Mallinckrodt plc
Form 10-K
February 26, 2019
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 28, 2018
or
o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number : 001-35803

Mallinckrodt plc

(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 x No o
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes x No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 **x** Accelerated filer o Non-accelerated filer **o** Smaller reporting company o Emerging growth company o

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. o
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x
The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant (assuming solely for the purposes of this calculation that all directors and executive officers of the Registrant are "affiliates") as of June 29, 2018, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $1,542.3 million (based upon the closing price of $18.66 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 22, 2019 was 83,505,008.
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 28, 2018, 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. 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. Our Specialty Brands segment's 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 Specialty Generics and Amitiza segment includes specialty generic drugs, active pharmaceutical ingredients ("API(s)") and Amitiza® (lubiprostone) ("Amitiza").

We continue to execute 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 focused on improving outcomes for underserved patients with severe and critical conditions.

On December 6, 2018, we announced our plans to spin off a new company consisting of the Specialty Generics/API business and the Amitiza product to our shareholders ("the Separation"). The Separation is expected to create two independent, appropriately capitalized, publicly traded companies – one focused on innovative specialty pharmaceutical brands, the other concentrated primarily in niche specialty generic products and API manufacturing – each positioned to optimize future success as they pursue independent growth strategies. We anticipate that the transaction will be in the form of a distribution of new publicly traded stock in the new company that is intended to be generally tax-free for United States ("U.S.") federal income tax purposes to our shareholders. Completion of the transaction is expected to be subject to certain conditions, including, among others, receipt of regulatory approvals, assurance as to the tax-free status of the spin-off of the business to our shareholders, the effectiveness of a Form 10 registration statement to be filed with the U.S. Securities and Exchange Commission ("SEC") and final approval by our Board of Directors. We currently expect completion of the transaction in the second half of 2019; however, there can be no assurance regarding the ultimate timing of the proposed transaction or that the transaction will be completed.

Beginning in the first quarter through the third quarter of fiscal 2018, the historical financial results attributable to "the Specialty Generics Disposal Group" were reflected in our interim condensed consolidated financial statements as discontinued operations. The Specialty Generics Disposal Group included (1) our Specialty Generics business comprised of what was our Specialty Generics segment in fiscal 2017, with the exception of BioVectra, Inc. - our wholly-owned subsidiary that operates a contract manufacturing business in Canada ("BioVectra"); (2) certain of our non-promoted brands business, which was previously reflected in our Specialty Brands segment; and (3) our ongoing, post-divestiture supply agreement with the acquirer of our contrast media and delivery systems ("CMDS") business, which was reflected in our Other non-operating segment.

As a result of the Separation announcement, the Specialty Generics Disposal Group no longer met the requirements to be classified as held-for-sale, and the historical financial results attributable to the Specialty Generics Disposal Group are now reflected in our consolidated financial statements as continuing operations for fiscal 2018.

During the three months ended December 28, 2018, the Specialty Generics Disposal Group was reclassified to held and used after being classified as held-for-sale since February 2018. In accordance with accounting principles generally accepted in the U.S. ("GAAP"), depreciation and amortization are not recorded during the period in which a disposal group is classified as held-for-sale. When the disposal group was reclassified to held and used, it was measured at its carrying amount before it was classified as held-for-sale, adjusted for depreciation and amortization expense that would have been recognized had the disposal group been continuously classified as held and used. The effect of the required adjustment has been reflected in income from continuing operations during the fourth quarter of 2018, the period in which the held-for-sale criteria were no longer met.

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

Fiscal Year

We report our results based on a "52-53 week" year ending on the last Friday of December. Fiscal 2018 and 2017 each consisted of 52 weeks and 2016 consisted of 53 weeks. 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.

Our principal executive offices are located at Three Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG, United Kingdom ("U.K."). In addition, we have other locations in the 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 and Amitiza 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

As a result of the planned Separation, we reassessed our segments based on the financial information viewed by the Chief Executive Officer ("CEO"), who is our chief operating decision maker ("CODM"), for the purposes of making resource allocation decisions and assessing the performance of the business. We have identified two reportable segments that align with the operations of the two independent, publicly traded companies anticipated post-separation: (1) Specialty Brands and (2) Specialty Generics and Amitiza, which are further described below:

- *Specialty Brands* includes innovative specialty pharmaceutical brands; and
- *Specialty Generics and Amitiza* includes niche specialty generic drug products, APIs and Amitiza.

We measure and evaluate 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.

Specialty Brands

Our Specialty Brands segment markets branded pharmaceutical products for autoimmune and rare disease in the specialty areas of neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; and analgesics. 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 substantially expanded our Specialty Brands portfolio, inclusive of our pipeline, through our business development and licensing transactions.

Our long-term strategy is to increase patient access and appropriate utilization of our existing products; develop new therapies and next-generation devices 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, pulmonologists, ophthalmologists, neonatologists, surgeons and pharmacy directors) with our own direct sales force of approximately 300 sales representatives as of December 28, 2018. These 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 (repository corticotropin injection) ("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 adjunctive therapy for short-term administration for an acute episode or exacerbation in rheumatoid arthritis ("RA"), including juvenile RA; monotherapy for the treatment of infantile spasms in infants and children under 2 years of age; treatment during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus; treatment of acute exacerbations of multiple sclerosis ("MS") in adults; including a diuresis or a remission of proteinuria in nephrotic syndrome ("NS") without uremia of the idiopathic type or that due to lupus; treatment during an exacerbation or as maintenance therapy in selected cases of systemic dermatomyositis (polymyositis); treatment of symptomatic sarcoidosis; and treatment of severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa including uveitis. 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.

Since acquiring H.P. Acthar Gel, we have initiated critical placebo-controlled trials in an effort to expand the product's evidence base and strengthen its clinical profile. There are currently eight ongoing Company-sponsored studies for which the areas of focus include focal segmental glomerular sclerosis ("FSGS") (a nephrotic condition), MS, pulmonary sarcoidosis, RA, systemic lupus erythematosus, uveitis, and amyotrophic lateral sclerosis ("ALS"), which is not a currently approved indication. We continue our efforts to extend the value of the product through Phase 4 studies and product enhancements including the ongoing development of the Acthar self-injection device. For example, our Phase 4 RA trial reached 100% completion of the open-label portion of the study with 259 patients enrolled, and primary end point results observed were consistent with those observed at the 50% milestone assessment, which showed 61% of 100 patients achieved low disease activity at 12 weeks. Enrollment for the Phase 2 study to evaluate H.P. Acthar Gel for patients with ALS, a progressive and fatal neurodegenerative disorder, continues to progress and has surpassed the 25% enrollment target.

- *Inomax® (nitric oxide) gas, for inhalation ("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. Development continues for the next-generation Inomax device which will offer a compact, portable design that we believe will further enhance the safety of the product, as well as the simplicity and flexibility of use in a number of settings. There has been recent patent litigation related to the Inomax product, as further described in Note 20 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

- *Ofirmev® (acetaminophen) injection ("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. 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® photopheresis ("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.
- *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 and Amitiza

Our Specialty Generics and Amitiza segment is focused on providing our customers high-quality specialty generic drugs, APIs and Amitiza, a leading product in the gastrointestinal market. Specialty Generics include a variety of product formulations containing hydrocodone-containing tablets, oxycodone-containing tablets and several other controlled substances, all of which are significant products for the treatment of pain. Our near-term pipeline in this segment includes the expected launch of up to five new products in fiscal 2019, with additional products in development long-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.

We are among the world's largest manufacturers of bulk acetaminophen and the only producer of acetaminophen in the North American and European regions. We manufacture controlled substances under the Drug Enforcement Administration ("DEA") quota restrictions and in calendar 2018 we estimated that we received approximately 38% 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 and Amitiza segment. 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 these 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.

We produce lubiprostone for use in Amitiza capsules, a branded gastrointestinal product approved in the U.S. and certain other geographies, for various forms of constipation. We own the registrations and manufacturing rights for Amitiza, and contract with third parties for commercialization of the product in Japan and the U.S.

The following is a list of significant products and product families in our Specialty Generics and Amitiza segment:

- hydrocodone (API) and hydrocodone-containing tablets;
- oxycodone (API) and oxycodone-containing tablets;
- acetaminophen (API) products;
- other controlled substances; and
- Amitiza.

Research and Development

We devote significant resources to the R&D of products and proprietary drug technologies. 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 portfolio, where we believe there is the greatest opportunity for growth and profitability.

Specialty Brands. We devote significant R&D resources to our branded products, both inline and pipeline. 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, including pipeline opportunities related to early- and late-stage development products to meet the needs of underserved patient populations, where we execute on the development process and perform clinical trials to support regulatory approval of new products.

Data generation is an important strategic driver for our key products, both inline and in development, as they extend evidence in approved uses, label enhancements and new indications. Our data 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 these:

- *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. During fiscal 2018 we achieved more than 75% of our total enrollment for the ongoing Phase 3 clinical study to evaluate the efficacy and safety of terlipressin (for injection) in subjects with HRS type 1. This Phase 3 clinical study is being conducted under an FDA Special Protocol Assessment. We continue to make progress on this clinical study as we proceed to full enrollment. Results of a pooled analysis of clinical trial data suggests that treatment with Terlipressin is particularly beneficial for patients with HRS type 1 and low Mean Arterial Pressure. We expect the Phase 3 study for HRS type 1 to be completed by the second half of 2019. We anticipate being able to submit the new drug application ("NDA") filing to the FDA in 2020. We also expect to complete a second Phase 3 study for this

development product.

StrataGraft regenerative skin tissue 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, conferring seven years exclusivity to be applied upon approval of the drug.

- 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 was 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. We are currently more than 75% enrolled for the Phase 3 study and given the RMAT designation, we will continue to engage with the FDA to evaluate an early submission if the data supports it. We expect to complete the Phase 3 trial for deep partial thickness in the second half of 2019 and target filing with the FDA by the end of 2019 or early 2020.

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.

- *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.

On May 3, 2018, in a joint meeting, the FDA's Gastrointestinal Drugs Advisory Committee and Pediatric Advisory Committee (the "Advisory Committee") recommended that the risk benefit profile of our stannsoporfin in-process research and development ("IPR&D") product does not support approval for the treatment of newborns ≥35 weeks of gestational age with indicators of hemolysis who are at risk of developing hyperbilirubinemia (severe jaundice). On August 9, 2018, we received a complete response letter from the FDA related to our NDA for stannsoporfin. In the letter, the FDA provided guidance regarding areas of further evaluation for resubmitting the stannsoporfin NDA for the treatment of newborns ≥35 weeks of gestational age with indicators of hemolysis who are at risk of developing hyperbilirubinemia.

In January 2019, we participated in a Type A meeting with the FDA, where we had meaningful discourse regarding the population, trial design and other issues outlined in the complete response letter related to stannsoporfin. We plan to refine the pivotal registration trial design and work with the FDA toward agreement on a Special Protocol Assessment. We are optimistic that we may advance a new therapy specifically targeting a higher risk population of infants suffering from severe hyperbilirubinemia and who are failing more intensive phototherapy intervention.

- *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 was granted FDA fast track designation in August 2018. The trial is being conducted under an FDA Special Protocol Agreement and the first patient was enrolled in December 2018.
- *MNK-6105 (IV) and MNK-6106 (oral)*, 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 and MNK-6106 are expected to be effective therapy formulations that rapidly eliminate 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-6106'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-6105/6106. The FDA also granted fast track designation to MNK-6105/6106. We are currently working with the FDA to initiate the Phase 3 trial for this development product.

VTS-270 is in Phase 3 development for Niemann-Pick Type C ("NPC"). NPC is a complicated, ultra-rare neurodegenerative disease that typically presents in childhood and is ultimately fatal. 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. Manifestations of the genetic disorder typically occur in

childhood with occasional late onset. 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.
In November 2018, we announced that the results of our recently completed registration trial for the product did not show a statistically significant separation from placebo. Neither the VTS-270 nor the placebo arm showed disease progression as would be expected for a neurodegenerative condition over 52 weeks of observation. We are in the process of evaluating this portion of the study in order to ensure the data was properly captured and of the highest quality. The FDA indicated at a Type A meeting in August 2018 that their view on the potential approvability will be based on the totality of data, not a single study or endpoint. Accordingly, our review of the data from the Phase 2b/3 trial, including the longer term open label portion, continues to proceed and is being assessed in combination with several other available data sources. We expect that a better understanding of the potential benefit of VTS-270 will emerge as we carefully consider the totality of data available and continue to work with the primary investigators and the FDA to determine the best path forward.

- *CPP-1X/sulindac* is in Phase 3 development for Familial Adenomatous Polyposis ("FAP") under a collaborative agreement with Cancer Prevention Pharmaceuticals ("CPP"). 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 likelihood 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 and Amitiza*. The R&D from this segment 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 and Amitiza headquarters and technical development center in Webster Groves, Missouri.

We are developing a number of complex generic pharmaceutical products that take advantage of our API and drug product manufacturing capabilities as well as our experience in working with API and contract manufacturing organizations. We currently have five Abbreviated New Drug Applications ("ANDAs") at various stages of review with the FDA and a diverse portfolio of oral solid and parenteral formulations under development. Our pipeline is focused on applying our capabilities to develop difficult formulations, utilizing our expertise in working with controlled substances to develop potent products, and expanding both our therapeutic and technology platforms into areas with less competitive pressure. We utilize our proven abilities to design around competitor patents to advantage both our API and drug product development opportunities and to create our own intellectual property.

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 only prescribed by physicians when numerous alternative treatments have failed to provide positive outcomes or are not well tolerated by the patient. Similarly, there is no direct competition on the U.S. market for Inomax, and we believe its highly differentiated service offering will help to substantially extend the product's durability longer term. 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 and service 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 need, 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 that 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 International plc, Johnson Matthey plc, Mylan N.V., Pfizer Inc., Purdue Pharma L.P., Teva Pharmaceutical Industries Ltd. and Allergan plc, among others. We believe our secure sources of opioid raw materials, vertically integrated manufacturing capabilities, broad offerings of API controlled substances and acetaminophen, comprehensive generic controlled substances product line and established relationships with national and regional distributors of generic drugs in the U.S. enable us to compete with larger generic 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 efficiently and effectively in this highly regulated, competitive environment.

The Specialty Generics and Amitiza 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 upon the specific product category and dosage strength. Among the large generic controlled substance providers, we are one of the only generic manufacturers that has its own controlled substance API manufacturing capability, and we believe that we offer more vertically integrated generic controlled substance products than any other U.S. manufacturer. New drugs and future developments in improved or advanced drug delivery technologies or other therapeutic techniques may provide therapeutic or cost advantages when compared to the products we sell. 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.

As it relates to our Amitiza product, in the U.S., there are an estimated 40-50 million patients who suffer from constipation that is idiopathic in nature or a consequence of other conditions such as irritable bowel syndrome or chronic opioid use. Many patients are currently treated for chronic idiopathic constipation ("CIC"), irritable bowel syndrome with constipation ("IBS-C") or opioid-induced constipation ("OIC") with a variety of medications. Over-the-counter medications are available and are generally intended to provide relief for occasional constipation. Prescription products are also available and are generally intended to provide relief for chronic constipation. As such,

the U.S. constipation market is expansive and diverse with a multitude of products intended to treat a large heterogeneous patient population. The prescription chronic constipation market can generally be bifurcated into two categories: 1) generic laxatives and 2) branded products. Generic laxatives make up roughly 80%-90% of the total prescription volume while branded prescriptions have grown to represent 10%-20% of the prescription market. Linzess is the leading branded competitor in this market, marketed by Allergan plc and Ironwood Pharmaceuticals. At this time, Amitiza is the only branded product with chloride two channel activator mechanism of action. Amitiza is also the only branded product on the market today to be indicated in three separate indications for CIC, IBS-C and OIC.

