmev and Therakos, 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 demand for these products;
- our ability to achieve hospital and other third-party payer formulary acceptance, and maintain reimbursement levels by third-party payers;
- our ability to maintain confidentiality of the proprietary know-how and trade secrets relating to H.P. Acthar Gel;
- 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 H.P. Acthar Gel, Ofirmev, Inomax and Therakos 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 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; and
- 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.

Moreover, net sales of H.P. Acthar Gel may also be materially impacted by the decrease in the relatively small number of prescriptions written for H.P. Acthar Gel as compared to other products in our portfolio, given H.P. Acthar Gel's use in treating rare diseases. Any disruption in our ability to generate net sales from H.P. Acthar Gel 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 business.

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. Distributors of our products are also forming strategic alliances and negotiating terms of sale more aggressively in an effort to increase their profitability. Failure to negotiate distribution arrangements having advantageous pricing and other terms of sale could cause us to lose market share to our competitors 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 H.P. Acthar Gel. 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 H.P. Acthar Gel.

Reimbursement of highly-specialized products, such as H.P. Acthar Gel, 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 increased public scrutiny of healthcare and pharmaceutical costs, which could reduce our future revenue and profitability.

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 H.P. Acthar Gel that occurred prior to our acquisition of the product. H.P. Acthar Gel represented 37% of our net sales for fiscal 2017. In addition, U.S. federal prosecutors have issued subpoenas to certain pharmaceutical companies seeking information about their drug pricing practices, among other issues, and members of the U.S. Congress have sought information from certain pharmaceutical companies 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 financial condition, results of operations and cash flows could be negatively affected.

Clinical trials demonstrating the efficacy for H.P. Acthar Gel are limited. The absence of such clinical trial data could cause physicians not to prescribe H.P. Acthar Gel, which could negatively impact our business.

Our net sales of H.P. Acthar Gel, 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. H.P. Acthar Gel 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 H.P. Acthar Gel during its approval of H.P. Acthar Gel 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 H.P. Acthar Gel 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 H.P. Acthar Gel in treatment of IS, the FDA again reviewed evidence of safety and efficacy of H.P. Acthar Gel, and added the IS indication to the label of approved indications while maintaining approval of H.P. Acthar Gel 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 H.P. Acthar Gel label, the FDA eliminated approximately 30 other indications from the label. The FDA review included a medical and scientific review of H.P. Acthar Gel 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 H.P. Acthar Gel.

Accordingly, evidence of efficacy is largely based on physician's clinical experience with H.P. Acthar Gel and does not include clinical trials except for the multiple sclerosis and infantile spasms indications. Despite recent increases in H.P. Acthar Gel prescriptions for several of its on-label indications, this limited clinical data of efficacy could impact future sales of H.P. Acthar Gel. We have initiated Phase 4 clinical trials to supplement the non-clinical evidence supporting the use of H.P. Acthar Gel 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 H.P. Acthar Gel 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 H.P. Acthar Gel to treat any of its approved indications. In addition, a clinical trial to evaluate the use of H.P. Acthar Gel to treat indications not on the current H.P. Acthar Gel label may not provide a basis to pursue adding such indications to the current H.P. Acthar Gel label. Furthermore, even if prescribed by a physician, third-party payers may implement restrictions on reimbursement of H.P. Acthar Gel due, in part, to the limited clinical data of efficacy, which may negatively impact our business, financial condition, results of operations and cash flows.

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 business.

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 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, as well as due to the biologic nature of some of our products which are inherently more difficult to manufacture than chemical-based products. 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 launch delays, product shortages, backorders, increased costs (including contractual damages for failure to meet supply requirements), lost revenue, damage to our reputation and 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 rely on third-party manufacturers to manufacture certain components of our products and certain of our finished products. In the event that these third-party manufacturers cease to manufacture sufficient quantities of our products or components in a timely manner and on terms acceptable to us, we could be forced to locate alternate third-party manufacturers. Additionally, if our third-party manufacturers experience a failure in their production process, are unable to obtain sufficient quantities of the components necessary to manufacture our products or otherwise fail to meet regulatory or quality requirements, we may be forced to delay the manufacture and sale of our products or locate an alternative third-party manufacturer. Several of our products are manufactured at a single manufacturing facility or stored at a single storage site. Loss or damage to a manufacturing facility or storage site due to a natural disaster or otherwise could adversely affect our ability to manufacture sufficient quantities of key products or otherwise deliver products to meet customer demand or contractual requirements which may result in a loss of revenue and other adverse business consequences. Furthermore, while we work closely with our suppliers to ensure the continuity of supply and to diversify our sources of components and materials, in certain instances we do acquire components and materials from a sole supplier. Although we do carry strategic inventory and maintain insurance to mitigate the potential risk related to any related supply disruption, there can be no assurance that such measures will be effective. Because of the time required to obtain regulatory approval and licensing of a manufacturing facility, an alternate third-party manufacturer may not be available on a timely basis to replace production capacity in the event we lose manufacturing capacity, experiences supply challenges, or products are otherwise not available due to natural disaster, regulatory action or otherwise.

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 of new products with different mechanisms that obviate the need for our treatments, acquisition or in-licensing of new products that may be more cost-effective than or have performance superior to our products, the introduction of generic versions when our proprietary products lose their patent protection or market exclusivity, and the coupling of separate technologies to replicate what our products accomplish through a single system. 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. 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, opioid related matters, promotional practices and compliance with laws relating to the manufacture and sale of controlled substances. For example, we, along with other opioid manufacturers and, often, distributors, have been named in lawsuits related to the manufacturing, distribution, marketing and promotion of opioids. In addition, we have also received various subpoenas and requests for information related to the distribution, marketing and sale of our opioid products. 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. Such litigation and related matters are described in 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. 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 $40.0 million of a loss in our primary liability policies and purchase an additional $135.0 million using a combination of umbrella/excess liability policies with respect to any such claims. We believe this coverage level is adequate to address our current risk exposure related to product liability claims and lawsuits. 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 business, financial condition, results of operations and cash flows.

The healthcare industry has been under increasing scrutiny from governments, legislative bodies and enforcement agencies related to the promotion of products and related activities, and changes to, or non-compliance with, relevant policies, laws, regulations or government guidance may result in actions that could adversely affect our business.

In the U.S. over the past several years, a significant number of pharmaceutical and biotechnology companies have been subject to 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, marketing and pricing practices, including the DOJ and various other agencies including the Office of the Inspector General within the Department of Health and Human Services (OIG), 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, data and patient privacy laws, export and import laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. The DOJ and the U.S. Securities and Exchange Commission ("SEC") have also increased their focus on the enforcement of the FCPA, particularly as it relates to the conduct of pharmaceutical companies.

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 the possible exclusion from federal healthcare programs including Medicare and Medicaid, 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 competitive position, business, financial condition, results of operations and cash flows.

Specific to our business, in September 2012, prior to our acquisition of Questcor Pharmaceuticals, Inc. ("Questcor") in August 2014, a subpoena was received from the United States Attorney's Office ("USAO") for the Eastern District of Pennsylvania, requesting documents pertaining to an investigation of its promotional practices, and we are fully cooperating with this investigation. If any of our current practices related to the legacy Questcor business 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. Further, 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, results of operations and cash flows could be materially adversely affected.

In addition, there has recently been enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance. If we are deemed to have failed to comply with relevant laws, regulations or government guidance in any of these areas, we could be subject to criminal and civil sanctions, including significant fines, civil monetary penalties and exclusion from participation in government healthcare programs, including Medicare and Medicaid, actions against executives overseeing our business, and burdensome remediation measures. The USAO for the Eastern District of Pennsylvania is looking into this issue. In addition, in December 2016, we received a subpoena from the USAO for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to patients and documents concerning our provision of financial assistance to patients prescribed H.P. Acthar Gel. Other companies have disclosed similar inquiries. We are cooperating with this inquiry. It is possible that any actions taken by the DOJ or one of the USAOs as a result of this inquiry or any future action taken by federal or local governments, legislative bodies and enforcement agencies on this subject could result in civil penalties or injunctive relief, negative publicity or other negative actions that could harm our reputation, and could reduce demand for our products and/or reduce coverage of our products, including by federal health care programs such as Medicare and Medicaid and state health care, which would negatively impact sales of our products. If any or all of these events occur, it could have an adverse effect on our business, financial condition, results of operations and cash flows.

Our operations expose us to the risk of violations, material health, safety and environmental liabilities and litigation.

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 has taken place 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 December 29, 2017, it was probable that we would incur remediation costs in the range of $37.6 million to $115.5 million. We also concluded that, as of December 29, 2017, the best estimate within this range was $75.4 million. For further information on our environmental obligations, refer to Item 3. Legal Proceedings and 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. 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, inadvertently or through fraudulent or negligent behavior of individual employees, or through 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 and our ability to attract and retain employees.

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, including the impact of the 2016 referendum by British voters to exit the European Union (EU) (commonly known as Brexit) and the related uncertainties;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and trade barriers;
- difficulties and costs of staffing and managing our 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.

Clinical studies required for our product candidates and new indications of our marketed products are expensive and time-consuming, and their outcome is highly uncertain. If any such studies are delayed or yield unfavorable results, regulatory approval for our product candidates or new indications of our marketed products may be delayed or become unobtainable.

We must conduct extensive testing of our product candidates and new indications of our marketed products before we can obtain regulatory approval to market and sell them. For example, 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 the Therakos systems are 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. Conducting such studies is a lengthy, time-consuming, and expensive process and obtaining regulatory approval is uncertain. 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. Success in early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results.

These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate (or prior or concurrent exposure to other products or product candidates), difficulty in enrolling and maintaining subjects in a clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to GLPs or GCPs. A clinical trial may fail because it did not include and retain a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting. 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 product candidate or a new indication for a product candidate. For example, our product candidate MNK-6105 failed to demonstrate statistical significance in the clinical endpoints in a recently completed Phase 2b clinical trial of intravenously-administered MNK-6105 in hospitalized patients with hepatic encephalopathy. We plan to meet with the FDA to discuss next steps regarding future development for the IV formulation of MNK-6105.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new studies, which are expensive and time consuming, or abandon that drug development program. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication(s) would preclude the successful development of those candidates for such indication(s), which would have a material adverse effect on our business, financial condition, results of operations and cash flows.

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, financial condition, results of operations and cash flows. 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, including those caused by our own employees or others to whom we have granted access to our systems, 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, human error, sabotage, industrial espionage, 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, and cash flows.

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, which was subsequently acquired by Medtronic plc, 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 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 December 29, 2017, we had $6,806.8 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;
- 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.

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 lease-back 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 December 29, 2017, we had $1,851.2 million outstanding variable-rate debt on our senior secured term loans, $900.0 million outstanding on our revolving credit facility and $200.0 million outstanding variable-rate debt on our receivables securitization. An unfavorable movement in interest rates, primarily London Interbank Offered Rate ("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 acquisition strategy, 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. On January 13, 2017, the U.S. Department of the Treasury and the U.S. Internal Revenue Service ("IRS") issued final and temporary regulations promulgated under Internal Revenue Code ("IRC") Section 7874 to reduce the tax benefits of, or preclude entirely, certain inversion transactions. We do not believe these final and temporary regulations will have a material impact to our 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 IRC 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 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 ("the OECD"), 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 U.K., E.U., Switzerland, 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 OECD’s recommendations on base erosion and profit shifting, the European Commission’s Anti-Tax Avoidance Directive ("ATAD II") formally adopted in May 2017, the Multilateral Convention to Implement Tax Treaty Related Measures to Prevent Base Erosion and Profit Shifting (“Multilateral Instrument”) signed by over 70 countries in June 2017, Ireland’s Budget 2018 published in October 2017 announcing a public consultation on changes to the corporate tax code, and Switzerland's Tax Proposal 17. 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.

The effect of recent U.S. Tax Reform legislation is subject to continued regulatory and interpretive guidance

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the “TCJA”). The TCJA makes broad and complex changes to the U.S. tax code, the effects of which have been incorporated into our fiscal 2017 provision for income taxes, as applicable. Financial results for fiscal 2017 reflect provisional estimates based on our initial analysis and current interpretation of the legislation. Given the complexity of the legislation, anticipated guidance from the U.S. Treasury, and the potential for additional guidance from the SEC or the Financial Accounting Standards Board, these provisional estimates may be adjusted during fiscal 2018.

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

A 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. For example, the new Multilateral Instrument, which was signed by both Ireland and the U.K., but not yet ratified, would supersede the application of article 4(3) of the Double Taxation Convention between Ireland and the U.K. in favor of a new process involving the competent authorities of Ireland and the U.K. If Mallinckrodt plc were considered to be a tax resident of Ireland, in addition to any U.K. tax consequences 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 may be 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, we entered into an internal installment sale transaction related to certain H.P. Acthar Gel intangible assets during the fiscal year ended September 25, 2015. During the fiscal year ended September 30, 2016, we entered into similar transactions with certain intangible assets acquired in the acquisitions of Ikaria, Inc. and Therakos, Inc. The installment sale transactions resulted in a taxable gain. During the fiscal year ended December 29, 2017, we sold our Intrathecal Therapy business with a portion of the consideration from the sale being in the form of a note receivable subject to the installment sale provisions described above. In accordance with IRC Section 453A the gain is considered taxable in the period in which installment payments are received. The 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 may be subject to fluctuations in interest rates, which may increase in future periods. As of December 29, 2017, we had an aggregate $553.6 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 potentially negative about the company or its products/reputation;
- 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. 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.

Our shareholders' percentage of ownership in Mallinckrodt may be diluted.

Our shareholders' 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. 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.

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 Staines-Upon-Thames, United Kingdom. In addition, we have other locations in the U.S., most notably our corporate shared services facility in Hazelwood, Missouri, our Specialty Brands commercial headquarters in Bedminster, New Jersey and our Specialty Generics headquarters and technical development center in Webster

Groves, Missouri. As of December 29, 2017, we owned a total of ten facilities in the U.S., Canada, and Ireland. Our owned facilities consist of approximately 2.3 million square feet, and our leased facilities consist of approximately 1.3 million square feet. We have nine manufacturing sites: one in Canada; one in Ireland; and seven 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.

See 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, which is incorporated by reference into this Part I, Item 3., for a description of the litigation, legal and administrative proceedings as of December 29, 2017.

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.

	High	Low
Fiscal Year Ended September 30, 2016		
Quarter ended December 25, 2015	$ 76.66	$ 53.41
Quarter ended March 25, 2016	75.88	53.42
Quarter ended June 24, 2016	66.27	55.97
Quarter ended September 30, 2016	83.06	54.05
Three months ended December 30, 2016	$ 71.17	$ 49.51
Fiscal Year Ended December 29, 2017		
Quarter ended March 31, 2017	$ 54.74	$ 42.54
Quarter ended June 30, 2017	46.92	39.63
Quarter ended September 29, 2017	47.42	33.76
Quarter ended December 29, 2017	38.87	19.98

There were approximately 2,779 shareholders of record of our ordinary shares as of February 23, 2018.

Dividends and Issuer Purchase of Equity Securities

Under Irish law, we can only pay dividends and repurchase shares out of distributable reserves. 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 December 29, 2017, we repurchased 9,383,758 of our ordinary shares related to our $1.0 billion share repurchase program, announced on March 1, 2017, 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 (in millions)
9/30/2017 - 10/27/2017	655,534	$ 31.62	651,876	$ 812.4
10/28/2017 - 12/01/2017	5,997,849	21.76	5,996,850	682.0
12/02/2017 - 12/29/2017	2,730,375	22.98	2,730,000	619.4
9/30/2017 - 12/29/2017	**9,383,758**	**22.80**		

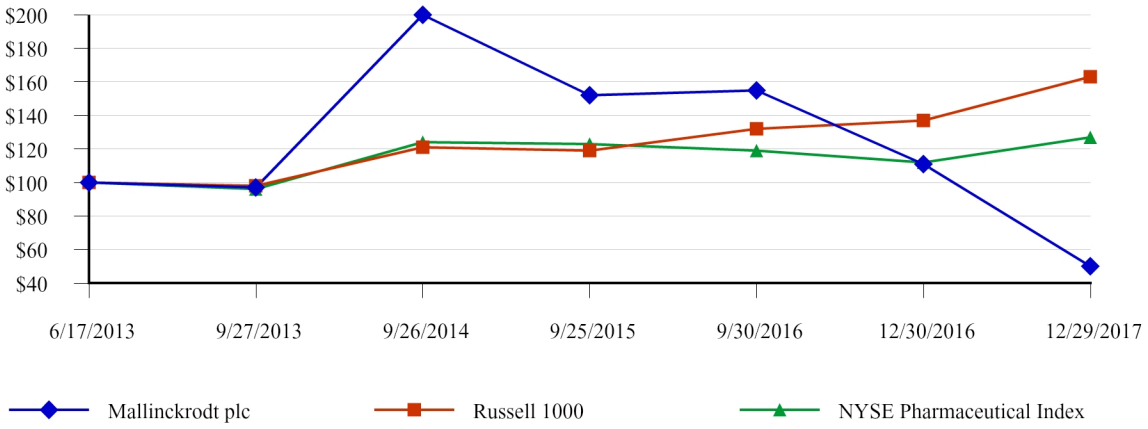
Performance Graph

The following performance graph and related information shall not be deemed "soliciting material" or to be "filed" with the U.S. SEC, 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 December 29, 2017.

Comparison of Cumulative Total Return*

Among Mallinckrodt plc, the Russell 1000 Index and NYSE Pharmaceutical Index



*$100 invested on June 17, 2013 in shares or index.

Performance Graph Data

	Mallinckrodt	Russell 1000 Index	NYSE Pharmaceutical Index
June 17, 2013	$ 100.00	$ 100.00	$ 100.00
September 27, 2013	96.82	104.02	100.18
September 26, 2014	200.00	121.42	124.26
September 25, 2015	152.11	118.54	122.72
September 30, 2016	155.07	132.37	118.73
December 30, 2016	110.71	136.71	111.85
December 29, 2017	50.13	163.15	126.57

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 U.S. SEC within 120 days after December 29, 2017.

Item 6. Selected Financial Data.

The following table sets forth selected financial data as of and for the periods presented. This selected financial data reflects the consolidated position of Mallinckrodt as an independent, publicly-traded company for periods on or after its legal separation from Covidien on June 28, 2013.

The consolidated statements of income data for fiscal 2017, 2016, and 2015 and three months ended December 30, 2016, and the consolidated balance sheet data as of December 29, 2017 and December 30, 2016 were derived from our consolidated financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K. The consolidated statements of income for fiscal 2014 and 2013 and the consolidated balance sheet data as of September 30, 2016, September 25, 2015, September 26, 2014 and September 27, 2013 were derived from our audited consolidated financial statements that are not included in this Annual Report on Form 10-K. In fiscal 2017 and 2016, the Company completed the sale of its Nuclear Imaging and CMDS businesses to IBA Molecular ("IBAM") and Guerbet S.A. ("Guerbet"), respectively.

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.

(in millions, except per share data)	Fiscal Year Ended [1]					Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	September 26, 2014	September 27, 2013 [2]	December 30, 2016
Consolidated and Combined Statement of Income Data:						
Net sales	$ 3,221.6	$ 3,380.8	$ 2,923.1	$ 1,650.3	$ 1,274.7	$ 829.9
Gross profit	1,656.3	1,855.0	1,622.9	884.6	610.5	445.8
Research and development expenses [3]	277.3	262.2	203.3	140.5	141.9	66.2
Operating income (loss) [4] [5]	420.1	617.3	353.8	43.4	20.0	(206.8)
Income (loss) from continuing operations before income taxes	61.6	233.4	107.3	(34.6)	2.2	(298.5)
Income (loss) from continuing operations	1,771.2	489.0	236.6	(22.0)	(27.6)	(176.8)
Share Data:						
Basic income (loss) from continuing operations per share	$ 18.13	$ 4.42	$ 2.03	$ (0.34)	$ (0.48)	$ (1.67)
Diluted income (loss) from continuing operations per share	18.09	4.39	2.00	(0.34)	(0.48)	(1.67)
Cash dividends per ordinary share	—	—	—	—	—	—
	December 29, 2017	September 30, 2016	September 25, 2015	September 26, 2014	September 27, 2013	December 30, 2016
Consolidated Balance Sheet Data:						
Total assets	$ 15,280.9	$ 15,498.7	$ 16,404.1	$ 12,787.3	$ 3,556.6	$ 15,206.3
Long-term debt	6,420.9	5,788.7	6,474.3	3,874.0	918.3	5,880.8
Shareholders' equity	6,522.0	5,270.7	5,311.2	4,958.0	1,255.6	4,984.3

(1) Fiscal 2016 included 53 weeks. All other fiscal years presented include 52 weeks. Refer to the Consolidated Financial Statements for detail on our change in fiscal year, as well as trends in financial condition and results of operations for the fiscal years ended December 29, 2017, September 30, 2016 and September 25, 2015 and the three months ended December 30, 2016.

(2) Represents combined historical business and operations of Covidien's Pharmaceuticals business as it was historically managed as part of Covidien and is 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 period presented, nor is it necessarily indicative of our future performance as an independent, publicly-traded company.

(3) 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.

(4) Fiscal 2014 and 2013 include restructuring charges, net of $68.0 million and $16.8 million. 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 includes costs related to the build-out of our corporate infrastructure of $70.6 million. Fiscal 2014 and 2013 include separation related costs of $9.6 million and $74.2 million, respectively.

(5) Fiscal 2013 includes expense allocations from Covidien of $39.6 million related to finance, legal, information technology, human resources, communications, employee benefits and incentives, insurance and share-based compensation. Effective with the Separation on June 28, 2013, we assumed responsibility for all of these functions and related costs.

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 specialty pharmaceutical products and therapies. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; analgesics and gastrointestinal products.

Through December 29, 2017, we operated our business in two reportable segments, which are further described below:

- *Specialty Brands* includes branded medicines; and
- *Specialty Generics* includes specialty generic drugs, active pharmaceutical ingredients ("APIs") and external manufacturing.

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 SG&A expenses and are now included in R&D expenses. As a result, $56.4 million of expenses previously included in SG&A for the fiscal year ended September 25, 2015 has 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.

Fiscal Year

We historically reported our results based on a "52-53 week" year ending on the last Friday of September. On May 17, 2016, our Board of Directors approved a change in our fiscal year end to the last Friday in December from the last Friday in September. The change in fiscal year became effective for our 2017 fiscal year, which began on December 31, 2016 and ended on December 29, 2017. As a result of the change in fiscal year end, we filed a Transition Report on Form 10-Q on February 7, 2017 covering the period from October 1, 2016 through December 30, 2016 ("the three months ended December 30, 2016") with the comparable period from September 26, 2015 through December 25, 2015 ("the three months ended December 25, 2015"). Fiscal 2016 covers the period from September 26, 2015 through September 30, 2016.

Significant Events

Acquisitions

In February 2018 (subsequent to our fiscal year ended December 29, 2017), we acquired Sucampo Pharmaceuticals, Inc. ("Sucampo"). Consideration for the transaction consisted of approximately $1.2 billion, including the assumption of Sucampo's third-party debt ("the Sucampo Acquisition"). Sucampo's commercialized products include AMITIZA® (lubiprostone), a leading global product in the branded constipation market, and RESCULA® (unoprostone isopropyl ophthalmic solution) 0.15%, which is indicated for ocular hypertension and open-angle glaucoma, and marketed in Japan. In addition, Sucampo has two pipeline products that are currently in Phase 3 development: VTS-270, a developmental product for Niemann-Pick Type C, a rare, neurodegenerative, and ultimately fatal disease that can present at any age, and CPP-1X/sulindac, a developmental product for Familial Adenomatous Polyposis under a collaborative agreement between Cancer Prevention Pharmaceuticals and Sucampo. The acquisition was funded through our issuance of $600.0 million aggregate principal amount of senior secured notes in February 2018, a $900.0 million borrowing under our revolving credit facility (that was fully drawn as of December 29, 2017) and cash on hand.

In December 2017, we acquired Ocera Therapeutics, Inc. ("Ocera") for upfront consideration of $42.4 million, of which $1.9 million of the consideration was paid subsequent to December 29, 2017, and contingent consideration up to $75.0 million based on the successful completion of certain development and sales milestones. Ocera is a clinical stage biopharmaceutical company focused on the development and commercialization of novel therapeutics for orphan and other serious liver diseases with a high unmet medical need. Ocera's developmental product MNK-6105 (previously OCR-002), an ammonia scavenger, is being studied for treatment of hepatic encephalopathy, a neuropsychiatric syndrome associated with hyperammonemia, a complication of acute or chronic liver disease. The acquisition was funded with cash on hand.

In October 2017, we entered into a licensing agreement for development and commercialization of NeuroproteXeon Inc.'s ("NeuroproteXeon" and the "Xenon Licensing Agreement") investigational, pharmaceutical-grade xenon gas for inhalation therapy being evaluated to improve survival and functional outcomes for patients resuscitated after a cardiac arrest. If approved, xenon gas for inhalation will expand our portfolio of hospital drug-device combination products providing therapies for critically ill patients. Under the terms of the Xenon Licensing Agreement, we paid $10.0 million upfront with cash on hand to reimburse NeuroproteXeon for certain product development costs, and gained exclusive rights to commercialize the therapy, if approved, in the U.S., Canada, Japan and Australia. The Xenon Licensing Agreement includes additional payments of up to $25.0 million dependent on developmental, regulatory and sales milestones. In addition, NeuroproteXeon will receive tiered royalties on applicable worldwide product sales and a transfer price for commercial product supply. NeuroproteXeon will continue to be responsible for the cost of development and will manage the development of the product in collaboration with us.

In September 2017, we acquired InfaCare Pharmaceutical Corporation ("InfaCare") in a transaction valued at approximately $80.4 million, with additional payments of up to $345.0 million dependent on regulatory and sales milestones ("the InfaCare Acquisition"). InfaCare is focused on development and commercialization of proprietary pharmaceuticals for neonatal and pediatric patient populations. InfaCare's developmental product stannsoporfin (previously stannsoporfin), a heme oxygenase inhibitor, is under investigation for its potential to reduce the production of bilirubin, the elevation of which can contribute to serious consequences in infants. The acquisition was funded with cash on hand.

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"). 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. The acquisition was funded with cash on hand.

In February 2016, we acquired three commercial stage topical hemostasis drugs from The Medicines Company ("the Hemostasis Acquisition") - Recothrom, PreveLeak and 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 acquisition was funded with cash on hand. As our emphasis has evolved to focus on a development portfolio of treatments for severe and critically ill infants and adults, these products are now less strategic for us, and in January 2018 we announced plans to divest Recothrom and Preveleak and to discontinue marketing of Raplixa. See the Divestitures and the Business Factors Influencing the Results of Operations sections below for further discussion.

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. Therakos' primary immunotherapy product relates to the administering of extracorporeal photopheresis therapies through the UVAR XTS® and CELLEX™ Photopheresis Systems. 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.

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. Ikaria's primary product was Inomax, a vital treatment option in neonatal critical care. 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.

Divestitures

To further execute upon our strategic vision, on February 22, 2018, our Board of Directors provided authorization to dispose of three areas of our business, which are referred to collectively as "the Specialty Generics Disposal Group" and include the following: (1) Our Specialty Generics business comprised of our Specialty Generics segment, with the exception of our external manufacturing operations; (2) certain of our non-promoted brands business, which is currently reflected in our Specialty Brands segment; and (3) our ongoing, post-divestiture supply agreement with the acquirer of the CMDS business, which is currently reflected in our Other non-operating segment. Given our shift in focus to patients with severe and critical conditions, the areas within the Specialty Generics Disposal Group no longer align with our strategic vision, as such, beginning in the first quarter of fiscal 2018, the historical financial results attributable to the Specialty Generics Disposal Group will be reflected in our consolidated financial statements as discontinued operations.

On January 8, 2018, we announced that we entered into a definitive agreement to sell our PreveLeak and Recothrom assets to Baxter International, Inc. ("Baxter") for approximately $185.0 million, with upfront payment of $153.0 million, inclusive of existing inventory, and the remainder in potential future milestones ("the PreveLeak/Recothrom Transaction"). Baxter will assume other expenses, including contingent liabilities associated with PreveLeak upon close of the transaction, which we expect to occur in the first quarter of 2018.

On March 17, 2017, we completed the sale of our Intrathecal Therapy business to Piramal Enterprises Limited's subsidiary in the United Kingdom ("U.K."), Piramal Critical Care ("Piramal"), for approximately $203.0 million, including fixed consideration of $171.0 million and contingent consideration of up to $32.0 million. We recorded a pre-tax gain on the sale of the business of $56.6 million during fiscal 2017, which excluded any potential proceeds from the contingent consideration and reflects a post-sale working capital adjustment. The financial results of the Intrathecal Therapy business are presented within continuing operations as this divestiture did not meet the criteria for discontinued operations classification.

On January 27, 2017, we completed the sale of our Nuclear Imaging business to IBA Molecular ("IBAM") for approximately $690.0 million before tax impacts, including up-front consideration of approximately $574.0 million, up to $77.0 million of contingent consideration and the assumption of certain liabilities. We recorded a pre-tax gain on the sale of the business of $362.8 million during fiscal 2017, which excluded any potential proceeds from the contingent consideration. The financial results for the Nuclear Imaging business, including the recast of prior year balances, are presented within discontinued operations.

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. The financial results for the CMDS business are presented as a discontinued operation.

Reorganization of Legal Entity Ownership

During the three months ended December 29, 2017, we completed a reorganization of our legal entity ownership ("the Reorganization") to align with our ongoing transformation to become an innovation-driven specialty pharmaceuticals growth company. Many factors were considered in effecting the Reorganization, including streamlining treasury functions, simplifying legal entity reporting processes and capital allocation efficiencies.

Given this Reorganization, the Internal Revenue Code required us to reallocate our tax basis from an investment in shares of a wholly-owned subsidiary to assets within another legal entity with no corresponding change in accounting basis. A deferred tax liability was not recognized on the wholly-owned subsidiary as there is a means for its recovery in a tax-free manner. The reallocation of tax basis resulted in a decrease to the net deferred tax liabilities associated with the assets within the other legal entity. As a result, during fiscal 2017, we recognized an income tax benefit, net of unrecognized tax benefits, of $1,054.8 million primarily as a result of a reduction to our net deferred tax liabilities. The reduction to net deferred tax liabilities was comprised of a $679.3 million reduction to interest-bearing U.S. deferred tax liabilities and the remainder primarily related to reductions to net deferred tax liabilities associated with intangible assets.

Tax Cuts and Jobs Act

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the “TCJA or U.S. Tax Reform”). The TCJA makes broad and complex changes to the U.S. tax code, the effects of which have been incorporated into our fiscal 2017 provision for income taxes, as applicable. The TCJA provisions effective within 2017, include, but are not limited to (1) requiring a one-time transition tax on certain undistributed earnings of our foreign subsidiaries of U.S. entities, (2) bonus depreciation that will allow for full expensing of qualified property, and (3) reducing the U.S. federal corporate statutory tax rate from 35% to 21%. The TCJA also establishes new tax laws that will affect fiscal 2018, including, but not limited to (1) elimination of the corporate alternative minimum tax, (2) creation of the base erosion anti-abuse tax, a new minimum tax, (3) a general elimination of U.S. federal income taxes on dividends from non-U.S. subsidiaries, (4) a new provision designed to tax global intangible low-taxed income, which allows for the possibility of using foreign tax credits and a deduction of up to 50% to offset the

income tax liability, (5) tightening the limitation on deductible interest expense, (6) limitations on net operating losses generated after December 31, 2017 to 80% of taxable income, and (7) reductions to the amount of the orphan drug research credit generated after December 31, 2017.