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 technical capabilities.

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. 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, as well as Amitiza, 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 ANDAs. If the FDA concludes that the facilities to be used do not or did not meet cGMP, good laboratory practice ("GLP") or good clinical practice ("GCP") requirements, it will not approve the application. Corrective actions to remedy the deficiencies must be performed and are usually verified in a subsequent inspection. In addition, manufacturers of both pharmaceutical products and API used to formulate the drug also ordinarily undergo a pre-approval inspection, although the inspection can be waived when the manufacturer has had a passing cGMP inspection in the immediate past. Failure of any facility to pass a pre-approval inspection will result in delayed approval and could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

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

United States

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

The FDA's authority to regulate the safety and efficacy of pharmaceuticals comes from the FFDCA. In addition to reviewing NDAs, for branded drugs, and ANDAs, for generic drugs, the FDA has the authority to ensure that pharmaceutical products introduced into interstate commerce are neither "adulterated" 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, and the imposition of 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 expected to have the same clinical effect and safety profile as the branded drug product when administered to patients under the conditions specified in the labeling.

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 an Investigational New Drug Application with the FDA 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 4 studies.

Clinical trials are typically conducted in four sequential phases, although they may overlap. The four phases are as follows:

- Phase 1 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 2 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 3 trial may be conducted.
- Phase 3 trials are often multi-institution studies that involve a large number of participants and are designed to show efficacy. Phase 3 (and some Phase 2) 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 4 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 2019, the user fee rate has been set at $2,588,480 for a 505(b)(1) NDA and $1,294,230 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 certain pre-clinical studies and clinical safety and efficacy trials and instead focuses on data establishing bioequivalence between the branded or Referenced Listed Drug ("RLD") and the ANDA product. Bioequivalence studies generally involve comparing the absorption rate and concentration levels of the active ingredient in a generic drug in the human body to that of the branded drug or RLD. In the event that the active ingredient in 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 is also the same dosage form, route of administration and strength as the RLD.

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 2019 user fee rate is set at $178,800 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. The FDA has set a target of approving 90% of ANDA submissions within 10 months of submission for submissions made in 2019.

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 grant final approval of (but will continue to review) an ANDA in which the RLD holder has sued, within 45 days of receiving a Paragraph IV notice of the ANDA filing, the ANDA holder for patent infringement until either the litigation has been resolved or 30 months have elapsed, whichever is earlier.

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 file an ANDA containing 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 or enters into a settlement agreement with the manufacturer of the branded product. 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 as it depends on several different factors.

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 solid oral dosage form opioid products, 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 providing prescriber education or restricting the dispensing of the drug product to 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.

In December 2011, the FDA approved a single, class-wide REMS program for TIRF products (called "the TIRF REMS Access Program"). 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, where the products can only be prescribed, dispensed and utilized by registered prescribers, pharmacies and patients in the system.

In February 2009, the FDA requested that drug manufacturers help develop a single, shared REMS for extended-release and long-acting ("ERLA") 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 training on appropriate prescribing practices available for healthcare providers ("HCPs") who prescribe these opioid analgesics and to distribute educational materials on their safe use to prescribers and patients. On September 18, 2018, the FDA approved the final "Opioid Analgesic REMS." This REMS now includes immediate release opioid products used in outpatient settings as well as the ERLA opioid products that have already been subject to a REMS since 2012.

The goal of the Opioid Analgesic REMS is to reduce unnecessary and/or inappropriate exposure to opioids by providing HCPs with information on appropriate prescribing recommendations and helping HCPs learn how to identify abuse by individual patients and know how to get patients with opioid use disorder into treatment. The Opioid Analgesic REMS program required HCP training be made available to all HCPs involved in the management of patients with pain, including nurses and pharmacists. We participate with other opioid product companies to provide unrestricted grants to accredited continuing education providers for the development of education courses for HCPs based on the FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain.

Drug Enforcement Administration. The DEA is the U.S. 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 Schedule II 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 classified as 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 2018, manufacturing and procurement quotas granted by the DEA were sufficient to meet our sales and inventory requirements on most products. In December 2018, the DEA reduced the manufacturing quota for the top six misused opioids that may be manufactured in the U.S. in calendar year 2019 by 10%. This includes oxycodone, hydrocodone, oxymorphone, hydromorphone, morphine, and fentanyl. The DEA has complete discretion to adjust or leave unchanged these quotas from time to time during the calendar year and to allocate manufacturing and procurement quota to manufacturers. A delay or refusal by the DEA to grant, in whole or in part, our quota requests for controlled substances could delay or result in stoppage of the manufacture of our marketed drug products, new product launches or the conduct of bioequivalence studies and clinical trials and could require us to allocate product among our customers.

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. In addition, as more fully described within 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, as part of a 2017 resolution of a DEA investigation, one of our subsidiaries agreed, among other things, to utilize all available transaction information to identify suspicious orders of any Mallinckrodt product and to report to the DEA when it concludes that chargeback data or other information indicates that a downstream registrant poses a risk of diversion.

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 $98.9 million, $91.6 million, $94.4 million and $18.0 million in fiscal 2018, 2017, 2016 and the three months ended December 30, 2016, respectively. The fiscal 2018 increase in provisions for Medicaid payments is primarily attributable to a $14.8 million increase associated with H.P. Acthar Gel offset by $7.0 million decrease in Specialty Generics products due to lower net sales in fiscal 2018 for generic and API products. The fiscal 2017 decrease in provisions for Medicaid payments is primarily attributable to an $8.5 million decrease associated with Specialty Generics products, due to lower net sales in fiscal 2017, which was partially offset by a $4.9 million increase associated with H.P. Acthar Gel because of increased net sales during fiscal 2017. Our business was also impacted by the annual fee on branded prescription pharmaceutical manufacturers and recorded expense of $18.4 million, $21.8 million, $23.3 million and $8.3 million in fiscal 2018, 2017, 2016 and the three months ended December 30, 2016, respectively, within selling, general and administrative expenses ("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 of 1977 ("FCPA") 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, distribution, 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 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 a 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 EMA, 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 branded 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) 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. Primarily due to past operations, operations of predecessor companies or past disposal practices, we have projects underway at a number of current and former manufacturing facilities as well as former disposal sites to investigate and remediate environmental contamination resulting from past operations, as further described in Item 3. Legal Proceedings and Note 20 to the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

We continue to be dedicated to environmental sustainability programs to minimize the use of natural resources and reduce the utilization and generation of hazardous materials from our manufacturing process and to remediate identified environmental concerns. 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 our 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 certain products in development, including oxycodone, oxymorphone, morphine, fentanyl and hydrocodone, are listed by the DEA as Schedule II

substances under the CSA. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation and the DEA limits the availability of narcotic raw materials and the production of APIs and generic Schedule II substances. As discussed in "Regulatory Matters" within this Item 1. Business, we must annually apply to the DEA for manufacturing and procurement 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 group purchasing organizations ("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 2018, 2017, 2016 and the three months ended December 30, 2016 were as follows:

	Fiscal Year Ended						Three Months Ended	
	December 28, 2018		December 29, 2017		September 30, 2016		December 30, 2016	
CuraScript, Inc.	35	%	40	%	38	%	43	%
McKesson Corporation	*		*		12	%	10	%

* 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 28, 2018, we had 12 manufacturing sites, including eight located in the U.S., as well as sites in Canada, Ireland and Japan, which handle production, assembly, quality assurance testing, packaging and sterilization of products for our Specialty Brands and Specialty Generics and Amitiza segments. Approximately 90%, 7% and 3% of our manufacturing production (as measured by cost of production) was performed within the U.S., Canada and Japan, respectively, in fiscal 2018.

As of December 28, 2018, we maintained distribution centers in nine 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 and Therakos products.

Backlog

Our backlog represents firm orders as well as estimated revenue from contracts that are expected to be recognized in the future related to performance obligations that are unsatisfied or partially unsatisfied as of December 28, 2018. As of December 28, 2018, our backlog was 13.0% of net sales, more than half of which is expected to be recognized as revenue in fiscal 2019.

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 the lack of warm temperatures that may exacerbate certain medical conditions. In addition, we have historically experienced lower operating cash flows during the first calendar quarter in which we pay annual employee compensation. 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 typically 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 28, 2018, we had approximately 3,700 employees, approximately 1,600 of which support the Specialty Generics and Amitiza segment. Of our total employees, approximately 3,100 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, 2019, and current positions of our executive officers.

Name	Age	Title
Mark Trudeau	57	President, Chief Executive Officer and Director
Mark Casey	55	General Counsel
Matthew Harbaugh	48	President, Specialty Generics
George Kegler	63	Executive Vice President and Chief Financial Officer, Interim
Hugh O'Neill	55	Executive Vice President and Chief Commercial Officer
Steven Romano, MD	59	Executive Vice President and Chief Scientific Officer
Dagmar Rosa-Björkeson	55	Chief Strategy and Corporate Development Officer
Dr. Frank Scholz	50	Executive Vice President and Chief Operations and Digital Innovation Officer
Karen Sheehy	57	Chief Compliance Officer
Ian Watkins	56	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 has been President, Chief Executive Officer and a director since June 2013. In anticipation of our spin transaction with Covidien plc, Mr. Trudeau joined Covidien in February 2012 as a Senior Vice President and President of its Pharmaceuticals business. He joined Covidien from Bayer HealthCare Pharmaceuticals LLC USA, the U.S. healthcare business of Bayer AG, where he served as Chief Executive Officer. He simultaneously served as President of Bayer HealthCare Pharmaceuticals, the U.S. organization of Bayer’s global pharmaceuticals business. In addition, he served as Interim President of the global specialty medicine business unit from January to August 2010. Prior to joining Bayer in 2009, Mr. Trudeau headed the Immunoscience Division at Bristol-Myers Squibb ("BMS"). During his 10-plus years at BMS, 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.

Mark Casey is our General Counsel, a role he assumed in February 2018. He has executive responsibility for all legal functions, including those related to litigation, intellectual property, environmental and regulatory matters, and mergers and acquisitions. Mr. Casey is also responsible for the Company’s government affairs, policy and patient advocacy functions. Prior to joining Mallinckrodt, he served as Senior Vice President, General Counsel & Secretary of Idera Pharmaceuticals from June 2015 to January 2018. Mr. Casey also served as Senior Vice President, Chief Administrative Officer, General Counsel & Secretary of Hologic, Inc. ("Hologic") from March 2012 to December 2014, and as Senior Vice President, General Counsel & Secretary at Hologic from October 2007 to February 2012. Mr. Casey began his career as a patent attorney for the Digital Equipment Corporation and for EMC Corporation, and served as Senior Patent Counsel for two years at Boston Scientific, after which he progressed to Chief Patent Counsel and Deputy General Counsel for Cytyc Corporation.

Matthew Harbaugh has been our President, Specialty Generics since May 2018, with executive responsibility for the Company's specialty generics and API products. Until December 2018, he also served as our Executive Vice President and Chief Financial Officer, a position to which he was named in 2013. 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 Company ("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.

George Kegler is our Executive Vice President and Chief Financial Officer, Interim, a role he assumed in December 2018. He has executive responsibility for the global finance function. Since 2013, Mr. Kegler has served as a Vice President of Finance for various businesses within Mallinckrodt, and served as interim President of the Company's Specialty Generics business in 2016. Prior to joining Mallinckrodt, from 2008 to 2012 he served as the Chief Financial Officer for Convatec, a private equity-owned company that was originally part of Bristol-Myers Squibb. Prior to that, he worked in various finance roles within Bristol-Myers Squibb including commercial, international, technical operations, and R&D, as well as the Assistant Controller of Internal Controls.

Hugh O'Neill is our Executive Vice President and Chief Commercial Officer. He has executive responsibility for the Company’s Specialty Brands products, directly managing all commercialization efforts and broad market access activities, as well as new product launch execution for assets in Mallinckrodt’s near-term development portfolio. From April 2015 to May 2018, Mr. O’Neill served as our Executive Vice President and President, Autoimmune and Rare Diseases, and 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 Inc.

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 R&D, medical affairs and regulatory affairs functions. Dr. Romano is a board-certified psychiatrist with more than 20 years of experience in the pharmaceutical industry. Previously, Dr. Romano spent 16 years at Pfizer, Inc. where he held a series of senior medical and R&D roles of increasing responsibility, culminating with his role as Senior Vice President, Head of 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 an additional six years.

Dagmar Rosa-Björkeson is our Chief Strategy and Corporate Development Officer, a position she assumed in April 2018. She has responsibility for corporate and therapeutic area strategy, business development, and the new product commercialization function. From May 2017 to September 2017, she served as our Senior Vice President, Autoimmune and Rare Diseases, and from September 2017 to April 2018, she served as our Senior Vice President, New Product Commercialization. Before joining Mallinckrodt, Ms. Rosa-Björkeson served as Executive Vice President and President, Biosimilars at Baxalta from 2014 to 2016. Prior to that she held roles of increasing responsibility at Novartis over the course of 17 years, most recently Vice President, Head of Multiple Sclerosis, U.S.; Vice President, Business Development and Licensing, U.S.; and Vice President, Respiratory, U.S.

Dr. Frank Scholz is our Executive Vice President and Chief Operations and Digital Innovation Officer. His responsibilities include global branded manufacturing operations, quality and supply chain functions; the Company’s contract manufacturing subsidiary; information technology and digital innovation; procurement; commercial alliance management; enterprise analytics; and strategic program management for the Company. He joined Mallinckrodt in March 2014 as Senior Vice President of Global Operations, was named Executive Vice President of Global Operations and President, Specialty Generics in September 2016, and assumed his current role in May 2018. Prior to joining Mallinckrodt, Dr. Scholz was a partner with McKinsey & Co ("McKinsey"), 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. She has executive responsibility for global corporate compliance and is the head of Mallinckrodt's compliance leadership team. Ms. Sheehy joined

Mallinckrodt from Sanofi S.A. where she worked for more than 16 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.

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 has also recently assumed responsibility for the Company's communications. 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 plc (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. SEC. Our reports filed with, or furnished to, the SEC are 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 any failure to comply with such laws and regulations, including any 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 our 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 us 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 various 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 certain obligations 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 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 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 intangible assets, which were $8,282.8 million at December 28, 2018. At least annually, we review the carrying value of our 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 intangible assets include, but are not limited to, a significant adverse change in the business climate or the legal or regulatory environment.

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 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 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, results of operation or cash flows 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 additional patents, which expire at various dates through 2036, including patents 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 in the Warnings and Precautions sections of the Inomax label. Other patents are 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 product 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. While Praxair received FDA approval of their ANDA for their Noxivent nitric oxide and clearance of their 510(k) for their NOxBOXi device on October 2, 2018, the Noxivent product received an AA-rating and the Noxivent label states that Noxivent must be delivered using the NOxBOXi device. An adverse outcome in the appeal of the Praxair litigation decision ultimately could result in the launch of a competitive nitric oxide product 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 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 a UVA light activated drug, UVADEX, followed by UVA radiation in the photopheresis instrument, prior to being returned to the patient. Patents related to the methoxsalen composition have

expired. Therakos historically manufactured 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"). While we no longer manufacture the UVAR XTS system, disposable, sterile kits are still supplied to customers for 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 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.

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 healthcare industry has been under increasing scrutiny from governments, legislative bodies and enforcement agencies related to sales, marketing and pricing practices, 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 OIG within the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the FDCA, the False Claims Act, the Prescription Drug Marketing Act,

anti-kickback laws, data and patient privacy laws, export and import laws, consumer protection 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 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 U.S. 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 healthcare 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.

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.

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.

The DEA regulates the availability of controlled substances, including 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 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 in the Schedule II category 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 needs. In 2018, 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 2018 by 20% and could take similar actions in the future. In December 2018, the DEA reduced the amount of the six most frequently misused opioids that may be manufactured in the U.S. in calendar year 2019 by an average of 10% as compared to the 2018 amount and could take similar actions in the future. 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.

Governmental investigations, inquiries, and regulatory actions and lawsuits brought against us by government agencies and private parties with respect to our historical commercialization of opioids could adversely affect our business, financial condition, results of operations and cash flows.

As a result of greater public awareness of the public health issue of opioid abuse, there has been increased scrutiny of, and investigation into, the commercial practices of opioid manufacturers by state and federal agencies. We, along with other opioid manufacturers, have been the subject of federal and state government investigations and enforcement actions, focused on the misuse and abuse of opioid medications in the U.S. Similar investigations may be initiated in the future.

In addition, a significant number of lawsuits have been filed against us, other opioid manufacturers, distributors, and others in the supply chain by cities, counties, state Attorney's General and private persons seeking to hold us and others accountable for opioid misuse and abuse. The lawsuits assert a variety of claims, including, but not limited to, public nuisance, negligence, civil conspiracy, fraud, violations of the Racketeer Influenced and Corrupt Organizations Act (“RICO”) or similar state laws, violations of state CSA or state False Claims Act, product liability, consumer fraud, unfair or deceptive trade practices, false advertising, insurance fraud, unjust enrichment and other common law and statutory claims arising from defendants’ manufacturing, distribution, marketing and promotion of opioids and seek restitution, damages, injunctive and other relief and attorneys’ fees and costs. The claims generally are based on alleged misrepresentations and/or omissions in connection with the sale and marketing of prescription opioid medications and/or an alleged failure to take adequate steps to prevent abuse and diversion. Other parties may file

similar lawsuits against us in the future.

As a company that first began processing opioids in the 1890s, we understand the utility of these products and that they are safe and effective when taken as appropriately prescribed. We are deeply committed to diversion control efforts, have sophisticated systems in place to identify suspicious orders, and engage in significant due diligence and ongoing monitoring of customers. While we are vigorously defending ourselves in these matters, the nature and scope of these matters is unique, and current public perceptions of the public health issue of opioid abuse may present challenges to favorable resolution of these claims. Accordingly, it is not feasible to predict the ultimate outcome of these investigations, enforcement actions and lawsuits. The allegations against us may negatively affect our business in various ways, including through harm to our reputation. We will continue to incur significant legal costs in defending these matters and could in the future be required to pay significant amounts as a result of fines, penalties, settlements or judgments, potentially in excess of established accruals. We may be unable to obtain or maintain insurance in the future on acceptable terms or with adequate coverage against potential liabilities or other losses. The resolution of, or increase in accruals for, one or more of these matters could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In addition, legislative, regulatory or industry measures to address the misuse of prescription opioid medications may also affect our business in ways that we are not able to predict. For example, the State of New York enacted the Opioid Stewardship Act ("OSA"), which went into effect on July 1, 2018 and established an aggregate $100 million annual assessment on sales of certain opioid medications in New York. The OSA was successfully challenged, and on December 19, 2018, the U.S. District Court for the Southern District of New York ruled that the OSA was unconstitutional and enjoined its enforcement. On January 17, 2019, the State of New York appealed this ruling. The litigation is still pending and the New York state legislature could take action to amend the law in such a way that its constitutionality is not an issue. Furthermore, other states are considering similar legislation that could require entities to pay an assessment or tax on the sale or distribution of opioid medications in those states and may vary in the assessment or tax amounts and the means of calculation from the OSA. If other state or local jurisdictions successfully enact such legislation and we are not able to mitigate the impact on our business through operational changes or commercial arrangements, such legislation in the aggregate may have a material adverse effect on our business, financial condition, results of operations and cash flows. See the risk factor "Extensive laws and regulations govern the industry in which we operate, and any failure to comply with such laws and regulations, including any changes to those laws and regulations may materially adversely affect us" for more information.

Furthermore, in the current climate, stories regarding prescription drug abuse and the diversion of opioids and other controlled substances are frequently in the media. Unfavorable publicity regarding the use or misuse of opioid drugs, the limitations of abuse-deterrent formulations, the ability of drug abusers to discover previously unknown ways to abuse our products, public inquiries and investigations into prescription drug abuse, litigation, or regulatory activity regarding sales, marketing, distribution or storage of opioids could have a material adverse effect on our reputation and impact on the results of litigation.

Finally, various government entities, including Congress, state legislatures or other policy-making bodies have in the past and may in the future hold hearings, conduct investigations and/or issue reports calling attention to the opioid crisis, and may mention or criticize the perceived role of manufacturers, including us, in the opioid crisis. Similarly, press organizations have and likely will continue to report on these issues, and such reporting may result in adverse publicity for us, resulting in reputational harm.

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 two of our distributors that supply our products to many end user customers, 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 GPOs, at commercially reasonable levels;
- whether the DOJ or other 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, and we may be negatively impacted by any changes to, 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. Our ability to commercialize our products depends, in part, on the extent to which reimbursement for the

costs of these products is available from government healthcare programs, such as Medicaid and Medicare, private health insurers and others. We cannot be certain that, over time, third-party reimbursements for our products will be adequate for us to maintain price levels sufficient for realization of an appropriate return on our investment. 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 35% of our net sales for fiscal 2018. 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, or payers not to reimburse the drug, which could negatively impact our business.

Our net sales of H.P. Acthar Gel, which have and are expected to comprise a significant portion of our overall product portfolio, could be negatively impacted by the level of clinical data available on the product. 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 FDCA. 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 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 MS and IS 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 MS, RA, FSGS, symptomatic sarcoidosis, uveitis and systemic lupus erythematosus. We also initiated a Phase 2 clinical trial for a potential new indication in ALS. 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 us 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 what was our Specialty Generics segment in fiscal 2015, additional competitors entered the marketplace for several of these products and prices subsequently decreased substantially. If customers do not maintain or increase existing sales volumes, 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 any restructuring activities we may undertake and such restructuring activities may adversely affect our business.

From time to time, we may 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 initially anticipated when such restructuring activities were

initiated. 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 such 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, experience 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. 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 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. 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, such as those brought against us related to our sale of opioids, 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.

Our operations expose us to the risk of violations of applicable health, safety and environmental laws and regulations and related 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 28, 2018, it was probable that we would incur remediation costs in the range of $36.4 million to $86.5 million. We also concluded that, as of December 28, 2018, the best estimate within this range was $61.8 million. For further information on our environmental obligations, refer to Item 3. Legal Proceedings and

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. 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 our industry, and we may not be able to continue to attract and retain the qualified personnel necessary for the development or operation 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 FCPA 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;
- potential inability to sell products into certain countries given the delay of foreign governments in responding to changes in our U.S. business licensing;
- political and economic instability, including the impact of the 2016 referendum by British voters to exit the E.U. (commonly known as Brexit) and the related uncertainties;
- the unpredictability of U.S. trade policy, including Section 301 tariffs and U.S. trade relations with other countries, that may increase raw material cost or impact our ability to obtain the raw materials we need to manufacture our products and impact our ability to sell our products outside of the U.S.;
- 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.

Our business depends on the continued effectiveness and availability of our information technology infrastructure, and failures of this infrastructure could harm our operations.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. To remain competitive in our industry, we must employ information technologies to support manufacturing processes, quality processes, distribution, financial reporting, as well as R&D and regulatory applications that capture, manage and analyze the

large streams of data generated in our clinical trials, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also 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.

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 all of our 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.

We have identified a material weakness in our internal control over financial reporting which could, if not remediated, adversely affect our business or the market price of our ordinary shares.

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 GAAP. As disclosed in Part II, Item 9A of this Annual Report on Form 10-K, our management identified a material weakness in our internal control over financial reporting related to review and approval controls over future cash flow forecasts used to develop certain management estimates, including those related to goodwill and other intangible assets. This control deficiency did not result in a material misstatement of our current or prior period consolidated financial statements. As a result of this material weakness, our management concluded that our internal control over financial reporting was not effective as of December 28, 2018. We are actively engaged in developing a remediation plan designed to address this material weakness. If our remedial measures are insufficient to address the material weakness, or we are otherwise unable to maintain effective internal control over financial reporting or disclosure controls and procedures, our ability to record, process and report financial information accurately, and to prepare financial statements within required time periods, could be adversely affected, which could subject us to litigation or investigations requiring management resources and payment of legal and other expenses and could result in negative publicity or other negative actions that could harm investor confidence in our financial statements. If any or all of

these events occur, it could have a material adverse effect on our business, financial condition, results of operations and cash flows or adversely affect the market price of our ordinary shares.

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 our separation from Covidien, certain conditions to the distribution and provisions governing the relationship between us and Covidien following such 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 28, 2018, total debt principal was $6,156.7 million.

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 28, 2018, we had $2,210.8 million outstanding variable-rate debt on our senior secured term loans, $220.0 million outstanding on our revolving credit facility and $250.0 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 us. Although we may enter into interest rate swaps, involving the exchange of floating for fixed-rate interest payments, to reduce interest rate volatility, we cannot provide assurance that we will enter into

such arrangements or that they will successfully mitigate such interest rate volatility.

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

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

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

Risks Related to Tax Matters

Our status as a foreign corporation for U.S. federal tax purposes could be affected by a change in law.
We believe that, under current law, we are treated as a foreign corporation for U.S. federal tax purposes. However, changes in tax law, such as additional changes to the inversion rules in Internal Revenue Code ("IRC") Section 7874 or the U.S. Treasury Regulations promulgated thereunder or other Internal Revenue Service ("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, previous 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 previously issued 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 Directives ("ATAD I" and "ATAD II"), the Multilateral Convention to Implement Tax Treaty Related Measures to Prevent Base Erosion and Profit Shifting (“Multilateral Instrument”), Ireland’s Budget 2019 published in October 2018 announcing changes to the corporate tax code including implementation of certain provisions of ATAD I, 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.

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. and ratified by the U.K. in 2018, but not yet ratified by Ireland, 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.

A loss of a major tax dispute or a challenge to our operating structure or intercompany pricing policies could result in a higher tax rate on our worldwide earnings, which could result in a material adverse effect on our financial condition and results of operations.
Income tax returns that we file are subject to review and examination. We recognize the benefit of income tax positions we believe are more likely than not to be sustained upon challenge by a tax authority. If any tax authority successfully challenges our operational structure, intercompany pricing or financing policies; if the terms of certain income tax treaties are interpreted in a manner that is adverse to our structure; or if we lose a material tax dispute in any country; our effective tax rate on our worldwide earnings could increase substantially and result in a material adverse effect on our financial condition.

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 approved by shareholders at our 2018 Annual General Meeting is due to expire on the earlier of our 2019 Annual General Meeting or August 16, 2019 unless renewed by shareholders for a further period. We anticipate seeking the renewal of this authority at our 2019 Annual General Meeting and in subsequent years, but we cannot guarantee that such renewal will always be approved. Additionally, subject to specified exceptions, including as opt-out approved by a shareholder vote, Irish law grants statutory pre-emptive rights to existing shareholders to subscribe for new issuances of shares for cash. An opt-out was approved by shareholders at our 2018 Annual General Meeting and is due to expire on the earlier of our 2019 Annual General Meeting or August 16, 2019, unless renewed for a further period. We anticipate seeking the renewal of this opt-out at our 2019 Annual General Meeting and in subsequent years but 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:

- market reaction to our proposed spin-off of the Specialty Generics and Amitiza business;
- 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.

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Risks Related to the Separation of the Specialty Generics and Amitiza Business

The proposed Separation of the Specialty Generics and Amitiza business is subject to various risks and uncertainties, and may not be completed on the terms or timeline currently contemplated, if at all.

On December 6, 2018, we announced our plan to spin off our Specialty Generics and Amitiza business. The Separation, which is expected to be completed in the second half fiscal 2019, is subject to customary conditions, including final approval by our board of directors, an opinion from tax counsel regarding the treatment of the spin-off as generally tax-free for U.S. federal income tax purposes to Mallinckrodt shareholders, and the SEC declaring the Form 10 registration statement effective. There can be no assurance that the Separation of the Specialty Generics and Amitiza business will be completed. Unanticipated developments in the proposed Separation, including, but not limited to, with respect to covenant waivers, regulatory approvals or clearances, receipt of a favorable ruling from the IRS, uncertainty of the financial markets and challenges in establishing infrastructure or processes, could delay or prevent the completion of the proposed Separation or cause the proposed Separation to occur on terms or conditions that are different from those currently expected.

The proposed Separation of the Specialty Generics and Amitiza business may be more expensive or challenging than anticipated, which may materially adversely affect our business.

Executing the proposed Separation will require us to incur costs, and could distract the attention of our senior management and key employees, which could disrupt operations and result in the loss of business opportunities, which could adversely affect our business, financial condition, and results of operations. We may also experience increased difficulties in attracting, retaining and motivating key employees during the pendency of the Separation and following its completion, which could harm our financial position, results of operations and cash flows.

We may not achieve some or all of the expected benefits of the Separation, and the Separation may materially adversely affect our business.

Even if the proposed Separation is completed, we may not realize the full strategic and financial benefits expected to result from the Separation, or the realization of such benefits may be delayed or not occur at all. The Separation is expected to provide the following benefits, among others:

- the ability of each company to focus on its own strategic and operational plans and capital structure;
- an appropriate capital structure for each company;
- a distinct investment identity allowing investors to evaluate the merits, performance and future prospects of us separately from the Specialty Generics and Amitiza business; and
- more effective equity-based compensation and currency for acquisitions.

We may not achieve these and other anticipated benefits for a variety of reasons, including, among others that: (a) the Separation will require significant amounts of management's time and effort, which may divert management's attention from operating and growing our businesses (b) following the Separation, we may be more susceptible to market fluctuations and other adverse events (c) following the Separation, our business will be less diversified than prior to completion of the Separation and (d) the actions required to separate the respective businesses could disrupt our operations. If we fail to achieve some or all of the benefits expected to result from the Separation, or if such benefits are delayed, it could have a material adverse effect on our financial position, results of operations and cash flows. There can be no assurance that the combined value of the shares of the two publicly traded companies following the completion of the proposed Separation will be equal to or greater than what the value of our ordinary shares would have been had the proposed Separation not occurred.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal executive offices are located at a facility in Staines-Upon-Thames, U.K. 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 and Amitiza headquarters and technical development center in Webster Groves,

Missouri. As of December 28, 2018, we owned a total of 11 facilities in the U.S., Canada, Ireland, and Japan. Our owned facilities consist of approximately 2.3 million square feet, and our leased facilities consist of approximately 1.1 million square feet. We have 12 manufacturing sites: one in Canada; one in Ireland; two in Japan; and eight 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 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, which is incorporated by reference into this Part I, Item 3., for a description of the litigation, legal and administrative proceedings as of December 28, 2018.

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."
There were approximately 83,505,008 shareholders of record of our ordinary shares as of February 22, 2019.

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 28, 2018, we repurchased 934 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)
9/29/2018 - 10/26/2018	116	$ 29.59	—	$ 564.2
10/27/2018 - 11/30/2018	818	27.37	—	564.2
12/1/2018 - 12/28/2018	—	—	—	564.2
9/29/2018 - 12/28/2018	**934**	**27.65**		

Performance Graph

The following performance graph and related information shall not be deemed "soliciting material" or to be "filed" with the 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 on September 27, 2013 in each of (a) Mallinckrodt ordinary shares, (b) the Russell 1000 index and (c) the NYSE Pharmaceutical Index. This graph covers the period from September 26, 2014 through December 28, 2018.

Comparison of Cumulative Total Return

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

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 SEC within 120 days after December 28, 2018.

Item 6. Selected Financial Data.