In connection with our initial analysis of the impact of the TCJA, a discrete net tax benefit of $456.9 million was recognized in fiscal 2017, primarily for the adjustment of our U.S. net deferred income tax liabilities for the reduction of the U.S. federal corporate statutory tax rate to 21%. These provisional estimates are based upon our initial analysis and current interpretation of the legislation. Given the complexity of the legislation, anticipated guidance from the U.S. Treasury, and the potential for additional guidance from the SEC or Financial Accounting Standards Board, these estimates may be adjusted during fiscal 2018 under the provisions of Staff Accounting Bulletin 118. For fiscal 2018, due to the TCJA's reduction to the U.S. federal corporate statutory tax rate from 35% to 21%, we expect a relative decrease to tax expense as a percentage of operating income mostly offset by an increase to tax expense resulting from tightened restrictions in deductibility of interest expense.

Business Factors Influencing the Results of Operations

Products

Specialty Brands

H.P. Acthar Gel Net sales of H.P. Acthar Gel for fiscal 2017 increased $34.7 million, or 3.0%, to $1,195.1 million, driven by favorable pricing and lower rebate expenses. However, during the latter half of fiscal 2017, net sales of H.P. Acthar Gel were impacted by patient withdrawal issues. We have taken a number of steps to address the issue, including engagement with payers, prescribers and patients and we remain focused on returning H.P. Acthar Gel to growth.

Raplixa As a result of lower than previously anticipated commercial opportunities for Raplixa, we recognized an impairment charge of $63.7 million to fully impair the Raplixa intangible asset and a $3.3 million inventory provision. In addition, we reduced the Raplixa contingent consideration liability to zero as of December 29, 2017, resulting in a $54.6 million fair value adjustment. The net impact of these Raplixa related adjustments was a $12.4 million charge in fiscal 2017. Furthermore, on January 8, 2018, we announced that we will discontinue marketing of Raplixa upon the close of the PreveLeak/Recothrom Transaction, which is expected to occur in the first quarter of 2018. As a result, we plan to terminate certain contracts related to the production of Raplixa. While we expect to incur a charge in fiscal 2018 upon the successful termination of these contracts, the actual liability will not be known until our negotiations with the respective vendors have concluded.

Specialty Generics

The Specialty Generics segment has and may continue to experience customer consolidation and increased generic product approvals leading to increased competition, which is expected to result in further downward pressure on net sales, operating income and cash flows from operations. Net sales from the Specialty Generics segment were $839.5 million, $1,025.2 million, $1,251.6 million, and $212.9 million in fiscal 2017, 2016, 2015 and the three months ended December 30, 2016, respectively

In November 2014, we were informed by the FDA that it believes our Methylphenidate ER products may not be therapeutically equivalent to the category reference listed drug and the FDA reclassified our Methylphenidate ER from freely substitutable at the pharmacy level (class AB) to presumed to be therapeutically inequivalent (class BX). The FDA has indicated that it has not identified any serious safety concerns with the products. We continue to market our Methylphenidate ER products as a class BX-rated drug. The FDA's action to reclassify our Methylphenidate ER products had, and is expected to continue to have, a negative impact on net sales and operating income. Net sales of our Methylphenidate ER products were $71.7 million, $103.5 million, $136.5 million and $22.0 million in fiscal 2017, 2016, 2015 and the three months ended December 30, 2016, respectively.

On October 18, 2016, the FDA initiated proceedings, proposing to withdraw approval of Mallinckrodt’s ANDA for Methylphenidate ER. We have requested a hearing in the withdrawal proceedings, which has been deferred by the FDA, in order to give the Center for Drug Evaluation and Research ("CDER") an opportunity to complete its production of documents which we have requested from CDER to enable us to prepare our legal arguments in support of gaining a hearing on the withdrawal issue. CDER shared an initial set of documents with us in June 2017 and a second set of documents in October 2017. Following our receipt of the October tranche of documents from CDER, we presented a supplemental document request to CDER to ensure all of our initial document requests were fulfilled, and on February 13, 2018, CDER provided a final set of documents in response to our requests. We are currently reviewing the CDER documents and preparing the legal arguments in support of our position in the withdrawal proceedings, which we will be filing in early third quarter 2018. We plan to vigorously set forth our position in the withdrawal

proceedings. A potential outcome of the withdrawal proceedings is that our Methylphenidate ER products may lose their FDA approval, which could have a material, negative impact to our Specialty Generics segment.

The FDA recently approved new products that are expected to compete with our Methylphenidate ER products, and one competitor recently launched their products. Additional products expected to compete with our Methylphenidate ER products may be launched over the next several quarters. All of these products have a class AB rating compared with the class BX rating on our Methylphenidate ER products. It is uncertain how these product approvals may impact the FDA's withdrawal proceedings associated with our Methylphenidate ER products.

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. The 2013 Mallinckrodt Program is substantially complete.

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. As of December 29, 2017, we incurred restructuring charges of $124.7 million under the 2013 Mallinckrodt Program and $50.6 million under the 2016 Mallinckrodt Program. In addition to the 2013 and 2016 Mallinckrodt Program, we have taken restructuring actions to generate synergies from our acquisitions.

Results of Operations

Fiscal Year Ended December 29, 2017 Compared with Fiscal Year Ended September 30, 2016

Net Sales

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

	Fiscal Year Ended		Percentage Change
	December 29, 2017	September 30, 2016	
U.S.	$ 2,899.0	$ 3,095.4	(6.3)%
Europe, Middle East and Africa	242.3	211.8	14.4
Other	80.3	73.6	9.1
Net sales	$ 3,221.6	$ 3,380.8	(4.7)

Net sales in fiscal 2017 decreased $159.2 million, or 4.7%, to $3,221.6 million, compared with $3,380.8 million in fiscal 2016. This decrease was driven by our Specialty Generics segment due to increased competition and customer consolidation, which has resulted in downward pricing pressure. Our Specialty Brands segment experienced an increase in net sales primarily due to favorable pricing for H.P. Acthar Gel, partially offset by previously mentioned patient withdrawal issues, and growth from Inomax. Partially offsetting the increase was a decrease in net sales from Other branded products primarily driven by the sale of our Intrathecal Therapy business in the first quarter of 2017 and a decrease in net sales of Exalgo (hydromorphone HCI) extended-release tablets, CII ("Exalgo"). In addition, overall net sales growth during fiscal 2017 was negatively impacted by the extra selling week during fiscal 2016. 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 2017 decreased $198.7 million, or 10.7%, to $1,656.3 million, compared with $1,855.0 million in fiscal 2016. Gross profit margin was 51.4% for fiscal 2017, compared with 54.9% for in fiscal 2016. The decrease in gross profit and gross profit margin was primarily attributable to channel consolidated and increased price competition in the Specialty Generics business, contributing to a $197.6 million decline in that segment's gross profit. Also negatively impacting

gross profit was an increase of $13.8 million in royalty expense and $13.2 million in inventory provision expense, both of which were primarily attributable to our Specialty Brands segment.

Selling, general and administrative expenses. SG&A expenses for fiscal 2017 were $920.9 million, compared with $925.3 million for fiscal 2016, a decrease of $4.4 million, or 0.5%. Fiscal 2017 included a $70.5 million charge from the recognition of previously deferred losses on the settlement of obligations associated with the termination of six defined benefit pension plans, offset by a $54.6 million decrease in fair value of the contingent consideration liability related to Raplixa, reflective of lower than previously anticipated commercial opportunities for the product. The remaining change consisted of various factors, including higher stock compensation expense and charitable contributions, partially offset by lower advertising and promotion expenses, legal fees, employee compensation costs, professional fees and pension expense following the settlement of our defined benefit pension plans. SG&A expenses were 28.6% of net sales for fiscal 2017 and 27.4% of net sales for fiscal 2016.

Research and development expenses. R&D expenses increased $15.1 million, or 5.8%, to $277.3 million in fiscal 2017, compared with $262.2 million in fiscal 2016. The increase was attributable to higher spend in the Specialty Brands segment, where our pipeline products are concentrated. This increase was partially offset by lower spend in the Specialty Generics segment and the sale of our Intrathecal Therapy business in the first quarter of 2017. 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 8.6% and 7.8% in fiscal 2017 and 2016, respectively.

Restructuring and related charges, net. During fiscal 2017, we recorded $36.4 million of restructuring and related charges, net, of which $5.2 million related to accelerated depreciation and was included in cost of sales. The remaining $31.2 million primarily related to exiting certain facilities and employee severance and benefits across both of our segments and corporate functions. During fiscal 2016, we recorded restructuring and related charges, net, of $38.2 million, 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.

Non-restructuring impairment charges. Non-restructuring impairment charges were $63.7 million for fiscal 2017 related to the Raplixa intangible asset, as previously mentioned. Non-restructuring impairment charges were $16.9 million for fiscal 2016 and related to in-process research and development intangible assets associated with the CNS Therapeutics acquisition in fiscal 2013, which 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 2017 and fiscal 2016, net interest expense was $364.5 million and $383.3 million, respectively. This decrease was primarily driven by the $12.9 million decrease in interest accrued on deferred tax liabilities associated with outstanding installment notes primarily due to the Reorganization and the TCJA that reduced the interest-bearing U.S. deferred tax liabilities balance by $1,031.1 million. This reduction in the interest-bearing U.S. deferred tax liabilities also resulted in a one-time charge of $8.4 million, which partially offsets the aforementioned decrease. In addition, the lower average outstanding debt balance in fiscal 2017 compared with fiscal 2016 contributed $2.4 million to the decrease and interest expense included $21.9 million and $26.4 million of non-cash interest expense during fiscal 2017 and fiscal 2016, respectively.

Other income, net. During fiscal 2017 and 2016, we recorded other income, net, of $6.0 million and loss of $0.6 million, respectively. Fiscal 2017 included a $10.0 million charge associated with the refinancing of our term loan, partially offset by an $8.3 million gain on debt repurchases, that aggregated to a total principal amount of $66.9 million. The remaining amounts in both fiscal years represented items including gains and losses on intercompany financing, foreign currency transactions and related hedging instruments.

Benefit from income taxes. In fiscal 2017, we recognized an income tax benefit of $1,709.6 million on income from continuing operations before income taxes of $61.6 million. The fiscal 2017 income tax benefit is comprised of $38.1 million of current tax expense and $1,747.7 million of deferred tax benefit which is predominantly related to the Reorganization, TCJA and acquired intangibles. In fiscal 2016, income tax benefit was $255.6 million on income from continuing operations before income taxes of $233.4 million. The fiscal 2016 income tax benefit is comprised of $120.8 million of current tax expense and $376.4 million of deferred tax benefit which is predominantly related to acquired intangible assets. Our effective tax rate was negative 2,775.3% and negative 109.5% for fiscal 2017 and 2016, respectively. Our effective tax rate for fiscal 2017 was most significantly impacted by the recognition of $1,054.8 million tax benefit associated with the Reorganization and $456.9 million of tax benefit associated with the TCJA. Further impacts include receiving $5.5 million of tax benefit associated with $100.1 million of restructuring costs and non-restructuring impairment charges, $0.7 million of tax expense associated with $41.4 million of income from the decrease in the fair value of contingent consideration liabilities, $28.3 million of tax benefit associated with $70.5 million from the termination and settlement of our funded U.S. pension plans, $38.9 million of tax expense associated with $56.6 million of pre-tax gain associated with the sale of our Intrathecal Therapy business, $13.8 million of tax benefit primarily associated with U.S. tax credits,

and $223.1 million of tax benefit associated with the rate difference between U.K. and non-U.K. jurisdictions (excluding the impact of above referenced restructuring, contingent consideration, pension plan and sale of our Intrathecal Therapy business). 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.

Income from discontinued operations, net of income taxes. We recorded income of $363.2 million and $154.7 million on discontinued operations, net of income taxes, during fiscal 2017 and 2016, respectively. During fiscal 2017, the income from discontinued operations included a $361.7 million gain on divestiture and $4.1 million of income from operating results, both net of tax, associated with the Nuclear Imaging business. The fiscal 2016 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.

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 Ended		
	September 30, 2016	September 25, 2015	Percentage Change
U.S.	$ 3,095.4	$ 2,647.0	16.9%
Europe, Middle East and Africa	211.8	159.0	33.2
Other	73.6	117.1	(37.1)
Net sales	$ 3,380.8	$ 2,923.1	15.7

Net sales in fiscal 2016 increased $457.7 million, or 15.7%, to $3,380.8 million, compared with $2,923.1 million in fiscal 2015. This increase was primarily driven by the full year inclusion of Inomax and Therakos net sales along with H.P. Acthar Gel 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. These increases were partially offset by a $148.8 million increase in amortization, primarily associated with Inomax and Therakos 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% in fiscal 2016, compared with 55.5% in 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 acquisition of Questcor Pharmaceuticals, Inc. ("Questcor") on August 14, 2014 ("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. R&D activities focused 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% for fiscal 2016 and 2015, respectively.

Restructuring and related charges, net. During fiscal 2016, we recorded restructuring and related charges, net, of $38.2 million, 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 non-vested 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. During fiscal 2016, we recorded $16.9 million of non-restructuring impairment charges. 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 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.

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. The fiscal 2016 income tax benefit is comprised of $120.8 million of current tax expense and $376.4 million of deferred tax benefit which is predominantly related to acquired intangible assets. In fiscal 2015, income tax benefit was $129.3 million on a loss from continuing operations before income taxes of $107.3 million. The fiscal 2015 income tax benefit is comprised of $67.5 million of current tax expense and $196.8 million of deferred tax benefit which is predominantly related to acquired intangible assets. Our effective tax rate was negative 109.5% and 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 from 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.

Three Months Ended December 30, 2016 Compared with Three Months Ended December 25, 2015

Net Sales

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

	Three Months Ended		Percentage Change
	December 30, 2016	December 25, 2015	
U.S.	$ 763.7	$ 740.2	3.2%
Europe, Middle East and Africa	52.8	49.3	7.1
Other	13.4	21.7	(38.2)
Net sales	$ 829.9	$ 811.2	2.3

Net sales during the three months ended December 30, 2016 increased $18.7 million, or 2.3%, to $829.9 million, compared with $811.2 million during the three months ended December 25, 2015. This increase was primarily driven by growth in the Specialty Brands segment with higher volume for H.P. Acthar Gel and Ofirmev, benefits of Inomax contracting and the fiscal 2016 Hemostasis Acquisition. These increases were partially offset by decreased net sales in the Specialty Generics segment attributable to increased competition and customer consolidation, which has resulted in downward pricing pressure. For further information on changes in our net sales, refer to "Business Segment Results" within Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Operating Income

Gross profit. Gross profit for the three months ended December 30, 2016 decreased $5.1 million, or 1.1%, to $445.8 million, compared with $450.9 million during the three months ended December 25, 2015. The decrease in gross profit primarily resulted from a $53.2 million decrease in gross profit from the Specialty Generics segment. This was partially offset by higher net sales in the Specialty Brands segment, primarily due to volume growth across our key brands, and a $12.6 million decrease in expense associated with fair value adjustments of acquired inventory. Gross profit margin was 53.7% for the three months ended December 30, 2016, compared with 55.6% for the three months ended December 25, 2015. The decrease in gross profit margin was primarily attributable to the increased price competition in the Specialty Generics business, partially offset by a higher percentage of overall sales relating to the higher-margin Specialty Brands business.

Selling, general and administrative expenses. SG&A expenses for the three months ended December 30, 2016 were $368.3 million, compared with $223.3 million for the three months ended December 25, 2015, an increase of $145.0 million, or 64.9%. The increase was primarily attributable to charges during the three months ended December 30, 2016 related to a $102.0 million settlement with the Federal Trade Commission ("FTC") and the states of Maryland, Texas, Washington, New York and Alaska (collectively, "the Settling States") and $45.0 million associated with the recognition of previously deferred pension related losses upon lump sum distribution to current and former employees under our pension plan termination. The three months ended December 25, 2015, included $11.5 million of legal reserve accruals. The remaining $9.5 million increase from the three months ended December 30, 2016 compared with December 25, 2015 is comprised of various minor increases and decreases. SG&A expenses were 44.4% of net sales for the three months ended December 30, 2016 and 27.5% of net sales for the three months ended December 25, 2015. The higher percentage of net sales is attributable to the aforementioned charges with the FTC and the Settling States along with the pension related settlement losses, which collectively represented 17.7% of net sales for the three months ended December 30, 2016.

Research and development expenses. R&D expenses increased $4.8 million, or 7.8%, to $66.2 million during the three months ended December 30, 2016, compared with $61.4 million during the three months ended December 25, 2015. R&D activities focused 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 8.0% and 7.6% for the three months ended December 30, 2016 and December 25, 2015, respectively.

Restructuring and related charges, net. During the three months ended December 30, 2016, we recorded $5.3 million of restructuring and related charges, net, including $1.5 million of accelerated depreciation in SG&A and cost of sales, primarily related to employee severance and benefits across our Specialty Brands segment and corporate functions. During the three months ended December 25, 2015, we recorded $4.2 million of restructuring and related charges, net, including $0.1 million of accelerated

depreciation in cost of sales, primarily related to employee severance benefits across both of our reportable segments and corporate functions.

Non-restructuring impairment charges. During the three months ended December 30, 2016, we recorded a $207.0 million impairment charge associated with our Specialty Generics segment and a $7.3 million impairment of a license associated with a product the Company elected to discontinue.

Non-Operating Items

Interest expense and interest income. During the three months ended December 30, 2016 and December 25, 2015, net interest expense was $90.8 million and $97.6 million, respectively. The decrease in net interest expense was impacted by a $2.8 million decrease in interest accrued on deferred tax liabilities associated with outstanding installment notes, due to payments that reduced the deferred tax liability balance. The decrease was also driven by lower average outstanding balances on the revolving credit facility and term loan borrowings. Interest expense during the three months ended December 30, 2016 and December 25, 2015 included $6.5 million and $6.7 million, respectively, of non-cash interest expense.

Other income (expense), net. During the three months ended December 30, 2016, we recorded other expense, net, of $0.9 million and during the three months ended December 25, 2015, we recorded other income, net, of $2.0 million both of which represented miscellaneous items, including gains and losses on intercompany financing, foreign currency transactions and related hedging instruments.

Benefit from income taxes. Income tax benefit was $121.7 million on a loss from continuing operations before income taxes of $298.5 million for the three months ended December 30, 2016. For the three months ended December 30, 2016 income tax benefit is comprised of $82.0 million of current tax expense and $203.7 million of deferred tax benefit which is predominantly related to acquired intangibles. Income tax benefit was $37.3 million on income from continuing operations before income taxes of $66.5 million for the three months ended December 25, 2015. For the three months ended December 25, 2015 income tax benefit is comprised of $17.6 million of current tax expense and $54.9 million of deferred tax benefit which is predominantly related to acquired intangibles. Our effective tax rates were 40.8% and negative 56.1% for the three months ended December 30, 2016 and December 25, 2015, respectively. The effective tax rate for the three months ended December 30, 2016 was impacted by receiving $12.7 million of tax benefit associated with an adjustment to the Company's wholly owned partnership investment, $0.6 million of tax benefit associated with $207.0 million of goodwill impairment, $36.6 million of tax benefit associated with the $102.0 million settlement with governmental authorities, and $72.3 million of tax benefit associated with the rate difference between U.K. and non-U.K. jurisdictions (excluding impact of above referenced settlement and impairment).The effective tax rate for the three months ended December 25, 2015 was impacted by $3.3 million of tax benefit associated with accrued income tax liabilities and uncertain tax positions, $3.6 million of tax benefit associated with U.S. credits and $45.1 million of tax benefit associated with the rate difference between U.K. and non-U.K. jurisdictions.

Income from discontinued operations, net of income taxes. We recorded income of $23.6 million and $107.3 million from discontinued operations, net of income taxes, during the three months ended December 30, 2016 and December 25, 2015, respectively. Income from discontinued operations for the three months ended December 30, 2016, primarily represented the operating results associated with the Nuclear Imaging business that was classified as held for sale during the period. Income from discontinued operations for the three months ended December 25, 2015, included a $97.0 million gain on the disposal of the CMDS business and $12.1 million of income from the operating results of the Nuclear Imaging business.

Business Segment Results

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 December 29, 2017 Compared with Fiscal Year Ended September 30, 2016

Net Sales

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

	Fiscal Year Ended		Percentage Change
	December 29, 2017	September 30, 2016	
Specialty Brands	$ 2,325.3	$ 2,300.6	1.1%
Specialty Generics	839.5	1,025.2	(18.1)
Net sales of operating segments	3,164.8	3,325.8	(4.8)
Other [(1)]	56.8	55.0	3.3
Net sales	$ 3,221.6	$ 3,380.8	(4.7)

(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 2017 increased $24.7 million, or 1.1%, to $2,325.3 million, compared with $2,300.6 million for fiscal 2016. The increased net sales were primarily driven by a $34.7 million or 3.0% increase in H.P. Acthar Gel net sales and a $30.9 million or 6.5% increase in Inomax net sales compared to fiscal 2016. The H.P. Acthar Gel net sales increase was primarily driven by favorable pricing, partially offset by previously mentioned patient withdrawal issues. Inomax net sales continue to benefit from a favorable 2016 contracting cycle. These increases were partially offset by a $79.0 million or 60.1% decrease in Other products compared with fiscal 2016. This decrease was primarily attributable to the sale of our Intrathecal Therapy business in the first quarter of fiscal 2017 and a $23.5 million or 91.9% decrease in Exalgo driven by lower volumes. Net sales of the Intrathecal Therapy business through the March 17, 2017 divestiture date were $8.0 million compared to $44.6 million for fiscal 2016. In addition, overall net sales growth during fiscal 2017 was negatively impacted by the extra selling week during fiscal 2016.

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

	Fiscal Year Ended		Percentage Change
	December 29, 2017	September 30, 2016	
U.S.	$ 2,244.9	$ 2,224.9	0.9%
Europe, Middle East and Africa	73.0	69.8	4.6
Other	7.4	5.9	25.4
Net sales	$ 2,325.3	$ 2,300.6	1.1

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

	Fiscal Year Ended		Percentage Change
	December 29, 2017	September 30, 2016	
H.P. Acthar Gel	$ 1,195.1	$ 1,160.4	3.0%
Inomax	505.2	474.3	6.5
Ofirmev	302.5	284.3	6.4
Therakos	214.9	207.6	3.5
Hemostasis products	55.1	42.5	29.6
Other	52.5	131.5	(60.1)
Specialty Brands	$ 2,325.3	$ 2,300.6	1.1

Specialty Generics. Net sales for fiscal 2017 decreased $185.7 million, or 18.1%, to $839.5 million, compared with $1,025.2 million for fiscal 2016. The decrease in net sales was driven by decreases of $61.2 million, $58.5 million and $47.4 million in net sales of hydrocodone-related products, other controlled substances and oxycodone-related products, respectively. These decreases were due to increased competition and customer consolidation, which has resulted in downward pricing pressure. Other products increased by $13.2 million or 7.3% primarily attributable to a discrete shipment of peptides that generated net sales of $12.9 million in fiscal 2017. In addition, overall net sales growth during fiscal 2017 was negatively impacted by the extra selling week during fiscal 2016.

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

	Fiscal Year Ended		Percentage Change
	December 29, 2017	September 30, 2016	
U.S.	$ 654.1	$ 870.5	(24.9)%
Europe, Middle East and Africa	112.5	87.0	29.3
Other	72.9	67.7	7.7
Net sales	$ 839.5	$ 1,025.2	(18.1)

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

	Fiscal Year Ended		Percentage Change
	December 29, 2017	September 30, 2016	
Hydrocodone (API) and hydrocodone-containing tablets	$ 85.3	$ 146.5	(41.8)%
Oxycodone (API) and oxycodone-containing tablets	78.8	126.2	(37.6)
Methylphenidate ER	71.7	103.5	(30.7)
Other controlled substances	409.6	468.1	(12.5)
Other	194.1	180.9	7.3
Specialty Generics	$ 839.5	$ 1,025.2	(18.1)

Operating Income

Operating income by segment and as a percentage of segment net sales for fiscal 2017 and 2016 is shown in the following table (dollars in millions):

	Fiscal Year Ended			
	December 29, 2017		September 30, 2016	
Specialty Brands	$ 1,155.2	49.7%	$ 1,166.2	50.7%
Specialty Generics	231.5	27.6	376.1	36.7
Segment operating income	1,386.7	43.8	1,542.3	46.4
Unallocated amounts:				
Corporate and allocated expenses	(172.0)		(169.8)	
Intangible asset amortization	(694.5)		(700.1)	
Restructuring and related charges, net [(1)]	(36.4)		(38.2)	
Non-restructuring impairment charges	(63.7)		(16.9)	
Total operating income	$ 420.1		$ 617.3	

(1) Includes restructuring-related accelerated depreciation.

Specialty Brands. Operating income for fiscal 2017 decreased $11.0 million to $1,155.2 million, compared with $1,166.2 million for fiscal 2016. Operating margin decreased to 49.7% for fiscal 2017, compared with 50.7% for fiscal 2016. The decrease in operating income and margin was impacted by increases of $17.2 million in royalty expense, $37.5 million in R&D expense and $12.3 million in inventory provision expense compared with fiscal 2016. Partially offsetting these increases was the $24.7 million increase in net sales, primarily attributable to H.P. Acthar Gel which experienced favorable pricing and lower rebate expenses. In addition, SG&A expenses decreased by $33.3 million as a result of cost benefits gained from restructuring actions.

Specialty Generics. Operating income for fiscal 2017 decreased $144.6 million to $231.5 million, compared with $376.1 million for fiscal 2016. Operating margin decreased to 27.6% for fiscal 2017, compared with 36.7% for fiscal 2016. The decrease in operating income and margin was impacted by the $185.7 million decrease in net sales, which resulted in a $197.6 million unfavorable gross profit impact, due to increased competition in several product categories.

Corporate and allocated expenses. Corporate and allocated expenses were $172.0 million and $169.8 million for fiscal 2017 and 2016, respectively. Fiscal 2017 included a $70.5 million charge from the recognition of previously deferred losses on the settlement of obligations associated with the termination of six defined benefit pension plans, a $56.6 million pre-tax gain associated with the sale of our Intrathecal Therapy business and $54.6 million of income resulting from the decrease in fair value of the contingent consideration liability related to Raplixa reflective of lower than previously anticipated commercial opportunities for the product. The remaining increase of $42.9 million consisted of various factors, including higher facility expenses, stock compensation expense and professional fees; all of which were partially offset by lower employee compensation costs, advertising and promotions expenses, legal fees and pension expense following the settlement of our six defined benefit pension plans.

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 Ended		
	September 30, 2016	September 25, 2015	Percentage Change
Specialty Brands	$ 2,300.6	$ 1,622.8	41.8%
Specialty Generics	1,025.2	1,251.6	(18.1)
Net sales of operating segments	3,325.8	2,874.4	15.7
Other [1]	55.0	48.7	12.9
Net sales	$ 3,380.8	$ 2,923.1	15.7

(1) 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, which increased net sales by $289.1 million and $207.6 million, respectively. In addition, net sales of H.P. Acthar Gel 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 Ended		
	September 30, 2016	September 25, 2015	Percentage Change
U.S.	$ 2,224.9	$ 1,610.3	38.2%
Europe, Middle East and Africa	69.8	9.9	605.1
Other	5.9	2.6	126.9
Net sales	$ 2,300.6	$ 1,622.8	41.8

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

	Fiscal Year Ended		Percentage Change
	September 30, 2016	September 25, 2015	
H.P. Acthar Gel	$ 1,160.4	$ 1,037.3	11.9%
Inomax	474.3	185.2	156.1
Ofirmev	284.3	263.0	8.1
Therakos	207.6	—	—
Hemostasis products	42.5	—	—
Other	131.5	137.3	(4.2)
Specialty Brands	$ 2,300.6	$ 1,622.8	41.8

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

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

	Fiscal Year Ended		Percentage Change
	September 30, 2016	September 25, 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	$ 1,025.2	$ 1,251.6	(18.1)

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

	Fiscal Year Ended		Percentage Change
	September 30, 2016	September 25, 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)
Methylphendiate ER	103.5	136.5	(24.2)
Other controlled substances	468.1	572.2	(18.2)
Other	180.9	221.1	(18.2)
Specialty Generics	$ 1,025.2	$ 1,251.6	(18.1)

Operating Income

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

	Fiscal Year Ended			
	September 30, 2016		September 25, 2015	
Specialty Brands	$ 1,166.2	50.7%	$ 637.6	39.3%
Specialty Generics	376.1	36.7	594.4	47.5
Segment operating income	1,542.3	46.4	1,232.0	42.9
Unallocated amounts:				
Corporate and allocated expenses	(169.8)		(282.6)	
Intangible asset amortization	(700.1)		(550.3)	
Restructuring and related charges, net [1]	(38.2)		(45.3)	
Non-restructuring impairment charges	(16.9)		—	
Total operating income	$ 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. Our 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. These higher net sales were partially offset by a net $16.4 million increase in SG&A expenses. The net increase in SG&A 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. Our 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.

Three Months Ended December 30, 2016 Compared with Three Months Ended December 25, 2015

Net Sales

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

	Three Months Ended		Percentage Change
	December 30, 2016	December 25, 2015	
Specialty Brands	$ 603.1	$ 543.2	11.0%
Specialty Generics	212.9	257.6	(17.4)
Net sales of operating segments	816.0	800.8	1.9
Other [1]	13.9	10.4	33.7
Net sales	$ 829.9	$ 811.2	2.3

(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 the three months ended December 30, 2016 increased $59.9 million, or 11.0%, to $603.1 million, compared with $543.2 million for the three months ended December 25, 2015. The increase in net sales was primarily driven by a $38.7 million or 13.5% increase in H.P. Acthar Gel net sales compared with the three months ended December 25, 2015 due to increased volume. The fiscal 2016 acquisition of Hemostasis products increased net sales by $13.4 million. Inomax net sales increased by $7.5 million due to a favorable contracting cycle while Ofirmev net sales increased $5.6 million due to volume. Therakos net sales decreased by $3.0 million primarily due to a product supply disruption.