The consolidated statements of income data for fiscal 2018, 2017, and 2016 and the three months ended December 30, 2016, and the consolidated balance sheet data as of December 28, 2018 and December 29, 2017 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 2015 and 2014 and the consolidated balance sheet data as of December 30, 2016, September 30, 2016, September 25, 2015 and September 26, 2014 were derived from our audited consolidated financial statements that are not included in this Annual Report on Form 10-K.

This selected financial information should be read in conjunction with our consolidated 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], [2]					Three Months Ended [2]
	December 28, 2018	December 29, 2017	September 30, 2016	September 25, 2015	September 26, 2014	December 30, 2016
Consolidated and Combined Statement of Income Data:						
Net sales	$3,215.6	$3,221.6	$3,380.8	$2,923.1	$1,650.3	$829.9
Gross profit	1,471.2	1,657.5	1,857.6	1,624.4	884.5	446.7
Research and development expenses	361.1	276.9	261.2	202.7	140.5	66.1
Operating (loss) income	(3,720.9)	492.9	633.1	362.4	42.9	(158.6)
(Loss) income from continuing operations before income taxes	(4,052.0)	61.6	233.4	107.3	(34.6)	(298.5)
Loss (income) from continuing operations	(3,621.9)	1,771.2	489.0	236.6	(22.0)	(176.8)
Share Data:						
Basic (loss) income from continuing operations per share	$(43.12)	$18.13	$4.42	$2.03	$(0.34)	$(1.67)
Diluted (loss) income from continuing operations per share	(43.12)	18.09	4.39	2.00	(0.34)	(1.67)
Cash dividends per ordinary share	—	—	—	—	—	—
Consolidated Balance Sheet Data:						
Total assets	$10,877.3	$15,280.9	$15,498.7	$16,404.1	$12,787.3	$15,206.3
Long-term debt	6,069.2	6,420.9	5,788.7	6,474.3	3,874.0	5,880.8
Shareholders' equity	2,887.3	6,522.0	5,270.7	5,311.2	4,958.0	4,984.3

(1) Fiscal 2016 included 53 weeks. All other fiscal years presented include 52 weeks. Refer to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K 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 28, 2018, December 29, 2017 and September 30, 2016 and the three months ended December 30, 2016.

(2) Financial data for all periods has been adjusted to reflect our change in accounting for pension and postretirement costs with the adoption of Accounting Standard Update ("ASU") 2017-07. See Note 4 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Item 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 within 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.

Fiscal Year

We report our results based on a "52-53 week" year ending on the last Friday of December. Fiscal 2018 and 2017 each consisted of 52 weeks and 2016 consisted of 53 weeks. 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.

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.

As a result of the planned Separation, discussed further below, we have identified two reportable segments that align with the operations of the two independent publicly traded companies anticipated post-separation: (1) Specialty Brands and (2) Specialty Generics and Amitiza, which are further described below:

- *Specialty Brands* includes innovative specialty pharmaceutical brands; and
- *Specialty Generics and Amitiza* includes niche specialty generic drug products, APIs and Amitiza.

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

Significant Events

Separation

On December 6, 2018, we announced our plans to spin off a new company consisting of the Specialty Generics business and the Amitiza product to our shareholders. The Separation is expected to create two independent, appropriately capitalized, publicly traded companies – one focused on innovative specialty pharmaceutical brands, the other concentrated primarily in niche specialty generic products and API manufacturing – each positioned to optimize future success as they pursue independent growth strategies. We anticipate that the transaction will be in the form of a distribution of new publicly traded stock in the new company that is intended to be generally tax-free for U.S. federal income tax purposes to our shareholders. Completion of the transaction is expected to be subject to certain conditions, including, among others, receipt of regulatory approvals, assurance as to the tax-free status of the spin-off of the business to our shareholders, the effectiveness of a Form 10 registration statement to be filed with the SEC and final approval by our Board of Directors. We currently expect completion of the transaction in the second half of 2019; however, there can be no assurance regarding the ultimate timing of the proposed transaction or that the transaction will be completed.

Beginning in the first quarter through the third quarter of fiscal 2018, the historical financial results attributable to "the Specialty Generics Disposal Group" were reflected in our interim condensed consolidated financial statements as

discontinued operations. The Specialty Generics Disposal Group included (1) our Specialty Generics business comprised of what was our Specialty Generics segment in fiscal 2017, with the exception of BioVectra - our wholly-owned subsidiary that operates a contract manufacturing business in Canada; (2) certain of our non-promoted brands business, which was previously reflected in our Specialty Brands segment; and (3) our ongoing, post-divestiture supply agreement with the acquirer of the CMDS business, which was previously reflected in our Other non-operating segment. As a result of the Separation announcement, the Specialty Generics

Disposal Group no longer met the requirements to be classified as held-for-sale, and the historical financial results attributable to the Specialty Generics Disposal Group are now currently reflected in our consolidated financial statements as continuing operations for fiscal 2018.

In accordance with U.S. GAAP, depreciation and amortization are not recorded during the period in which a disposal group is classified as held-for-sale, thus our financial results during the first three quarters did not include $17.7 million and $6.8 million of depreciation and amortization expense, respectively, related to the Specialty Generics Disposal Group. During the fourth quarter of 2018, the Specialty Generics Disposal Group was reclassified to held and used and measured at its carrying amount before it was classified as held-for-sale, adjusted for depreciation and amortization expense that would have been recognized had the disposal group been continuously classified as held and used. The total adjustment of $24.5 million was reflected in loss from continuing operations during the fourth quarter of 2018, the period in which the held-for-sale criteria were no longer met.

Separation Costs

During fiscal 2018, we incurred $6.0 million in costs related to the separation of our Specialty Generics and Amitiza segment. These costs, which are included in SG&A, primarily relate to professional fees and incremental costs incurred to build out the corporate infrastructure of the new company. We expect to continue to incur costs related to the Separation in fiscal 2019.

Acquisitions

In February 2018, we acquired Sucampo Pharmaceuticals, Inc. ("Sucampo") through the acquisition of all the outstanding common stock of 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 term loan, a $900.0 million borrowing under our revolving credit facility and cash on hand.

Through this acquisition, we acquired VTS-270, a Phase 3 development product for Niemann-Pick Type C, a complicated, ultra-rare neurodegenerative disease that typically presents in childhood and is ultimately fatal. Also acquired was an option to exercise a collaborative agreement with CPP associated with the development of CPP-1X/sulindac, a Phase 3 development product for FAP.

Subsequent to this acquisition, we also produce lubiprostone for use in Amitiza capsules, a branded gastrointestinal product approved in the U.S. and several other geographies. We own the registrations and manufacturing rights for Amitiza, and contract with third parties for commercialization of the product in Japan and the U.S. in exchange for royalties on net sales of the product. Amitiza contributed net sales of $183.8 million for fiscal 2018, which includes both royalty revenue and product sales. Our cost of sales for fiscal 2018 included $118.8 million of expense recognition associated with the fair value adjustments of acquired inventory and $62.9 million of amortization associated with intangibles recognized from this acquisition. Included within SG&A in our consolidated statement of income was $5.2 million and $4.2 million of transaction costs incurred during fiscal 2018 and 2017, respectively, associated with our acquisition.

Divestitures

In March 2018, we completed the sale of a portion of our Hemostasis business, inclusive of its PreveLeak™ Surgical Sealant ("PreveLeak") and RECOTHROM® Thrombin topical (Recombinant) ("Recothrom") products to Baxter International Inc. ("Baxter") for approximately $185.0 million, with a base payment of $153.0 million, inclusive of existing inventory and subject to a closing inventory adjustment, with the remainder in potential future milestones. Baxter assumed other expenses, including contingent liabilities associated with PreveLeak. During fiscal 2018, we recorded a pre-tax loss on the sale of $0.8 million, which excluded any potential proceeds from the attainment of future milestones and reflected a post-sale closing inventory adjustment of $13.7 million. The financial results associated with the operations of PreveLeak and Recothrom are presented within continuing operations as this divestiture did not meet the criteria for discontinued operations classification.

2018 Annual Goodwill Impairment Assessment

We performed our 2018 annual goodwill impairment analysis for the Specialty Brands reporting unit as of the first day of the fourth quarter. Our 2018 annual assessment first considered our internally developed future cash flows, which reflect our overall strategy, future growth and value proposition. There continues to be a disparity between our anticipated future performance and present uncertainty reflected in our market capitalization, driven by a sustained decrease in our share price. We continue to believe that our share price has been adversely affected primarily by uncertainties regarding patient withdrawal issues impacting net sales

of H.P. Acthar Gel, ongoing Inomax patent litigation and the perceived value of our various pipeline products. Given the passage of time since first experiencing this substantial decline in our share price during the three months ended December 29, 2017 and the fact that the aforementioned uncertainties are not expected to be resolved in the near-term, our 2018 annual goodwill impairment analysis resulted in the recognition of a full goodwill impairment of $3,672.8 million.

MNK-1411

We perform the annual impairment analysis for our IPR&D assets as of the first day of the fourth quarter. As a result of this analysis, we recognized a full impairment on our IPR&D asset related to MNK-1411 of $218.3 million, primarily driven by lower than previously anticipated pricing assumptions. We continue to enroll patients in our Phase 2 trial as we assess future opportunities for this development program.

Reorganization of Intercompany Financing and Legal Entity Ownership

During fiscal 2018, we initiated a reorganization of our intercompany financing and associated legal entity ownership in response to the changing global tax environment. As a result, we recognized current income tax expense of $25.5 million and a deferred income tax benefit of $281.5 million with a corresponding reduction to net deferred tax liabilities. The reduction in net deferred tax liabilities is comprised of a $310.6 million decrease in interest-bearing deferred tax obligations, a $58.9 million increase in deferred tax liabilities associated with investment in partnership, a $58.9 million decrease in deferred tax liabilities predominately associated with intangible assets, a $39.7 million increase related to a change in valuation allowances, a $9.3 million decrease in various other net deferred tax liabilities, and a $1.3 million decrease associated with generation of tax loss and credit carryforwards.

On January 26, 2019, we completed a reorganization of our intercompany financing and associated legal entity ownership in response to the changing global tax environment. We initiated the reorganization during the three months ended September 28, 2018 and continued the reorganization during the three months ended December 28, 2018.

During the three months ending March 29, 2019, we expect to recognize a net income tax benefit of $125.0 million to $175.0 million which will serve to reduce our net deferred tax liabilities by a similar amount. The reduction to net deferred tax liabilities is expected to be comprised predominantly of the elimination of the December 28, 2018 balance of interest-bearing U.S. deferred tax liabilities of $227.5 million offset by a decrease to other deferred tax assets. The elimination of the interest-bearing deferred tax obligation will also eliminate the annual Internal Revenue Code section 453A interest expense.

Stannsoporfin

On May 3, 2018, in a joint meeting, the FDA Gastrointestinal Drugs Advisory Committee and the Pediatric Advisory Committee (the "Advisory Committee") recommended that the risk benefit profile of our stannsoporfin IPR&D product does not support approval for the treatment of newborns ≥35 weeks of gestational age with indicators of hemolysis who are at risk of developing hyperbilirubinemia (severe jaundice). On August 9, 2018, we received a complete response letter from the FDA related to our NDA for stannsoporfin, which provided guidance regarding areas of further evaluation for resubmitting the stannsoporfin NDA.

In January 2019, we participated in a Type A meeting with the FDA, where we had meaningful discourse regarding the population, trial design and other issues outlined in the complete response letter related to stannsoporfin. We plan to refine the pivotal registration trial design and work toward submission of a Special Protocol Assessment later in 2019. We are optimistic that we may advance a new therapy specifically targeting a higher risk population of infants suffering from severe hyperbilirubinemia and who are failing more intensive phototherapy intervention. We will continue to assess the impact of any changes to planned revenue or earnings on the fair value of the associated IPR&D asset of $113.5 million included within intangible assets, net on the consolidated balance sheets as of December 28, 2018.

As part of the acquisition of InfaCare Pharmaceutical Corporation ("InfaCare" or "the InfaCare Acquisition") in September 2017, we 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. Due to recent developments and discussions with the FDA, the timing of the development has shifted outward. During fiscal 2018, we recognized a $35.0 million fair value adjustment due to this shift in timing and its impact on the achievement of milestones per the purchase agreement. As of December 28, 2018, the fair value of the contingent consideration was zero after the aforementioned adjustment.

VTS-270

VTS-270 is our development product to treat Niemann-Pick Type C, a complicated, ultra-rare neurodegenerative disease that typically presents in childhood and is ultimately fatal. In November 2018, we announced that the results of our recently completed registration trial for the product did not show a statistically significant separation from placebo. Neither the VTS-270 nor the placebo arm showed disease progression as would be expected for a neurodegenerative condition over 52 weeks of observation. We are in the process of evaluating this portion of the study in order to ensure the data was properly captured and of the highest quality. The FDA indicated to us at a Type A meeting in August 2018 that their view on the potential approvability will be based on the totality of data, not a single study or endpoint. Accordingly, our review of the data from the Phase 2b/3 trial, including the longer term open label portion, continues to proceed and is being assessed in combination with several other available data sources. We expect that a better understanding of the potential benefit of VTS-270 will emerge as we carefully consider the totality of data available and continue to work with the primary investigators and the FDA to determine the best path forward. We will continue to assess the impact of any changes to planned revenue or earnings on the fair value of the associated IPR&D asset of $274.5 million included within intangible assets, net on the consolidated balance sheet as of December 28, 2018.

Business Factors Influencing the Results of Operations

Products

Specialty Brands

Net sales of H.P. Acthar Gel for fiscal 2018 decreased $85.0 million, or 7.1%, to $1,110.1 million as the brand continues to recover from the residual impact of the previously reported patient withdrawal issues from fiscal 2017 while navigating growing payer scrutiny on overall specialty pharmaceutical spending. This is offset by strength in Ofirmev, Inomax and Therakos demand.

Specialty Generics and Amitiza

The Specialty Generics and API products have continued to experience customer consolidation and increased generic product approvals leading to increased competition, which has been partially offset by the net sales from Amitiza acquired during fiscal 2018. Net sales from the Specialty Generics and Amitiza segment was $909.4 million for fiscal 2018. After experiencing contraction over the last several years, the business is projected to return to growth in 2019, primarily driven by share recapture in specialty generic products.

The U.S. generic market is growing overall in volume, but has been declining in value over the past several years due to pricing pressure. Hydrocodone, oxycodone and other controlled substances products have experienced significant volume declines due to continued downward pressure on the use of opioids in the U.S. Despite this market contraction, acetaminophen and opioids are still viewed as the standard of care for many types of pain. Pain management represents the second largest therapeutic area in the U.S. based upon prescriptions dispensed, with pain medications accounting for approximately one out of every 11 dispensed prescriptions in 2018. We expect the decline in usage rates for opioids in the U.S. to continue, stabilizing at levels consistent with historical prescribing patterns and aligning with treatment guidelines being developed by the medical community. Globally, we expect the use of acetaminophen and opioids to trend with population rates for the foreseeable future.

Opioid Related Matters

As a result of the greater awareness of the public health issue of opioid abuse, there has been increased scrutiny of, and investigation into, the commercial practices of opioid manufacturers, distributors, and others in the supply chain by state and federal agencies. We, along with other opioid manufacturers, have been the subject of federal and state government investigations and enforcement actions, as well as lawsuits by private parties, focused on the misuse and abuse of opioid medications in the U.S. Similar investigations, lawsuits and other actions may be initiated in the future. We will continue to incur significant legal costs in defending these matters and could in the future be required

to pay significant amounts as a result of fines, penalties, settlements or judgments. Such litigation and related matters are described in Note 20 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

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 February 2018, our Board of Directors approved a $100.0 million to $125.0 million restructuring program

("the 2018 Mallinckrodt Program") designed to further improve our cost structure as we continue to transform our business. The utilization of the 2018 Mallinckrodt Program commenced during 2018 upon substantial completion of our 2016 restructuring program. There is no specified time period associated with the 2018 Mallinckrodt Program. During fiscal 2018, we incurred aggregate restructuring charges of $108.2 million under our restructuring programs. In addition, we have taken restructuring actions to generate synergies from our acquisitions. We currently have $119.8 million under our 2018 Mallinckrodt Program remaining to spend in future periods.