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

	Three Months Ended		Percentage Change
	December 30, 2016	December 25, 2015	
U.S.	$ 585.2	$ 524.8	11.5%
Europe, Middle East and Africa	16.2	17.0	(4.7)
Other	1.7	1.4	21.4
Net sales	$ 603.1	$ 543.2	11.0

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

	Three Months Ended		Percentage Change
	December 30, 2016	December 25, 2015	
H.P. Acthar Gel	$ 325.4	$ 286.7	13.5%
Inomax	118.3	110.8	6.8
Ofirmev	72.5	66.9	8.4
Therakos	47.4	50.4	(6.0)
Hemostasis products	13.4	—	—
Other	26.1	28.4	(8.1)
Specialty Brands	$ 603.1	$ 543.2	11.0

Specialty Generics. Net sales for the three months ended December 30, 2016 decreased $44.7 million, or 17.4%, to $212.9 million, compared with $257.6 million for the three months ended December 25, 2015. The decrease in net sales was driven by decreases in all product categories, most notably decreases of $13.5 million, $9.2 million and $12.6 million in hydrocodone related products, Methylphenidate ER and other products, respectively. The Specialty Generics segment has experienced customer consolidation that has led to increased competition, which resulted in decreased net sales. Methylphenidate ER net sales continue to be negatively impacted by the FDA reclassification of these products to therapeutically inequivalent status.

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

	Three Months Ended		Percentage Change
	December 30, 2016	December 25, 2015	
U.S.	$ 178.5	$ 215.3	(17.1)%
Europe, Middle East and Africa	22.7	22.1	2.7
Other	11.7	20.2	(42.1)
Net sales	$ 212.9	$ 257.6	(17.4)

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

	Three Months Ended		
	December 30, 2016	December 25, 2015	Percentage Change
Hydrocodone (API) and hydrocodone-containing tablets	$ 23.2	$ 36.7	(36.8)%
Oxycodone (API) and oxycodone-containing tablets	24.3	28.9	(15.9)
Methylphendiate ER	22.0	31.2	(29.5)
Other controlled substances	104.9	109.7	(4.4)
Other	38.5	51.1	(24.7)
Specialty Generics	$ 212.9	$ 257.6	(17.4)

Operating (Loss) Income

Operating (loss) income by segment and as a percentage of segment net sales for the three months ended December 30, 2016 and December 25, 2015 is shown in the following table (dollars in millions):

	Three Months Ended			
	December 30, 2016		December 25, 2015	
Specialty Brands	$ 317.2	52.6%	$ 269.1	49.5%
Specialty Generics	52.7	24.8	115.2	44.7
Segment operating income	369.9	45.3	384.3	48.0
Unallocated amounts:				
Corporate and allocated expenses	(181.4)		(44.6)	
Intangible asset amortization	(175.7)		(173.4)	
Restructuring and related charges, net [(1)]	(5.3)		(4.2)	
Non-restructuring impairment charges	(214.3)		—	
Total operating (loss) income	$ (206.8)		$ 162.1	

(1) Includes restructuring-related accelerated depreciation.

Specialty Brands. Operating income for the three months ended December 30, 2016 increased $48.1 million to $317.2 million, compared with $269.1 million during the three months ended December 25, 2015. Our operating margin increased to 52.6% for the three months ended December 30, 2016, compared with 49.5% for the three months ended December 25, 2015. The increase in operating income and margin was impacted by the $59.9 million increase in net sales, primarily attributable to H.P. Acthar Gel volume growth and the Hemostasis Acquisition. The increase in gross profit also reflects a $12.6 million decrease in expense associated with fair value adjustments of acquired inventory. SG&A and R&D expenses were reasonably consistent across both periods.

Specialty Generics. Operating income for the three months ended December 30, 2016 decreased $62.5 million to $52.7 million, compared with $115.2 million for the three months ended December 25, 2015. Our operating margin decreased to 24.8% for the three months ended December 30, 2016, compared with 44.7% for the three months ended December 25, 2015. The decrease in operating income and margin was impacted by the $44.7 million decrease in net sales due to customer consolidation and additional competitors that has led to price decreases, which resulted in a $53.2 million unfavorable gross profit impact. The gross profit impact exceeded the net sales impact primarily due to unfavorable product mix. In addition, there were increases in SG&A and R&D expenses of $9.3 million in total.

Corporate and allocated expenses. Corporate and allocated expenses were $181.4 million and $44.6 million for the three months ended December 30, 2016 and December 25, 2015, respectively. The three months ended December 30, 2016 included charges related to a $102.0 million settlement with the FTC and the Settling States and $45.0 million associated with the recognition of previously deferred pension related losses upon lump sum distribution to employees under our pension plan termination. The three months ended December 25, 2015, included $11.5 million of legal reserve accruals. The remaining $1.3 million increase was comprised of various minor increases and decreases.

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 licensing agreements. Historically, we have 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 February 2018, in conjunction with the acquisition of Sucampo on February 13, 2018, we entered into a $600.0 million senior secured term loan. The variable-rate loan bears an interest rate of LIBOR plus 300 basis points and was issued with a discount of 25 basis points. The incremental term loan matures on February 25, 2025 under terms generally consistent with our existing term loan. In addition, we utilized available capacity under the $900.0 million revolving credit facility. The revolving credit facility was fully drawn on December 29, 2017 in anticipation of the Sucampo Acquisition.

Upon completion of the Sucampo acquisition, Sucampo's 3.25% convertible senior notes due 2021 ("the Sucampo Notes") became eligible to receive increased consideration in conjunction with a make-whole fundamental change, such that each $1,000 principal face amount of Sucampo Notes may be converted into $1,221 in cash. Under terms of the Indenture dated December 27, 2016 (the "Sucampo Indenture"), between Sucampo and U.S. Bank National Association, the Sucampo Notes may be converted at the option of their holders and be eligible to receive increased consideration during a period of time following consummation of the merger transaction, or remain outstanding and earn the stated 3.25% rate of interest. It is the expectation that all holders will eventually exercise their conversion rights under the Sucampo Indenture. At the time of this filing approximately $73.5 million of the $300.0 million of issued convertible debt remains outstanding.

In fiscal 2018, we intend to fund capital expenditures with cash generated from operations. At December 29, 2017, we had capital expenditure commitments of $8.4 million.

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

	Fiscal Year Ended			Three Months Ended	
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016	December 25, 2015
Net cash provided by (used in):					
Operating activities	$ 727.3	$ 1,184.6	$ 930.5	$ 195.6	$ 311.4
Investing activities	318.4	(155.6)	(2,299.7)	(77.2)	215.4
Financing activities	(130.2)	(1,162.3)	1,035.8	(53.9)	(369.5)
Effect of currency exchange rate changes on cash and cash equivalents	2.5	0.3	(11.6)	(3.0)	(1.5)
Net increase (decrease) in cash and cash equivalents	$ 918.0	$ (133.0)	$ (345.0)	$ 61.5	$ 155.8

Operating Activities

Net cash provided by operating activities of $727.3 million for fiscal 2017 was primarily attributable to income from continuing operations, as adjusted for non-cash items, offset by an outflow of $1,744.1 million of deferred income taxes related to the reduction in our deferred tax liabilities primarily as a result of the Reorganization and the TCJA and a $188.8 million outflow from net investment in working capital. The working capital outflow included cash payments of $102.0 million for the FTC settlement, $35.0 million for settlement of the DEA investigation, a $62.3 million contribution to terminated pension plans that were settled during the period, a $34.2 million outflow from net tax related balances, a $25.8 million decrease in accounts payable, net, and a $70.5 million net inflow related to other assets and liabilities.

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 $930.5 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 $195.6 million for the three months ended December 30, 2016 was primarily attributable to income from continuing operations, as adjusted for non-cash items, in addition to a $125.3 million inflow from net investment in working capital. The working capital inflow was primarily driven by a $109.1 million increase in other assets and liabilities and a $36.5 million decrease in accounts receivable, net, partially offset by a $26.3 million increase in inventory. The increase in other assets and liabilities primarily resulted from the establishment of a reserve for the $102.0 million settlement with the FTC and the Settling States, the recognition of a $45.0 million charge associated with our pension settlement partially offset by payment of annual employee cash bonuses.

Net cash provided by operating activities of $311.4 million for the three months ended December 25, 2015 was primarily attributable to income from continuing operations, as adjusted for non-cash items, in addition to an $87.6 million inflow from net investment in working capital. The working capital inflow was primarily driven by an $82.3 million increase in the net tax related balances due to the timing of expected tax payments, and a $68.4 million decrease in accounts receivable, net, partially offset by a $35.6 million decrease in other assets and liabilities, a $14.5 million increase in inventories and a $13.0 million decrease in accounts payable. The decrease in accounts receivable, net was primarily due to timing of annual customer incentive payments and sales within the quarter. The $35.6 million decrease in other assets and liabilities resulted largely from the annual payout of employee cash bonuses for performance in the prior fiscal year and restructuring payments.

The aforementioned cash flows from operating activities include cash flows from the ongoing operations of the Nuclear Imaging and CMDS businesses that are included within discontinued operations. Subsequent to the completion of these transactions, we will no longer generate cash flows from these businesses. See further discussion of our discontinued operations in Note 5 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 provided by investing activities increased $474.0 million to $318.4 million for fiscal 2017, compared with $155.6 million used in investing activities for fiscal 2016. The increase primarily resulted from the $576.9 million cash inflow related to the disposal of the Nuclear Imaging and Intrathecal businesses, compared to the $266.7 million cash inflow related to the disposal of the CMDS business in fiscal 2016. In addition, during fiscal 2017 we had payments, net of cash acquired, of $36.8 and $39.5 million related to the acquisitions of InfaCare and Ocera, respectively; compared with fiscal 2016 payments, net of cash acquired, of $170.2 million and $75.8 million related to the acquisitions of Hemostasis and Stratatech, respectively.

Net cash used in investing activities decreased $2,144.1 million to $155.6 million for fiscal 2016, compared with $2,299.7 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 $266.7 million cash inflow related to the disposal of the CMDS business. 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 was $77.2 million for the three months ended December 30, 2016, compared with a $215.4 million cash inflow for the three months ended December 25, 2015. The $292.6 million change primarily resulted from the receipt of $263.7 million in proceeds related to the sale of CMDS that occurred during the three months ended December 25, 2015. The remaining $28.9 million decrease in cash inflows was primarily impacted by a $16.2 million increase in capital expenditures and a $11.2 million increase in cash outflows for short-term investments.

Under our term loan credit agreement, the proceeds from the sale of assets and businesses must be either reinvested into capital expenditures or business development activities within one year of the respective transaction or we are required to make repayments on our term loan.

Financing Activities

Net cash used in financing activities was $130.2 million for fiscal 2017, compared with $1,162.3 million used in financing activities for fiscal 2016. The change largely resulted from a $1,018.1 million increase in cash inflows from the issuance of external debt, net of debt repayment, in fiscal 2017 compared with fiscal 2016. The inflow in fiscal 2017 is primarily due to the $900.0 million draw on our revolving credit facility to fund the Sucampo Acquisition. Also included in the repayments of debt during fiscal 2017 was the repayment of $30.0 million of assumed debt from the InfaCare Acquisition, which was repaid upon close of the acquisition. In addition we drew $500.0 million on our revolving credit facility and repaid the balance in full during fiscal 2017, which is reported on a gross basis in our consolidated statements of cash flows.

Net cash used in financing activities was $1,162.3 million for fiscal 2016, compared with $1,035.8 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. 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 used in financing activities was $53.9 million for the three months ended December 30, 2016, compared with $369.5 million net cash used in financing activities for the three months ended December 25, 2015. The $315.6 million decrease in cash outflows largely resulted from a $128.0 million increase in cash proceeds from the issuance of debt, a $116.6 million decrease in share repurchases, and a $42.9 million decrease in repayment of debt. The remaining decrease in cash outflows was primarily impacted by a $30.0 million payment of contingent consideration to the former owners of BioVectra that was made during the three months ended December 25, 2015.

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.

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 December 29, 2017, total debt principal was $6,806.8 million compared with $6,237.6 million at December 30, 2016. The increase in total debt principal resulted primarily from the $900.0 million draw on our revolving credit facility offset by $66.9 million of repurchased debt and an $83.5 million prepayment of the previous term loans that were refinanced during fiscal 2017. Total debt principal at December 29, 2017 is comprised of the following:

	December 29, 2017
Variable-rate instruments:	
Term loan due September 2024	$ 1,851.2
Receivable Securitization program	200.0
Revolving credit facility [(1)]	900.0
Fixed-rate instruments	3,855.4
Capital lease obligations	0.2
Debt principal	$ 6,806.8

(1) Our revolving credit facility was fully drawn as of December 29, 2017.

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 December 29, 2017, our fixed-rate instruments had a weighted-average interest rate of 5.3% and pay interest at various dates throughout the fiscal year. As of December 29, 2017, the applicable interest rate on outstanding borrowings under the Receivable Securitization was 2.5%, which is determined as the one month LIBOR rate plus a margin of 0.90%. The Receivable Securitization has a capacity of $250.0 million that may, subject to certain conditions, be increased to $300.0 million.

At December 29, 2017, $314.2 million of our total debt is classified as current as these payments are expected to be made within the next fiscal year.

Under the terms of one of our capital 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 December 29, 2017, 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 2017, we repurchased debt that aggregated to a principal amount of $66.9 million.

For additional information regarding our debt agreements, refer to Note 13 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 $6,522.0 million at December 29, 2017 compared with $4,984.3 million at December 30, 2016. The increase in shareholders' equity is primarily attributed to the increase in retained earnings primarily due to a one-time tax benefit from the Reorganization and the TCJA.

During December 2017, we canceled approximately 26.5 million treasury shares. Irish law requires a company's treasury share value to represent less than 10% of Company capital. The cancellation of treasury shares had a net zero impact on shareholders' equity as $5.3 million was reflected in both common stock and additional paid in capital.

On November 19, 2015, the Company's Board of Directors authorized a $500.0 million share repurchase program (the "November 2015 Program"), which was completed in the three months ended December 30, 2016. On March 16, 2016, the Company's Board of Directors authorized an additional $350.0 million share repurchase program (the "March 2016 Program"), which was completed during the three months ended March 31, 2017. On March 1, 2017, the Company's Board of Directors authorized an additional $1.0 billion share repurchase program (the "March 2017 Program"), which commenced upon the completion of the March 2016 Program. The March 2017 Program has no time limit or expiration date, and the Company currently expects to fully utilize the program.

Dividends

We currently do not anticipate paying any cash dividends for the foreseeable future, as we intend to retain earnings to finance acquisitions, R&D 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 December 29, 2017 (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	$ 6,806.6	$ 314.0	$ 937.4	$ 1,836.3	$ 3,718.9
Interest on long-term debt obligations [1]	1,730.7	299.4	601.0	544.5	285.8
Capital lease obligations [1]	0.2	0.2	—	—	—
Operating lease obligations	150.9	23.1	36.6	29.6	61.6
Purchase obligations [2]	311.7	122.6	133.2	31.5	24.4
Total contractual obligations	$ 9,000.1	$ 759.3	$ 1,708.2	$ 2,441.9	$ 4,090.7

(1) Interest on long-term debt obligations and capital lease obligations are projected for future periods using interest rates in effect as of December 29, 2017. 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 $598.6 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 December 29, 2017, we have accrued $246.4 million for these potential payments, of which $182.3 million is considered to be long-term. For further information on our contingent consideration arrangements, refer to 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.

We are obligated to pay royalties under certain agreements with third parties. During fiscal 2017 and the three months ended December 30, 2016, we made payments under these arrangements of $86.0 million and $20.7 million, respectively. The timing and amounts to be paid in future periods are uncertain as they are dependent upon generating net sales in future periods.

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 December 29, 2017, was $94.1 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 8 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 December 29, 2017, we had net unfunded pension and postretirement benefit obligations of $27.8 million and $45.6 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 2018, but may elect to make voluntary contributions to its defined pension plans or its postretirement benefit plans during fiscal 2018. The Company settled all outstanding obligations associated with their six U.S. qualified pension plans during the first half of fiscal 2017 and made contributions of $62.3 million associated with the unfunded portion of these obligations.

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 December 29, 2017, we believe that it is probable that we will incur investigation and remediation costs of approximately $75.4 million, of which $2.2 million is included in accrued and other current liabilities on our consolidated balance sheet at December 29, 2017. 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 provides additional information regarding environmental matters.

Legal Proceedings

See 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, which is incorporated by reference into this Part II, Item 7., for a description of the legal proceedings and claims as of December 29, 2017.

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 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. These representations, warranties and indemnities are discussed 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.

Off-Balance Sheet Arrangements

We were previously 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. Following the sale of the Nuclear Imaging business, the surety bond was canceled in April 2017 and the Company is no longer required to provide financial assurance to the U.S. Nuclear Regulatory Commission. As of December 29, 2017, we had various other letters of credit and guarantee and surety bonds totaling $28.7 million.

Through December 29, 2017, the Company exchanged title to $16.0 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 obligations and IRB assets are recorded net in the consolidated balance sheets. The Company expects that the right of offset will be applied to payments required under these arrangements.

In addition, in connection with the Separation, the parties agreed to provide 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, 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 net 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 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	491.3	5.6	18.4	515.3
Payments or credits	(468.0)	(13.2)	(20.8)	(502.0)
Balance at December 30, 2016	349.1	31.4	10.8	391.3
Provisions	1,897.2	38.7	72.6	2,008.5
Payments or credits	(1,918.9)	(35.6)	(68.7)	(2,023.2)
Balance at December 29, 2017	$ 327.4	$ 34.5	$ 14.7	$ 376.6

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

Total provisions for fiscal 2017 decreased $22.3 million compared with fiscal 2016. The decrease in rebates and chargebacks of $40.7 million primarily related to a $47.6 million decrease in Specialty Generics as increased competition resulted in lower customer volume, partially offset by a $6.9 million increase in Specialty Brands. Provisions for returns increased $24.4 million from fiscal 2016 to fiscal 2017, due to a $10.6 million increase in Specialty Generics due to increased competition and an increase in the Specialty Brands segment primarily due to an $8.7 million favorable change in estimate associated with the Exalgo returns reserve within the Specialty Brands segment in fiscal 2016. Other sales deductions decreased by $6.0 million, primarily attributable to increased competition within the Specialty Generics segment.

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 H.P. Acthar Gel volume, a greater percentage of H.P. Acthar Gel prescriptions being covered under managed care contracts and the impact from acquisitions. Provisions for returns were relatively consistent across periods, due to $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.

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 test goodwill on the first day of the fourth quarter of each year for impairment or whenever events or changes in circumstances indicate that the carrying value may not be recoverable. The impairment test is comprised of comparing the carrying value of a reporting unit to its estimated fair value. We estimate the fair value of a reporting unit through internal analyses and valuation, utilizing an income approach (a level three measurement technique) 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 goodwill impairment in future periods. If the carrying value of a reporting unit exceeds its fair value, we will recognize the excess of the carrying value over the fair value as a goodwill impairment loss.

The results of our annual goodwill impairment test for fiscal 2017 showed that the fair value of our Specialty Brands reporting unit exceeded its carrying value. During the three months ended December 29, 2017, the Company experienced a substantial decline in its market capitalization, providing an indication that goodwill may be impaired at December 29, 2017. As a result, the annual goodwill impairment test was updated and the Company determined that there was no goodwill impairment at December 29, 2017. During the three months ended December 30, 2016, we recognized a $207.0 million goodwill impairment in the Specialty Generics segment. For further information on our goodwill impairment analyses, refer to Notes 3 and 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.

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 five 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 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 intangible asset 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 the Raplixa patent and the XARTEMIS™ XR (oxycodone HCl and acetaminophen) extended release tablets license associated with products that we elected to discontinue were recorded during the fiscal year ended December 29, 2017 and three months ended December 30, 2016, respectively. 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. For more information on our intangible impairment analysis, refer to Notes 3 and 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.

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. We then allocate 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, 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.

Our 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, we consider, 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 annually 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 associated with 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, government investigations, environmental matters and other legal proceedings as further discussed in Note 19 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 4 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 and have entered into derivative instruments to mitigate the exposure of movement in certain of these foreign currency transactions.

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 December 29, 2017, our outstanding debt included $1,851.2 million variable-rate debt on our senior secured term loan, $200.0 million variable-rate debt on our receivables securitization program and $900.0 million variable-rate debt on our revolving credit facility. Assuming a one percent increase in the applicable interest rates, in excess of applicable minimum floors, annual interest expense for fiscal 2018 would increase by approximately $29.5 million.

The remaining outstanding debt as of December 29, 2017 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 statements 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 December 29, 2017 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 $0.1 million as of December 29, 2017. 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 December 29, 2017 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 $15.5 million as of December 29, 2017. The change in the net financial position associated with the translation of these currencies is generally recorded as an unrealized gain or loss on foreign currency translation within accumulated other comprehensive income in shareholders' equity of our consolidated balance sheets.

Item 8. Financial Statements and Supplementary Data.

INDEX TO FINANCIAL STATEMENTS

Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Mallinckrodt plc:

We have audited the accompanying consolidated balance sheets of Mallinckrodt plc and subsidiaries (the "Company") as of December 29, 2017 and December 30, 2016, the related consolidated statements of income, comprehensive income, changes in shareholders' equity, and cash flows for the fiscal years ended December 29, 2017, September 30, 2016 and September 25, 2015 and the three-month period ended December 30, 2016, and the related notes and the schedule listed in the Index at Item 15 (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 29, 2017 and December 30 2016, and the results of its operations and its cash flows for the fiscal years ended December 29, 2017, September 30, 2016 and September 25, 2015 and the three-month period ended December 30, 2016, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 29, 2017, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 27, 2018, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ DELOITTE & TOUCHE LLP

St. Louis, Missouri
February 27, 2018

We have served as the Company's auditor since 2011.

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

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Net sales	$ 3,221.6	$ 3,380.8	$ 2,923.1	$ 829.9
Cost of sales	1,565.3	1,525.8	1,300.2	384.1
Gross profit	1,656.3	1,855.0	1,622.9	445.8
Selling, general and administrative expenses	920.9	925.3	1,023.8	368.3
Research and development expenses	277.3	262.2	203.3	66.2
Restructuring charges, net	31.2	33.3	45.0	3.8
Non-restructuring impairment charges	63.7	16.9	—	214.3
Gain on divestiture and license	(56.9)	—	(3.0)	—
Operating income (loss)	420.1	617.3	353.8	(206.8)
Interest expense	(369.1)	(384.6)	(255.6)	(91.3)
Interest income	4.6	1.3	1.0	0.5
Other income (expense), net	6.0	(0.6)	8.1	(0.9)
Income (loss) from continuing operations before income taxes	61.6	233.4	107.3	(298.5)
Benefit from income taxes	(1,709.6)	(255.6)	(129.3)	(121.7)
Income (loss) from continuing operations	1,771.2	489.0	236.6	(176.8)
Income from discontinued operations, net of tax expense of $5.4, $43.5, $47.9 and $15.3	363.2	154.7	88.1	23.6
Net income (loss)	$ 2,134.4	$ 643.7	$ 324.7	$ (153.2)
Basic earnings per share (Note 9):				
Income (loss) from continuing operations	$ 18.13	$ 4.42	$ 2.03	$ (1.67)
Income from discontinued operations, net of income taxes	3.72	1.40	0.75	0.22
Net income (loss)	$ 21.85	$ 5.82	$ 2.78	$ (1.45)
Basic weighted-average shares outstanding	97.7	110.6	115.8	105.7
Diluted earnings per share (Note 9):				
Income (loss) from continuing operations	$ 18.09	$ 4.39	$ 2.00	$ (1.67)
Income from discontinued operations, net of income taxes	3.71	1.39	0.75	0.22
Net income (loss)	$ 21.80	$ 5.77	$ 2.75	$ (1.45)
Diluted weighted-average shares outstanding	97.9	111.5	117.2	105.7

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(in millions)

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Net income (loss)	$ 2,134.4	$ 643.7	$ 324.7	$ (153.2)
Other comprehensive income (loss), net of tax				
Currency translation adjustments	11.3	(58.6)	(70.8)	(21.1)
Unrecognized gain on derivatives, net of tax expense of $0.3, $0.2, $0.2 and $-	1.0	0.5	0.4	0.2
Unrecognized gain (loss) on benefit plans, net of tax expense (benefit) of $30.8, ($15.0), ($2.1) and ($19.3)	45.8	(28.4)	5.6	34.0
Unrecognized gain on investments	1.5	—	—	—
Total other comprehensive income (loss), net of tax	59.6	(86.5)	(64.8)	13.1
Comprehensive income (loss)	$ 2,194.0	$ 557.2	$ 259.9	$ (140.1)

See Notes to Consolidated Financial Statements.

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

	December 29, 2017	December 30, 2016
Assets		
Current Assets:		
Cash and cash equivalents	$ 1,260.9	$ 342.0
Accounts receivable, less allowance for doubtful accounts of $3.9 and $4.0	445.8	431.0
Inventories	340.4	350.7
Prepaid expenses and other current assets	84.1	131.9
Notes receivable	154.0	—
Current assets held for sale	—	310.9
Total current assets	2,285.2	1,566.5
Property, plant and equipment, net	966.8	881.5
Goodwill	3,482.7	3,498.1
Intangible assets, net	8,375.0	9,000.5
Other assets	171.2	259.7
Total Assets	$ 15,280.9	$ 15,206.3
Liabilities and Shareholders' Equity		
Current Liabilities:		
Current maturities of long-term debt	$ 313.7	$ 271.2
Accounts payable	113.3	112.1
Accrued payroll and payroll-related costs	98.5	76.1
Accrued interest	57.0	68.7
Income taxes payable	15.8	101.7
Accrued and other current liabilities	452.1	557.1
Current liabilities held for sale	—	120.3
Total current liabilities	1,050.4	1,307.2
Long-term debt	6,420.9	5,880.8
Pension and postretirement benefits	67.1	136.4
Environmental liabilities	73.2	73.0
Deferred income taxes	689.0	2,398.1
Other income tax liabilities	94.1	70.4
Other liabilities	364.2	356.1
Total Liabilities	8,758.9	10,222.0
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; 92,196,662 and 118,182,944 issued; 86,336,232 and 104,667,545 outstanding	18.4	23.6
Ordinary shares held in treasury at cost, 5,860,430 and 13,515,399	(1,564.7)	(919.8)
Additional paid-in capital	5,492.6	5,424.0
Retained earnings	2,588.6	529.0
Accumulated other comprehensive income	(12.9)	(72.5)
Total Shareholders' Equity	6,522.0	4,984.3
Total Liabilities and Shareholders' Equity	$ 15,280.9	$ 15,206.3

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in millions)

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Cash Flows From Operating Activities:				
Net income (loss)	$ 2,134.4	$ 643.7	$ 324.7	$ (153.2)
Adjustments to reconcile net cash provided by operating activities:				
Depreciation and amortization	808.3	834.5	672.5	203.2
Share-based compensation	59.2	42.9	117.0	11.0
Deferred income taxes	(1,744.1)	(432.9)	(191.6)	(204.3)
Non-cash impairment charges	63.7	16.9	—	214.3
Inventory provisions	34.1	29.2	—	8.5
Gain on disposal of discontinued operations	(418.1)	(95.3)	—	—
Other non-cash items	(21.4)	29.6	(25.5)	(9.2)
Changes in assets and liabilities, net of the effects of acquisitions:				
Accounts receivable, net	(16.2)	31.2	0.7	36.5
Inventories	(23.6)	(17.3)	61.3	(26.3)
Accounts payable	(25.8)	(9.7)	20.4	5.4
Income taxes	(34.2)	93.9	30.2	0.6
Other	(89.0)	17.9	(79.2)	109.1
Net cash from operating activities	727.3	1,184.6	930.5	195.6
Cash Flows From Investing Activities:				
Capital expenditures	(186.1)	(182.9)	(148.0)	(65.2)
Acquisitions and intangibles, net of cash acquired	(76.3)	(245.4)	(2,154.7)	(1.8)
Proceeds from disposal of discontinued operations, net of cash	576.9	266.7	—	—
Other	3.9	6.0	3.0	(10.2)
Net cash from investing activities	318.4	(155.6)	(2,299.7)	(77.2)
Cash Flows From Financing Activities:				
Issuance of external debt	1,465.0	98.3	3,010.0	190.0
Repayment of external debt and capital leases	(917.2)	(568.6)	(1,848.4)	(86.7)
Debt financing costs	(12.7)	(0.1)	(39.9)	—
Proceeds from exercise of share options	4.1	14.0	34.4	0.4
Repurchase of shares	(651.7)	(652.9)	(92.2)	(158.8)
Other	(17.7)	(53.0)	(28.1)	1.2
Net cash from financing activities	(130.2)	(1,162.3)	1,035.8	(53.9)
Effect of currency rate changes on cash	2.5	0.3	(11.6)	(3.0)
Net change in cash, cash equivalents and restricted cash	918.0	(133.0)	(345.0)	61.5
Cash, cash equivalents and restricted cash at beginning of period	361.1	432.6	777.6	299.6
Cash, cash equivalents and restricted cash at end of period	$ 1,279.1	$ 299.6	$ 432.6	$ 361.1
Cash and cash equivalents at end of period	$ 1,260.9	$ 280.5	$ 365.9	$ 342.0
Restricted cash included in prepaid expenses and other assets at end of period	—	0.1	47.7	0.1
Restricted cash included in other long-term assets at end of period	18.2	19.0	19.0	19.0
Cash, cash equivalents and restricted cash at end of period	$ 1,279.1	$ 299.6	$ 432.6	$ 361.1
Supplemental Disclosures of Cash Flow Information:				
Cash paid for interest	$ 339.1	$ 332.4	$ 200.5	$ 95.4
Cash paid for income taxes, net	73.4	165.4	123.8	95.6

See Notes to Consolidated Financial Statements.