On January 8, 2018, we announced that we would discontinue the marketing of Raplixa® ("Raplixa") after an evaluation of strategic options. During fiscal 2018, we incurred restructuring expenses of $51.1 million under the 2016 Mallinckrodt Program, consisting primarily of contract termination costs related to the production of Raplixa. Amounts paid in the future may differ from the amount currently recorded.

Research and Development

We devote significant resources to R&D of products and proprietary drug technologies. During fiscal 2018, we incurred R&D expenses of $361.1 million. We expect to continue to pursue targeted investments in R&D activities, both for existing products and the development of new portfolio assets. We intend to focus our R&D investments in the specialty pharmaceuticals areas, specifically investments to support our Specialty Brands portfolio, where we believe there is the greatest opportunity for growth and profitability.

In April 2018 (the "Exercise Date"), we exercised the option under our collaborative agreement with CPP to negotiate terms of an exclusive license to commercialize CPP-1X/sulindac in North America. In addition, we provided CPP with a $10.0 million upfront R&D payment for expenses related to the FAP pivotal trial incurred during the "Negotiation Period," or the period from the Exercise Date through the execution of such license agreement. CPP shall return to us any portion of the R&D payment that is not utilized during the Negotiation Period. Of the $10.0 million upfront payment, $7.3 million was utilized during fiscal 2018 and recorded as R&D expense within the consolidated statement of income. The remaining $2.7 million was included in prepaid expenses and other current assets on the consolidated balance sheet as of December 28, 2018.

In August 2018, the license agreement with CPP was executed and we paid $5.0 million upfront with cash on hand and gained exclusive rights to develop and commercialize the product in North America, if approved. The agreement includes additional payments of up to $185.0 million dependent on developmental, regulatory and sales milestones, subject to reduction up to $15.0 million related to amounts provided by us in advance of entering into this agreement, and provides for both parties' reimbursement of R&D expenses from future profits. Following the commercialization of the product, we and CPP will share profits in accordance with the agreement. We will manage the development of the product in North America.

Results of Operations

Fiscal Year Ended December 28, 2018 Compared with Fiscal Year Ended December 29, 2017

Net Sales

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

	Fiscal Year Ended		
	December 28, 2018	December 29, 2017	Percentage Change
U.S.	$2,834.5	$ 2,899.0	(2.2)%
Europe, Middle East and Africa	256.8	242.3	6.0
Other	124.3	80.3	54.8
Net sales	$3,215.6	$ 3,221.6	(0.2)

Net sales in fiscal 2018 decreased $6.0 million, or 0.2%, to $3,215.6 million, compared with $3,221.6 million in fiscal 2017. This decrease was driven by our Specialty Brands segment primarily due to H.P. Acthar Gel, as the brand

continues to recover from the residual impact of the previously reported patient withdrawal issues from fiscal 2017 while navigating growing payer scrutiny on overall specialty pharmaceutical spending. In addition, we experienced lower net sales in Other branded products primarily due to the sale of Recothrom during the first quarter of 2018. These decreases were partially offset by strength in Ofirmev, Inomax and Therakos demand. Our Specialty Generics and Amitiza segment experienced an increase in net sales primarily due to our newly acquired Amitiza product, partially offset by increased competition and customer consolidation for the other products in this segment, which has resulted in downward pricing pressure. 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 2018 decreased $186.3 million, or 11.2%, to $1,471.2 million, compared with $1,657.5 million in fiscal 2017. Gross profit margin was 45.8% for fiscal 2018, compared with 51.4% in fiscal 2017. The decrease in gross profit and gross profit margin was primarily attributable to the amortization of the Amitiza intangible asset and expense recognition of inventory fair value adjustments associated with the product.

Selling, general and administrative expenses. SG&A expenses for fiscal 2018 were $834.1 million, compared with $849.7 million for fiscal 2017, a decrease of $15.6 million, or 1.8%. Fiscal 2018 included a $49.9 million decrease in fair value of the contingent consideration liabilities related to stannsoporfin and MNK-1411 and cost benefits gained from restructuring actions, including lower employee compensation costs and stock compensation expense. These decreases were partially offset by increased legal fees and provisions for settlement agreements. SG&A expenses were 25.9% of net sales for fiscal 2018 and 26.4% of net sales for fiscal 2017.

Research and development expenses. R&D expenses increased $84.2 million, or 30.4%, to $361.1 million in fiscal 2018, compared with $276.9 million in fiscal 2017. The increase was attributable to higher spend in the Specialty Brands segment, where our pipeline products are concentrated, including those pipeline products acquired in the past year. This increase was partially offset by lower spend in the Specialty Generics and Amitiza segment. 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 11.2% and 8.6% in fiscal 2018 and 2017, respectively.

Restructuring and related charges, net. During fiscal 2018, we recorded $108.2 million of restructuring and related charges, net, of which $5.2 million related to accelerated depreciation and was included in cost of sales and SG&A. The remaining $103.0 million was primarily attributable to contract termination costs related to the production of Raplixa, exiting certain facilities and employee severance and benefits across both of our segments and corporate functions. 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.

Non-restructuring impairment charges. Non-restructuring impairment charges were $3,893.1 million for fiscal 2018 primarily related to the $3,672.8 million full goodwill impairment and the $218.3 million full impairment related to our MNK-1411 intangible asset, both as previously mentioned. Non-restructuring impairment charges were $63.7 million for fiscal 2017 related to the Raplixa intangible asset, which resulted from lower than previously anticipated pricing assumptions.

Losses (gains) on divestiture. During fiscal 2018, we sold a portion of our Hemostasis business, inclusive of our PreveLeak and Recothrom products. As a result of this sale, we recorded a pre-tax loss of $0.8 million. In fiscal 2017, we recorded a $56.6 million pre-tax gain associated with the sale of our Intrathecal Therapy business.

Non-Operating Items

Interest expense and interest income. During fiscal 2018 and fiscal 2017, net interest expense was $362.0 million and $364.5 million, respectively. This decrease was primarily driven by a $3.6 million increase in interest income related to higher interest earned on our money market funds. This increase was partially offset by the $1.1 million increase in interest expense which includes an increase of $48.1 million due to our higher average outstanding debt balance in fiscal 2018 following the close of the Sucampo acquisition compared to fiscal 2017, partially offset by a $45.6 million decrease in interest accrued on deferred tax liabilities associated with outstanding installment notes primarily due to the reorganization of our legal entity ownership and the Tax Cuts and Jobs Act ("TCJA" or "U.S. Tax Reform") that reduced the interest-bearing U.S. deferred tax liabilities balance during late fiscal 2017.

Other income (expense), net. During fiscal 2018 and 2017, we recorded other income, net, of $30.9 million and other expense, net, of $66.8 million, respectively. Fiscal 2018 included royalty income of $15.5 million, a gain of $12.7 million on debt repurchases that aggregated to a total principal amount of $81.8 million, and a refund of $3.4 million of the initial cash contribution related to the settlement of remaining obligations of six defined benefit pension plans that were terminated during fiscal 2016. Fiscal 2017 included a $70.5 million charge from recognition of previously deferred losses on the settlement of obligations associated with the termination of six defined benefit pension plans. In addition, there was 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 non-service pension expense and other items, including gains and losses on intercompany financing, foreign currency transactions and related hedging instruments.

Benefit from income taxes. In fiscal 2018, we recognized an income tax benefit of $430.1 million on a loss from continuing operations before income taxes of $4,052.0 million. The fiscal 2018 income tax benefit was comprised of $112.8 million of current tax expense and $542.9 million of deferred tax benefit which was predominantly related to the reorganization of our intercompany financing and associated legal entity ownership and generation of net operating losses. In fiscal 2017, income tax benefit was $1,709.6 million on income from continuing operations before income taxes of $61.6 million. The fiscal 2017 income tax benefit was comprised of $38.1 million of current tax expense and $1,747.7 million of deferred tax benefit which was predominantly related to the reorganization of our legal entity ownership, TCJA and acquired intangibles. Our effective tax rate was 10.6% and negative 2,775.3% for fiscal 2018 and 2017, respectively. Our effective tax rate for fiscal 2018 was most significantly impacted by the recognition of $256.0 million tax benefit associated with the reorganization of our intercompany financing and associated legal entity ownership; partially offset by a decrease to tax benefit of $73.2 million associated with accrued income tax liabilities and uncertain tax positions. Further impacts include receiving $60.9 million of tax benefit associated with the $4,001.3 million of restructuring costs and non-restructuring impairment charges, $25.9 million of tax benefit primarily associated with U.S. tax credits, $2.7 million of tax benefit associated with $0.8 million of pre-tax loss associated with the sale of our PreveLeak and Recothrom assets, and $2.2 million of tax expense associated with $50.2 million of income from the decrease in the fair value of contingent consideration liabilities. Any remaining impacts were related to the impact of recent acquisitions and the reduction in the U.S. federal corporate statutory rate from U.S. Tax Reform. 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 of our legal entity ownership and $456.9 million of tax benefit associated with the TCJA. Further impacts included 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, and $13.8 million of tax benefit primarily associated with U.S. tax credits.

Income from discontinued operations, net of income taxes. We recorded income of $14.9 million and $363.2 million on discontinued operations, net of income taxes, during fiscal 2018 and 2017, respectively. During fiscal 2018, the income from discontinued operations included $13.6 million of income, net of tax, from the receipt of contingent consideration related to the sale of the Nuclear Imaging business. 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 remaining amounts in both periods represented various post-sale adjustments associated with our previous divestitures.

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		
	December 29, 2017	September 30, 2016	Percentage Change
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 and Amitiza 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, growth from Inomax and 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. 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 $200.1 million, or 10.8%, to $1,657.5 million, compared with $1,857.6 million in fiscal 2016. Gross profit margin was 51.4% for fiscal 2017, compared with 54.9% for fiscal 2016. The decrease in gross profit and gross profit margin was primarily attributable to channel consolidation and increased price competition in the Specialty Generics and Amitiza segment, contributing to a $241.9 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 $849.7 million, compared with $913.7 million for fiscal 2016, a decrease of $64.0 million, or 7.0%. Fiscal 2017 included 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 and professional fees. SG&A expenses were 26.4% of net sales for fiscal 2017 and 27.0% of net sales for fiscal 2016.

Research and development expenses. R&D expenses increased $15.7 million, or 6.0%, to $276.9 million in fiscal 2017, compared with $261.2 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 and Amitiza 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 7.7% 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 $37.6 million, of which $4.9 million related to accelerated depreciation and was included in cost of sales. The remaining $32.7 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 IPR&D 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 of our legal entity ownership 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 (expense), net. During fiscal 2017 and 2016, we recorded other expense, net, of $66.8 million and $16.4 million, 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 and 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 non-service pension expense and other 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 was comprised of $38.1 million of current tax expense and $1,747.7 million of deferred tax benefit which was predominantly related to the reorganization of our legal entity ownership, 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 was comprised of $120.8 million of current tax expense and $376.4 million of deferred tax benefit which was 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 of our legal

entity ownership 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.

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 December 30, 2016	December 25, 2015	Percentage Change
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 acquisition of three commercial stage topical hemostasis drugs from The Medicines Company ("the Hemostasis Acquisition"). These increases were partially offset by decreased net sales in the Specialty Generics and Amitiza 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 $4.5 million, or 1.0%, to $446.7 million, compared with $451.2 million during the three months ended December 25, 2015. The decrease in gross profit primarily resulted from a $37.2 million decrease in gross profit from the Specialty Generics and Amitiza 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 53.8% 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 $321.1 million, compared with $221.8 million for the three months ended December 25, 2015, an increase of $99.3 million, or 44.8%. 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"). The three months ended December 25, 2015, included $11.5 million of legal reserve accruals. The remaining $8.8 million increase from the three months ended December 30, 2016 compared with the three months ended December 25, 2015 is comprised of various minor increases and decreases. SG&A expenses were 38.7% of net sales for the three months ended December 30, 2016 and 27.3% 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, which represented 12.3% 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 $66.1 million during the three months ended December 30, 2016, compared with $61.3 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 and Amitiza segment and a $7.3 million impairment of a license associated with a product we 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 $49.1 million and during the three months ended December 25, 2015, we recorded other income, net, of $0.1 million. The three months ended December 30, 2016 included a $45.0 million charge associated with the recognition of previously deferred pension related losses upon lump sum distribution to current and former employees under our pension plan termination and the remaining amounts in both periods represented non-service pension expense and 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 the income tax benefit was comprised of $82.0 million of current tax expense and $203.7 million of deferred tax benefit which was 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 the income tax benefit was comprised of $17.6 million of current tax expense and $54.9 million of deferred tax benefit which was 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 our 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

As a result of the planned Separation, we reassessed our segments based on the financial information viewed by the CEO, who is our CODM, for the purposes of making resource allocation decisions and assessing the performance of the business. We have identified two reportable segments that align with the operations of the two independent publicly traded companies anticipated post-separation: (1) Specialty Brands and (2) Specialty Generics and Amitiza. Prior year amounts have been recast to conform to current presentation.

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, 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 28, 2018 Compared with Fiscal Year Ended December 29, 2017

Net Sales

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

	Fiscal Year Ended		
	December 28, 2018	December 29, 2017	Percentage Change
Specialty Brands	$2,306.2	$ 2,352.0	(1.9)%
Specialty Generics and Amitiza	909.4	869.6	4.6
Net sales	$3,215.6	$ 3,221.6	(0.2)

Specialty Brands. Net sales for fiscal 2018 decreased $45.8 million, or 1.9%, to $2,306.2 million, compared with $2,352.0 million for fiscal 2017. This decrease was primarily driven by decreases of $85.0 million or 7.1% and $52.4 million or 65.8% in net sales of H.P. Acthar Gel and Other product sales, respectively. The decrease in H.P. Acthar Gel net sales was driven by the residual impact of previously reported patient withdrawal issues from fiscal 2017 while navigating growing payer scrutiny on overall specialty pharmaceutical spending. The decrease in Other products was primarily attributable to a decrease of $42.9 million and $7.8 million of net sales related to the sale of Recothrom during the first quarter of 2018 and the Intrathecal Therapy business during the first quarter of 2017, respectively. These decreases were partially offset by increases of $39.4 million or 13.0%, $37.5 million or 7.4% and $16.3 million or 7.6% in net sales of Ofirmev, Inomax, and Therakos, respectively, driven by increased demand during the year.

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

	Fiscal Year Ended		
	December 28, 2018	December 29, 2017	Percentage Change
U.S.	$2,165.4	$ 2,216.9	(2.3)%
Europe, Middle East and Africa	79.8	73.0	9.3
Other	61.0	62.1	(1.8)
Net sales	$2,306.2	$ 2,352.0	(1.9)

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

	Fiscal Year Ended		
	December 28, 2018	December 29, 2017	Percentage Change
H.P. Acthar Gel	$1,110.1	$ 1,195.1	(7.1)%
Inomax	542.7	505.2	7.4
Ofirmev	341.9	302.5	13.0
Therakos	231.2	214.9	7.6
BioVectra	53.1	54.7	(2.9)
Other	27.2	79.6	(65.8)
Specialty Brands	$2,306.2	$ 2,352.0	(1.9)

Specialty Generics and Amitiza. Net sales for fiscal 2018 increased $39.8 million, or 4.6%, to $909.4 million, compared with $869.6 million for fiscal 2017. The increase in net sales was driven by net sales of $183.8 million from our newly acquired Amitiza product and an increase of $7.2 million in net sales of acetaminophen products compared to fiscal 2017. These increases were partially offset by decreases of $21.9 million and $19.4 million in net sales of oxycodone-related products and hydrocodone-related products, respectively. These decreases were due to increased competition and customer consolidation, which has resulted in downward pricing pressure. Other controlled substances products also decreased by $68.2 million or 16.6%, primarily attributable to a $31.2 million decrease in Methylphenidate ER due to the FDA's 2014 reclassification of these products to therapeutically inequivalent status. Other products also decreased $41.7 million or 42.2%, primarily due to a $33.8 million decrease from our ongoing supply agreement with the acquirer of our CMDS business.