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

	Ordinary Shares		Treasury Shares				Accumulated Other Comprehensive Income	Total Shareholders' Equity
	Number	Par Value	Number	Amount	Additional Paid-In Capital	Retained Earnings		
Balance at September 26, 2014	116.2	$ 23.2	0.2	$ (17.5)	$ 5,172.4	$ (285.8)	$ 65.7	$ 4,958.0
Net income	—	—	—	—	—	324.7	—	324.7
Currency translation	—	—	—	—	—	—	(70.8)	(70.8)
Change in derivatives, net of tax	—	—	—	—	—	—	0.4	0.4
Minimum pension liability, net of taxes	—	—	—	—	—	—	5.6	5.6
Share options exercised	1.2	0.2	—	—	34.2	—	—	34.4
Vesting of restricted shares	1.3	0.3	—	—	(0.3)	—	—	—
Shares canceled	(1.2)	(0.2)	—	—	0.2	—	—	—
Excess tax benefit from share-based compensation	—	—	—	—	34.1	—	—	34.1
Share-based compensation	—	—	—	—	117.0	—	—	117.0
Repurchase of shares	—	—	1.0	(92.2)	—	—	—	(92.2)
Balance at September 25, 2015	117.5	$ 23.5	1.2	$ (109.7)	$ 5,357.6	$ 38.9	$ 0.9	$ 5,311.2
Net income	—	—	—	—	—	643.7	—	643.7
Currency translation	—	—	—	—	—	—	(58.6)	(58.6)
Change in derivatives, net of tax	—	—	—	—	—	—	0.5	0.5
Minimum pension liability, net of taxes	—	—	—	—	—	—	(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 shares	—	—	9.8	(652.9)	—	—	—	(652.9)
Balance at September 30, 2016	118.1	$ 23.6	11.0	$ (762.6)	$ 5,412.7	$ 682.6	$ (85.6)	$ 5,270.7
Net loss	—	—	—	—	—	(153.2)	—	(153.2)
Currency translation	—	—	—	—	—	—	(21.1)	(21.1)
Change in derivatives, net of tax	—	—	—	—	—	—	0.2	0.2
Minimum pension liability, net of taxes	—	—	—	—	—	—	34.0	34.0
Share options exercised	0.1	—	—	—	0.4	—	—	0.4
Vesting of restricted shares	—	—	—	—	—	—	—	—
Excess tax benefit from share-based compensation	—	—	—	—	(0.1)	—	—	(0.1)
Share-based compensation	—	—	—	—	11.0	—	—	11.0
Reissuance of Treasury shares	—	—	—	1.6	—	(0.4)	—	1.2
Repurchase of shares	—	—	2.5	(158.8)	—	—	—	(158.8)
Balance at December 30, 2016	118.2	$ 23.6	13.5	$ (919.8)	$ 5,424.0	$ 529.0	$ (72.5)	$ 4,984.3
Impact of accounting standard adoptions	—	—	—	—	—	(72.1)	—	(72.1)
Net income	—	—	—	—	—	2,134.4	—	2,134.4
Currency translation	—	—	—	—	—	—	11.3	11.3
Change in derivatives, net of tax	—	—	—	—	—	—	1.0	1.0
Minimum pension liability, net of taxes	—	—	—	—	—	—	45.8	45.8
Unrecognized gain on investments	—	—	—	—	—	—	1.5	1.5
Share options exercised	0.1	—	—	—	4.1	—	—	4.1
Vesting of restricted shares	0.4	0.1	—	—	—	—	—	0.1
Shares canceled	(26.5)	(5.3)	(26.5)	—	5.3	—	—	—
Share-based compensation	—	—	—	—	59.2	—	—	59.2
Reissuance of Treasury shares	—	—	—	6.8	—	(2.7)	—	4.1
Repurchase of shares	—	—	18.9	(651.7)	—	—	—	(651.7)
Balance at December 29, 2017	92.2	$ 18.4	5.9	$ (1,564.7)	$ 5,492.6	$ 2,588.6	$ (12.9)	$ 6,522.0

See Notes to Consolidated Financial Statements.

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. As of December 29, 2017, areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; and analgesics. Our core strengths include the acquisition and management of highly regulated raw materials and specialized chemistry, formulation and manufacturing capabilities.

Our business is operated in two reportable segments, which are further described below:

- *Specialty Brands* includes branded medicines; and
- *Specialty Generics* includes specialty generic drugs, active pharmaceutical ingredients ("API") and external manufacturing.

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 United States ("U.S.") Securities and Exchange Commission ("SEC") reporting requirements and the applicable corporate governance rules of the New York Stock Exchange.

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 50% of the voting shares, or have the ability to control through similar rights. All intercompany balances and transactions have been eliminated in consolidation and all normal recurring adjustments necessary for a fair presentation have been included in the results reported.

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. As such, when the Company completed the sale of its Nuclear Imaging business and contrast media and delivery systems ("CMDS") businesses on January 27, 2017 and November 27, 2015, respectively, prior year balances were recast to present the financial results of these business as discontinued operations.

Beginning in the first quarter of fiscal year 2016, the Company 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 of expenses previously included in SG&A for the fiscal year ended September 25, 2015 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 historically reported its results based on a "52-53 week" year ending on the last Friday of September. 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 became effective for the Company's 2017 fiscal year, which began on December 31, 2016 and ended on December 29, 2017. As a result of the change in fiscal year end, the Company filed a Transition Report on Form 10-Q on February 7, 2017 covering the period from October 1, 2016 through December 30, 2016 ("the three months ended December 30, 2016") with the comparable period from September 26, 2015 through December 25, 2015. Fiscal 2016 covers the period from September 26, 2015 through September 30, 2016 and fiscal 2015 covers the period from September 27, 2014 through September 25, 2015.

2. Transition Period

The Company is presenting audited financial statements for the three month period ended December 30, 2016. The following tables provide certain unaudited comparative financial information for the same period of the prior year.

Consolidated Statements of Income	Three Months Ended	
	December 30, 2016	(unaudited) December 25, 2015
Net sales	$ 829.9	$ 811.2
Cost of sales	384.1	360.3
Gross profit	445.8	450.9
Selling, general and administrative expenses	368.3	223.3
Research and development expenses	66.2	61.4
Restructuring charges, net	3.8	4.1
Non-restructuring impairment charges	214.3	—
Operating (loss) income	(206.8)	162.1
Interest expense	(91.3)	(97.8)
Interest income	0.5	0.2
Other (expense) income, net	(0.9)	2.0
(Loss) income from continuing operations before income taxes	(298.5)	66.5
Benefit from income taxes	(121.7)	(37.3)
(Loss) income from continuing operations	(176.8)	103.8
Income from discontinued operations	23.6	107.3
Net (loss) income	$ (153.2)	$ 211.1
Basic earnings per share (Note 9):		
(Loss) income from continuing operations	$ (1.67)	$ 0.90
Income from discontinued operations, net of income taxes	0.22	0.93
Net (loss) income	$ (1.45)	$ 1.83
Basic weighted-average shares outstanding	105.7	115.4
Diluted earnings per share (Note 9):		
(Loss) income from continuing operations	$ (1.67)	$ 0.89
Income from discontinued operations, net of income taxes	0.22	0.92
Net (loss) income	$ (1.45)	$ 1.82
Diluted weighted-average shares outstanding	105.7	116.3

Consolidated Statements of Cash Flows	Three Months Ended	
	December 30, 2016	(unaudited) December 25, 2015
Cash Flows From Operating Activities:		
Net (loss) income	$ (153.2)	$ 211.1
Adjustments to reconcile net cash provided by operating activities:		
Depreciation and amortization	203.2	206.0
Share-based compensation	11.0	8.5
Deferred income taxes	(204.3)	(108.9)
Non-cash impairment charges	214.3	—
Inventory provisions	8.5	1.2
Gain on disposal of discontinued operations	—	(97.0)
Other non-cash items	(9.2)	2.9
Changes in assets and liabilities, net of the effects of acquisitions:		
Accounts receivable, net	36.5	68.4
Inventories	(26.3)	(14.5)
Accounts payable	5.4	(13.0)
Income taxes	0.6	82.3
Other	109.1	(35.6)
Net cash from operating activities	195.6	311.4
Cash Flows From Investing Activities:		
Capital expenditures	(65.2)	(49.0)
Acquisitions and intangibles, net of cash acquired	(1.8)	—
Proceeds from disposal of discontinued operations, net of cash	—	263.7
Other	(10.2)	0.7
Net cash from investing activities	(77.2)	215.4
Cash Flows From Financing Activities:		
Issuance of external debt	190.0	62.0
Repayment of external debt and capital leases	(86.7)	(129.6)
Debt financing costs	—	(0.1)
Proceeds from exercise of share options	0.4	3.6
Repurchase of shares	(158.8)	(275.4)
Other	1.2	(30.0)
Net cash from financing activities	(53.9)	(369.5)
Effect of currency rate changes on cash	(3.0)	(1.5)
Net change in cash, cash equivalents and restricted cash	61.5	155.8
Cash, cash equivalents and restricted cash at beginning of period	299.6	432.6
Cash, cash equivalents and restricted cash at end of period	$ 361.1	$ 588.4
Cash and cash equivalents at end of period	$ 342.0	$ 521.9
Restricted cash included in prepaid expenses and other assets at end of period	$ 0.1	$ 47.5
Restricted cash included in other long-term assets at end of period	$ 19.0	$ 19.0
Cash, cash equivalents and restricted cash at end of period	$ 361.1	$ 588.4

3. 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 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 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 SG&A expenses in continuing operations were as follows:

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Shipping and handling costs	$ 13.9	$ 12.4	$ 11.6	$ 3.4

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 2017, fiscal 2015 and the three months ended December 30, 2016, the Company had $2.5 million, $31.6 million and $9.0 million of foreign currency gains, respectively, and during fiscal 2016, the Company had $3.6 million of foreign currency losses included within income (loss) from continuing operations. The Company entered into derivative instruments to mitigate the exposure of movements in certain of these foreign currency transactions and recognized losses of $4.1 million, $24.8 million and $8.9 million in fiscal 2017, fiscal 2015 and the three months ended December 30, 2016, and a gain of $0.2 million in fiscal 2016, respectively, within income (loss) 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 rebates payable to customers for whom the Company has trade accounts receivable and the right of offset exists.

Inventories

Inventories are recorded at the lower of cost or net realizable 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 R&D. 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 R&D 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 annually 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 on the first day of the fourth quarter of each fiscal year, or whenever events or changes in circumstances indicate that the carrying value may not be recoverable. The impairment test is comprised of comparing the carrying value of a reporting unit to its estimated fair value. The Company estimates the fair value of a reporting unit 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 recognize the excess of the carrying value over the fair value as a goodwill impairment loss.

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	7	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 SG&A.

When a triggering event occurs, the Company evaluates 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, or whenever events or changes in circumstances indicate that the carrying value may not be recoverable by either a qualitative or income approach. The Company will compare the fair value of the assets with their carrying value and record an impairment when the carrying value exceeds the fair value.

Contingencies

The Company is subject to various patent infringement, product liability, government investigations, environmental matters 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).

Restructuring

The Company recognizes charges associated with board approved restructuring programs designed to transform its business and improve its cost structure. Restructuring charges can include severance costs, infrastructure charges, distributor contract cancellations and other items. The Company records restructuring charges based on estimated consolidation plans and accrues for costs when they are probable and reasonably estimable.

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 U.S. Internal Revenue Service ("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.

4. Recently Issued Accounting Standards

Adopted

The Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2017-04, "Intangibles - Goodwill and Other: Simplifying the Test for Goodwill Impairment," in January 2017. This update eliminates the two step test utilized in goodwill impairment testing, and requires the goodwill impairment test to be performed by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit’s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The Company early adopted this standard in fiscal 2017, which did not have a material impact to the consolidated financial statements. The Company will apply this standard to prospective goodwill impairment tests.

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 Company early adopted this standard in fiscal 2017, which resulted in a $75.0 million decrease to beginning retained earnings with an offsetting decrease of $67.2 million to other assets and a $7.8 million decrease to prepaid expenses on the consolidated balance sheet. The prior periods were not restated.

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. These updates provide 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 Company early adopted these standards in fiscal 2017 and revised the prior year statement of cash flow. The adoption of ASU 2016-18, regarding presentation of restricted cash, increased the net cash used in investing activities during fiscal 2016 and 2015 by $47.3 million and $3.1 million, respectively. The adoption of ASU 2016-15, regarding the other targeted clarifications, did not result in any material changes to the consolidated financial statements.

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. Upon adoption, the entity must 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 Company adopted this guidance in fiscal 2017, which resulted in a $2.9 million increase to beginning retained earnings to recognize net operating loss carryforwards, net of a valuation allowance, attributable to excess tax benefits on stock compensation that had not been previously recognized in additional paid-in capital.

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 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. The Company adopted this standard in fiscal 2017, which did not have a material impact to the consolidated financial statements.

The 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 International Financial Reporting Standards ("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 Company adopted this standard in fiscal 2017, which did not have a material impact to the consolidated financial statements.

Not Yet Adopted

The FASB issued ASU 2017-12, "Derivatives and Hedging: Targeted Improvements to Accounting for Hedging Activities" in August 2017. This update simplifies the application of hedge accounting and enhances the economics of the entity’s risk management activities in its financial statements. The update amends the guidance on designation and measurement for qualifying hedging relationships requiring the application of a modified retrospective approach on the date of adoption. This guidance is effective for the Company in the first quarter of fiscal 2019. The Company is assessing the impact of this guidance on its consolidated financial statements.

The FASB issued ASU 2017-09, "Compensation - Stock Compensation: Scope of Modification Accounting," in May 2017. Under the new guidance, the effects of a modification should be accounted for unless all of the following are met: (1) the fair value or calculated intrinsic value of the modified award is the same as the fair value of the original award immediately before the original award is modified; (2) the vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified; and (3) the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The amendments should be applied prospectively to an award modified on or after the adoption date. This guidance is effective for the Company in the first quarter of fiscal 2018. The Company expects the impact of this guidance to be immaterial to the consolidated financial statements upon adoption.

The FASB issued ASU 2017-07, "Compensation - Retirement Benefits: Improving the Presentation of Net Periodic Pension Cost and Net Periodic Post Retirement Benefit Cost," in March 2017. This update requires that the service cost component be disaggregated from the other components of net benefit cost. Service cost should be reported in the same line item or items as other compensation costs arising from services rendered by pertinent employees during the period. The other components of net benefit cost should be presented in the income statement separately from the service cost component and outside a subtotal of income from operations, if one is presented. This guidance is effective for the Company in the first quarter of fiscal 2018. The Company expects the impact of this guidance to be immaterial to the consolidated financial statements upon adoption.

The FASB issued ASU 2017-01, "Business Combinations (Topic 805): Clarifying the Definition of a Business," in January 2017. This update provides a screen to determine whether or not a set of assets is a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set of assets is not a business. If the screen is not met, the amendments in this update (1) require that to be

considered a business, a set of assets must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. This guidance is effective for the Company in the first quarter of fiscal 2018. The Company does not anticipate a significant impact upon adoption.

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. 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 currently identifying all lease arrangements and will assess the potential impact of this guidance. At this time, the Company does not anticipate a significant impact upon adoption. However, identification of further lease or embedded lease arrangements may identify a more significant impact.

The 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 has substantially completed its assessment of its customer arrangements for which the Company currently recognizes revenues and does not anticipate a material impact upon adoption. The Company will utilize the modified retrospective transition approach of adopting the ASU. Upon adoption, the Company will recognize the cumulative effect of adopting this guidance as an adjustment to beginning retained earnings, the impact of which is not expected to be material. The prior periods will not be restated.

5. Discontinued Operations and Divestitures

Discontinued Operations

Nuclear Imaging: On January 27, 2017, the Company completed the sale of its Nuclear Imaging business to IBA Molecular ("IBAM") for approximately $690.0 million before tax impacts, including up-front considerations of approximately $574.0 million, up to $77.0 million of contingent considerations and the assumption of certain liabilities. The Company recorded a pre-tax gain on the sale of the business of $362.8 million during fiscal 2017, which excluded any potential proceeds from the contingent consideration. The following table summarizes the financial results of the Nuclear Imaging business for fiscal years 2017, 2016 and 2015 and the three months ended December 30, 2016 as presented in the consolidated statements of income:

	Fiscal Year Ended			Three Months Ended
Major line items constituting income from discontinued operations	**December 29, 2017**	**September 30, 2016**	**September 25, 2015**	**December 30, 2016**
Net sales	$ 31.6	$ 418.6	$ 423.8	$ 99.4
Cost of sales	15.6	216.6	193.1	44.7
Selling, general and administrative	7.8	83.7	89.6	16.4
Restructuring charges, net	—	2.3	(4.6)	—
Other	(0.2)	5.7	37.7	0.2
Income from discontinued operations	8.4	110.3	108.0	38.1
Gain on disposal of discontinued operations	362.8	—	—	—
Income from discontinued operations, before income taxes	371.2	110.3	108.0	38.1
Income tax expense	5.2	49.0	36.4	15.3
Income from discontinued operations, net of tax	$ 366.0	$ 61.3	$ 71.6	$ 22.8

The fiscal 2017 income tax expense of $0.9 million was associated with the $362.8 million gain on divestiture and a $4.3 million income tax expense was associated with the $8.4 million income from discontinued operations. The tax impact of the gain recognized on divestiture was favorably impacted by a benefit from permanently deductible items. The income tax expense of $4.3 million was impacted by tax expense of $0.8 million associated with the rate difference between United Kingdom ("U.K.") and Non-U.K. jurisdictions, $3.3 million of tax expense associated with accrued income tax liabilities and uncertain tax positions, and $0.2 million of tax expense associated with permanently nondeductible, nontaxable, and other items. 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 U.K. and Non-U.K. 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 U.K. and Non-U.K. jurisdictions and $0.4 million of tax expense associated with permanently nondeductible, nontaxable, and other items. The income tax expense for the three months ended December 30, 2016 of $15.3 million was impacted by tax expense of $4.4 million associated with the rate difference between U.K. and Non-U.K. jurisdictions, $3.3 million of tax expense associated with accrued income tax liabilities and uncertain tax positions, and $0.1 million of tax expense associated with permanently nondeductible, nontaxable, and other items.

Fiscal 2017 reflects $0.2 million of Non-U.K. current income tax benefit, and $5.4 million of Non-U.K. deferred income tax expense. Fiscal 2016 reflects $0.1 million of U.K. current income tax expense, $52.5 million of Non-U.K. current income tax expense, and $3.6 million of Non-U.K. deferred income tax benefit. Fiscal 2015 reflects $0.1 million of U.K. current income tax expense, $27.8 million of Non-U.K. current income tax expense, and $8.6 million of Non-U.K. deferred income tax expense. The three months ended December 30, 2016 reflects $15.8 million of Non-U.K. current income tax expense and $0.5 million of Non-U.K. deferred income tax benefit.

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 at the end of each period:

	December 29, 2017	December 30, 2016
Carrying amounts of major classes of assets included as part of discontinued operations		
Accounts receivable	$ —	$ 49.6
Inventories	—	20.0
Property, plant and equipment, net	—	188.7
Other current and non-current assets	—	52.6
Total assets classified as held for sale in the balance sheet	$ —	$ 310.9
Carrying amounts of major classes of liabilities included as part of discontinued operations		
Accounts payable	$ —	$ 19.7
Other current and non-current liabilities	—	100.6
Total liabilities classified as held for sale in the balance sheet	$ —	$ 120.3

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 2017, 2016 and 2015 and the three months ended December 30, 2016:

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Depreciation	$ —	$ 20.9	$ 13.1	$ —
Capital expenditures	0.3	9.7	7.6	2.0

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.

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 2017, 2016 and 2015 and the three months ended December 30, 2016 as presented in the consolidated statements of income:

	Fiscal Year Ended			Three Months Ended
Major line items constituting (loss) income from discontinued operations	**December 29, 2017**	**September 30, 2016**	**September 25, 2015**	**December 30, 2016**
Net sales	$ —	$ 61.0	$ 413.8	$ —
Cost of sales	—	46.9	306.4	—
Selling, general and administrative	—	20.3	97.5	—
Restructuring charges, net	—	—	0.3	—
Other	—	1.2	4.7	—
(Loss) income from discontinued operations	—	(7.4)	4.9	—
Gain on disposal of discontinued operations	—	95.3	—	—
(Loss) income from discontinued operations, before income taxes	—	87.9	4.9	—
Income tax (benefit) expense	—	(2.5)	10.8	—
(Loss) income from discontinued operations net of tax	$ —	$ 90.4	$ (5.9)	$ —

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. Fiscal 2016 reflects $0.9 million of Non-U.K. current income tax expense, $3.4 million of Non-U.K. deferred income tax benefit, and none being allocable to the U.K. income tax provision. Fiscal 2015 reflects $14.9 million of Non-U.K. current income tax expense, $4.4 million of non-U.K. deferred income tax benefit, and none being allocable to the U.K. income tax provision.

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 2017, 2016 and 2015 and the three months ended December 30, 2016:

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	**September 30, 2016**	**September 25, 2015**	**December 30, 2016**
Depreciation	$ —	$ —	$ 15.5	$ —
Amortization	—	—	2.3	—
Capital expenditures	—	1.6	9.5	—

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 2017, 2016 and 2015, the Company recorded a loss, net of tax, of $0.6 million, a gain, net of tax, of $3.0 million and a loss, net of tax of $0.1 million, respectively. The Company recorded a gain of $0.6 million, net of tax, during the three months ended December 30, 2016. The gains and losses were primarily related to the indemnification obligations to the purchaser, which are discussed in Note 18.

Other: Prior to the Company's legal separation from Covidien plc ("Covidien") on June 28, 2013, 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.

Divestitures

On March 17, 2017, the Company completed its sale of its Intrathecal Therapy business to Piramal Enterprises Limited's subsidiary in the U.K., Piramal Critical Care ("Piramal"), for approximately $203.0 million, including fixed consideration of $171.0 million and contingent consideration of up to $32.0 million. The $171.0 million of fixed consideration consisted of $17.0 million received at closing and a $154.0 million note receivable that is due one year from the transaction closing date. The Company recorded a pre-tax gain on the sale of the business of $56.6 million during fiscal 2017, which excluded any potential proceeds from the contingent consideration and reflects a post-sale working capital adjustment. The financial results of the Intrathecal Therapy business are presented within continuing operations as this divestiture did not meet the criteria for discontinued operations classification.

As part of the divestiture and calculation of the gain, the Company wrote off intangible assets of $48.7 million and goodwill of $49.8 million, from the Specialty Brands segment, ascribed to the Intrathecal Therapy business. The Company is committed to reimburse up to $7.3 million of product development expenses incurred by Piramal, of which $6.5 million remains on the consolidated balance sheet as of December 29, 2017. The remaining items included in the gain calculation are attributable to inventory transferred and transaction costs incurred by the Company.

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.

6. Acquisitions and License Agreements

Business Acquisitions

Ocera Therapeutics, Inc.

On December 11, 2017, the Company acquired Ocera Therapeutics, Inc. ("Ocera") for upfront consideration of approximately $42.4 million, of which $1.9 million of the consideration was paid subsequent to December 29, 2017, and contingent consideration up to $75.0 million based on the successful completion of certain development and sales milestones ("the Ocera Acquisition"). Ocera is a clinical stage biopharmaceutical company focused on the development and commercialization of novel therapeutics for orphan and other serious liver diseases with a high unmet medical need. Ocera’s developmental product MNK-6105 (previously OCR-002), an ammonia scavenger, is being studied for treatment of hepatic encephalopathy, a neuropsychiatric syndrome associated with hyperammonemia, a complication of acute or chronic liver disease. The Ocera Acquisition was funded with cash on hand.

InfaCare Pharmaceutical Corporation

On September 25, 2017, the Company acquired InfaCare Pharmaceutical Corporation ("InfaCare") in a transaction valued at approximately $80.4 million, with additional payments of up to $345.0 million dependent on regulatory and sales milestones ("the InfaCare Acquisition"). Consideration for the transaction consisted of approximately $37.2 million in cash paid to the prior shareholders of InfaCare and the assumption of approximately $43.2 million of debt and other liabilities, which was repaid in conjunction with the InfaCare Acquisition. InfaCare is focused on development and commercialization of proprietary pharmaceuticals for neonatal and pediatric patient populations. InfaCare's developmental product stannsoporfin, a heme oxygenase inhibitor, is under investigation for its potential to reduce the production of bilirubin, the elevation of which can contribute to serious consequences in infants. The InfaCare Acquisition was funded with cash on hand.

Stratatech Corporation

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 Hemostasis Acquisition was funded through cash on hand. As the Company shifts its focus to the critical care, autoimmune and rare disease spaces, it has entered into a transaction to sell the Recothrom and PreveLeak assets and is currently evaluating strategic options for Raplixa. See further discussion in Notes 12, 20 and 24 to the consolidated financial statements.

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.

Fair Value Allocation

The following amounts represent the allocation of the fair value of the identifiable assets acquired and liabilities assumed for the respective acquisitions:

	Ocera [2]	InfaCare [2]	Stratatech	Hemostasis[1]	Therakos	Ikaria
Acquisition Date	December 2017	September 2017	August 2016	February 2016	September 2015	April 2015
Cash	$ 1.0	$ 1.3	$ 0.2	$ 3.3	$ 41.3	$ 77.3
Accounts receivable	—	—	1.3	—	22.0	73.8
Inventory	—	—	—	94.6	23.5	26.3
Intangible assets	64.5	113.5	99.8	132.7	1,170.0	1,971.0
Goodwill (non-tax deductible)	25.1	11.4	55.1	3.3	429.9	795.0
Other assets, current and non-current	0.4	0.1	1.9	7.9	18.2	100.5
Total assets acquired	91.0	126.3	158.3	241.8	1,704.9	3,043.9
Current liabilities	14.5	14.5	4.3	3.6	24.7	33.0
Other liabilities (non-current)	—	—	—	10.6	0.6	15.8
Deferred tax liabilities, net (non-current)	23.2	8.7	22.1	2.1	315.7	620.5
Contingent consideration (non-current)	12.8	35.0	54.9	52.0	—	—
Total debt	—	30.0	1.0	—	344.8	1,121.0
Total liabilities assumed	50.5	88.2	82.3	68.3	685.8	1,790.3
Net assets acquired	$ 40.5	$ 38.1	$ 76.0	$ 173.5	$ 1,019.1	$ 1,253.6

(1) During fiscal 2017, the Company recorded a non-restructuring impairment charge relating to one of its intangible assets and reduced the associated contingent consideration. Refer to Note 12 and 20, respectively, for further information.

(2) The fair value allocations for these acquisitions are preliminary and subject to measurement period adjustments.

The following reconciles the total consideration to net assets acquired:

	Ocera	InfaCare	Stratatech	Hemostasis	Therakos	Ikaria
Total consideration, net of cash	$ 63.4	$ 71.8	$ 130.7	$ 222.2	$ 977.8	$ 1,176.3
Plus: cash assumed in acquisition	1.0	1.3	0.2	3.3	41.3	77.3
Total consideration	64.4	73.1	130.9	225.5	1,019.1	1,253.6
Less: unpaid purchase consideration	(1.9)	—	—	—	—	—
Less: non-cash contingent consideration	(22.0)	(35.0)	(54.9)	(52.0)	—	—
Net assets acquired	$ 40.5	$ 38.1	$ 76.0	$ 173.5	$ 1,019.1	$ 1,253.6

Intangible assets acquired consist of the following:

Acquisition	Intangible Asset Acquired	Amount	Amortization Period	Discount Rate
Ocera	In-process research and development - MNK-6105	$ 64.5	Non-Amortizable	15.5%
InfaCare	In-process research and development - stannsoporfin	113.5	Non-Amortizable	13.5%
Stratatech	In-process research and development - StrataGraft	99.8	Non-Amortizable	16.5%
Hemostasis	Completed technology - Raplixa[1]	73.0	15 years	17.0%
Hemostasis	Completed technology - Recothrom	42.7	13 years	16.0%
Hemostasis	Completed technology - PreveLeak	17.0	13 years	17.0%
Therakos	Completed technology - Extracorporeal photopheresis treatment therapies	1,170.0	15 years	17.0%
Ikaria	Completed technology	1,820.0	15 years	14.5%
Ikaria	Trademark	70.0	22 years	14.5%
Ikaria	In-process research and development - Terlipressin	81.0	Non-Amortizable	17.0%

(1) During fiscal 2017, the Company recorded a non-restructuring impairment charge relating to the Raplixa intangible asset. Refer to Note 12 for further information.

The fair value of the intangible assets were determined using the income approach. The fair value of the IPR&D, completed technology and trademark 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 discount rates were 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.

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

	Fiscal Year Ended			Three Months Ended
Net sales	**December 29, 2017**	**September 30, 2016**	**September 25, 2015**	**December 30, 2016**
Ocera	$ —	$ —	$ —	$ —
InfaCare	—	—	—	—
Therakos	214.9	207.6	—	47.4
Ikaria	515.1	491.5	191.9	121.4
Total	$ 730.0	$ 699.1	$ 191.9	$ 168.8
Operating income				
Ocera	$ (0.4)	$ —	$ —	$ —
InfaCare	(5.4)	—	—	—
Therakos	27.0	12.5	—	9.2
Ikaria	202.8	201.1	47.1	51.0
Total	$ 224.0	$ 213.6	$ 47.1	$ 60.2

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

	Fiscal Year Ended			Three Months Ended
Intangible asset amortization	**December 29, 2017**	**September 30, 2016**	**September 25, 2015**	**December 30, 2016**
Ocera	$ —	$ —	$ —	$ —
InfaCare	—	—	—	—
Therakos	61.7	78.0	—	19.5
Ikaria	124.5	124.5	57.1	31.1
Total	$ 186.2	$ 202.5	$ 57.1	$ 50.6

During fiscal 2017, 2016 and 2015 and the three months ended December 30, 2016, the Company recognized $10.1 million, $24.3 million, $44.1 million and $3.6 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 for each of the acquisitions discussed above were as follows:

	Fiscal Year Ended			Three Months Ended
Acquisition-related costs	**December 29, 2017**	**September 30, 2016**	**September 25, 2015**	**December 30, 2016**
Ocera	$ 0.9	$ —	$ —	$ —
Xenon Licensing Agreement	0.1	—	—	—
InfaCare	1.2	—	—	—
Stratatech	—	3.7	—	—
Hemostasis Products	—	2.7	—	0.1
Therakos	—	0.3	22.5	—
Ikaria	—	0.2	30.9	—
Total acquisition-related costs	$ 2.2	$ 6.9	$ 53.4	$ 0.1

License Agreements

Xenon Gas for Inhalation

On October 2, 2017, the Company entered into a licensing agreement for development and commercialization of NeuroproteXeon Inc.'s ("NeuroproteXeon" and "the Xenon Licensing Agreement") investigational, pharmaceutical-grade xenon gas for inhalation therapy being evaluated to improve survival and functional outcomes for patients resuscitated after a cardiac arrest. If approved, xenon gas for inhalation will expand the Company's portfolio of hospital drug-device combination products providing therapies for critically ill patients. The Company paid $10.0 million upfront with cash on hand to reimburse NeuroproteXeon for certain product development costs, and gained exclusive rights to commercialize the therapy, if approved, in the U.S., Canada, Japan and Australia. The Licensing Agreement includes additional payments of up to $25.0 million dependent on developmental, regulatory and sales milestones. In addition, NeuroproteXeon will receive tiered royalties on applicable worldwide net sales and a transfer price for commercial product supply. NeuroproteXeon will continue to be responsible for the cost of development and will manage the development of the product in collaboration with the Company. The initial $10.0 million upfront cash payment was recorded within R&D expense during the year ended December 29, 2017. Of the $25.0 million additional payments, certain payments may be expensed as R&D, cost of sales, or capitalized as an intangible asset dependent upon the successful completion of certain milestone events.

Mesoblast

In January 2017, $21.5 million of consideration was remitted to Mesoblast Limited ("Mesoblast") in exchange for equity shares and rights to a nine month exclusivity period related to any potential commercial and development agreements the Company may enter into for Mesoblast's therapy products used to treat acute graft versus host disease and/or chronic lower back pain. As a result of this transaction the Company recorded an available for sale investment of $19.7 million included within prepaid and other current assets and an intangible asset of $1.8 million in the consolidated balance sheet. This intangible asset was fully amortized as of December 29, 2017 as the nine month exclusivity period had ended.

Ofirmev

As part of the acquisition of Cadence Pharmaceuticals, Inc. ("Cadence" or "Cadence Acquisition") in March 2014, 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 2017, 2016, 2015 and the three months ended December 30, 2016, the Company paid royalties of $53.9 million, $46.3 million, $43.9 million and $14.7 million, respectively, which were recorded within cost of sales on the consolidated statements of income.

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 2017, $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 2017, 2016, 2015 and the three months ended December 30, 2016, the Company paid royalties of $0.2 million, $0.9 million, $3.2 million and $0.2 million, respectively, which were recorded within cost of sales on the consolidated statements of income.