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

	Fiscal Year Ended		
	December 28, 2018	December 29, 2017	Percentage Change
U.S.	$669.1	$ 682.1	(1.9)%
Europe, Middle East and Africa	177.0	169.3	4.5
Other	63.3	18.2	247.8
Net sales	$909.4	$ 869.6	4.6

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

	Fiscal Year Ended		
	December 28, 2018	December 29, 2017	Percentage Change
Hydrocodone (API) and hydrocodone-containing tablets	$65.9	$ 85.3	(22.7)%
Oxycodone (API) and oxycodone-containing tablets	66.1	88.0	(24.9)
Acetaminophen (API)	192.7	185.5	3.9
Amitiza	183.8	—	—
Other controlled substances	343.8	412.0	(16.6)
Other	57.1	98.8	(42.2)
Specialty Generics and Amitiza	$909.4	$ 869.6	4.6

Operating (Loss) Income

Operating (loss) income by segment and as a percentage of segment net sales for fiscal 2018 and 2017 is shown in the following table (dollars in millions):

	Fiscal Year Ended			
	December 28, 2018		December 29, 2017	
Specialty Brands	$1,077.4	46.7%	$1,146.3	48.7%
Specialty Generics and Amitiza [1]	105.0	11.5	266.4	30.6
Segment operating income	1,182.4	36.8	1,412.7	43.9
Unallocated amounts:				
Corporate and allocated expenses	(155.8)		(125.2)	
Intangible asset amortization	(740.2)		(694.5)	
Restructuring and related charges, net [2]	(108.2)		(36.4)	
Non-restructuring impairment charges	(3,893.1)		(63.7)	
Separation costs	(6.0)		—	
Total operating (loss) income	$(3,720.9)		$492.9	

(1) Includes $118.8 million of inventory fair-value step up expense, primarily related to Amitiza during the fiscal year ended December 28, 2018.
(2) Includes restructuring-related accelerated depreciation.

Specialty Brands. Operating income for fiscal 2018 decreased $68.9 million to $1,077.4 million, compared with $1,146.3 million for fiscal 2017. Operating margin decreased to 46.7% for fiscal 2018, compared with 48.7% for fiscal 2017. The decrease in operating income was impacted by an increase of $96.5 million in R&D expenses related to the increased investment in our pipeline products. Also negatively impacting operating income was a decrease in gross profit of $30.0 million compared with fiscal 2017, primarily driven by the previously mentioned $45.8 million decrease in net sales of H.P. Acthar Gel. These changes were partially offset by a decrease of $57.4 million in SG&A expenses as compared to fiscal 2017, primarily due to cost benefits gained from restructuring actions, including lower employee compensation costs and stock compensation expense, lower legal, professional and advertising and promotion fees and various minor increases and decreases.

Specialty Generics and Amitza. Operating income for fiscal 2018 decreased $161.4 million to $105.0 million, compared with $266.4 million for fiscal 2017. Operating margin decreased to 11.5% for fiscal 2018, compared with 30.6% for fiscal 2017. The decrease in operating income and margin was impacted by a $104.9 million decrease in gross profit primarily due to the expense recognition of inventory fair value adjustments associated with Amitiza and a $66.0 million increase in SG&A primarily due to higher legal expense related to opioid defense costs.

Corporate and allocated expenses. Corporate and allocated expenses were $155.8 million and $125.2 million for fiscal 2018 and 2017, respectively. Fiscal 2018 included $19.7 million of provisions for legal matters, offset by a $49.9 million decrease in fair value of the contingent consideration liabilities related to stannsoporfin and MNK-1411. Fiscal 2017 included 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 liability related to Raplixa. The remaining $50.4 million decrease was primarily attributable to cost benefits gained from restructuring actions, including lower stock compensation expense and employee compensation costs, lower professional fees and various minor increases and decreases.

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		
	December 29, 2017	September 30, 2016	Percentage Change
Specialty Brands	$2,352.0	$ 2,288.8	2.8 %
Specialty Generics and Amitiza	869.6	1,092.0	(20.4)
Net sales	$3,221.6	$ 3,380.8	(4.7)

Specialty Brands. Net sales for fiscal 2017 increased $63.2 million, or 2.8%, to $2,352.0 million, compared with $2,288.8 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 continued to benefit from a favorable 2016 contracting cycle. These increases were partially offset by a $33.1 million or 29.4% 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. 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		
	December 29, 2017	September 30, 2016	Percentage Change
U.S.	$2,216.9	$ 2,163.6	2.5 %
Europe, Middle East and Africa	73.0	69.8	4.6
Other	62.1	55.4	12.1
Net sales	$2,352.0	$ 2,288.8	2.8

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

	Fiscal Year Ended		
	December 29, 2017	September 30, 2016	Percentage Change
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
BioVectra	54.7	49.5	10.5
Other	79.6	112.7	(29.4)
Specialty Brands	$2,352.0	$ 2,288.8	2.8

Specialty Generics and Amitiza. Net sales for fiscal 2017 decreased $222.4 million, or 20.4%, to $869.6 million, compared with $1,092.0 million for fiscal 2016. The decrease in net sales was driven by decreases of $61.2 million, $51.9 million and $131.9 million in net sales of hydrocodone-related products, oxycodone-related products and other controlled substances, respectively. These decreases were due to increased competition and customer consolidation, which has resulted in downward pricing pressure. Other controlled substances decrease was driven by a $31.8 million decrease in Methylphenidate ER, primarily attributable to the 2014 FDA reclassification of these products to therapeutically inequivalent status, a Hydromorphone ER decrease of $30.2 million, due to increased competition and customer consolidation, and a $23.5 million or 91.9% decrease in Exalgo® (hydromorphone HCl) extended-release tablets ("Exalgo") driven by lower volumes. 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 and Amitiza by geography are as follows (dollars in millions):

	Fiscal Year Ended		
	December 29, 2017	September 30, 2016	Percentage Change
U.S.	$682.1	$ 931.8	(26.8)%
Europe, Middle East and Africa	169.3	142.0	19.2
Other	18.2	18.2	—
Net sales	$869.6	$ 1,092.0	(20.4)

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

	Fiscal Year Ended		
	December 29, 2017	September 30, 2016	Percentage Change
Hydrocodone (API) and hydrocodone-containing tablets	$85.3	$ 146.5	(41.8)%
Oxycodone (API) and oxycodone-containing tablets	88.0	139.9	(37.1)
Acetaminophen (API)	185.5	169.1	9.7
Other controlled substances	412.0	543.9	(24.3)
Other	98.8	92.6	6.7
Specialty Generics and Amitiza	$869.6	$ 1,092.0	(20.4)

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	$1,146.3	48.7%	$1,060.7	46.3%
Specialty Generics and Amitiza	266.4	30.6	444.7	40.7
Segment operating income	1,412.7	43.9	1,505.4	44.5
Unallocated amounts:				
Corporate and allocated expenses	(125.2)		(117.7)	
Intangible asset amortization	(694.5)		(700.1)	
Restructuring and related charges, net [(1)]	(36.4)		(37.6)	
Non-restructuring impairment charges	(63.7)		(16.9)	
Total operating income	$492.9		$633.1	

(1) Includes restructuring-related accelerated depreciation.

Specialty Brands. Operating income for fiscal 2017 increased $85.6 million to $1,146.3 million, compared with $1,060.7 million for fiscal 2016. Operating margin increased to 48.7% for fiscal 2017, compared with 46.3% for fiscal 2016. The increase in operating income and margin was impacted by a $60.9 million decrease in SG&A expense as a result of cost benefits gained from restructuring actions and lower professional, advertising and promotion and legal fees, partially offset by increased charitable contributions. Also contributing to the increase was a $59.9 million increase in gross margin primarily attributable to the increase in net sales of $63.2 million, partially offset by an increase of $18.1 million in royalty expenses. Partially offsetting the increases was a $35.8 million increase in R&D expense related to the increased investment in our pipeline products.

Specialty Generics and Amitiza. Operating income for fiscal 2017 decreased $178.3 million to $266.4 million, compared with $444.7 million for fiscal 2016. Operating margin decreased to 30.6% for fiscal 2017, compared with 40.7% for fiscal 2016. The decrease in operating income and margin was impacted by the $222.4 million decrease in

net sales, which resulted in a $241.9 million unfavorable gross profit impact, due to increased competition in several product categories.

Corporate and allocated expenses. Corporate and allocated expenses were $125.2 million and $117.7 million for fiscal 2017 and 2016, respectively. Fiscal 2017 included 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 liability related to Raplixa reflective of lower than previously anticipated commercial opportunities for the product. Fiscal 2016 included $14.5 million of legal reserve charges. The remaining increase of $133.2 million consisted of various factors, including higher stock compensation expense, employee compensation costs, professional fees and facility expense; all of which were partially offset by lower advertising and promotions expense.

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 December 30, 2016	December 25, 2015	Percentage Change
Specialty Brands	$600.1	$ 544.8	10.2 %
Specialty Generics and Amitiza	229.8	266.4	(13.7)
Net sales	$829.9	$ 811.2	2.3

Specialty Brands. Net sales for the three months ended December 30, 2016 increased $55.3 million, or 10.2%, to $600.1 million, compared with $544.8 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 December 30, 2016	December 25, 2015	Percentage Change
U.S.	$574.8	$ 512.2	12.2 %
Europe, Middle East and Africa	16.2	17.0	(4.7)
Other	9.1	15.6	(41.7)
Net sales	$600.1	$ 544.8	10.2

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

	Three Months Ended December 30, 2016	December 25, 2015	Percentage Change
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)
BioVectra	7.4	14.2	(47.9)
Other	29.1	15.8	84.2
Specialty Brands	$600.1	$ 544.8	10.2

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Specialty Generics and Amitiza. Net sales for the three months ended December 30, 2016 decreased $36.6 million, or 13.7%, to $229.8 million, compared with $266.4 million for the three months ended December 25, 2015. The decrease in net sales was driven by decreases of $13.5 million, $5.3 million and $23.2 million in hydrocodone-related products, oxycodone-related products and other controlled substances, respectively. The hydrocodone and oxycodone-related products decreases were due to customer consolidation that has led to increased competition. The other controlled substances decrease primarily related to a $9.2 million decrease in Methylphenidate ER net sales, which were negatively impacted by the 2014 FDA reclassification of these products to therapeutically inequivalent status.

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

	Three Months Ended December 30, 2016	December 25, 2015	Percentage Change
U.S.	$188.9	$ 228.0	(17.1)%
Europe, Middle East and Africa	36.6	32.3	13.3
Other	4.3	6.1	(29.5)
Net sales	$229.8	$ 266.4	(13.7)

Net sales for Specialty Generics and Amitiza 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	27.2	32.5	(16.3)
Acetaminophen (API)	40.8	37.8	7.9
Other controlled substances	117.4	140.6	(16.5)
Other	21.2	18.8	12.8
Specialty Generics and Amitiza	$229.8	$ 266.4	(13.7)

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	$295.2	49.2%	$270.3	49.6%
Specialty Generics and Amitiza	64.6	28.1	108.5	40.7
Segment operating income	359.8	43.4	378.8	46.7
Unallocated amounts:				
Corporate and allocated expenses	(123.1)		(37.2)	
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	$(158.6)		$164.0	

(1) Includes restructuring-related accelerated depreciation.

Specialty Brands. Operating income for the three months ended December 30, 2016 increased $24.9 million to $295.2 million, compared with $270.3 million during the three months ended December 25, 2015. Our operating margin

decreased to 49.2% for the three months ended December 30, 2016, compared with 49.6% for the three months ended December 25, 2015. The increase in operating income was impacted by the $55.3 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. The increase in gross profit was partially offset by increases in SG&A and R&D expenses primarily attributable to increased legal and professional fees and focus on investment in our pipeline products, respectively.

Specialty Generics and Amitiza. Operating income for the three months ended December 30, 2016 decreased $43.9 million to $64.6 million, compared with $108.5 million for the three months ended December 25, 2015. Our operating margin decreased to 28.1% for the three months ended December 30, 2016, compared with 40.7% for the three months ended December 25, 2015. The decrease in operating income and margin was impacted by the $36.6 million decrease in net sales due to customer consolidation and additional competitors that has led to price decreases, which resulted in a $37.2 million unfavorable gross profit impact. The gross profit impact exceeded the net sales impact primarily due to unfavorable product mix. In addition, there were decreases in SG&A and R&D expenses of $4.1 million and $2.6 million, respectively.

Corporate and allocated expenses. Corporate and allocated expenses were $123.1 million and $37.2 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. The three months ended December 25, 2015, included $11.5 million of legal reserve accruals. The remaining $4.6 million decrease was primarily attributable to decreased employee compensation costs and 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.

Upon completion of the Separation, it is our expectation that both independent publicly traded companies will be structured to generate positive cash flows from operations and maintain adequate resources to fund working capital needs, capital expenditures and strategic investments.

In fiscal 2019, we intend to fund capital expenditures with cash generated from operations. At December 28, 2018, we had capital expenditure commitments of $22.8 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 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016	December 25, 2015
Net cash provided by (used in):					
Operating activities	$665.5	$ 727.3	$ 1,184.6	$195.6	$ 311.4
Investing activities	(480.3)	318.4	(155.6)	(77.2)	215.4
Financing activities	(1,095.0)	(130.2)	(1,162.3)	(53.9)	(369.5)
Effect of currency exchange rate changes on cash	(1.8)	2.5	0.3	(3.0)	(1.5)
Net (decrease) increase in cash, cash equivalents and restricted cash	$(911.6)	$ 918.0	$ (133.0)	$61.5	$ 155.8

Operating Activities

Net cash provided by operating activities of $665.5 million for fiscal 2018 was primarily attributable to income from continuing operations, as adjusted for non-cash items including a $3,893.1 million adjustment for non-cash impairment charges, as previously mentioned, and a $46.4 million inflow from net investment in working capital. The

working capital inflow was primarily attributable to a $99.0 million cash inflow from net tax related balances, a $63.1 million decrease in inventory balances, a $24.6 million increase in accounts payable, net, and a $5.5 million net inflow related to other assets and liabilities, offset by a $145.8 million increase in accounts receivable, net.

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 including 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 of our legal entity ownership and the TCJA. The income from continuing operations, as adjusted for non-cash items, was offset by a $188.8 million outflow from net investment in working capital.