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 2017, 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 was capitalized as an intangible asset. During the three months ended December 30, 2016, the Company elected to discontinue this product and recorded a $7.3 million non-restructuring impairment charge associated with the Xartemis intangible asset.

7. 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 Medical 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. The 2013 Mallinckrodt Program is substantially complete.

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 Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Specialty Brands	$ 25.4	$ 23.3	$ 36.5	$ 2.6
Specialty Generics	7.7	3.4	4.5	0.8
Corporate	3.3	11.5	4.3	1.9
Restructuring and related charges, net	36.4	38.2	45.3	5.3
Less: accelerated depreciation	(5.2)	(4.9)	(0.3)	(1.5)
Restructuring charges, net	$ 31.2	$ 33.3	$ 45.0	$ 3.8

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

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
2016 Mallinckrodt Program	$ 36.2	$ 8.3	$ —	$ 5.2
2013 Mallinckrodt Program	(0.7)	26.2	12.0	—
Acquisition programs	0.9	3.7	33.6	0.1
Other programs	—	—	(0.3)	—
Total programs	36.4	38.2	45.3	5.3
Less: non-cash charges, including impairments and accelerated share based compensation expense	(5.2)	(4.9)	(10.1)	(1.5)
Total charges expected to be settled in cash	$ 31.2	$ 33.3	$ 35.2	$ 3.8

Non-cash charges in fiscal 2015 include $9.8 million of accelerated share based compensation expense related to employee terminations, primarily related to the acquisition of Questcor Pharmaceuticals, Inc. ("Questcor") in fiscal 2014.

The following table summarizes cash activity for restructuring reserves, substantially all of which related to employee severance and benefits and exiting of certain facilities:

	2016 Mallinckrodt Program	2013 Mallinckrodt Program	Acquisition Programs	Other Programs	Total
Balance at September 26, 2014	$ —	$ 26.6	$ 7.9	$ 0.4	$ 34.9
Charges from continuing operations	—	11.7	25.3	—	37.0
Charges from discontinued operations	—	4.7	—	—	4.7
Changes in estimate from continuing operations	—	—	(1.5)	(0.3)	(1.8)
Changes in estimate from discontinued operations	—	(8.9)	—	—	(8.9)
Cash payments	—	(22.5)	(21.7)	(0.1)	(44.3)
Reclassifications [1]	—	(3.0)	—	—	(3.0)
Currency translation	—	(0.6)	—	—	(0.6)
Balance at September 25, 2015	—	8.0	10.0	—	18.0
Charges from continuing operations	6.4	24.6	5.0	—	36.0
Charges from discontinued operations	—	2.5	—	—	2.5
Changes in estimate from continuing operations	—	(1.4)	(1.3)	—	(2.7)
Changes in estimate from discontinued operations	—	(0.3)	—	—	(0.3)
Cash payments	(0.2)	(20.3)	(13.2)	—	(33.7)
Reclassifications [1]	—	(1.3)	—	—	(1.3)
Balance at September 30, 2016	6.2	11.8	0.5	—	18.5
Charges from continuing operations	3.7	—	0.1	—	3.8
Cash payments	(0.4)	(6.7)	(0.4)	—	(7.5)
Balance at December 30, 2016	9.5	5.1	0.2	—	14.8
Charges from continuing operations	35.8	—	0.9	—	36.7
Changes in estimate from continuing operations	(4.8)	(0.7)	—	—	(5.5)
Cash payments	(26.1)	(4.4)	(0.3)	—	(30.8)
Reclassifications [1]	0.3	—	—	—	0.3
Balance at December 29, 2017	$ 14.7	$ —	$ 0.8	$ —	$ 15.5

(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	$ 32.5	$ 18.8
Specialty Generics	9.1	18.3
Discontinued Operations (including Nuclear and CMDS)	—	69.9
Corporate	9.0	17.7
	$ 50.6	$ 124.7

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

8. Income Taxes

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the “TCJA” or "U.S. Tax Reform"). The TCJA makes broad and complex changes to the U.S. tax code, the effects of which have been incorporated into the Company’s fiscal 2017 provision for income taxes, as applicable. The TCJA provisions effective within 2017, include, but are not limited to (1) requiring a one-time transition tax on certain undistributed earnings of the Company’s foreign subsidiaries of U.S. entities, (2) bonus depreciation that will allow for full expensing of qualified property, and (3) reducing the U.S. federal corporate statutory tax rate from 35% to 21%. The TCJA also establishes new tax laws that will affect fiscal 2018, including, but not limited to (1) elimination of the corporate alternative minimum tax, (2) creation of the base erosion anti-abuse tax, a new minimum tax, (3) a general elimination of U.S. federal income taxes on dividends from non-U.S. subsidiaries, (4) a new provision designed to tax global intangible low-taxed income, which allows for the possibility of using foreign tax credits and a deduction of up to 50% to offset the income tax liability, (5) tightening the limitation on deductible interest expense, (6) limitations on net operating losses generated after December 31, 2017 to 80% of taxable income, and (7) reductions to the amount of the orphan drug research credit generated after December 31, 2017.

Accounting Standards Codification ("ASC") Topic 740, *Income Taxes* ("ASC 740"), requires companies to recognize the effects of tax law changes in the period of enactment, which for Mallinckrodt is the fourth quarter of 2017, even though the effective date of most provisions of TCJA is January 1, 2018. The SEC staff issued Staff Accounting Bulletin ("SAB") 118, which provides guidance on accounting for the tax effects of the TCJA. SAB 118 provides a measurement period that should not extend beyond one year from the TCJA enactment date for companies to complete the accounting. In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the TCJA for which the accounting is complete. To the extent that a company’s accounting for certain income tax effects of the TCJA is incomplete but it is able to determine a reasonable estimate, it must record a provisional estimate in the financial statements. If a company cannot determine a provisional estimate to be included in the financial statements, it should continue to apply ASC 740 on the basis of the provisions of the tax laws that were in effect immediately before the enactment of the TCJA.

In connection with the Company's initial analysis of the impact of the TCJA, a discrete net tax benefit of $456.9 million was recognized in fiscal 2017, primarily for the adjustment of the Company’s U.S. net deferred income tax liabilities for the reduction of the U.S. federal corporate statutory tax rate to 21%. For various reasons that are discussed more fully below, the Company has not yet completed its accounting for the income tax effects of certain elements of the TCJA and therefore a reasonable estimate of such impact has been provided.

The TCJA reduces the U.S. federal corporate tax rate to 21%, effective January 1, 2018. For the Company's U.S. net deferred income tax liabilities a provisional decrease of $444.8 million was recognized resulting in a corresponding deferred income tax benefit in fiscal 2017. While the Company is able to make a reasonable estimate of the impact of the reduction in the U.S. federal corporate statutory tax rate, it may be affected by other analyses related to the TCJA, including, but not limited to, having a U.S. tax return year that straddles the effective date of the statutory rate change and that is different than the Company's financial statement year, the calculation of deemed repatriation of deferred foreign income, and the state tax effect of adjustments made to federal temporary differences.

The one-time transition tax under the TCJA on certain of the Company’s subsidiaries is a tax on previously untaxed cumulative undistributed earnings. To determine the amount of such tax, the Company must determine, in addition to other factors, the amount of post-1986 cumulative undistributed earnings of the relevant subsidiaries, the amount of non-U.S. income taxes paid on such earnings, and the application of the law and interpretative guidance to the Company's global legal entity structure. While the Company currently

estimates this item will not result in any current or future tax, additional information will continue to be gathered to finalize this conclusion.

Because of the complexity and uncertainties of the new global intangible low-taxed income rules, the Company continues to evaluate this portion of the TCJA and the application of ASC 740. Under GAAP, the Company is allowed to make an accounting policy choice of either (1) treating taxes due on future U.S. inclusions in taxable income related to global intangible low-taxed income as a current-period expense when incurred or (2) factoring such amounts into a company's measurement of its deferred taxes. The Company's selection of an accounting policy with respect to these new tax rules will depend on whether it expects to have future U.S. inclusions in taxable income related to global intangible low-taxed income and, if so, what the tax impact is expected to be. Whether the Company expects to have future U.S. inclusions in taxable income depends on not only the Company's current structure and estimated future results of global operations but also its intent and ability to modify its structure and/or business. While the Company estimates these rules will not have a material tax impact, it is not yet able to finalize the effect of this portion of the TCJA. Therefore, the Company has not made any adjustments related to this item in its consolidated financial statements and has not made a policy decision regarding whether to record deferred taxes on global intangible low-taxed income.

Finally, the Company must assess whether its valuation allowance analyses are affected by the various aspects of the TCJA. Since, as discussed herein, the Company has recorded provisional amounts related to certain portions of the TCJA, any corresponding determination of the need for or change in a valuation allowance is also provisional.

The U.K. and non-U.K. components of income (loss) from continuing operations before income taxes were as follows:

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
U.K.	$ (165.9)	$ (275.3)	$ (107.5)	$ (97.4)
Non-U.K.	227.5	508.7	214.8	(201.1)
Total	$ 61.6	$ 233.4	$ 107.3	$ (298.5)

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

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Current:				
U.K.	$ 0.4	$ 0.3	$ 0.2	$ —
Non-U.K.	37.7	120.5	67.3	82.0
Current income tax provision	38.1	120.8	67.5	82.0
Deferred:				
U.K.	$ 0.6	$ 0.7	$ (0.8)	$ (0.5)
Non-U.K.	(1,748.3)	(377.1)	(196.0)	(203.2)
Deferred income tax benefit	(1,747.7)	(376.4)	(196.8)	(203.7)
	$ (1,709.6)	$ (255.6)	$ (129.3)	$ (121.7)

The fiscal 2017 U.K. current income tax provision reflects a tax benefit of $14.3 million from utilization of net operating losses. The U.K. net operating loss utilization relates to net operating losses carried forward from the three months ended December 30, 2016. The fiscal 2017 non-U.K. current income tax provision reflects a tax benefit of $57.2 million from utilization of net operating losses and $5.6 million of U.S. credits. In addition, the non-U.K. current income tax provision includes a tax benefit of $27.2 million related to carryback claims filed in fiscal 2017. The non-U.K. net operating loss utilization relates to net operating losses carried forward from the three months ended December 30, 2016. The U.S. credit utilization is comprised of credits carried forward from the three months ended December 30, 2016 and generated during fiscal 2017

The fiscal 2016 U.K. current income tax provision reflects a tax benefit of $1.0 million from utilization of net operating losses. The U.K. net operating loss utilization is comprised of net operating losses carried forward from fiscal 2015. The fiscal 2016 non-U.K. current income tax provision reflects a tax benefit of $29.2 million from utilization of net operating losses and $9.5 million of U.S. credits. The non-U.K. 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 non-U.K. current income tax provision reflects a tax benefit of $7.0 million from utilization 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 of the utilization relating to credits carried forward or generated during fiscal 2015.

The three months ended December 30, 2016 non-U.K. current income tax provision reflects a tax benefit of $0.3 million from utilization of net operating losses and $2.0 million of U.S. credits. The non-U.K. net operating loss utilization relates to net operating losses carried forward from fiscal 2016. The U.S. credit utilization is comprised of credits carried forward from fiscal 2016 and generated during the three months ended December 30, 2016.

During fiscal years 2017, 2016, and 2015 net cash payments for income taxes was $73.4 million, $165.4 million and $123.8 million, respectively. During the three months ended December 30, 2016 net cash payments for income taxes was $95.6 million.

The Company has a provincial tax holiday in Canada that expires on April 1, 2027. The tax holiday reduced non-U.K. tax expense by $1.8 million, $1.0 million and $5.1 million for the fiscal years 2017, 2016 and 2015, respectively. Due to an operating loss, there is no benefit from the tax holiday for the three months ended December 30, 2016.

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

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Provision (benefit) for income taxes at U.K. statutory income tax rate [1]	$ 11.7	$ 46.6	$ 21.4	$ (59.7)
Adjustments to reconcile to income tax provision:				
Rate difference between U.K. and non-U.K. jurisdictions [2] [5]	(219.9)	(249.3)	(152.9)	(123.0)
Valuation allowances, nonrecurring	(3.7)	2.1	(2.1)	—
Adjustments to accrued income tax liabilities and uncertain tax positions [7]	5.1	(14.9)	(7.0)	0.9
Interest and penalties on accrued income tax liabilities and uncertain tax positions	0.2	(16.4)	0.3	(0.1)
Investment in partnership	—	—	—	(12.7)
Credits, principally research and orphan drug [3] [4]	(13.8)	(33.7)	(8.1)	(0.7)
Impairments non deductible	—	—	—	75.3
Permanently nondeductible and nontaxable items	6.4	7.9	14.7	1.6
Pension plan settlement, release of tax effects lodged in other comprehensive income	(2.4)	—	—	—
Divestiture of Intrathecal Therapy Business	18.2	—	—	—
U.S. Tax Reform [6]	(456.9)	—	—	—
Legal Entity Reorganization [7]	(1,054.8)	—	—	—
Other	0.3	2.1	4.4	(3.3)
Benefit for income taxes	$ (1,709.6)	$ (255.6)	$ (129.3)	$ (121.7)

(1) The statutory tax rate reflects the U.K. statutory tax rate of 19% for fiscal 2017 and 20% for fiscal 2016, 2015 and the three months ended December 30, 2016.

(2) Includes the impact of certain recurring valuation allowances for U.K. and non-U.K. jurisdictions.

(3) During fiscal 2015, the Research Credit tax law 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) During fiscal 2016, the Company realized a tax benefit of $27.4 million resulting from a U.K. tax credit on a dividend between affiliates.

(5) During the three months ended December 30, 2016, the rate difference between U.K. and non-U.K. jurisdictions was favorably impacted by a benefit of $16.1 million on a $102.0 million settlement with the Federal Trade Commission and a benefit of $34.5 million on a $207.0 million goodwill impairment in the Specialty Generics segment.

(6) Reflects redetermination of the Company's deferred tax liabilities as a result of the new U.S. statutory income tax rate of 21% at the date of enactment. Other line items, to the extent U.S. related, are reflected at the former U.S. statutory income tax rate of 35%.

(7) Associated unrecognized tax benefit netted within this line.

The rate difference between U.K. and Non-U.K. jurisdictions changed from $249.3 million of tax benefit to $219.9 million of tax benefit for fiscal 2016 to fiscal 2017, respectively. The $29.4 million decrease in the tax benefit included $37.6 million of decreases primarily attributed to the divestiture of the Intrathecal Therapy business and the planned divestiture of the PreveLeak and Recothrom assets and fiscal 2016 one-time items that did not recur in fiscal 2017, and $15.2 million of decreases to the tax benefit associated with the impact of U.S. Tax Reform on a U.S. tax return year that straddles the effective date of the statutory rate change; partially offset by increases of $23.4 million to the tax benefit attributed to changes in operating income and termination and settlement of the Company's funded U.S. pension plan in fiscal 2017.

The rate difference between U.K. and Non-U.K. 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.

During the three months ended December 29, 2017, the Company completed a reorganization of its legal entity ownership (“the Reorganization”) to align with its ongoing transformation to become an innovation-driven specialty pharmaceuticals growth company. Many factors were considered in effecting the Reorganization, including streamlining treasury functions, simplifying legal entity reporting processes, and capital allocation efficiencies. Given this Reorganization, the Internal Revenue Code required the Company to reallocate its tax basis from an investment in shares of a wholly-owned subsidiary to assets within another legal entity with no corresponding change in accounting basis. A deferred tax liability was not recognized on the wholly-owned subsidiary as there is a means for its recovery in a tax-free manner. The reallocation of tax basis resulted in a decrease to the net deferred tax liabilities associated with the assets within the other legal entity. As a result, during fiscal 2017, the Company recognized an income tax benefit, net of unrecognized tax benefits, of $1,054.8 million primarily as a result of a reduction to its net deferred tax liabilities.

In fiscal 2017, the Company recognized an income tax expense of $5.2 million associated with the Nuclear Imaging business divestiture, as discussed in Note 5, in discontinued operations within the consolidated statement of income.

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

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Balance at beginning of period	$ 118.7	$ 89.2	$ 82.0	$ 114.8
Additions related to current year tax positions	79.9	63.8	4.5	5.0
Additions related to prior period tax positions	0.3	10.8	19.9	—
Reductions related to prior period tax positions	(13.6)	(37.8)	(7.7)	(1.1)
Reductions related to disposition transactions	—	(6.6)	—	—
Settlements	—	(2.6)	(7.8)	—
Lapse of statute of limitations	(2.8)	(2.0)	(1.7)	—
Balance at end of period	$ 182.5	$ 114.8	$ 89.2	$ 118.7

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. IRS in connection with the settlement of certain tax matters for 2008 and 2009.

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

	December 29, 2017	December 30, 2016
Accrued and other current liabilities	$ 1.5	$ —
Other income tax liabilities	82.6	58.3
Deferred income taxes (non-current liability)	98.4	60.4
	$ 182.5	$ 118.7

Included within total unrecognized tax benefits at December 29, 2017, September 30, 2016, September 25, 2015 and December 30, 2016, were $180.8 million, $113.1 million, $87.4 million and $116.9 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 2017, the Company recorded $2.6 million of additional interest through tax provision and acquisition accounting and decreased accrued interest by $2.7 million related to prior period reductions. During fiscal 2016, 2015 and the three months ended December 30, 2016, the Company accrued additional interest of $4.1 million, $5.7 million and zero, respectively. The total amount of accrued interest related to uncertain tax positions was $7.1 million, $7.2 million, $41.7 million and $7.1 million, respectively.

It is reasonably possible that within the next twelve months, as a result of the resolution of various U.K. and non-U.K. examinations and appeals and the expiration of various statutes of limitation, that the unrecognized tax benefits could decrease by up to $38.4 million. Interest and penalties could decrease by up to $4.9 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:

	December 29, 2017	December 30, 2016
Income taxes payable	$ 15.8	$ 101.7
Other income tax liabilities	94.1	70.4
	$ 109.9	$ 172.1

Tax items inherent in other assets decreased from $67.2 million at December 30, 2016 to zero as of December 29, 2017. The $67.2 million decrease was as a result of the early adoption of ASU 2016-16 which moved capitalized tax payments associated with non-current deferred intercompany transactions to retained earnings. Tax items inherent in prepaid expenses and other current assets decreased from $50.3 million at December 30, 2016 to $6.1 million as of December 29, 2017. The $44.2 million decrease was primarily due to the receipt of a $25.4 million U.K. tax credit receivable and a $7.8 million decrease related to the early adoption of ASU 2016-16. Prepaid expenses and other current assets includes $4.2 million and $40.2 million of receivables associated with tax payments on account with the taxing authorities and tax payments of $1.9 million and $10.1 million associated with current deferred intercompany transactions at December 29, 2017 and December 30, 2016, respectively.

	December 29, 2017	December 30, 2016
Other assets	$ —	$ 67.2
Prepaid expenses and other current assets	6.1	50.3
	$ 6.1	$ 117.5

With a few exceptions, as of December 29, 2017, the earliest open years for U.S. federal and state tax jurisdictions are 2010 and 2009, respectively. Additionally, a number of tax periods from 2013 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:

	December 29, 2017	December 30, 2016
Deferred tax assets:		
Accrued liabilities and reserves	$ 62.7	$ 103.3
Inventories	22.3	36.5
Tax loss and credit carryforwards	1,734.5	1,173.7
Environmental liabilities	17.0	28.5
Rebate reserves	1.6	48.0
Expired product	7.5	9.7
Postretirement benefits	14.0	47.5
Federal and state benefit of uncertain tax positions and interest	11.3	17.2
Share-based compensation	23.6	26.1
Intangible assets	575.1	383.2
Other	16.0	—
	2,485.6	1,873.7
Deferred tax liabilities:		
Property, plant and equipment	(47.0)	(110.9)
Intangible assets	(181.0)	(759.2)
Interest-bearing deferred tax obligations	(553.5)	(1,801.4)
Investment in partnership	(108.8)	(173.6)
Other	—	(2.0)
	(890.3)	(2,847.1)
Net deferred tax asset (liability) before valuation allowances	1,595.3	(973.4)
Valuation allowances	(2,267.9)	(1,398.3)
Net deferred tax liability	$ (672.6)	$ (2,371.7)

The deferred tax asset valuation allowances of $2,267.9 million and $1,398.3 million at December 29, 2017 and December 30, 2016, respectively, relate primarily to the uncertainty of the utilization of certain deferred tax assets, driven by non-U.K. net operating losses, credits 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. The increase in tax loss and credit carryforwards and valuation allowances are primarily related to statutory deductions associated with internal transactions.

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

	December 29, 2017	December 30, 2016
Other assets	$ 16.4	$ 26.4
Deferred income taxes (non-current liability)	(689.0)	(2,398.1)
Net deferred tax liability	$ (672.6)	$ (2,371.7)

Non-current deferred tax liability decreased from $2,398.1 million at December 30, 2016 to $689.0 million at December 29, 2017, primarily due to $1,122.3 million of decreases associated with the Reorganization, $444.8 million of decreases associated with the TCJA's reduction of the U.S. federal corporate statutory tax rate from 35% to 21%, $270.6 million of decreases associated with the payment of internal installment sale obligations and $63.6 million of decreases associated with the amortization of intangibles. These decreases are partially offset by $47.0 million of increases related to reductions of deferred tax assets associated with rebate reserves, $38.9 million of increases related to the divestiture of the Intrathecal Therapy business, $37.5 million of increases related to reductions of deferred tax assets associated with legal settlements, $29.7 million of increases related to recent acquisitions, $29.6 million of increases related to reductions of deferred tax assets associated with the termination and settlement of the Company's funded U.S. pension plans and $9.5 million of net increases related to operational activity.

The Company refined its acquisition accounting estimate associated with the measurement of its acquired Stratatech net deferred tax liabilities in fiscal 2017, resulting in a decrease to the acquired net deferred tax liabilities from $24.3 million to $22.1 million prior to recording the impact from the TCJA.

The InfaCare Acquisition resulted in a net deferred tax liability increase of $8.7 million prior to recording the impact from the TCJA. Significant components of this include $13.8 million of net deferred tax liabilities associated with intangibles partially offset by $4.7 million of deferred tax assets associated with non U.K. net operating losses.

The Ocera Acquisition resulted in a net deferred tax liability increase of $23.2 million prior to recording the impact from the TCJA, which is primarily associated with intangibles.

The divestiture of the Intrathecal Therapy Business was completed on March 17, 2017. This divestiture resulted in a net deferred tax liability increase of $38.9 million prior to recording the impact from the TCJA. Significant components of this increase include an increase of $56.4 million of deferred tax liability associated with future consideration, a decrease of $2.3 million of deferred tax asset associated with net operating losses, a decrease of $16.6 million of deferred tax liability associated with intangibles, an increase of $2.7 million of deferred tax asset associated with committed product development, and an increase of $0.5 million of other net deferred tax assets.

At December 29, 2017, the Company had approximately $1,604.0 million of net operating loss carryforwards in certain non-U.K. jurisdictions measured at the applicable statutory rates, of which $1,489.9 million have no expiration and the remaining $114.1 million will expire in future years through 2038. As a result of the TCJA, the Company's Non-U.K. net operating losses decreased by $6.2 million. The Company had $106.4 million of U.K. net operating loss carryforwards measured at the applicable statutory rates at December 29, 2017, which have no expiration date.

At December 29, 2017 the Company also had $24.1 million of tax credits available to reduce future income taxes payable, primarily in jurisdictions within the U.S., of which $2.4 million have no expiration and the remainder expire during fiscal 2017 through 2038.

As of December 29, 2017, there are no remaining cumulative undistributed earnings of the Company's subsidiaries that may be subject to tax. The net decrease in such undistributed earnings was attributable to the removal of the earnings for the entities reclassified to discontinued operations, undistributed earnings associated with income and losses attributed to the current year activity, and a reduction of the remaining cumulative undistributed earnings pursuant to the TCJA. The Company has preliminarily evaluated the impact of the TCJA with respect to the one-time tax imposed upon the deemed repatriation of undistributed earnings and estimated that no tax will be imposed upon the Company under such provisions.

In fiscal 2017, the Company early adopted ASU 2016-16 utilizing the modified retrospective basis adoption method, with a cumulative-effect adjustment directly to retained earnings as of the beginning of the period for $75.0 million with an offsetting decrease of $67.2 million to other assets and a $7.8 million decrease to prepaid expenses on its consolidated balance sheets. The prior periods were not restated.

In fiscal 2017, the Company adopted ASU 2016-09 and recorded an adjustment to retained earnings of $2.9 million to recognize net operating loss carryforwards, net of a valuation allowance, attributable to excess tax benefits on stock compensation that had not been previously recognized in additional paid-in capital.

9. Earnings (Loss) per Share

Basic earnings (loss) per share is 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 years prior, 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 acquisition of Questcor in August 2014 ("the Questcor Acquisition"), 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.

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Earnings (loss) per share numerator:				
Income (loss) from continuing operations attributable to common shareholders before allocation of earnings to participating securities	$ 1,771.2	$ 489.0	$ 236.6	$ (176.8)
Less: earnings allocated to participating securities	—	—	2.0	—
Income (loss) from continuing operations attributable to common shareholders, after earnings allocated to participating securities	1,771.2	489.0	234.6	(176.8)
Income from discontinued operations	363.2	154.7	88.1	23.6
Less: earnings from discontinued operations allocated to participating securities	—	—	0.7	—
Income from discontinued operations attributable to common shareholders, after allocation of earnings to participating securities	363.2	154.7	87.4	23.6
Net income (loss) attributable to common shareholders, after allocation of earnings to participating securities	$ 2,134.4	$ 643.7	$ 322.0	$ (153.2)
Earnings (loss) per share denominator:				
Weighted-average shares outstanding - basic	97.7	110.6	115.8	105.7
Impact of dilutive securities	0.2	0.9	1.4	—
Weighted-average shares outstanding - diluted	97.9	111.5	117.2	105.7
Basic earnings (loss) per share attributable to common shareholders:				
Income (loss) from continuing operations	$ 18.13	$ 4.42	$ 2.03	$ (1.67)
Income from discontinued operations	3.72	1.40	0.75	0.22
Net income (loss) attributable to common shareholders	$ 21.85	$ 5.82	$ 2.78	$ (1.45)
Diluted earnings (loss) per share attributable to common shareholders:				
Income (loss) from continuing operations	$ 18.09	$ 4.39	$ 2.00	$ (1.67)
Income from discontinued operations	3.71	1.39	0.75	0.22
Net income (loss) attributable to common shareholders	$ 21.80	$ 5.77	$ 2.75	$ (1.45)

The computation of diluted earnings per share for fiscal 2017, 2016, 2015 and the three months ended December 30, 2016, excludes approximately 4.2 million, 1.7 million, 0.1 million and 2.4 million, respectively, of equity awards because the effect would have been anti-dilutive. As the Company incurred a net loss in the three months ended December 30, 2016, 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.

10. Inventories

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

	December 29, 2017	December 30, 2016
Raw materials and supplies	$ 70.0	$ 72.6
Work in process	167.1	178.4
Finished goods	103.3	99.7
Inventories	$ 340.4	$ 350.7

11. 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:

	December 29, 2017	December 30, 2016
Land	$ 44.0	$ 46.9
Buildings	355.5	291.1
Capitalized software	109.0	87.2
Machinery and equipment	1,123.8	1,052.0
Construction in process	209.7	202.2
	1,842.0	1,679.4
Less: accumulated depreciation	(875.2)	(797.9)
Property, plant and equipment, net	$ 966.8	$ 881.5

Depreciation expense, including amounts related to capitalized leased assets, for continuing operations was as follows:

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Depreciation expense	$ 113.8	$ 113.3	$ 90.8	$ 27.5

12. Goodwill and Intangible Assets

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

	December 29, 2017		December 30, 2016	
	Gross Carrying amount	Accumulated Impairment	Gross Carrying amount	Accumulated Impairment
Specialty Brands	$ 3,482.7	$ 0.0	$ 3,498.1	$ 0.0
Specialty Generics	207.0	(207.0)	207.0	(207.0)
Total	$ 3,689.7	$ (207.0)	$ 3,705.1	$ (207.0)

During the fiscal year ended December 29, 2017, the gross carrying value of goodwill in the Specialty Brands segment decreased by $15.4 million. The decrease was primarily attributable to the sale of the Intrathecal Therapy business to Piramal for which $49.8 million of goodwill was ascribed and was factored into the gain on sale of the business. The decrease was partially offset by $25.1 million from the Ocera Acquisition and $11.4 million from the InfaCare Acquisition. The remaining change in goodwill was related to a purchase accounting adjustment for the Stratatech Acquisition primarily attributable to changes in deferred tax balances.

Goodwill Impairment Analysis

Fiscal Year ended December 29, 2017

The Company performed its annual goodwill impairment analysis for the Specialty Brands reporting unit as of the first day of the fourth quarter. For purposes of assessing impairment of goodwill for the Specialty Brands reporting unit, the Company made various assumptions regarding estimated future cash flows, discount rate and other factors in determining the respective fair value of the reporting unit using the income approach.

These assumptions resulted in a fair value of the Specialty Brands reporting unit in excess of its net book value. The fair value of the Specialty Brands reporting unit was assessed for reasonableness by aggregating the fair values of the Company's businesses and comparing this to its market capitalization with a control premium. Based upon the Company's annual assessment, no goodwill impairment was identified.

During the three months ended December 29, 2017, the Company experienced a substantial decline in its market capitalization, providing an indication that goodwill may be impaired at December 29, 2017. The decline in the Company's market capitalization was driven by a decrease in its share price. The Company believes that its share price has been adversely affected most notably by patient withdrawal issues impacting net sales of H.P. Acthar Gel, ongoing Inomax patent litigation, uncertainty regarding the perceived value of its various pipeline products and an incomplete understanding of its complex income tax structure.

In response to the decline in the Company's market capitalization, the annual valuation was updated and the Company determined that there was no goodwill impairment at December 29, 2017.

The projections used in both the annual and the year ended December 29, 2017 valuations for the Specialty Brands reporting unit include management's best estimate of long-term revenue and operating income. The Company's projections of future cash flows were discounted based on a weighted average cost of capital of 12.5%, for both valuations, that was determined from relevant market comparisons, adjusted upward for specific reporting unit risks. A terminal value growth rate was applied to the terminal year cash flows, representing the Company's estimate of stable, sustainable growth. The fair value of the Specialty Brands reporting unit represents the sum of the discounted cash flows from the discrete period and the terminal year cash flows. These assumptions resulted in a fair value of the Specialty Brands reporting unit in excess of its net book value by a mid-single digits in both valuations. The fair value of the Specialty Brands reporting unit was assessed for reasonableness by aggregating the fair value of the Company's businesses and comparing this to its market capitalization with a control premium and consideration of the aforementioned adverse effects the Company believes have impacted its share price.

Should the Specialty Brands reporting unit fail to experience growth, revise its long-term projections for its products downward or market conditions dictate utilization of a higher discount rate, the Specialty Brands reporting unit could be subject to impairment in future periods. In addition, the Company will continue to assess the impact of its market capitalization. It is possible that if the Company's market capitalization decline is sustained, such decline could result in an impairment of goodwill and other long-lived assets associated with its reporting units.

The Three Months Ended December 30, 2016

The Specialty Generics reporting unit has experienced customer consolidation and increased competition that have and are expected to result in further downward pressure to net sales and operating income in this reporting unit. During the three months ended December 30, 2016, the FDA approved new products that are expected to compete with the Company's methylphenidate HCI extended-release tablets USP (CII) ("Methylphenidate ER") products and that one competitor launched their Methylphenidate ER products. Additional products expected to compete with the Company's Methylphenidate ER products were launched during fiscal 2017. All of these products have a class AB rating compared with the class BX rating on the Company's Methylphenidate ER products. It is uncertain how these product approvals may impact the FDA's withdrawal proceedings associated with the Company's Methylphenidate ER products. The Company determined that these events represented a triggering event and the Company performed an assessment of the goodwill associated with the Specialty Generics reporting unit as of December 30, 2016.

The Company's projections in the Specialty Generics reporting unit included long-term net sales and operating income at lower than historical levels primarily attributable to customer consolidation and increased competition, including the competition effects on Methylphenidate ER. The Company utilized a weighted average cost of capital of 9.5% which reflects the Company's risk premium associated with the projected cash flows. These assumptions resulted in a fair value of the Specialty Generics reporting unit that was less than its net book value. As this impairment analysis was performed prior to the Company's adoption of ASU 2017-04 in fiscal 2017, the Company performed step two of the goodwill impairment test and recognized a $207.0 million goodwill impairment in the Specialty Generics segment.

Intangible Assets

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

	December 29, 2017		December 30, 2016	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortizable:				
Completed technology	$ 9,882.8	$ 2,260.8	$ 10,028.7	$ 1,617.1
License agreements	177.1	121.1	177.1	112.7
Trademarks	82.1	14.5	82.1	10.9
Customer relationships	29.5	12.2	27.6	8.4
Other	8.6	8.6	6.7	6.7
Total	$ 10,180.1	$ 2,417.2	$ 10,322.2	$ 1,755.8
Non-Amortizable:				
Trademarks	$ 35.0		$ 35.0	
In-process research and development	577.1		399.1	
Total	$ 612.1		$ 434.1	

The Company recorded impairment charges totaling $63.7 million in fiscal 2017 related to the Raplixa intangible asset and $16.9 million in fiscal 2016 related to certain Specialty Brands in-process research and development intangible assets acquired as part of the CNS Therapeutics acquisition in fiscal 2013. In both fiscal 2017 and 2016, the valuation method used to approximate fair value was based on the estimated discounted cash flows for the respective asset. The Raplixa impairment charge resulted from the lower than previously anticipated commercial opportunities for the product, while the CNS Therapeutics IPR&D impairment charge 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 is as follows:

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Amortization expense	$ 694.5	$ 700.1	$ 550.3	$ 175.7

The estimated aggregate amortization expense on intangible assets owned by the Company is expected to be as follows:

Fiscal 2018	$ 681.8
Fiscal 2019	681.4
Fiscal 2020	681.1
Fiscal 2021	680.9
Fiscal 2022	553.9

13. Debt

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

	December 29, 2017		December 30, 2016	
	Principal	Unamortized Discount and Debt Issuance Costs	Principal	Unamortized Discount and Debt Issuance Costs
Current maturities of long-term debt:				
Variable-rate receivable securitization due July 2017	$ —	$ —	$ 250.0	$ 0.3
3.50% notes due April 2018	300.0	0.2	—	—
Term loans due March 2021	—	—	20.0	0.3
4.00% term loan due February 2022	—	—	1.0	—
Term loan due September 2024	14.0	0.3	—	—
Capital lease obligation and vendor financing agreements	0.2	—	0.8	—
Total current debt	314.2	0.5	271.8	0.6
Long-term debt:				
3.50% notes due April 2018	—	—	300.0	0.9
4.875% notes due April 2020	700.0	5.7	700.0	8.2
Variable-rate receivable securitization due July 2020	200.0	0.7	—	—
Term loans due March 2021	—	—	1,928.5	33.4
4.00% term loan due February 2022	—	—	5.5	—
9.50% debentures due May 2022	10.4	—	10.4	—
5.75% notes due August 2022	884.0	9.5	884.0	11.6
8.00% debentures due March 2023	4.4	—	4.4	—
4.75% notes due April 2023	526.5	4.5	600.0	6.1
5.625% notes due October 2023	738.0	9.7	738.0	11.4
Term loan due September 2024	1,837.2	26.7	—	—
5.50% notes due April 2025	692.1	9.0	695.0	10.2
Revolving credit facility	900.0	5.9	100.0	3.2
Total long-term debt	6,492.6	71.7	5,965.8	85.0
Total debt	$ 6,806.8	$ 72.2	$ 6,237.6	$ 85.6

Mallinckrodt International Finance S.A. ("MIFSA") is a wholly-owned subsidiary of the Company. MIFSA functions as a holding company, established to own, directly or indirectly, substantially all of the operating subsidiaries of the Company, as well as to issue debt securities and to perform treasury operations.

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 15th and October 15th of each year, which commenced on October 15, 2013.

In August 2014, MIFSA and Mallinckrodt CB LLC ("MCB") ("the Issuers") 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 by Mallinckrodt plc and each of its subsidiaries that guarantee the obligations under the 2017 Facilities (as defined below). 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. The Issuers may redeem some or all of the 2022 Notes prior to August 1, 2017 by paying a make-whole premium. The Issuers may redeem some or all of the 2022 Notes on or after August 1, 2017 at specified redemption prices. In addition, on or prior to August 1, 2017, the Issuers 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 1st and August 1st of each year, which commenced on February 1, 2015.

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 2017 Facilities, which following the Ikaria Acquisition includes Compound Holdings II, Inc. (or its successors) 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, on or 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 15th and October 15th 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 2017 Facilities, which following the Therakos Acquisition includes TGG Medical Solutions, Inc (or its successors). 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, on or 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 15th and October 15th of each year, which commenced on April 15, 2016.

On February 28, 2017, MIFSA and MCB refinanced the March 2014 and August 2014 term loans, both of which were due in March 2021 ("the Existing Term Loans"). The refinanced term loans had an initial aggregate principal amount of $1,865.0 million, are due in September 2024 and bear interest at London Interbank Offered Rate ("LIBOR") plus 2.75% ("the 2017 Term Loan"). The 2017 Term Loan requires quarterly principal amortization payments in an amount equal to 0.25% of the original principal balance of the 2017 Term Loan, and may be reduced by making optional prepayments. The quarterly principal amortization is payable on the last day of each calendar quarter, which commenced on June 30, 2017, with the remaining balance due on September 24, 2024. The Company accounted for the term loan refinancing as a debt modification. As of December 29, 2017, the interest rate for the 2017 Term Loan was 4.44%, and outstanding principal under this agreement totaled approximately $1,851.2 million.

In conjunction with the term loan refinancing, MIFSA and MCB replaced the existing revolving credit facility of $500.0 million due in March 2019 with a $900.0 million facility that matures on February 28, 2022 ("the 2017 Revolving Credit Facility"). The 2017 Revolving Credit Facility bears interest at LIBOR plus 2.25%. The 2017 Revolving Credit Facility reduced the letter of credit provision from $150.0 million to $50.0 million. Unused commitments on the 2017 Revolving Credit Facility are subject to an annual commitment fee, which was 0.275% as of December 29, 2017, and the fee applied to outstanding letters of credit is based on the interest rate applied to borrowings. As of December 29, 2017, there was $900.0 million in outstanding borrowings under the 2017 Revolving Credit Facility, the applicable interest rate was 3.94% as of December 29, 2017. The 2017 Revolving Credit Facility added certain wholly-owned subsidiaries of the Company as borrowers, in addition to MIFSA and MCB.

The 2017 Term Loan and 2017 Revolving Credit Facility (collectively "the 2017 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 wholly-owned U.S. subsidiaries and certain of its other subsidiaries (collectively, "the Guarantors"). The 2017 Facilities are secured by a security interest in certain assets of MIFSA, MCB and the

Guarantors. The 2017 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.

As a result of the 2017 Facilities financing transaction and the write-off of certain deferred financing costs associated with an $83.5 million payment on the Existing Term Loans, the Company recorded a $10.0 million charge included within the other expense line in the consolidated statement of income.

On July 28, 2017, Mallinckrodt Securitization S.à r.l. ("Mallinckrodt Securitization"), a wholly owned special purpose subsidiary of the Company, entered into a $250.0 million accounts receivable securitization facility ("the Receivable Securitization") with a three year term. The Receivable Securitization was entered into upon the maturity of the original July 2017 Securitization. Mallinckrodt Securitization may, from time to time, obtain up to $250.0 million in third-party borrowings secured by certain receivables. The borrowings under the Receivable Securitization are to be repaid as the secured receivables are collected. Loans under the Receivable Securitization will bear interest (including facility fees) at a rate equal to one month LIBOR rate plus a margin of 0.9%. Unused commitments on the Receivables Securitization are subject to an annual commitment fee of 0.4%. The Receivable Securitization agreements contain customary representations, warranties, and affirmative and negative covenants. The size of the securitization facility may be increased to $300.0 million upon approval of the third-party lenders. As of December 29, 2017, the applicable interest rate on outstanding borrowings under the Receivable Securitization was 2.46% and outstanding borrowings totaled $200.0 million.

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

Fiscal 2018	$	314.2
Fiscal 2019		18.7
Fiscal 2020		918.7
Fiscal 2021		23.3
Fiscal 2022		1,813.0

14. Retirement Plans

Pension Plan Termination

On March 31, 2016, the Company terminated six of its previously frozen U.S. pension plans. During fiscal 2017, approximately $212.9 million of obligations and corresponding pension assets were transferred to a third party for settlement of the terminated pension plans through the purchase of annuity contracts. As a result of the settlement, the Company made a $62.3 million cash contribution to the terminated plans and recognized a $70.5 million charge included within SG&A expense during fiscal 2017.

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 December 29, 2017, U.S. plans represented 39% of the Company's remaining 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			
	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Service cost	$ 1.4	$ 1.8	$ 2.4	$ 0.8
Interest cost	2.3	13.2	14.5	2.0
Expected return on plan assets	(1.3)	(16.7)	(18.9)	(2.3)
Amortization of net actuarial loss	2.7	11.3	9.2	3.5
Amortization of prior service cost	0.2	—	—	0.1
Loss on plan settlements	71.1	8.1	5.9	45.0
Curtailment gain	(1.0)	—	—	—
Net periodic benefit cost	$ 75.4	$ 17.7	$ 13.1	$ 49.1

	Postretirement Benefits			
	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Service cost	$ —	$ 0.1	$ 0.1	$ 0.1
Interest cost	1.7	2.0	1.9	0.4
Amortization of prior service credit	(2.0)	(2.1)	(4.0)	(0.5)
Gain on plan settlements	(0.9)	—	—	—
Net periodic benefit credit	$ (1.2)	$ —	$ (2.0)	$ —

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 each period:

	Pension Benefits			Postretirement Benefits		
	December 29, 2017	December 30, 2016	September 30, 2016	December 29, 2017	December 30, 2016	September 30, 2016
Change in benefit obligations:						
Projected benefit obligations at beginning of year	$ 257.4	$ 409.1	$ 375.5	$ 47.5	$ 50.8	$ 52.2
Service cost	1.4	0.8	1.8	—	0.1	0.1
Interest cost	2.3	2.0	13.2	1.7	0.4	2.0
Actuarial (gain) loss	(9.0)	(23.2)	65.5	0.2	(2.8)	0.5
Benefits and administrative expenses paid	(9.4)	(5.3)	(20.1)	(2.9)	(1.0)	(4.0)
Plan settlements	(217.0)	(125.9)	(26.5)	(0.9)	—	—
Plan curtailments and amendments	—	—	(0.4)	—	—	—
Net transfer in	—	1.1	—	—	—	—
Currency translation	2.1	(1.2)	0.1	—	—	—
Projected benefit obligations at end of year	$ 27.8	$ 257.4	$ 409.1	$ 45.6	$ 47.5	$ 50.8
Change in plan assets:						
Fair value of plan assets at beginning of year	$ 161.0	$ 309.5	$ 309.9	$ —	$ —	$ —
Actual return on plan assets	0.3	(18.1)	29.5	—	—	—
Employer contributions	68.0	0.8	16.7	2.9	1.0	4.0
Benefits and administrative expenses paid	(9.4)	(5.3)	(20.1)	(2.9)	(1.0)	(4.0)
Plan settlements	(217.0)	(125.9)	(26.5)	—	—	—
Net transfer out	(2.9)	—	—	—	—	—
Fair value of plan assets at end of year	$ —	$ 161.0	$ 309.5	$ —	$ —	$ —
Funded status at end of year	$ (27.8)	$ (96.4)	$ (99.6)	$ (45.6)	$ (47.5)	$ (50.8)

	Pension Benefits		Postretirement Benefits	
	December 29, 2017	December 30, 2016	December 29, 2017	December 30, 2016
Amounts recognized on the consolidated balance sheet:				
Non-current assets	$ —	$ 1.4	$ —	$ —
Current liabilities	(2.4)	(5.5)	(3.9)	(4.2)
Non-current liabilities	(25.4)	(92.3)	(41.7)	(43.3)
Net amount recognized on the consolidated balance sheet	$ (27.8)	$ (96.4)	$ (45.6)	$ (47.5)
Amounts recognized in accumulated other comprehensive income consist of:				
Net actuarial loss	$ (8.6)	$ (89.7)	$ (3.0)	$ (2.8)
Prior service (cost) credit	(0.5)	0.4	10.2	12.3
Net amount recognized in accumulated other comprehensive income	$ (9.1)	$ (89.3)	$ 7.2	$ 9.5

The estimated amounts that will be amortized from accumulated other comprehensive income into net periodic benefit cost (credit) in fiscal 2018 are as follows:

	Pension Benefits	Postretirement Benefits
Amortization of net actuarial loss	$ (0.5)	$ (0.1)
Amortization of prior service (cost) credit	(0.1)	2.1

Additional information related to pension plans is as follows:

	December 29, 2017	December 30, 2016
Pension plans with accumulated benefit obligations in excess of plan assets:		
Accumulated benefit obligation	$ 27.3	$ 251.2
Fair value of plan assets	—	153.8

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 all of the Company's pension plans are frozen.

Actuarial Assumptions

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

	U.S. Plans				Non-U.S. Plans			
	Fiscal Year Ended			Three Months Ended	Fiscal Year Ended			Three Months Ended
	2017	2016	2015	December 30, 2016	2017	2016	2015	December 30, 2016
Discount rate	3.0%	3.9%	3.8%	2.2%	1.8%	2.0%	2.4%	1.3%
Expected return on plan assets	3.5%	5.8%	6.0%	3.5%	—%	2.0%	2.0%	—%
Rate of compensation increase	—%	—%	—%	—%	2.5%	—%	—%	—%

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

	U.S. Plans				Non-U.S. Plans			
	Fiscal Year Ended			Three Months Ended	Fiscal Year Ended			Three Months Ended
	2017	2016	2015	December 30, 2016	2017	2016	2015	December 30, 2016
Discount rate	3.3%	2.3%	3.9%	3.0%	1.9%	1.3%	2.4%	1.8%
Rate of compensation increase	—%	—%	—%	—%	2.5%	—%	—%	0.3%

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. For the Company's U.S. plans that were funded in prior periods, the discount rate was 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.

Prior to the settlement of the funded U.S. plans in fiscal 2017, the Company determined the expected return on pension plan assets, through its considerations of 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 was to obtain a long-term return on plan assets that was consistent with the level of investment risk that was considered appropriate. Investment risks and returns were reviewed regularly against benchmarks to ensure objectives were 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:

	Fiscal Year			Three Months Ended
	2017	2016	2015	December 30, 2016
Net periodic benefit cost	3.7%	4.0%	3.6%	3.2%
Benefit obligations	3.4%	3.2%	3.9%	3.8%

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

	December 29, 2017	December 30, 2016
Healthcare cost trend rate assumed for next fiscal year	6.9%	6.9%
Rate to which the cost trend rate is assumed to decline	4.5%	4.5%
Fiscal year the ultimate trend rate is achieved	2038	2038

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

	One-Percentage-Point Increase	One-Percentage-Point Decrease
Effect on total of service and interest cost	$ —	$ —
Effect on postretirement benefit obligation	0.2	(0.4)

Plan Assets

As of December 29, 2017, the Company had no pension plan assets as a result of the termination and settlement of the Company's funded U.S. plans in fiscal 2017. Prior to, and in anticipation of, the settlement of these defined benefit pension plans, the asset allocation at December 30, 2016 was concentrated in debt securities, in an attempt to mitigate fluctuations in both interest rates and the equity markets.

The following table provides a summary of plan assets held by the Company's pension plans and the respective weighted-average asset allocations as of December 30, 2016:

	December 30, 2016 [1]	Weighted-Average Asset Allocation
Equity Securities:		
U.S. large cap	$ 1.7	1%
Debt securities:		
Diversified fixed income funds [2]	148.3	92
Cash and cash equivalents	11.0	7
Total	$ 161.0	100%

(1) All plan assets were measured at fair value on a recurring basis and were categorized as Level 1 with quoted prices in active markets for identical assets.
(2) 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 consisted of mutual funds with underlying investments in foreign equity and domestic equity markets. The fair value of these investments were 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).

Debt securities. Debt securities were 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 were based on the net asset value of the units held in the respective fund which were determined by obtaining quoted prices on nationally recognized securities exchanges.

Cash and cash equivalents. Cash and cash equivalents were invested in a money market mutual fund, the fair value of which was determined by obtaining quoted prices on nationally recognized securities exchanges (level 1).

Mallinckrodt shares were not a direct investment of the Company's pension funds; however, the pension funds might have indirectly included Mallinckrodt shares. The aggregate amount of the Mallinckrodt shares were 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 2017, 2016 and the three months ended December 30, 2016, the Company made $68.0 million, $16.7 million and $0.8 million in contributions, respectively, to the Company's pension plans. The fiscal 2017 contribution included additional payments to settle the terminated plans.

Expected Future Benefit Payments

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

	Pension Benefits	Postretirement Benefits
Fiscal 2018	$ 2.4	$ 3.9
Fiscal 2019	1.8	3.7
Fiscal 2020	1.8	3.5
Fiscal 2021	1.7	3.3
Fiscal 2022	1.6	3.2
Fiscal 2023 - 2027	7.5	14.2

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 $25.2 million, $25.3 million, $22.1 million and $4.2 million for fiscal 2017, 2016, 2015 and the three months ended December 30, 2016, 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 20 provides additional information regarding the debt and equity securities. The carrying value of the 124 life insurance contracts held by these trusts was $58.1 million and $59.9 million at December 29, 2017 and December 30, 2016, respectively. These contracts had a total death benefit of $145.8 million and $150.7 million at December 29, 2017 and December 30, 2016, respectively. However, there are outstanding loans against the policies amounting to $44.5 million and $44.0 million at December 29, 2017 and December 30, 2016, respectively.

The Company has insurance contracts which serve as collateral for certain of the Company's non-U.S. pension plan benefits, which totaled $8.8 million and $7.7 million at December 29, 2017 and December 30, 2016, respectively. These amounts were also included in other assets on the consolidated balance sheets.

15. 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 December 29, 2017. 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 January 23, 2015, the Company's Board of Directors authorized a $300.0 million share repurchase program (the "January 2015 Program"), which was completed during fiscal 2016. On November 19, 2015, the Company's Board of Directors authorized a $500.0 million share repurchase program (the "November 2015 Program"), which was completed in the three months ended December 30, 2016. On March 16, 2016, the Company's Board of Directors authorized an additional $350.0 million share repurchase program (the "March 2016 Program"), which was completed during fiscal 2017. On March 1, 2017, the Company's Board of Directors authorized an additional $1.0 billion share repurchase program (the "March 2017 Program"), which commenced upon the completion of the March 2016 Program. The March 2017 Program has no time limit or expiration date, and the Company currently expects to fully utilize the program.

	March 2017 Repurchase 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	Number of Shares	Amount
Authorized repurchase amount		$ 1,000.0		$ 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
Three months ended December 30, 2016	—	—	1,501,676	84.0	1,063,337	74.4	—	—
Fiscal 2017	13,490,448	380.6	5,366,741	266.0	—	—	—	—
Remaining amount available		$ 619.4		$ —		$ —		$ —

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 $5.1 million, $2.3 million, $17.2 million and $0.4 million to acquire shares in connection with equity-based awards in fiscal 2017, 2016, 2015 and the three months ended December 30, 2016, respectively.

Treasury Shares

During December 2017, the Company canceled approximately 26.5 million treasury shares. Irish law requires a company's treasury share value to represent less than 10% of Company capital. The cancellation of treasury shares had a net zero impact on shareholders' equity as $5.3 million was reflected in both common stock and additional paid in capital.

16. Share Plans

Total share-based compensation cost from continuing operations was $58.5 million, $41.4 million, $115.0 million and $10.6 million for fiscal 2017, 2016, 2015 and the three months ended December 30, 2016, respectively. These amounts are generally included within SG&A 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 SG&A expenses and $9.8 million is included within restructuring charges, net. The Company recognized a related tax benefit associated with this expense of $11.0 million, $13.1 million, $41.3 million and $3.6 million in fiscal 2017, 2016, 2015 and the three months ended December 30, 2016, respectively. During fiscal 2017, the $11.0 million tax benefit was comprised of $16.0 million associated with amortization and net stock exercises, partially offset by $5.0 million associated with U.S. Tax Reform re-measurement.

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 December 29, 2017, 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		
Granted	3,742	60.01		
Exercised	(16,382)	36.42		
Expired/Forfeited	(22,522)	70.82		
Outstanding at December 30, 2016	3,386,694	61.24		
Granted	1,719,532	51.57		
Exercised	(113,605)	47.74		
Expired/Forfeited	(348,637)	68.08		
Outstanding at December 29, 2017	4,643,984	57.78	6.9	$ 0.2
Vested and non-vested expected to vest as of December 29, 2017	3,882,733	60.62	7.5	$ (0.6)
Exercisable at December 29, 2017	1,944,709	52.19	4.7	0.2

As of December 29, 2017, there was $37.7 million of total unrecognized compensation cost related to non-vested share option awards, which is expected to be recognized over a weighted-average period of 2.5 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 2017, 2016, 2015 and the three months ended December 30, 2016, along with the weighted-average grant-date fair value, were as follows:

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Expected share price volatility	36%	31%	29%	35%
Risk-free interest rate	2.00%	1.74%	1.72%	1.23%
Expected annual dividend per share	—%	—%	—%	—%
Expected life of options (in years)	5.3	5.3	5.3	5.3
Fair value per option	$ 18.36	$ 22.82	$ 30.08	$ 20.04

In fiscal 2017, 2016, 2015 and the three months ended December 30, 2016, the total intrinsic value of options exercised was $1.4 million, $15.3 million, $89.5 million and $0.3 million, respectively, and the related tax benefit was $0.5 million, $5.7 million, $33.1 million and $0.1 million, respectively.

Restricted share units. Recipients of restricted share units ("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
Expired/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
Expired/Forfeited	(99,260)	79.95
Non-vested at September 30, 2016	894,459	70.40
Granted	36,731	69.08
Exercised	(30,919)	47.54
Expired/Forfeited	(16,809)	49.62
Non-vested at December 30, 2016	883,462	71.03
Granted	655,282	50.74
Exercised	(263,189)	69.14
Expired/Forfeited	(169,789)	68.57
Non-vested at December 29, 2017	1,105,766	60.08

The total fair value of Mallinckrodt RSU awards granted during fiscal 2017 was $50.7 million. The total vest date fair value of Mallinckrodt RSUs vested during fiscal 2017 was $69.1 million. As of December 29, 2017, there was $42.0 million of total unrecognized compensation cost related to non-vested restricted share units granted. The cost is expected to be recognized over a weighted-average period of 2.4 years.

Performance share units. Similar to recipients of RSUs, recipients of performance share units ("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 [1]:

	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
Forfeited	(997)	154.42
Non-vested at December 30, 2016	265,648	88.51
Granted	348,963	51.73
Forfeited	(48,606)	107.00
Vested	(61,554)	62.65
Non-vested at December 29, 2017	504,451	64.44

(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:

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Expected stock price volatility	48%	41%	27%	48%
Peer group stock price volatility	40%	36%	32%	40%
Correlation of returns	17%	24%	14%	17%

The weighted-average grant-date fair value per share of PSUs granted was $51.73 in fiscal 2017. As of December 29, 2017, there was $18.5 million of unrecognized compensation cost related to PSUs, which is expected to be recognized over a weighted-average period of 1.8 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. The weighted average grant-date fair value per share is $70.88.

	Shares
Non-vested at September 26, 2014	1,432,031
Vested	(1,362,823)
Forfeited	(34,646)
Non-vested at September 25, 2015	34,562
Vested	(9,760)
Forfeited	(7,936)
Non-vested at September 30, 2016	16,866
Vested	(1,087)
Forfeited	(911)
Non-vested at December 30, 2016	14,868
Vested	(7,970)
Forfeited	(2,223)
Non-vested at December 29, 2017	4,675

The total vest date fair value of Mallinckrodt restricted share awards vested during fiscal 2017 was $0.4 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 the Internal Revenue Code 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 2015) of the employee's payroll deduction up to a $25,000 per employee annual contribution. All shares purchased under the Old ESPP were purchased on the open market by a designated broker.

17. 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	Unrecognized Gain on Equity Securities	Accumulated Other Comprehensive Income
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	1.6	(5.9)	(81.3)	—	(85.6)
Other comprehensive income (loss), net	(21.1)	—	5.3	—	(15.8)
Reclassification from other comprehensive income (loss)	—	0.2	28.7	—	28.9
Balance at December 30, 2016	(19.5)	(5.7)	(47.3)	—	(72.5)
Other comprehensive income (loss), net	16.0	—	5.2	1.5	22.7
Reclassification from other comprehensive income (loss)	(4.7)	1.0	40.6	—	36.9
Balance at December 29, 2017	$ (8.2)	$ (4.7)	$ (1.5)	$ 1.5	$ (12.9)

The following summarizes reclassifications from accumulated other comprehensive income:

	Amount Reclassified From Accumulated Other Comprehensive Income			
	December 29, 2017	September 30, 2016	December 30, 2016	Line Item in the Consolidated Statement of Income
Amortization of unrealized loss on derivatives	$ 1.3	$ 0.7	$ 0.2	Interest expense
Income tax provision	(0.3)	(0.2)	—	Provision for income taxes
Net of income taxes	1.0	0.5	0.2	
Amortization of pension and post-retirement benefit plans:				
Net actuarial loss	2.7	11.4	1.0	(1)
Prior service credit	(1.9)	(2.7)	(0.6)	(1)
Disposal of discontinued operations	(3.1)	0.8	—	
Plan settlements	70.2	8.1	45.0	(1)
Total before tax	67.9	17.6	45.4	
Income tax provision	(27.3)	(6.5)	(16.7)	Provision for income taxes
Net of income taxes	40.6	11.1	28.7	
Currency translation	(4.7)	(59.4)	—	
Total reclassifications for the period	$ 36.9	$ (47.8)	$ 28.9	

(1) These accumulated other comprehensive income components are included in the computation of net periodic benefit cost. See Note 14 for additional details.

18. 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 December 29, 2017 and December 30, 2016 was $14.9 million and $15.1 million, of which $12.1 million and $12.4 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 December 29, 2017 and December 30, 2016. As of December 29, 2017, the maximum future payments the Company could be required to make under these indemnification obligations was $70.2 million. The Company was required to pay $30.0 million into an escrow account as collateral to the purchaser, of which $18.3 million and $19.0 million remained in other assets on the consolidated balance sheets at December 29, 2017 and December 30, 2016, respectively.

The Company has recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 19. 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 was 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. Following the sale of the Nuclear Imaging business, the surety bond was canceled in April 2017 and the Company is no longer required to provide

financial assurance to the U.S. Nuclear Regulatory Commission for that facility. As of December 29, 2017, the Company had various other letters of credit and guarantee and surety bonds totaling $28.7 million.

In addition, the separation and distribution agreement entered into with Covidien 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.

19. Commitments and Contingencies

The Company has purchase obligations related to commitments to purchase certain goods and services. At December 29, 2017, such obligations were as follows:

Fiscal 2018	$ 122.6
Fiscal 2019	72.3
Fiscal 2020	60.9
Fiscal 2021	16.1
Fiscal 2022	15.4

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

Opioid Related Matters

Multidistrict Litigation. The Company has been named in lawsuits court brought by various counties, cities, Native American tribes, hospitals, third-party payers and others against opioid manufacturers and, often, distributors. In general, the lawsuits assert claims of public nuisance, negligence, civil conspiracy, fraud, violations of the Racketeer Influenced and Corrupt Organizations Act or similar state laws, consumer fraud, deceptive trade practices, insurance fraud, unjust enrichment and other common law claims arising from defendants' manufacturing, distribution, marketing and promotion of opioids and seek restitution, damages, injunctive and other relief and attorneys' fees and costs. These lawsuits were originally filed against, or amended to include, the Company in various U.S. District Courts or in state courts with the state court lawsuits subsequently removed to U.S. District Court. On December 5, 2017 the Judicial Panel in Multidistrict Litigation ("JPML") issued its order establishing a Multidistrict Litigation ("MDL") in the Northern District of Ohio for opioid litigation cases and transferring those cases to the MDL that are originally filed in U.S. District Courts or removed to U.S. District Courts from state court. There are currently approximately 262 lawsuits naming the Company that are either in the MDL or are expected to be transferred to the MDL. The Company intends to vigorously defend itself in these matters.

State Court Lawsuits. On December 20, 2017, the State of New Mexico, through its Attorney General, amended its lawsuit pending in the First Judicial District Court in the County of Santa Fe against certain opioid distributors and manufacturers, to add the Company. The lawsuit asserts violations of public nuisance laws and the New Mexico Unfair Practices, Medicaid Fraud and Racketeering Acts and seeks relief similar to that sought in other state and federal actions.

In addition, the Company is currently named in 18 lawsuits pending in state courts in California (6), Florida (1), Louisiana (1), Maryland (1), New Jersey (1), Ohio (1), Pennsylvania (1), Tennessee (3) and West Virginia (3). These state lawsuits are brought on behalf of towns, counties, Medicaid managed care organizations, Native American tribes and an addiction recovery corporation. The lawsuits assert claims and seek damages similar to those sought in the cases pending before the MDL. The Company intends to vigorously defend itself in these state court matters.

Investigations. The Company has also received various subpoenas and requests for information related to the distribution, marketing and sale of the Company's opioid products. On July 26, 2017, the Company received a subpoena from the Department of Justice ("DOJ"), on August 24, 2017, the Company received a Civil Investigative Demand ("CID") from the Missouri Attorney General's Office, on September 22, 2017, the Company received a subpoena from the New Hampshire Attorney General's Office, on January 9, 2018, the Company received a subpoena and CID from the Kentucky Attorney General's Office, on January 16, 2018, the Company received a CID from the Attorney General's Office for the State of Washington and on February 5, 2018, the Company

received a subpoena from the Attorney General's Office from the State of Alaska. In addition, on January 27, 2018 the Company received a grand jury subpoena from the U.S. Attorneys' Office ("USAO") for the Southern District of Florida for documents related to the Company's distribution, marketing and sale of its oxymorphone generic products. The Company is in the process of responding to these subpoenas and CIDs.