The working capital outflow included cash payments of $102.0 million for the settlement with the FTC and the Settling States, $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 $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, and 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 no longer generated cash flows from these businesses. See further discussion of our discontinued operations in Note 6 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Investing Activities

Net cash used in investing activities was $480.3 million for fiscal 2018, compared with $318.4 million provided by investing activities for fiscal 2017. The increase primarily resulted from the cash outflows related to the Sucampo Acquisition of $698.0 million. These cash outflows were partially offset by the inflow of $159.0 million in proceeds received, net of transaction costs, from the divestiture of a portion of the Hemostasis business, inclusive of the PreveLeak and Recothrom products during fiscal 2018; proceeds received of $154.0 million related to the note receivable from the purchaser of the Intrathecal Therapy business which was sold during fiscal 2017; and a $25.5 million cash inflow related to the sale of our investment in Mesoblast Limited ("Mesoblast") during fiscal 2018. This is compared with $576.9 million of proceeds received from the divestiture of the Nuclear Imaging and Intrathecal Therapy businesses during fiscal 2017, offset by cash outflows of payments, net of cash acquired, of $36.8 and $39.5 million related to the acquisitions of InfaCare and Ocera, respectively; and $21.5 million related to the investment in Mesoblast that was made in fiscal 2017. Additionally, there was a $59.1 million decrease in capital expenditures, compared to fiscal 2017.

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 Therapy 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 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 an $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 $1,095.0 million for fiscal 2018, compared with $130.2 million used in financing activities for fiscal 2017. The $964.8 million increase in cash outflows was attributable to a $776.4 million increase in debt repayments, and $774.7 million less cash provided by issuance of external debt, offset by a $594.2 million decrease in shares repurchased. The significant components of our current year debt repayments included $680.0 million related to our revolving credit facility, a $225.0 million repayment of the variable-rate term loan maturing in 2024, repayment of $366.0 million of assumed debt from the Sucampo Acquisition, a $300.0 million repayment of fully matured unsecured fixed rate notes and open market debt repurchases that aggregated to a total principal amount of $81.8 million.

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 repayments, in fiscal 2017 compared with fiscal 2016. The inflow in fiscal 2017 was 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 closure 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 $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

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 2018, we repurchased debt that aggregated to a principal amount of $81.8 million.

As of December 28, 2018, total debt principal was $6,156.7 million compared with $6,806.8 million as of December 29, 2017, with total debt reduction of $650.1 million during fiscal 2018. Total debt principal at December 28, 2018 is comprised of the following:

	December 28, 2018
Variable-rate instruments:	
Term loan due September 2024	$ 1,613.8
Term loan due February 2025	597.0
Receivable Securitization program	250.0
Revolving credit facility	220.0
Fixed-rate instruments	3,475.9
Debt principal	$ 6,156.7

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 28, 2018, our fixed-rate instruments had a weighted-average interest rate of 5.44% and pay interest at various dates throughout the fiscal year. As of December 28, 2018, the applicable interest rate on outstanding borrowings under the Receivable Securitization was 3.22%, 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.

On December 31, 2018, we made a $25.0 million voluntary prepayment on our outstanding term loan due September 2024 and a $5.6 million quarterly principal amortization payment on our outstanding term loans. On February 14, 2019, we made a $175.0 million voluntary prepayment on our outstanding term loan due February 2025. Subsequent to fiscal 2018 and through the date of this filing, we repurchased debt that aggregated to a principal amount of $75.0 million.

As of December 28, 2018, $22.7 million of our total debt is classified as current as these payments are expected to be made within the next fiscal year.

As of December 28, 2018, we were, and expect to remain, in compliance with the provisions and covenants associated with our debt agreements.

For additional information regarding our debt agreements, refer to Note 14 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 $2,887.3 million at December 28, 2018 compared with $6,522.0 million at December 29, 2017. The decrease in shareholders' equity is primarily attributed to the one-time goodwill impairment charge reflected within the decrease in retained (deficit) earnings.

On November 19, 2015, our 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, our 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, our 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 we currently expect to fully utilize the program. During fiscal 2018, we spent $55.2 million on share repurchases, a significant decrease from $646.6 million in fiscal 2017 due to our shift to net debt reduction as one of our primary focuses of our capital allocation strategy for fiscal 2018 and fiscal 2019.

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 28, 2018 (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	$6,156.7	$22.7	$1,000.9	$2,346.8	$2,786.3
Interest on long-term debt obligations [(1)]	1,532.5	333.5	606.6	442.7	149.7
Operating lease obligations	111.6	22.3	29.2	20.9	39.2
Purchase obligations [(2)]	164.7	110.3	45.7	3.8	4.9
Total contractual obligations	$7,965.5	$488.8	$1,682.4	$2,814.2	$2,980.1

(1) Interest on long-term debt obligations are projected for future periods using interest rates in effect as of December 28, 2018. 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 $652.8 million, primarily consisting of obligations under our pension and postretirement benefit plans, unrecognized tax benefits for uncertain tax positions and related accrued interest and penalties, contingent consideration liabilities, environmental liabilities and asset retirement obligations, because the timing of their future cash outflow is uncertain. The most significant of these liabilities are discussed below.

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 28, 2018, we have accrued $151.4 million for these potential payments, of which $117.3 million is considered to be long-term. For further information on our contingent consideration arrangements, refer to 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.

As part of our divestitures and licensing agreements, we have the potential to earn in excess of $250.0 million in milestone payments in the future. During fiscal 2018, we received royalty income of $15.5 million, milestone payments of $6.0 million and preferred equity certificates of $9.0 million. For further information, refer to Notes 6 and 7 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

We are obligated to pay royalties under certain agreements with third parties. During fiscal 2018 and 2017, we made payments under these arrangements of $106.4 million and $86.0 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 28, 2018, was $228.0 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 related to tax positions we take. For further information on income tax related matters, refer to Note 9 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 28, 2018, we had net unfunded pension and postretirement benefit obligations of $26.1 million and $39.8 million, respectively. The timing and amounts of long-term funding requirements for pension and postretirement obligations are uncertain. We do not anticipate making material involuntary contributions in fiscal 2019, but may elect to make voluntary contributions to our defined pension plans or our postretirement benefit plans during fiscal 2019. We settled all outstanding obligations associated with our 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 28, 2018, we believe that it is probable that we will incur investigation and remediation costs of approximately $61.8 million, of which $2.1 million is included in accrued and other current liabilities on our consolidated balance sheet at December 28, 2018. 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 provides additional information regarding environmental matters.

Legal Proceedings

See 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, which is incorporated by reference into this Part II, Item 7., for a description of the legal proceedings and claims as of December 28, 2018.

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. We assess the probability of potential liabilities related to such representations, warranties and indemnities and adjust potential liabilities as a result of changes in facts and circumstances. We believe, given the information currently available, that our ultimate resolution will not have a material adverse effect on our financial condition, results of operations and cash flows. These representations, warranties and indemnities are discussed 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.

Off-Balance Sheet Arrangements

As of December 28, 2018, we had various other letters of credit and guarantee and surety bonds totaling $38.7 million.

Critical Accounting Policies and Estimates

The consolidated financial statements have been prepared in U.S. dollars and in accordance with 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

Product Sales Revenue

We sell products through independent channels, including direct to retail pharmacies, end user customers and through distributors who resell our products to retail pharmacies, institutions and end user customers, while certain products are sold and distributed directly to hospitals. We also enter into arrangements with indirect customers, such as health care providers and payers, wholesalers, government agencies, institutions, managed care organizations and group purchasing organizations to establish contract pricing for certain products that provides for government-mandated and/or privately-negotiated rebates, sale incentives, chargebacks, distribution service agreement fees, fees for services and administration fees, and discounts with respect to the purchase of the our products.

Reserve for Variable Considerations

Product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. These reserves result from estimated chargebacks, rebates, product returns and other sales deductions that are offered within contracts between us and our customers, health care providers and payers relating to the sales of our products. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as our 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. Overall, these reserves reflect our best estimate of the amount of consideration to which it is entitled based on the terms of the contract. The amount of

variable consideration which is included in the transaction price may be constrained (reduced), and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. We adjust reserves for chargebacks, rebates, product returns and other sales deductions to reflect differences between estimated and actual experience. Such adjustments impact the amount of net sales recognized in the period of adjustment.

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 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	2,281.3	39.3	66.9	2,387.5
Payments or credits	(2,254.4)	(39.8)	(64.5)	(2,358.7)
Balance at December 28, 2018	$ 354.3	$ 34.0	$ 17.1	$ 405.4

Provisions presented in the table above are recorded as reductions to net sales. For our presentation of net sales by product family, refer to Note 22 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K

Total provisions for fiscal 2018 increased $379.0 million compared with fiscal 2017. The increase in rebates and chargebacks of $384.1 million primarily related to a $350.4 million increase in the Specialty Generics products as additional indirect customers were added to our distributors' customer base resulting in additional chargebacks, coupled with a $33.7 million increase in Specialty Brands. Provisions for returns increased $0.6 million and other sales deductions decreased by $5.7 million from fiscal 2017 to fiscal 2018, due to increased competition within the Specialty Generics and Amitiza segment.

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 $52.1 million decrease in the Specialty Generics and Amitiza segment as increased competition resulted in lower customer volume, partially offset by a $11.4 million increase in Specialty Brands. Provisions for returns increased $24.4 million from fiscal 2016 to fiscal 2017, due to a $21.3 million increase in the Specialty Generics and Amitiza segment due to increased competition, primarily driven by an $8.7 million favorable change in the estimate associated with the Exalgo returns reserve in fiscal 2016. Other sales deductions decreased by $6.0 million, primarily attributable to increased competition within the Specialty Generics and Amitiza segment.

Product sales are recognized when the customer obtains control of our product. Control is transferred either at a point in time, generally upon delivery to the customer site, or in the case of certain of our products, over the period in which the customer has access to the product and related services. Revenue recognized over time is based upon either consumption of the product or passage of time based upon our determination of the measure that best aligns with how the obligation is satisfied. Our considerations of why such measures provide a faithful depiction of the transfer of our products are as follows:

- For those contracts whereby revenue is recognized over time based upon consumption of the product, we either have:
  1. the right to invoice the customer in an amount that directly corresponds with the value to the customer of our performance to date, for which the practical expedient to recognize in proportion to the amount it has the right to invoice has been applied, or
  2. the remaining goods and services to which the customer is entitled is diminished upon consumption.

For those contracts whereby revenue is recognized over time based upon the passage of time, the benefit that the customer receives from unlimited access to our product does not vary, regardless of consumption. As a result, our obligation diminishes with the passage of time; therefore, it was determined that ratable recognition of the transaction price over the contract period is the measure that best aligns with how the obligation is satisfied.

Costs to obtain a contract

As the majority of our contracts are short-term in nature, sales commissions are generally expensed when incurred as the amortization period would have been less than one year. These costs are recorded within SG&A. For contracts that extend beyond one year, the incremental expense recognition matches the recognition of related revenue.

Costs to fulfill a contract

We capitalize the costs associated with the devices used in our portfolio of drug-device combination products, which are used in satisfaction of future performance obligations. Capital expenditures for these devices represent cash outflows for our cost to produce

the asset, which is classified in property, plant and equipment, net on the consolidated balance sheet and expensed to cost of sales over the useful life of the equipment.

Product Royalty Revenues

In relation to our acquisition of Sucampo, we acquired an arrangement which we license certain rights to Amitiza to a third party in exchange for royalties on net sales of the product. We recognize such royalty revenue as the related sales occur.

Contract Balances

Accounts receivable are recorded when the right to consideration becomes unconditional. Payments received from customers are typically based upon payment terms of between 30 to 90 days depending on the customer. We do not maintain contract asset balances aside from the accounts receivable balance as presented on the consolidated balance sheet as costs to obtain a contract are expensed when incurred as the amortization period would have been less than one year. These costs are recorded within SG&A.

Contract liabilities are recorded when cash payments are received in advance of our performance, including amounts which are refundable.

For additional information, refer to Notes 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.

Goodwill and Other Intangible Assets

In performing goodwill assessments, management relies on a number of factors including operating results, business plans, economic projections, internally developed 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. The fair value of our reporting units is reconciled to our share price and market capitalization as a corroborative step. If the carrying value of a reporting unit exceeds its fair value, we recognize the excess of the carrying value over the fair value as a goodwill impairment loss. For further information on our goodwill impairment analyses, refer to Notes 3 and 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.

Intangible assets include completed technology, licenses, trademarks and IPR&D. 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. We annually test 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. We compare the fair value of the assets with their carrying value and record an impairment when the carrying value exceeds the fair value.

For more information on our intangible impairment analyses and the results thereof, refer to Notes 3 and 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.

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 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. For additional information, refer to 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.

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 claims, product liability matters, government investigations, environmental matters, employment disputes, contractual disputes and other commercial disputes, and other legal proceedings as further discussed in Note 20 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 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.

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.

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 28, 2018, our outstanding debt included $2,210.8 million variable-rate debt on our senior secured term loans, $250.0 million variable-rate debt on our receivables securitization program and $220.0 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 2019 would increase by approximately $26.8 million.

The remaining outstanding debt as of December 28, 2018 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 28, 2018 that measured 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 $0.2 million as of December 28, 2018. 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 performed a sensitivity analysis as of December 28, 2018 that measured the change in the net financial position arising from a hypothetical 10% adverse movement in the exchange rates of all foreign currencies used, including 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 $14.6 million as of December 28, 2018. 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:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Mallinckrodt plc and subsidiaries (the "Company") as of December 28, 2018 and December 29, 2017, the related consolidated statements of income, comprehensive income, changes in shareholders' equity, and cash flows for the fiscal years ended December 28, 2018, December 29, 2017 and September 30, 2016 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 28, 2018 and December 29, 2017, and the results of its operations and its cash flows for the fiscal years ended December 28, 2018, December 29, 2017 and September 30, 2016 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 28, 2018, 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 26, 2019, expressed an adverse opinion on the Company's internal control over financial reporting because of a material weakness.

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 26, 2019

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

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

	Fiscal Year Ended			Three Months Ended
	December 28, 2018	**December 29, 2017**	**September 30, 2016**	**December 30, 2016**
Net sales	$3,215.6	$3,221.6	$3,380.8	$829.9
Cost of sales	1,744.4	1,564.1	1,523.2	383.2
Gross profit	1,471.2	1,657.5	1,857.6	446.7
Selling, general and administrative expenses	834.1	849.7	913.7	321.1
Research and development expenses	361.1	276.9	261.2	66.1
Restructuring charges, net	103.0	31.2	32.7	3.8
Non-restructuring impairment charges	3,893.1	63.7	16.9	214.3
Losses (gains) on divestiture	0.8	(56.9)	—	—
Operating (loss) income	(3,720.9)	492.9	633.1	(158.6)
Interest expense	(370.2)	(369.1)	(384.6)	(91.3)
Interest income	8.2	4.6	1.3	0.5
Other income (expense), net	30.9	(66.8)	(16.4)	(49.1)
(Loss) income from continuing operations before income taxes	(4,052.0)	61.6	233.4	(298.5)
Benefit from income taxes	(430.1)	(1,709.6)	(255.6)	(121.7)
(Loss) income from continuing operations	(3,621.9)	1,771.2	489.0	(176.8)
Income from discontinued operations, net of tax expense of $1.4, $5.4, $43.5, and $15.3	14.9	363.2	154.7	23.6
Net (loss) income	$(3,607.0)	$2,134.4	$643.7	$(153.2)
Basic earnings per share (Note 10):				
(Loss) income from continuing operations	$(43.12)	$18.13	$4.42	$(1.67)
Income from discontinued operations, net of income taxes	0.18	3.72	1.40	0.22
Net (loss) income	$(42.94)	$21.85	$5.82	$(1.45)
Basic weighted-average shares outstanding	84.0	97.7	110.6	105.7
Diluted earnings per share (Note 10):				
(Loss) income from continuing operations	$(43.12)	$18.09	$4.39	$(1.67)
Income from discontinued operations, net of income taxes	0.18	3.71	1.39	0.22
Net (loss) income	$(42.94)	$21.80	$5.77	$(1.45)
Diluted weighted-average shares outstanding	84.0	97.9	111.5	105.7

See Notes to Consolidated Financial Statements.