The Company has been contacted by the coalition of State Attorneys General investigating the role manufacturers and distributors may have had in contributing to the increased use of opioids in the U.S. The Company intends to cooperate fully in these investigations.

Since these lawsuits and investigations are in early stages, the Company is unable to predict its outcome or estimate a range of reasonably possible losses.

Other Matters

SEC Subpoena. In January 2017, the Company received a subpoena from the SEC for documents related to the Company's public statements, filings and other disclosures regarding H.P. Acthar Gel sales, profits, revenue, promotion and pricing. The Company has responded to this subpoena, and in February 2018, the SEC notified the Company that it had concluded its investigation and that no enforcement action was recommended against the Company.

Boston Subpoena. In December 2016, the Company received a subpoena from the USAO for the District of Massachusetts for documents related to the Company's provision of financial and other support to patients, including through charitable foundations, and related matters. The Company is in the process of responding to this subpoena, and the Company intends to cooperate fully in the investigation.

Texas Pricing Investigation. 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. The Company has responded to these requests.

Mallinckrodt Inc. v. U.S. Food and Drug Administration and United States of America. In November 2014, the Company filed a Complaint ("the Complaint") in the U.S. District Court for the District of Maryland Greenbelt Division against the FDA and the United States 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. The Company also sought a temporary restraining order ("TRO") directing the FDA to reinstate the Orange Book AB rating for the Company's Methylphenidate ER products. The court denied the Company's motion for a TRO and 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 the Company's Abbreviated New Drug Application ("ANDA") for Methylphenidate ER. On October 21, 2016, the United States Court of Appeals for the Fourth Circuit issued an order 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 an extension of the deadline for submitting documentation supporting the necessity of a hearing. The FDA granted the Company's initial request to extend the deadline, and on February 21, 2017, the FDA suspended the deadline in order to give the Center for Drug Evaluation and Research ("CDER") an opportunity to complete its production of documents. CDER shared an initial set of documents with the Company in June 2017 and a second set of documents in October 2017. Following the Company's receipt of the October tranche of documents from CDER, the Company presented a supplemental document request to CDER to ensure all of its initial document requests were fulfilled, and on February 13, 2018, CDER provided a final set of documents in response to the Company's requests. The Company is preparing the legal arguments in support of its position in the withdrawal proceedings, which it will be filing in early third quarter of fiscal 2018. A potential outcome of the withdrawal proceedings is that the Company's Methylphenidate ER products may lose their FDA approval, which could have a material, negative impact to the Company's Specialty Generics segment.

FTC Investigation. In June 2014, Questcor received a subpoena and 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 MNK-1411 (the product formerly described as Synacthen Depot®) from Novartis AG and Novartis Pharma AG (collectively, "Novartis") violates antitrust laws. Subsequently, California, Maryland, Texas, Washington, New York and Alaska (collectively, "the Investigating States") commenced similar investigations focused on whether the transaction violates state antitrust laws. On January 17, 2017, the FTC, all Investigating States (except California) ("the Settling States") and the Company entered into an agreement to resolve this matter for a one-time cash payment of $102.0 million and an agreement to license MNK-1411 to a third party designated by the FTC for possible development in Infantile Spasms ("IS") and Nephrotic Syndrome ("NS") in the U.S. To facilitate that settlement, a complaint was filed on January 18, 2017, in the U.S. District Court for the District of Columbia. The settlement was approved by the court on January 30, 2017. On July 16, 2017, the Company announced the completion of the U.S. license of both the Synacthen trademark and certain intellectual property associated with

MNK-1411 to West Pharmaceuticals to develop and pursue possible FDA approval of the product in IS and NS. The Company retains the right to develop MNK-1411 for all other indications in the U.S. and retains rights to the Synacthen trademark outside the U.S.

Therakos Investigation. 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' 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. The Company is in the process of responding to these requests.

DEA Investigation. In November 2011 and October 2012, the Company received subpoenas from the U.S. Drug Enforcement Administration ("DEA") requesting production of documents relating to its suspicious order monitoring program for controlled substances. The USAO for the Eastern District of Michigan investigated 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. DEA investigated 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. In July 2017, the Company entered into a final settlement with the DEA and the USAOs for Eastern District of Michigan and the Northern District of New York to settle these investigations. As part of the agreement, the Company paid $35.0 million to resolve all potential claims.

Questcor DOJ Investigation. 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 H.P. Acthar Gel. 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 were participating in the investigation to review Questcor's promotional practices and related matters related to H.P. Acthar Gel. 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 H.P. Acthar Gel. The Company intends to cooperate fully in the investigation.

Patent Litigation

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 Inter Partes Review ("IPR") and Praxair litigation proceedings to prevent the marketing of infringing generic products prior to the expiration of the patents covering Inomax. Trial of the suit filed in February 2015 was held in March 2017 and a decision was rendered September 5, 2017 that ruled five patents invalid and six patents not infringed. The Company has appealed the decision to the Court of Appeals for the Federal Circuit. An adverse outcome in the appeal of the Praxair litigation decision 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.

Inomax Patents: IPR Proceedings. In February 2015 and March 2015, the U.S. Patent and Trademark Office ("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. Oral argument of that appeal occurred on January 9, 2017. 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.

Ofirmev Patent Litigation: Aurobindo Pharma U.S.A., Inc. In December 2017, Mallinckrodt Hospital Products Inc. and Mallinckrodt IP Unlimited Company, subsidiaries of the Company, and New Pharmatop LP, the current 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 Aurobindo Pharma U.S.A., Inc. (“Aurobindo”) alleging that Aurobindo infringed U.S. Patent No. 6,992,218 ("the ‘218 patent"), U.S. Patent No. 9,399,012 ("the ‘012 patent") and U.S. Patent No. 9,610,265 ("the ‘265 patent") following receipt of a November 2017 notice from Aurobindo concerning its submission of an ANDA, containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev.

Ofirmev Patent Litigation: B. Braun Medical Inc. In April 2017, Mallinckrodt Hospital Products Inc. and Mallinckrodt IP, subsidiaries of the Company, and Pharmatop, the then 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 B. Braun Medical Inc. ("B. Braun") alleging that B. Braun infringed the ‘218 patent and the ‘012 patent following receipt of a February 2017 notice from B. Braun concerning its submission of a New Drug Application ("NDA"), containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev. Following receipt of a second Paragraph IV notice letter from B. Braun on April 24, 2017 directed to the ‘012 patent, Mallinckrodt Hospital Products Inc. and Mallinckrodt IP filed suit in June 2017 in the U.S. District Court for the District of Delaware against B. Braun alleging that B. Braun infringed the ‘012 patent and the ‘265 patent. In both instances, a protective suit was filed in the U.S. District Court for the Eastern District of Pennsylvania to protect the 30-month stay against any venue challenge in Delaware. In July 2017, B. Braun filed motions to dismiss both actions in Delaware due to improper venue based on the recent U.S. Supreme Court *TC Heartland* decision on venue in patent cases, and also filed a separate motion to dismiss in the original action in Pennsylvania. Following receipt of a third Paragraph IV notice letter from B. Braun on July 13, 2017 that included a certification to the ‘265 patent, amended complaints were filed in July 2017 in the U.S. District Courts for the Districts of Delaware and Eastern District of Pennsylvania by Mallinckrodt Hospital Products Inc., Mallinckrodt IP and Pharmatop. Also in July 2017, Mallinckrodt Hospital Products Inc., Mallinckrodt IP and Pharmatop filed a motion to stay the action in the Eastern District of Pennsylvania. A hearing occurred August 24, 2017 in the U.S. District Court for the District of Delaware regarding B. Braun’s motion to dismiss the Delaware actions for improper venue. The judge in the Delaware District Court denied B. Braun’s motion to dismiss the amended complaint without prejudice and ordered venue-related discovery on December 14, 2017. Subsequently, B. Braun withdrew the challenge to venue in Delaware but proceeded to file new motions to dismiss the Delaware actions on January 5, 2018. A scheduling conference occurred October 4, 2017 in the U.S. District Court for the Eastern District of Pennsylvania and no decisions were rendered on any of the pending motions. The actions in the U.S. District Court for the Eastern District of Pennsylvania were dismissed by stipulation on December 28, 2017.

Ofirmev Patent Litigation: InnoPharma Licensing LLC and InnoPharma, Inc. In September 2014, Cadence and Mallinckrodt IP, subsidiaries of the Company, and Pharmatop, the then 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. (both are subsidiaries of Pfizer and 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 NDA, containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev. Separately, on December 1, 2016 Mallinckrodt IP Filed suit in the U.S. District Court for the District of Delaware against InnoPharma alleging that InnoPharma infringed the '012 patent. On May 4, 2017 the parties entered into settlement agreements on both suits under which InnoPharma was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its NDA on or after December 6, 2020, or earlier under certain circumstances.

Ofirmev Patent Litigation: Agila Specialties Private Limited, Inc. (now Mylan Laboratories Ltd.) and Agila Specialties Inc. (a Mylan Inc. Company), (collectively “Agila”). In December 2014, Cadence and Mallinckrodt IP, subsidiaries of the Company, and Pharmatop, the then 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. Separately, on December 1, 2016 Mallinckrodt IP filed suit in the U.S. District Court for the District of Delaware against Agila alleging that Agila infringed the '012 patent. On December 31, 2016, the parties entered into settlement agreements on both suits under which Agila was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its NDA on or after December 6, 2020, or earlier under certain circumstances.

The Company has successfully asserted the ‘222 and ‘218 patents and maintained their validity in both litigation and proceedings at the 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.

Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland v. Mallinckrodt PLC, Mallinckrodt Inc. and Mallinckrodt LLC. In January 2018, Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland ("Jazz") filed suit in the U.S. District Court for the District of New Jersey against the Company alleging that the Company infringed United States Patent Nos. 7,668,730 (the "'730 patent"), 7,765,106 (the "'106 patent"), 7,765,107 (the "'107 patent"), 7,895,059 (the "'059 patent"), 8,457,988 (the "'988 patent"), 8,589,182 (the "'182 patent"), 8,731,963 (the "'963 patent"), 8,772,306 (the "'306 patent"), 9,050,302 (the "'302 patent"), and 9,486,426 (the "'426 patent") following receipt of a November 2017 notice from the Company concerning its submission of an ANDA, containing a Paragraph IV patent certification with the FDA for a competing version of Xyrem.

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 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. In March 2017, the parties entered into a settlement agreement and the case was dismissed.

Commercial and Securities Litigation

Putative Class Action Litigation (MSP). On October 30, 2017, a putative class action lawsuit was filed against the Company and United BioSource Corporation ("UBC") in the U.S. District Court for the Central District of California. The case is captioned *MSP Recovery Claims, Series II LLC, et al. v. Mallinckrodt ARD, Inc., et al.* The complaint purports to be brought on behalf of two classes: all Medicare Advantage Organizations and related entities in the U.S. who purchased or provided reimbursement for H.P. Acthar Gel pursuant to (i) Medicare Part C contracts (Class 1) and (ii) Medicare Part D contracts (Class 2) since January 1, 2011, with certain exclusions. The complaint alleges that the Company engaged in anticompetitive, unfair, and deceptive acts to artificially raise and maintain the price of H.P. Acthar Gel. To this end, the complaint alleges that the Company unlawfully maintained a monopoly in a purported ACTH product market by acquiring the U.S. rights to Synacthen Depot and reaching anti-competitive agreements with the other defendants by selling H.P. Acthar Gel through an exclusive distribution network. The complaint purports to allege claims under federal and state antitrust laws and state unfair competition and unfair trade practice laws. Pursuant to a motion filed by defendants, this case has been transferred to the U.S. District Court for the Northern District of Illinois. The Company intends to vigorously defend itself in this matter.

Putative Class Action Litigation. On April 6, 2017, a putative class action lawsuit was filed against the Company and UBC in the U.S. District Court for the Northern District of Illinois. The case is captioned *City of Rockford v. Mallinckrodt ARD, Inc., et al.* The complaint was subsequently amended, most recently on December 8, 2017, to include an additional named plaintiff and additional defendants. As amended, the complaint purports to be brought on behalf of all self-funded entities in the U.S. and its Territories, excluding any Medicare Advantage Organizations, related entities and certain others, that paid for H.P. Acthar Gel from August 2007 to the present. The lawsuit alleges that the Company engaged in anticompetitive, unfair, and deceptive acts to artificially raise and maintain the price of H.P. Acthar Gel. To this end, the suit alleges that the Company unlawfully maintained a monopoly in a purported ACTH product market by acquiring the U.S. rights to Synacthen Depot; conspired with UBC and violated anti-racketeering laws by selling H.P. Acthar Gel through an exclusive distributor; and committed a fraud on consumers by failing to correctly identify H.P. Acthar Gel's active ingredient on package inserts. The Company intends to vigorously defend itself in this matter.

Employee Stock Purchase Plan Securities Litigation. On July 20, 2017, a purported purchaser of Mallinckrodt stock through Mallinckrodt's Employee Stock Purchase Plans ("ESPPs"), filed a derivative lawsuit in the Federal District Court in the Eastern District of Missouri, captioned *Solomon v. Mallinckrodt plc, et al.*, against the Company, its Chief Executive Officer Mark C. Trudeau ("CEO"), its Chief Financial Officer Matthew K. Harbaugh ("CFO"), its Controller Kathleen A. Schaefer, and current and former directors of the Company. On September 6, 2017, plaintiff voluntarily dismissed its complaint in the Federal District Court for the Eastern District of Missouri and refiled virtually the same complaint in the U.S. District Court for the District of Columbia. The complaint purports to be brought on behalf of all persons who purchased or otherwise acquired Mallinckrodt stock between November 25, 2014, and January 18, 2017, in the ESPPs. In the alternative, the plaintiff alleges a class action for those same purchasers/acquirers of stock in the ESPPs during the same period. The complaint asserts claims under Section 11 of the Securities Act, and for breach of fiduciary duty, misrepresentation, non-disclosure, mismanagement of the ESPPs' assets and breach of contract arising from substantially similar allegations as those contained in the putative class action securities litigation described in the following paragraph. The Company intends to vigorously defend itself in this matter.

Putative Class Action Securities Litigation. On January 23, 2017, a putative class action lawsuit was filed against the Company and its CEO in the U.S. District Court for the District of Columbia, captioned *Patricia A. Shenk v. Mallinckrodt plc, et al*. The complaint purports to be brought on behalf of all persons who purchased Mallinckrodt's publicly traded securities on a domestic exchange between November 25, 2014 and January 18, 2017. The lawsuit generally alleges that the Company made false or misleading statements related to H.P. Acthar Gel and Synacthen to artificially inflate the price of the Company's stock. In particular, the complaint alleges a failure by the Company to provide accurate disclosures concerning the long-term sustainability of H.P. Acthar Gel revenues, and the exposure of H.P. Acthar Gel to Medicare and Medicaid reimbursement rates. On January 26, 2017, a second putative class action lawsuit, captioned *Jyotindra Patel v. Mallinckrodt plc, et al.* was filed against the same defendants named in the *Shenk* lawsuit in the U.S. District Court for the District of Columbia. The *Patel* complaint purports to be brought on behalf of shareholders during the same period of time as that set forth in the *Shenk* lawsuit and asserts claims similar to those set forth in the *Shenk* lawsuit. On March 13, 2017, a third putative class action lawsuit, captioned *Amy T. Schwartz, et al., v. Mallinckrodt plc, et al.,* was filed against the same defendants named in the *Shenk* lawsuit in the U.S. District Court for the District of Columbia. The *Schwartz* complaint purports to be brought on behalf of shareholders who purchased shares of the Company between July 14, 2014 and January 18, 2017 and asserts claims similar to those set forth in the *Shenk* lawsuit. On March 23, 2017, a fourth putative class action lawsuit, captioned *Fulton County Employees' Retirement System v. Mallinckrodt plc, et al.,* was filed against the Company and its CEO and CFO in the U.S. District Court for the District of Columbia. The *Fulton County* complaint purports to be brought on behalf of shareholders during the same period of time as that set forth in the *Schwartz* lawsuit and asserts claims similar to those set forth in the *Shenk* lawsuit. On March 27, 2017, four separate plaintiff groups moved to consolidate the pending cases and to be appointed as lead plaintiffs in the consolidated case. Since that time, two of the plaintiff groups have withdrawn their motions. The Company intends to vigorously defend itself in this matter.

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.

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 Securities Exchange Act of 1934 ("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.

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.

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. SACvl2-1623 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 l0(b) and/or 20(a) of the Exchange Act, as amended, by making allegedly false and/or misleading statements concerning the clinical evidence to support the use of H.P. Acthar Gel for indications other than infantile spasms, the promotion of the sale and use of H.P. Acthar Gel in the treatment of multiple sclerosis and nephrotic syndrome, reimbursement for H.P. Acthar Gel from third-party insurers, and Questcor's outlook and potential market growth for H.P. Acthar Gel. 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.

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 H.P. Acthar Gel. 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 H.P. Acthar Gel 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.

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 December 29, 2017, it was probable that it would incur remediation costs in the range of $37.6 million to $115.5 million. The Company also concluded that, as of December 29, 2017, the best estimate within this range was $75.4 million, of which $2.2 million was included in accrued and other current liabilities and the remainder was included in environmental liabilities on the consolidated balance sheet at December 29, 2017. 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 DOJ, 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 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 ("EE/CA") to characterize the nature and extent of the contamination. In January 2017, the EPA issued its Action memorandum regarding the EE/CA. The parties have negotiated a third AOC to implement the removal action. This third AOC replaces the first two AOCs, and became effective August 8, 2017. 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 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. 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.

By letter dated March 30, 2017, the EPA notified the Company, limited to its former Lodi facility, and nineteen other PRPs of their eligibility to enter into a cash out settlement for the lower 8 miles of the River. In exchange for the settlement, the Company would receive, *inter alia*, a covenant not to sue and contribution protection. There is no reopener provision should costs exceed estimated amounts. The Company submitted the executed settlement agreement to EPA on July 26, 2017. The settlement was announced in the Federal Register on January 12, 2018, opening a 30-day period for public comment, after which EPA will determine whether to proceed with the settlement.

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. 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 December 29, 2017, there were approximately 11,600 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 December 29, 2017, the Company exchanged title to $16.0 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.

Interest-Bearing Deferred Tax Obligation

As part of the integration of Questcor, the Company entered into an internal installment sale transaction related to certain H.P. Acthar Gel intangible assets during the three months ended December 26, 2014. Installment sale transactions result 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. 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. During the three months ended March 31, 2017, the Company sold its Intrathecal Therapy business with a portion of the consideration from the sale being in the form of a note receivable subject to the installment sale provisions described above. The interest-bearing deferred tax liabilities associated with installment notes decreased from $1,801.4 million at December 30, 2016 to $553.6 million at December 29, 2017 primarily attributable to decreases of $679.3 million related to the Reorganization, $351.8 million related to the TCJA, and $270.6 million

related to current year payments and tax attribute offsets, partially offset by an increase of $53.9 million related to the sale of the Intrathecal Therapy business.

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 $69.3 million, $73.8 million, $36.5 million and $15.9 million for fiscal 2017, 2016, 2015 and the three months ended December 30, 2016, respectively. Fiscal 2017 includes a one-time charge of $8.4 million resulting primarily from the Reorganization.

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 of $46.0 million and $30.3 million as of December 29, 2017 and December 30, 2016, respectively. 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 $30.4 million, $23.9 million, $22.2 million and $7.2 million for fiscal 2017, 2016, 2015 and the three months ended December 30, 2016, 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 December 29, 2017:

	Operating Leases	Capital Leases
Fiscal 2018	$ 23.1	$ 0.2
Fiscal 2019	19.2	—
Fiscal 2020	17.4	—
Fiscal 2021	15.8	—
Fiscal 2022	13.8	—
Thereafter	61.6	—
Total minimum lease payments	$ 150.9	$ 0.2

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.

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.

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.

20. 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:

	December 29, 2017	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Debt and equity securities held in rabbi trusts	$ 35.4	$ 24.0	$ 11.4	$ —
Equity securities	22.7	22.7	—	—
Foreign exchange forward and option contracts	0.1	0.1	—	—
	$ 58.2	$ 46.8	$ 11.4	$ —
Liabilities:				
Deferred compensation liabilities	$ 42.7	$ —	$ 42.7	$ —
Contingent consideration and acquired contingent liabilities	246.4	—	—	246.4
Foreign exchange forward and option contracts	0.1	0.1	—	—
	$ 289.2	$ 0.1	$ 42.7	$ 246.4

	December 30, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Debt and equity securities held in rabbi trusts	$ 33.6	$ 22.8	$ 10.8	$ —
Foreign exchange forward and option contracts	0.7	0.7	—	—
	$ 34.3	$ 23.5	$ 10.8	$ —
Liabilities:				
Deferred compensation liabilities	$ 32.5	$ —	$ 32.5	$ —
Contingent consideration and acquired contingent liabilities	250.5	—	—	250.5
Foreign exchange forward and option contracts	3.4	3.4	—	—
	$ 286.4	$ 3.4	$ 32.5	$ 250.5

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.

Equity securities. Equity securities consist of shares in Mesoblast Ltd., for which quoted prices are available in an active market; therefore, the investment is classified as level 1 and is valued based on quoted market prices reported on a nationally recognized securities exchange.

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 3 and 12 to the consolidated financial statements.

Contingent consideration and acquired contingent liabilities.

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 MNK-1411 (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 December 29, 2017 and December 30, 2016 were $111.8 million and $124.7 million, respectively.

Under the terms of the license agreement with Novartis, the Company made a $25.0 million payment in fiscal 2017, and is obligated to make annual payments of $25.0 million subsequent to fiscal 2017 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 December 29, 2017, the total remaining payments under the license agreement shall not exceed $140.0 million. The terms of the license agreement allow the Company to terminate the license agreement upon the occurrence of certain events following the fiscal 2020 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, the Company made a $5.0 million CAD payment. 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 December 29, 2017, 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 $7.0 million and $17.1 million, respectively, at December 29, 2017 compared to $58.9 million and $11.2 million, respectively, at December 30, 2016. As of December 29, 2017, the contingent consideration liability associated with Raplixa was reduced to zero, reflective of lower than previously anticipated commercial opportunities for the product, resulting in a $54.6 million fair value adjustment during fiscal 2017.

As part of the Stratatech Acquisition, the Company provided contingent consideration to the prior shareholders of Stratatech, 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 $53.5 million and $55.7 million at December 29, 2017 and December 30, 2016, respectively.

As part of the InfaCare Acquisition, the Company provided contingent consideration to the prior shareholders of InfaCare in the form of both regulatory approval milestones for full-term and pre-term neonates for stannsoporfin and sales-based milestones associated with stannsoporfin. The Company determined the fair value of the contingent consideration based on an option pricing model to be $35.0 million as of December 29, 2017.

As part of the Ocera Acquisition, the Company provided contingent consideration to the prior shareholders of Ocera in the form of both patient enrollment clinical study milestones for IV and Oral formulations of MNK-6105 and sales-based milestones associated with MNK-6105. The Company determined the fair value of the contingent consideration based on an option pricing model to be $22.0 million as of December 11, 2017.

Of the total fair value of the contingent consideration of $246.4 million, $64.0 million was classified as current and $182.4 million was classified as non-current in the consolidated balance sheets as of December 29, 2017. The following table summarizes the fiscal 2017 activity for contingent considerations:

Balance at December 30, 2016	$	250.5
Acquisition date fair value of contingent consideration		57.0
Payments		(25.0)
Accretion expense		5.3
Fair value adjustment		(41.4)
Balance at December 29, 2017	$	246.4

Financial Instruments Not Measured at Fair Value

The following methods and assumptions were used by the Company in estimating fair values for financial instruments not measured at fair value as of December 29, 2017 and December 30, 2016:

- 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 $18.3 million and $19.1 million as of December 29, 2017 and December 30, 2016, respectively (level 1), substantially all of which is included in other assets on the consolidated balance sheets.
- The Company received a portion of consideration for the sale of the Intrathecal business in the form of a note receivable. The fair value of the note receivable was equivalent to its carrying value of $154.0 million as of December 29, 2017 (level 1).
- The Company entered into short-term investment certificates during the three months ended December 30, 2016. These certificates are carried at cost, which approximates fair value, of zero and $11.1 million at December 29, 2017 and December 30, 2016, respectively (level 2). These certificates are included in prepaid expenses and other current 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 $67.0 million and $67.6 million at December 29, 2017 and December 30, 2016, 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, and is therefore classified as level 1. 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:

	December 29, 2017		December 30, 2016	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Level 1:				
Variable-rate receivable securitization due July 2017	$ —	$ —	$ 250.0	$ 250.0
3.50% notes due April 2018	300.0	299.1	300.0	298.7
4.875% notes due April 2020	700.0	675.2	700.0	699.5
Variable-rate receivable securitization due July 2020	200.0	200.0	—	—
5.75% notes due August 2022	884.0	804.8	884.0	850.3
4.75% notes due April 2023	526.5	412.4	600.0	520.9
5.625% notes due October 2023	738.0	628.8	738.0	682.4
5.50% notes due April 2025	692.1	564.5	695.0	615.7
Revolving credit facility	900.0	900.0	100.0	100.0
Level 2:				
Term loans due March 2021	—	—	1,948.5	1,953.2
9.50% debentures due May 2022	10.4	10.9	10.4	12.0
8.00% debentures due March 2023	4.4	4.4	4.4	4.9
Term loan due September 2024	1,851.2	1,848.7	—	—
Level 3:				
4.00% term loan due February 2022	—	—	6.5	6.5

Concentration of Credit and Other Risks

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of accounts receivable. The Company generally 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 Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
CuraScript, Inc.	40%	38%	35%	43%
McKesson Corporation	*	12%	20%	10%
AmerisourceBergen Corporation	*	*	10%	*
Cardinal Health, Inc.	*	*	11%	*

* Net sales to these distributors were less than 10% of total net sales during the respective periods presented above.

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:

	December 29, 2017	December 30, 2016
McKesson Corporation	26%	28%
AmerisourceBergen Corporation	15%	15%
CuraScript, Inc.	14%	15%
Cardinal Health, Inc.	11%	10%

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

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
H.P. Acthar Gel	37%	34%	35%	39%
Inomax	16%	14%	6%	14%

21. Segment and Geographical Data

Through December 29, 2017, the Company operated its business under two reportable segments, which are described below:

- *Specialty Brands* includes branded medicines; and
- *Specialty Generics* includes specialty generic drugs, API and external manufacturing.

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, but are not limited to, revenues and expenses associated with 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 following reconciliations presented below.

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 $15.3 billion and $15.2 billion at December 29, 2017 and December 30, 2016, respectively.

As a result of the sales of the CMDS and Nuclear Imaging businesses to Guerbet and IBAM, respectively, the financial results of these businesses are presented as discontinued operations. Therefore, prior year amounts have been recast to conform to current presentation.

Selected information by business segment is as follows:

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Net sales:				
Specialty Brands	$ 2,325.3	$ 2,300.6	$ 1,622.8	$ 603.1
Specialty Generics	839.5	1,025.2	1,251.6	212.9
Net sales of operating segments [1]	3,164.8	3,325.8	2,874.4	816.0
Other [2]	56.8	55.0	48.7	13.9
Net sales	$ 3,221.6	$ 3,380.8	$ 2,923.1	$ 829.9
Operating income:				
Specialty Brands	$ 1,155.2	$ 1,166.2	$ 637.6	$ 317.2
Specialty Generics	231.5	376.1	594.4	52.7
Segment operating income	1,386.7	1,542.3	1,232.0	369.9
Unallocated amounts:				
Corporate and allocated expenses [3]	(172.0)	(169.8)	(282.6)	(181.4)
Intangible asset amortization	(694.5)	(700.1)	(550.3)	(175.7)
Restructuring and related charges, net [4]	(36.4)	(38.2)	(45.3)	(5.3)
Non-restructuring impairments	(63.7)	(16.9)	—	(214.3)
Operating income	$ 420.1	$ 617.3	$ 353.8	$ (206.8)
Depreciation and amortization [5]:				
Specialty Brands	$ 708.2	$ 716.6	$ 559.5	$ 178.4
Specialty Generics	100.1	96.8	81.6	24.8
	$ 808.3	$ 813.4	$ 641.1	$ 203.2

(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 Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
H.P. Acthar Gel	$ 1,195.1	$ 1,160.4	$ 1,037.3	$ 325.4
Inomax	505.2	474.3	185.2	118.3
Ofirmev	302.5	284.3	263.0	72.5
Therakos	214.9	207.6	—	47.4
Hemostasis products	55.1	42.5	—	13.4
Other	52.5	131.5	137.3	26.1
Specialty Brands	2,325.3	2,300.6	1,622.8	603.1
Hydrocodone (API) and hydrocodone-containing tablets	85.3	146.5	167.2	23.2
Oxycodone (API) and oxycodone-containing tablets	78.8	126.2	154.6	24.3
Methylphenidate ER	71.7	103.5	136.5	22.0
Other controlled substances	409.6	468.1	572.2	104.9
Other	194.1	180.9	221.1	38.5
Specialty Generics	839.5	1,025.2	1,251.6	212.9
Other [1]	56.8	55.0	48.7	13.9
Net sales	$ 3,221.6	$ 3,380.8	$ 2,923.1	$ 829.9

(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 Ended			Three Months Ended
	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Net sales [1]:				
U.S.	$ 2,899.0	$ 3,095.4	$ 2,647.0	$ 763.7
Europe, Middle East and Africa	242.3	211.8	159.0	52.8
Other	80.3	73.6	117.1	13.4
	$ 3,221.6	$ 3,380.8	$ 2,923.1	$ 829.9

	Fiscal Year Ended	
Long-lived assets [2]:	December 29, 2017	December 30, 2016
U.S.	$ 788.5	$ 759.1
Europe, Middle East and Africa [3]	127.0	82.9
Other	63.5	51.5
	$ 979.0	$ 893.5

(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, net.

(3) Includes long-lived assets located in Ireland of $126.0 million and $80.9 million as of December 29, 2017 and December 30, 2016, respectively.

22. Selected Quarterly Financial Data (Unaudited)

A summary of quarterly financial information for fiscal 2017 and fiscal 2016 is as follows:

	For the Quarter Ended			
	March 31, 2017	June 30, 2017	September 29, 2017	December 29, 2017
Net sales	$ 810.9	$ 824.5	$ 793.9	$ 792.3
Gross profit	418.6	416.1	400.6	421.0
Income from continuing operations [2]	28.9	70.6	64.3	1,607.4
Income from discontinued operations	370.3	(7.8)	(0.6)	1.3
Net income	399.2	62.8	63.7	1,608.7
Basic earnings per share from continuing operations [1]	$ 0.28	$ 0.72	$ 0.66	$ 17.43
Diluted earnings per share from continuing operations [1]	0.28	0.72	0.66	17.40

	For the Quarter Ended			
	December 25, 2015	March 25, 2016	June 24, 2016	September 30, 2016
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 [1]	$ 0.90	$ 0.89	$ 1.63	$ 1.02
Diluted earnings per share from continuing operations [1]	0.89	0.88	1.62	1.01

(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.

(2) Income from continuing operations for the quarter ended December 29, 2017 reflects one-time effects for the completion of the Reorganization and the impact of U.S. Tax Reform.

23. 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 December 29, 2017 and December 30, 2016 and condensed consolidating statements of comprehensive income and cash flows for the fiscal three years ended December 29, 2017 and the three months ended December 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 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 December 29, 2017
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Assets					
Current Assets:					
Cash and cash equivalents	$ 0.7	$ 908.8	$ 351.4	$ —	$ 1,260.9
Accounts receivable, net	—	—	445.8	—	445.8
Inventories	—	—	340.4	—	340.4
Deferred income taxes	—	—	—	—	—
Prepaid expenses and other current assets	1.0	0.2	82.9	—	84.1
Notes receivable	—	—	154.0	—	154.0
Current assets held for sale	—	—		—	—
Intercompany receivable	70.0	173.4	831.4	(1,074.8)	—
Total current assets	71.7	1,082.4	2,205.9	(1,074.8)	2,285.2
Property, plant and equipment, net	—	—	966.8	—	966.8
Goodwill	—	—	3,482.7	—	3,482.7
Intangible assets, net	—	—	8,375.0	—	8,375.0
Long-term assets held for sale	—	—	—	—	—
Investment in subsidiaries	6,551.6	23,217.8	12,356.2	(42,125.6)	—
Intercompany loan receivable	593.1	—	4,664.8	(5,257.9)	—
Other assets	—	—	171.2	—	171.2
Total Assets	$ 7,216.4	$ 24,300.2	$ 32,222.6	$ (48,458.3)	$ 15,280.9
Liabilities and Shareholders' Equity					—
Current Liabilities:					
Current maturities of long-term debt	$ —	$ 313.5	$ 0.2	$ —	$ 313.7
Accounts payable	0.1	—	113.2	—	113.3
Accrued payroll and payroll-related costs	—	—	98.5	—	98.5
Accrued interest	—	53.0	4.0	—	57.0
Income taxes payable	—	—	15.8	—	15.8
Accrued and other current liabilities	0.8	0.4	450.9	—	452.1
Current liabilities held for sale	—	—	—	—	—
Intercompany payable	693.5	104.6	276.7	(1,074.8)	—
Total current liabilities	694.4	471.5	959.3	(1,074.8)	1,050.4
Long-term debt	—	6,206.8	214.1	—	6,420.9
Pension and postretirement benefits	—	—	67.1	—	67.1
Environmental liabilities	—	—	73.2	—	73.2
Deferred income taxes	—	—	689.0	—	689.0
Other income tax liabilities	—	—	94.1	—	94.1
Long-term liabilities held for sale	—	—	—	—	—
Intercompany loans payable	—	5,257.9	—	(5,257.9)	—
Other liabilities	—	7.8	356.4	—	364.2
Total liabilities	694.4	11,944.0	2,453.2	(6,332.7)	8,758.9
Shareholders' equity	6,522.0	12,356.2	29,769.4	(42,125.6)	6,522.0
Total Liabilities and Shareholders' Equity	$ 7,216.4	$ 24,300.2	$ 32,222.6	$ (48,458.3)	$ 15,280.9

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

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Assets					
Current Assets:					
Cash and cash equivalents	$ 0.5	$ 44.5	$ 297.0	$ —	$ 342.0
Accounts receivable, net	—	—	431.0	—	431.0
Inventories	—	—	350.7	—	350.7
Deferred income taxes	—	—	—	—	—
Prepaid expenses and other current assets	1.0	—	130.9	—	131.9
Notes receivable	—	—	—	—	—
Current assets held for sale	—	—	310.9	—	310.9
Intercompany receivable	59.7	65.1	1,081.3	(1,206.1)	—
Total current assets	61.2	109.6	2,601.8	(1,206.1)	1,566.5
Property, plant and equipment, net	—	—	881.5	—	881.5
Goodwill	—	—	3,498.1	—	3,498.1
Intangible assets, net	—	—	9,000.5	—	9,000.5
Long-term assets held for sale	—	—	—	—	—
Investment in subsidiaries	5,534.1	20,624.1	10,988.5	(37,146.7)	—
Intercompany loan receivable	3.5	—	3,325.9	(3,329.4)	—
Other assets	—	—	259.7	—	259.7
Total Assets	$ 5,598.8	$ 20,733.7	$ 30,556.0	$ (41,682.2)	$ 15,206.3
Liabilities and Shareholders' Equity					
Current Liabilities:					
Current maturities of long-term debt	$ —	$ 19.7	$ 251.5	$ —	$ 271.2
Accounts payable	0.1	0.1	111.9	—	112.1
Accrued payroll and payroll-related costs	—	—	76.1	—	76.1
Accrued interest	—	53.9	14.8	—	68.7
Income taxes payable	—	—	101.7	—	101.7
Accrued and other current liabilities	1.9	7.5	547.7	—	557.1
Current liabilities held for sale	—	—	120.3	—	120.3
Intercompany payable	612.5	467.1	126.5	(1,206.1)	—
Total current liabilities	614.5	548.3	1,350.5	(1,206.1)	1,307.2
Long-term debt	—	5,860.6	20.2	—	5,880.8
Pension and postretirement benefits	—	—	136.4	—	136.4
Environmental liabilities	—	—	73.0	—	73.0
Deferred income taxes	—	—	2,398.1	—	2,398.1
Other income tax liabilities	—	—	70.4	—	70.4
Long-term liabilities held for sale	—	—	—	—	—
Intercompany loans payable	—	3,329.4	—	(3,329.4)	—
Other liabilities	—	7.0	349.1	—	356.1
Total liabilities	614.5	9,745.3	4,397.7	(4,535.5)	10,222.0
Shareholders' equity	4,984.3	10,988.4	26,158.3	(37,146.7)	4,984.3
Total Liabilities and Shareholders' Equity	$ 5,598.8	$ 20,733.7	$ 30,556.0	$ (41,682.2)	$ 15,206.3

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME
Fiscal year ended December 29, 2017
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Net sales	$ —	$ —	$ 3,221.6	$ —	$ 3,221.6
Cost of sales	2.6	—	1,562.7	—	1,565.3
Gross profit	(2.6)	—	1,658.9	—	1,656.3
Selling, general and administrative expenses	59.5	0.7	860.7	—	920.9
Research and development expenses	5.1	—	272.2	—	277.3
Restructuring charges, net	—	—	31.2	—	31.2
Non-restructuring impairment charges	—	—	63.7	—	63.7
Separation costs	—	—	—	—	—
Gains on divestiture and license	—	—	(56.9)	—	(56.9)
Operating income (loss)	(67.2)	(0.7)	488.0	—	420.1
Interest expense	(13.8)	(353.9)	(74.2)	72.8	(369.1)
Interest income	7.3	1.2	68.9	(72.8)	4.6
Other income (expense), net	20.3	(1.7)	(12.6)	—	6.0
Intercompany interest and fees	(18.3)	—	18.3	—	—
Equity in net income of subsidiaries	2,200.0	2,901.8	2,549.9	(7,651.7)	—
Income from continuing operations before income taxes	2,128.3	2,546.7	3,038.3	(7,651.7)	61.6
Benefit from income taxes	(6.1)	(5.3)	(1,698.2)	—	(1,709.6)
Income from continuing operations	2,134.4	2,552.0	4,736.5	(7,651.7)	1,771.2
(Loss) income from discontinued operations, net of income taxes	—	(2.1)	365.3	—	363.2
Net income	2,134.4	2,549.9	5,101.8	(7,651.7)	2,134.4
Other comprehensive income, net of tax	59.6	59.6	118.2	(177.8)	59.6
Comprehensive income	$ 2,194.0	$ 2,609.5	$ 5,220.0	$ (7,829.5)	$ 2,194.0

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
Net sales	$ —	$ —	$ 3,380.8	$ —	$ 3,380.8
Cost of sales	—	—	1,525.8	—	1,525.8
Gross profit	—	—	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 impairments	—	—	16.9	—	16.9
Separation costs	—	—	—	—	—
Gains on divestiture and license	—	—	—	—	—
Operating (loss) income	(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)	—
Income from continuing operations before income taxes	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)
Income from continuing operations	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
Net income	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)
Comprehensive income	$ 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
Net sales	$ —	$ —	$ 2,923.1	$ —	$ 2,923.1
Cost of sales	—	—	1,300.2	—	1,300.2
Gross profit	—	—	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)
Operating (loss) income	(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)	—
Income from continuing operations before income taxes	309.7	250.5	624.5	(1,077.4)	107.3
Benefit from income taxes	(15.9)	—	(113.4)	—	(129.3)
Income from continuing operations	325.6	250.5	737.9	(1,077.4)	236.6
(Loss) income from discontinued operations, net of income taxes	(0.9)	—	89.0	—	88.1
Net income	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)
Comprehensive income	$ 259.9	$ 185.7	$ 757.0	$ (942.7)	$ 259.9

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME
Three months ended December 30, 2016
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Net sales	$ —	$ —	$ 829.9	$ —	$ 829.9
Cost of sales	—	—	384.1	—	384.1
Gross profit	—	—	445.8	—	445.8
Selling, general and administrative expenses	13.4	0.2	354.7	—	368.3
Research and development expenses	—	—	66.2	—	66.2
Restructuring charges, net	—	—	3.8	—	3.8
Non-restructuring impairments	—	—	214.3	—	214.3
Separation costs	—	—	—	—	—
Gains on divestiture and license	—	—	—	—	—
Operating loss	(13.4)	(0.2)	(193.2)	—	(206.8)
Interest expense	(2.9)	(81.1)	(17.9)	10.6	(91.3)
Interest income	—	0.1	11.0	(10.6)	0.5
Other income (expense), net	1.8	0.7	(3.4)	—	(0.9)
Intercompany interest and fees	(4.4)	—	4.4	—	—
Equity in net income of subsidiaries	(136.5)	35.2	(44.5)	145.8	—
Loss from continuing operations before income taxes	(155.4)	(45.3)	(243.6)	145.8	(298.5)
Benefit from income taxes	(2.2)	(0.3)	(119.2)	—	(121.7)
Loss from continuing operations	(153.2)	(45.0)	(124.4)	145.8	(176.8)
Income from discontinued operations, net of income taxes	—	0.4	23.2	—	23.6
Net loss	(153.2)	(44.6)	(101.2)	145.8	(153.2)
Other comprehensive income, net of tax	13.1	13.1	26.0	(39.1)	13.1
Comprehensive loss	$ (140.1)	$ (31.5)	$ (75.2)	$ 106.7	$ (140.1)

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS
Fiscal year ended December 29, 2017
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Cash Flows From Operating Activities:					
Net cash from operating activities	$ 1,233.2	$ 1,139.4	$ 2,274.9	$ (3,920.2)	$ 727.3
Cash Flows From Investing Activities:					
Capital expenditures	—	—	(186.1)	—	(186.1)
Acquisitions and intangibles, net of cash acquired	—	—	(76.3)	—	(76.3)
Proceeds from disposal of discontinued operations, net of cash	—	—	576.9	—	576.9
Intercompany loan investment	(589.5)	—	(1,157.9)	1,747.4	—
Investment in subsidiary	—	(1,475.3)	—	1,475.3	—
Proceeds from sale of subsidiary	—	—	—	—	—
Acquisition of subsidiary	—	—	—	—	—
Restricted cash	—	—	—	—	—
Other	—	—	3.9	—	3.9
Net cash from investing activities	(589.5)	(1,475.3)	(839.5)	3,222.7	318.4
Cash Flows From Financing Activities:					
Issuance of external debt	—	1,400.0	65.0	—	1,465.0
Repayment of external debt and capital leases	—	(764.5)	(152.7)	—	(917.2)
Debt financing costs	—	(12.7)	—	—	(12.7)
Proceeds from exercise of share options	4.1	—	—	—	4.1
Intercompany loan borrowings	—	1,747.4	—	(1,747.4)	—
Intercompany dividends	—	(1,170.0)	(2,750.2)	3,920.2	—
Capital contribution	—	—	1,475.3	(1,475.3)	—
Repurchase of shares	(651.7)	—	—	—	(651.7)
Other	4.1	—	(21.8)	—	(17.7)
Net cash from financing activities	(643.5)	1,200.2	(1,384.4)	697.5	(130.2)
Effect of currency rate changes on cash	—	—	2.5	—	2.5
Net increase (decrease) in cash, cash equivalents and restricted cash	0.2	864.3	53.5	—	918.0
Cash, cash equivalents and restricted cash at beginning of period	0.5	44.5	316.1	—	361.1
Cash, cash equivalents and restricted cash at end of period	$ 0.7	$ 908.8	$ 369.6	$ —	$ 1,279.1
Cash and cash equivalents at end of period	$ 0.7	$ 908.8	$ 351.4	$ —	$ 1,260.9
Restricted cash included in prepaid expenses and other assets at end of period	—	—	—	—	—
Restricted cash included in other long-term assets at end of period	—	—	18.2	—	18.2
Cash, cash equivalents and restricted cash at end of period	$ 0.7	$ 908.8	$ 369.6	$ —	$ 1,279.1

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
Cash Flows From Operating Activities:					
Net cash from operating activities	$ 17.9	$ (47.4)	$ 1,214.1	$ —	$ 1,184.6
Cash Flows From Investing Activities:					
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	32.7	—	266.7
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	—
Other	—	—	6.0	—	6.0
Net cash from investing activities	3.4	(802.4)	(2,107.5)	2,750.9	(155.6)
Cash Flows From Financing Activities:					
Issuance of external debt	—	—	98.3	—	98.3
Repayment of external debt and capital leases	—	(549.2)	(19.4)	—	(568.6)
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 from 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
Net increase (decrease) in cash, cash equivalents and restricted cash	0.2	(127.1)	(6.1)	—	(133.0)
Cash, cash equivalents and restricted cash at beginning of period	0.1	152.1	280.4	—	432.6
Cash, cash equivalents and restricted cash at end of period	$ 0.3	$ 25.0	$ 274.3	$ —	$ 299.6
Cash and cash equivalents at end of period	$ 0.3	$ 25.0	$ 255.2	$ —	$ 280.5
Restricted cash included in prepaid expenses and other assets at end of period	—	—	0.1	—	0.1
Restricted cash included in other long-term assets at end of period	—	—	19.0	—	19.0
Cash, cash equivalents and restricted cash at end of period	$ 0.3	$ 25.0	$ 274.3	$ —	$ 299.6

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

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Cash Flows From Operating Activities:					
Net cash from operating activities	$ 207.0	$ (148.2)	$ 871.7	$ —	$ 930.5
Cash Flows From Investing Activities:					
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	—
Subsidiary dividend proceeds	—	—	—	—	—
Investment in subsidiary	—	(3,014.4)	—	3,014.4	—
Other	—	—	3.0	—	3.0
Net cash from investing activities	(149.4)	(3,014.4)	(2,853.9)	3,718.0	(2,299.7)
Cash Flows From Financing Activities:					
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)
Debt financing costs	—	(39.1)	(0.8)	—	(39.9)
Proceeds from exercise of share options	34.4	—	—	—	34.4
Subsidiary dividend payment	—	—	—	—	—
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 from financing activities	(57.8)	3,296.2	1,515.4	(3,718.0)	1,035.8
Effect of currency rate changes on cash	—	—	(11.6)	—	(11.6)
Net (decrease) increase in cash, cash equivalents and restricted cash	(0.2)	133.6	(478.4)	—	(345.0)
Cash, cash equivalents and restricted cash at beginning of period	0.3	18.5	758.8	—	777.6
Cash, cash equivalents and restricted cash at end of period	$ 0.1	$ 152.1	$ 280.4	$ —	$ 432.6
Cash and cash equivalents at end of period	$ 0.1	$ 152.1	$ 213.7	$ —	$ 365.9
Restricted cash included in prepaid expenses and other assets at end of period	—	—	47.7	—	47.7
Restricted cash included in other long-term assets at end of period	—	—	19.0	—	19.0
Cash, cash equivalents and restricted cash at end of period	$ 0.1	$ 152.1	$ 280.4	$ —	$ 432.6

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS
Three months ended December 30, 2016
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Cash Flows From Operating Activities:					
Net cash from operating activities	$ 17.4	$ (94.0)	$ 272.2	$ —	$ 195.6
Cash Flows From Investing Activities:					
Capital expenditures	—	—	(65.2)	—	(65.2)
Acquisitions and intangibles, net of cash acquired	—	—	(1.8)	—	(1.8)
Intercompany loan investment	—	—	(424.7)	424.7	—
Subsidiary dividend proceeds	—	—	—	—	—
Investment in subsidiary	—	(260.0)	—	260.0	—
Other	—	—	(10.2)	—	(10.2)
Net cash from activities	—	(260.0)	(501.9)	684.7	(77.2)
Cash Flows From Financing Activities:					
Issuance of external debt	—	175.0	15.0	—	190.0
Repayment of external debt and capital leases	—	(86.2)	(0.5)	—	(86.7)
Debt financing costs	—	—	—	—	—
Proceeds from exercise of share options	0.4	—	—	—	0.4
Subsidiary dividend payment	—	—	—	—	—
Intercompany loan borrowings	140.0	284.7	—	(424.7)	—
Capital contribution	—	—	260.0	(260.0)	—
Repurchase of shares	(158.8)	—	—	—	(158.8)
Other	1.2	—	—	—	1.2
Net cash from financing activities	(17.2)	373.5	274.5	(684.7)	(53.9)
Effect of currency rate changes on cash	—	—	(3.0)	—	(3.0)
Net increase in cash, cash equivalents and restricted cash	0.2	19.5	41.8	—	61.5
Cash, cash equivalents and restricted cash at beginning of period	0.3	25.0	274.3	—	299.6
Cash, cash equivalents and restricted cash at end of period	$ 0.5	$ 44.5	$ 316.1	$ —	$ 361.1
Cash and cash equivalents at end of period	$ 0.5	$ 44.5	$ 297.0	$ —	$ 342.0
Restricted cash included in prepaid expenses and other assets at end of period	—	—	0.1	—	0.1
Restricted cash included in other long-term assets at end of period	—	—	19.0	—	19.0
Cash, cash equivalents and restricted cash at end of period	$ 0.5	$ 44.5	$ 316.1	$ —	$ 361.1

24. Subsequent Events

Discontinued Operations and Divestitures

On January 8, 2018, the Company announced that it entered into a definitive agreement to sell its PreveLeak and Recothrom assets to Baxter International, Inc ("Baxter") for approximately $185.0 million, with upfront payment of $153.0 million, inclusive of existing inventory, and the remainder in potential future milestones. Baxter will assume other expenses, including contingent liabilities associated with PREVELEAK®. Baxter is a global medical products company that is committed to advancing surgical innovation with a variety of products and delivery devices used in the surgical suite. The Company expects the sale to close in the first quarter of 2018.

On February 22, 2018, the Company's Board of Directors authorized commencement of a process to dispose of (1) the Company's Specialty Generics business comprised of its Specialty Generics segment, with the exception of its external manufacturing operations, (2) certain of the Company's non-promoted brands business, which is currently reflected in the Specialty Brands segment; and (3) the Company's ongoing, post-divestiture supply agreement with the acquirer of the CMDS business, which is currently reflected in the Other non-operating segment (referred to collectively as the "Specialty Generics Disposal Group"). The Company evaluated the criteria prescribed by GAAP for recording a disposal group as held for sale and discontinued operations. This criteria was not met as of December 29, 2017. Therefore, this disposal group was not presented as a discontinued operation in the accompanying consolidated balance sheets and consolidated statements of income. Beginning in the first quarter of fiscal 2018, the historical financial results attributable to the Specialty Generics Disposal Group will be reflected in the Company's consolidated financial statements as discontinued operations.

Sucampo Acquisition

On February 13, 2018, the Company acquired Sucampo Pharmaceuticals, Inc. ("Sucampo"). Consideration for the transaction consisted of approximately $1.2 billion, including the assumption of Sucampo's third-party debt ("the Sucampo Acquisition"). The acquisition was funded through the issuance of $600.0 million aggregate principal amount of senior secured notes (as discussed further below), a $900.0 million borrowing under the Revolver and cash on hand. Sucampo's commercialized products include AMITIZA® (lubiprostone), a leading global product in the branded constipation market, and RESCULA® (unoprostone isopropyl ophthalmic solution) 0.15%, which is indicated for ocular hypertension and open-angle glaucoma, and marketed in Japan. In addition, Sucampo has two pipeline products that are currently in Phase 3 development: VTS-270, a development product for Niemann-Pick Type C, a rare, neurodegenerative, and ultimately fatal disease that can present at any age, and CPP-1X/sulindac, a development product for Familial Adenomatous Polyposis under a collaborative agreement between Cancer Prevention pharmaceuticals and Sucampo.

The Company incurred acquisition costs within the consolidated statements of income for fiscal 2017 of $4.2 million, which were included within SG&A.

The Company has not yet completed a preliminary allocation of the total consideration to the identifiable assets acquired and liabilities assumed for the Sucampo Acquisition. However, the Company expects that significant assets acquired will primarily consist of intangible assets, but will also include inventory adjusted to fair value, and that significant liabilities assumed will include the existing Sucampo third-party debt and deferred tax liabilities associated with assets acquired. The Company expects to complete a preliminary allocation of the total consideration during the first quarter of fiscal 2018.

Upon completion of the Sucampo Acquisition, Sucampo's 3.25% convertible senior notes due 2021 ("the Sucampo Notes") became eligible to receive increased consideration in conjunction with a make-whole fundamental change, such that each $1,000 principal face amount of Sucampo notes may be converted into $1,221 cash. Under terms of the Indenture dated December 27, 2016 (the "Sucampo Indenture"), between Sucampo and U.S. Bank National Association, the Sucampo Notes may be converted at the option of their holders and be eligible to receive increased consideration during a period of time following consummation of the merger transaction, or remain outstanding and earn the stated 3.25% rate of interest. It is the expectation that all holders will eventually exercise their conversion rights under the Sucampo Indenture. At the time of this filing approximately $73.5 million of the $300.0 million of issued convertible debt remains outstanding.

Sucampo Acquisition Financing

In February 2018, in conjunction with the Sucampo Acquisition, the Company entered into a $600.0 million senior secured term loan. The variable-rate loan bears an interest rate of LIBOR plus 300 basis points and was issued with a discount of 25 basis points. The incremental term loan matures on February 25, 2025 under terms generally consistent with the Company's existing term loan.

Financing Activities

On January 16, 2018, the Company made a $225.0 million voluntary prepayment on its outstanding term loan. In making this payment the Company satisfies certain obligations included within external debt agreements to reinvest proceeds from the sale of assets and businesses within one year of the respective transaction or use the proceeds to pay down debt.

On February 21, 2018, the Company borrowed an additional $25.0 million on its Receivable Securitization, bringing total outstanding borrowings to $225.0 million for this instrument. The Company also made a $275.0 million payment on the 2017 Revolving Credit Facility, bringing total outstanding borrowings to $625.0 million for this instrument.

Commitments and Contingencies

Certain litigation matters occurred in fiscal 2017 or prior, but had subsequent updates in January and February 2018. See further discussion in Note 19 to the consolidated financial statements.

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 December 29, 2017. 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 December 29, 2017. 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 December 29, 2017.

Management's assessment of internal control over financial reporting, as discussed above, excluded Ocera Therapeutics, Inc. and InfaCare Pharmaceutical Corporation, acquired by the Company in fiscal 2017, which represented less than 1% of our total net sales and approximately 1% of our total assets as of and for the period ended December 29, 2017, respectively. Because management's assessment of internal control over financial reporting included the accounting for goodwill and intangible assets from these acquisitions, the percentage of total assets at December 29, 2017 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 December 29, 2017 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 December 29, 2017 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:

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Mallinckrodt plc and subsidiaries (the "Company") as of December 29, 2017, based on the criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 29, 2017, based on the criteria established in *Internal Control—Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the accompanying consolidated balance sheets as of December 29, 2017 and December 30, 2016, the related consolidated statements of income, comprehensive income, changes in shareholders' equity, and cash flows, for the fiscal years ended December 29, 2017, September 30, 2016 and September 25, 2015 and the three-month period ended December 30, 2016, and the related notes and the schedule listed in the Index at Item 15 (collectively referred to as the "financial statements"), of the Company and our report, dated February 27, 2018, expressed an unqualified opinion.

As described in *Management's Report* on *Internal Control over Financial Reporting*, management excluded from its assessment the internal control over financial reporting at InfaCare Corporation ("InfaCare"), which was acquired on September 25, 2017, whose financial statements constitute approximately less than 1% of total net sales and less than 1% of total assets of the consolidated financial statement amounts as of and for the year ended December 29, 2017. Management also excluded from its assessment the internal control over financial reporting at Ocera Therapeutics Inc. ("Ocera"), which was acquired December 11, 2017, whose financial statements constitute approximately less than 1% of total net sales and less than 1% of total assets of the consolidated financial statement amounts as of and for the year ended December 29, 2017. Accordingly, our audit did not include the internal control over financial reporting at InfaCare or Ocera.

Basis for Opinion

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 are a public accounting firm registered with the PCAOB and required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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.

Definitions and Limitations of Internal Control over Financial Reporting

A company's 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 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 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.

/s/ DELOITTE & TOUCHE LLP
St. Louis, Missouri
February 27, 2018

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 December 29, 2017.

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 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 December 29, 2017.

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 December 29, 2017.

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 December 29, 2017.

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 December 29, 2017.

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 December 29, 2017, September 30, 2016 and September 25, 2015 and the three months ended December 30, 2016
- Consolidated Statement of Comprehensive Income for the fiscal year ended December 29, 2017, September 30, 2016 and September 25, 2015 and the three months ended December 30, 2016
- Consolidated Balance Sheets as of December 29, 2017 and December 30, 2016
- Consolidated Statement of Cash Flows for the fiscal year ended December 29, 2017, September 30, 2016 and September 25, 2015 and the three months ended December 30, 2016
- Consolidated Statement of Changes in Shareholders' Equity for the period from September 26, 2014 to December 29, 2017
- 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
Allowance for doubtful accounts:					
Fiscal year ended December 29, 2017	$ 4.0	$ 0.6	$ —	$ (0.7)	$ 3.9
Three months ended December 30, 2016	4.0	0.1	—	(0.1)	4.0
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
Sales reserve accounts:					
Fiscal year ended December 29, 2017	$ 391.3	$ 2,008.5	$ —	$ (2,023.2)	$ 376.6
Three months ended December 30, 2016	378.0	515.3	—	(502.0)	391.3
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
Tax valuation allowance:					
Fiscal year ended December 29, 2017	$ 1,398.3	$ 804.6	$ 4.0	$ 61.0	$ 2,267.9
Three months ended December 30, 2016	564.9	833.4	—	—	1,398.3
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

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

February 27, 2018

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
/s/ Mark C. Trudeau Mark C. Trudeau	President, Chief Executive Officer and Director *(principal executive officer)*	February 27, 2018
/s/ Matthew K. Harbaugh Matthew K. Harbaugh	Executive Vice President and Chief Financial Officer *(principal financial officer)*	February 27, 2018
/s/ Kathleen A. Schaefer Kathleen A. Schaefer	Senior Vice President and Corporate Controller *(principal accounting officer)*	February 27, 2018
/s/ Melvin D. Booth Melvin D. Booth	Chairman of the Board of Directors	February 27, 2018
/s/ David R. Carlucci David R. Carlucci	Director	February 27, 2018
/s/ J. Martin Carroll J. Martin Carroll	Director	February 27, 2018
/s/ Diane H. Gulyas Diane H. Gulyas	Director	February 27, 2018
/s/ David Y. Norton David Y. Norton	Director	February 27, 2018
/s/ JoAnn A. Reed JoAnn A. Reed	Director	February 27, 2018
/s/ Angus C. Russell Angus C. Russell	Director	February 27, 2018
/s/ Kneeland C. Youngblood, M.D. Kneeland C. Youngblood, M.D.	Director	February 27, 2018
/s/ Joseph A. Zaccagnino Joseph A. Zaccagnino	Director	February 27, 2018

EXHIBIT INDEX

Exhibit Number	Exhibit
2.1	Separation and Distribution Agreement between Covidien plc and Mallinckrodt plc, dated June 28, 2013 (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed July 1, 2013).
2.2	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).
2.3	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).
2.4	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).
2.5	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).
2.6	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).
2.7	First Amendment to Share Purchase Agreement, dated as of December 15, 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 2.2 to the Company's Current Report on Form 8-K filed January 27, 2017).
2.8	Agreement and Plan of Merger, dated as of December 23, 2017, by and among Mallinckrodt plc, Sun Acquisition Co. and Sucampo Pharmaceuticals, Inc (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed December 26, 2017).
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	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).

10.4	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).
10.5	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).
10.6	Letter Agreement dated September 30, 2016 between Mallinckrodt International Finance, S.A. and Deutsche Bank AG New York Branch, as administrative agent (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K for the year ended September 30, 2016).
10.7	Refinancing Amendment No. 2 and Incremental Assumption Agreement No. 3, dated as of February 28, 2017, 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 March 1, 2017).
10.8	Incremental Assumption Agreement No. 4, dated as of February 13, 2018, by and among Mallinckrodt plc, Mallinckrodt International Finance, S.A., Mallinckrodt CB LLC, the other subsidiaries of Mallinckrodt plc party thereto and Deutsche Bank AG New York Branch, as administrative agent (incorporated by reference to Exhibit (b)(3) of the Schedule TO/A filed with the SEC by Mallinckrodt plc and Sun Acquisition Co. on February 13, 2018).
10.9	Amendment, dated as of February 21, 2018, to the Credit Agreement, dated as of March 19, 2014, by and 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.
10.10	Amended and Restated Note Purchase Agreement, dated as of July 28, 2017, 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 on Form 8-K filed August 1, 2017).
10.11	Amended and Restated Purchase and Sale Agreement, dated as of July 28, 2017, 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 August 1, 2017).
10.12	Form of Sale Agreement, dated as of July 28, 2017, between Mallinckrodt LLC and each Sub-Originator (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed August 1, 2017).
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	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).
10.15	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).
10.16*	Mallinckrodt Pharmaceuticals Severance Plan for U.S. Officers and Executives, amended May 18, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed August 8, 2017).
10.17*	Mallinckrodt Pharmaceuticals Change in Control Severance Plan for Certain U.S. Officers and Executives, amended May 18, 2017 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed August 8, 2017).
10.18*	Mallinckrodt Pharmaceuticals Stock and Incentive Plan, amended May 18, 2017 (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed August 8, 2017).
10.19*	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).
10.20*	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).
10.21*	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).
10.22*	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 filed May 5, 2015).
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 3, 2016).

10.24*	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 filed May 3, 2016).
10.25*	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 filed May 3, 2016).
10.26*	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 filed May 3, 2016).
10.27*	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).
10.28*	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 filed November 25, 2014).
10.29*	Mallinckrodt Pharmaceuticals Supplemental Savings and Retirement Plan.
21.1	Subsidiaries of Mallinckrodt plc.
23.1	Consent of Deloitte & Touche LLP.
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 December 29, 2017 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.