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MALLINCKRODT PLC
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(in millions)

	Fiscal Year Ended			Three Months Ended
	December 28, 2018	**December 29, 2017**	**September 30, 2016**	**December 30, 2016**
Net (loss) income	$ (3,607.0)	$ 2,134.4	$ 643.7	$ (153.2)
Other comprehensive (loss) income, net of tax				
Currency translation adjustments	(12.2)	11.3	(58.6)	(21.1)
Unrecognized gain on derivatives, net of tax expense of $0.2, $0.3, $0.2, and $-	0.7	1.0	0.5	0.2
Unrecognized gain (loss) on benefit plans, net of tax expense (benefit) of $0.5, $30.8, ($15.0), and ($19.3)	1.6	45.8	(28.4)	34.0
Unrecognized gain on investments	—	1.5	—	—
Total other comprehensive (loss) income, net of tax	(9.9)	59.6	(86.5)	13.1
Comprehensive (loss) income	$ (3,616.9)	$ 2,194.0	$ 557.2	$ (140.1)

See Notes to Consolidated Financial Statements.

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

	December 28, 2018	December 29, 2017
Assets		
Current Assets:		
Cash and cash equivalents	$ 348.9	$ 1,260.9
Accounts receivable, less allowance for doubtful accounts of $5.0 and $3.9	623.3	445.8
Inventories	322.3	340.4
Prepaid expenses and other current assets	132.7	84.1
Notes receivable	—	154.0
Total current assets	1,427.2	2,285.2
Property, plant and equipment, net	982.0	966.8
Goodwill	—	3,482.7
Intangible assets, net	8,282.8	8,375.0
Other assets	185.3	171.2
Total Assets	$ 10,877.3	$ 15,280.9
Liabilities and Shareholders' Equity		
Current Liabilities:		
Current maturities of long-term debt	$ 22.4	$ 313.7
Accounts payable	147.5	113.3
Accrued payroll and payroll-related costs	124.0	98.5
Accrued interest	77.6	57.0
Income taxes payable	25.0	15.8
Accrued and other current liabilities	547.2	452.1
Total current liabilities	943.7	1,050.4
Long-term debt	6,069.2	6,420.9
Pension and postretirement benefits	60.5	67.1
Environmental liabilities	59.7	73.2
Deferred income taxes	324.3	689.0
Other income tax liabilities	228.0	94.1
Other liabilities	304.6	364.2
Total Liabilities	7,990.0	8,758.9
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; 92,705,747 and 92,196,662 issued; 83,323,877 and 86,336,232 outstanding	18.5	18.4
Ordinary shares held in treasury at cost, 9,381,870 and 5,860,430	(1,617.4)	(1,564.7)
Additional paid-in capital	5,528.2	5,492.6
Retained (deficit) earnings	(1,017.7)	2,588.6
Accumulated other comprehensive loss	(24.3)	(12.9)
Total Shareholders' Equity	2,887.3	6,522.0
Total Liabilities and Shareholders' Equity	$ 10,877.3	$ 15,280.9

See Notes to Consolidated Financial Statements.

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MALLINCKRODT PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in millions)

	Fiscal Year Ended			Three Months Ended
	December 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Cash Flows From Operating Activities:				
Net (loss) income	$ (3,607.0)	$ 2,134.4	$ 643.7	$ (153.2)
Adjustments to reconcile net cash provided by operating activities:				
Depreciation and amortization	852.1	808.3	834.5	203.2
Share-based compensation	34.6	59.2	42.9	11.0
Deferred income taxes	(541.5)	(1,744.1)	(432.9)	(204.3)
Non-cash impairment charges	3,893.1	63.7	16.9	214.3
Inventory provisions	37.9	34.1	29.2	8.5
Loss (gain) on divestiture	0.8	(418.1)	(95.3)	—
Other non-cash items	(50.9)	(21.4)	29.6	(9.2)
Changes in assets and liabilities, net of the effects of acquisitions:				
Accounts receivable, net	(145.8)	(16.2)	31.2	36.5
Inventories	63.1	(23.6)	(17.3)	(26.3)
Accounts payable	24.6	(25.8)	(9.7)	5.4
Income taxes	99.0	(34.2)	93.9	0.6
Other	5.5	(89.0)	17.9	109.1
Net cash from operating activities	665.5	727.3	1,184.6	195.6
Cash Flows From Investing Activities:				
Capital expenditures	(127.0)	(186.1)	(182.9)	(65.2)
Acquisitions, net of cash acquired	(699.9)	(76.3)	(245.4)	(1.8)
Proceeds from divestiture, net of cash	313.0	576.9	266.7	—
Other	33.6	3.9	6.0	(10.2)
Net cash from investing activities	(480.3)	318.4	(155.6)	(77.2)
Cash Flows From Financing Activities:				
Issuance of external debt	690.3	1,465.0	98.3	190.0
Repayment of external debt and capital lease obligation	(1,693.6)	(917.2)	(568.6)	(86.7)
Debt financing costs	(12.1)	(12.7)	(0.1)	—
Proceeds from exercise of share options	1.0	4.1	14.0	0.4
Repurchase of shares	(57.5)	(651.7)	(652.9)	(158.8)
Other	(23.1)	(17.7)	(53.0)	1.2
Net cash from financing activities	(1,095.0)	(130.2)	(1,162.3)	(53.9)
Effect of currency rate changes on cash	(1.8)	2.5	0.3	(3.0)
Net change in cash, cash equivalents and restricted cash	(911.6)	918.0	(133.0)	61.5
Cash, cash equivalents and restricted cash at beginning of period	1,279.1	361.1	432.6	299.6
Cash, cash equivalents and restricted cash at end of period	$ 367.5	$ 1,279.1	$ 299.6	$ 361.1
Cash and cash equivalents at end of period	$ 348.9	$ 1,260.9	$ 280.5	$ 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	18.6	18.2	19.0	19.0
Cash, cash equivalents and restricted cash at end of period	$ 367.5	$ 1,279.1	$ 299.6	$ 361.1

Supplemental Disclosures of Cash Flow Information:				
Cash paid for interest	$309.7	$339.1	$ 332.4	$95.4
Cash paid for income taxes, net	12.4	73.4	165.4	95.6

See Notes to Consolidated Financial Statements.

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

	Ordinary Shares		Treasury Shares		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total Shareholders' Equity
	Number	Par Value	Number	Amount				
Balance at September 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 tax	—	—	—	—	—	—	(28.4)	(28.4)
Share options exercised	0.4	0.1	—	—	13.9	—	—	14.0
Vesting of restricted shares	0.2	—	—	—	—	—	—	—
Excess tax benefit from share-based compensation	—	—	—	—	(1.7)	—	—	(1.7)
Share-based compensation	—	—	—	—	42.9	—	—	42.9
Repurchase of 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 tax	—	—	—	—	—	—	34.0	34.0
Share options exercised	0.1	—	—	—	0.4	—	—	0.4
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 tax	—	—	—	—	—	—	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
Impact of accounting standard adoptions	—	—	—	—	—	2.6	(1.5)	1.1
Net loss	—	—	—	—	—	(3,607.0)	—	(3,607.0)
Currency translation	—	—	—	—	—	—	(12.2)	(12.2)
Change in derivatives, net of tax	—	—	—	—	—	—	0.7	0.7
Minimum pension liability, net of tax	—	—	—	—	—	—	1.6	1.6
Share options exercised	—	—	—	—	1.0	—	—	1.0
Vesting of restricted shares	0.5	0.1	0.1	(2.3)	—	—	—	(2.2)
Share-based compensation	—	—	—	—	34.6	—	—	34.6
Reissuance of Treasury shares	—	—	(0.2)	4.8	—	(1.9)	—	2.9

Repurchase of shares	—	—	3.6	(55.2)	—	—	—	(55.2)
Balance at December 28, 2018	92.7	$18.5	9.4	$(1,617.4)	$5,528.2	$(1,017.7)	$ (24.3)	$2,887.3

See Notes to Consolidated Financial Statements.

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

1. Background and Basis of Presentation

Background

Mallinckrodt plc and its subsidiaries (collectively, "Mallinckrodt" or "the Company"), is a global business that develops, manufactures, markets and distributes specialty pharmaceutical products and therapies. As of December 28, 2018, 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. 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 innovative specialty pharmaceutical brands; and
- *Specialty Generics and Amitiza* includes niche specialty generic drug products, active pharmaceutical ingredients ("API(s)") and Amitiza® (lubiprostone) ("Amitiza").

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 (loss) income.

On December 6, 2018, the Company announced its plans to spin off a new company consisting of the Specialty Generics/API business and the Amitiza product to the Company's shareholders ("the Separation"). The Separation is expected to create two independent, appropriately capitalized, publicly traded companies – one focused on innovative specialty pharmaceutical brands, the other concentrated primarily in niche specialty generic products and API manufacturing – each positioned to optimize future success as they pursue independent growth strategies. The Company anticipates that the transaction will be in the form of a distribution of new publicly traded stock in the new company that is intended to be generally tax-free for U.S. federal income tax purposes to the Company's shareholders. Completion of the transaction is expected to be subject to certain conditions, including, among others, receipt of regulatory approvals, assurance as to the tax-free status of the spin-off of the business to the Company's shareholders, the effectiveness of a Form 10 registration statement to be filed with the SEC and final approval by the Company's Board of Directors. The Company currently expects completion of the transaction in the second half of 2019; however, there can be no assurance regarding the ultimate timing of the proposed transaction or that the transaction will be completed.

Beginning in the first quarter through the third quarter of fiscal 2018, the historical financial results attributable to "the Specialty Generics Disposal Group" were reflected in the Company's interim condensed consolidated financial statements as discontinued operations. The Specialty Generics Disposal Group included (1) the Company's Specialty Generics business comprised of what was the Company's Specialty Generics segment in fiscal 2017, with the exception of BioVectra, Inc. - a wholly owned subsidiary of the Company that operates a contract manufacturing business in Canada ("BioVectra"); (2) certain of the Company's non-promoted brands business, which was previously reflected in the Company's Specialty Brands segment; and (3) the Company's ongoing, post-divestiture supply agreement with the acquirer of the contrast media and delivery systems ("CMDS") business, which was previously reflected in the Company's Other non-operating segment. As a result of the Separation announcement, the Specialty Generics Disposal Group no longer met the requirements to be classified as held-for-sale, and the historical financial results attributable to the Specialty

Generics Disposal Group have been recast in the Company's consolidated financial statements as continuing operations. Prior year amounts have been recast to conform to current presentation. See further discussion in Note 23.

Fiscal Year

The Company reports its results based on a "52-53 week" year ending on the last Friday of December. Fiscal 2018 and 2017 each consisted of 52 weeks and fiscal 2016 consisted of 53 weeks. 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.

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	
		(unaudited)
	December 30, 2016	December 25, 2015 [1]
Net sales	$829.9	$ 811.2
Cost of sales	383.2	360.0
Gross profit	446.7	451.2
Selling, general and administrative expenses	321.1	221.8
Research and development expenses	66.1	61.3
Restructuring charges, net	3.8	4.1
Non-restructuring impairment charges	214.3	—
Operating (loss) income	(158.6)	164.0
Interest expense	(91.3)	(97.8)
Interest income	0.5	0.2
Other (expense) income, net	(49.1)	0.1
(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 10):		
(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 10):		
(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

(1) Financial data for this period has been adjusted to reflect the change in accounting for pension and postretirement costs with the adoption of Accounting Standards Update ("ASU") 2017-07. See Note 4 for further information on this ASU.

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

Product Sales Revenue

The Company sells its 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, while certain products are sold and distributed to hospitals. The Company also enters into arrangements with indirect customers, such as health care providers and payers, wholesalers, government agencies, institutions, managed care organizations and group purchasing organizations to establish contract pricing for certain products that provide for government-mandated and/or privately-negotiated rebates, sales incentives, chargebacks, distribution service agreements fees, fees for services and administration fees, and discounts with respect to the purchase of the Company's products.

Reserve for Variable Considerations

Product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. These reserves result from estimated chargebacks, rebates, product returns and other sales deductions that are offered within contracts between the Company and its customers, health care providers and payers relating to the Company's sales of its products. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as the Company's 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. Overall, these reserves reflect the Company's best estimate of the amount of consideration to which it is entitled based on the terms of the contract. The amount of variable consideration which is included in the transaction price may be constrained (reduced), and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. The Company adjusts reserves for chargebacks, rebates, product returns and other sales deductions to reflect differences between estimated and actual experience. Such adjustments impact the amount of net sales recognized in the period of adjustment.

Product sales are recognized when the customer obtains control of the Company's product. Control is transferred either at a point in time, generally upon delivery to the customer site, or in the case of certain of the Company's products, over the period in which the customer has access to the product and related services. Revenue recognized over time is based upon either consumption of the product or passage of time based upon the Company's determination of the measure that best aligns with how the obligation is satisfied. The Company's considerations of why such measures provide a faithful depiction of the transfer of its products are as follows:

- For those contracts whereby revenue is recognized over time based upon consumption of the product, the Company either has:
  1. the right to invoice the customer in an amount that directly corresponds with the value to the customer of the Company's performance to date, for which the practical expedient to recognize in proportion to the amount it has the right to invoice has been applied, or
  2. the remaining goods and services to which the customer is entitled is diminished upon consumption.
- For those contracts whereby revenue is recognized over time based upon the passage of time, the benefit that the customer receives from unlimited access to the Company's product does not vary, regardless of consumption. As a result, the Company's obligation diminishes with the passage of time; therefore, it was determined that ratable recognition of the transaction price over the contract period is the measure that best aligns with how the obligation is satisfied.

Transaction price allocated to the remaining performance obligations

The majority of the Company's contracts are less than one year; therefore, the related disclosure of the amount of transaction price allocated to the performance obligations that are unsatisfied at period end has been omitted.

Cost to obtain a contract

As the majority of the Company's contracts are short-term in nature, sales commissions are generally expensed when incurred as the amortization period would have been less than one year. These costs are recorded within selling, general and administrative expense ("SG&A") in the consolidated statements of income. For contracts that extend beyond one year, the incremental expense recognition matches the recognition of related revenue.

Costs to fulfill a contract

The Company capitalizes the costs associated with the devices used in the Company's portfolio of drug-device combination products, which are used in satisfaction of future performance obligations. Capital expenditures for these devices represent cash outflows for the Company's cost to produce the asset, which is classified in property, plant and equipment, net on the consolidated balance sheets and expensed to cost of sales over the useful life of the equipment.

Product Royalty Revenues

In relation to the Company's acquisition of Sucampo Pharmaceuticals, Inc. ("Sucampo") in fiscal 2018, as discussed further in Note 7, it acquired an arrangement under which the Company licenses certain rights to Amitiza to a third party in exchange for royalties on net sales of the product. The Company recognizes such royalty revenue as the related sales occur.

Contract Balances

Accounts receivable are recorded when the right to consideration becomes unconditional. Payments received from customers are typically based upon payment terms of 30 days. The Company does not maintain contract asset balances aside from the accounts receivable balance as presented on the consolidated balance sheets as costs to obtain a contract are expensed when incurred as the amortization period would have been less than one year. These costs are recorded within SG&A on the consolidated statements of income. Contract liabilities are recorded when cash payments are received in advance of the Company's performance, including amounts which are refundable.

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.

For additional information, refer to Note 5.

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 SG&A. 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 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Shipping and handling costs	$12.8	$ 13.9	$ 12.4	$ 3.4

Research and Development

Internal research and development costs are expensed as incurred. Research and development ("R&D") 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 loss. 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. The Company also entered into derivative instruments to mitigate the exposure of movements in certain of these foreign currency transactions. The Company recognized the following during the respective periods:

	Fiscal Year Ended			Three Months Ended
	December 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Foreign currency (losses), gains	$(3.1)	$ 2.5	$ (3.6)	$ 9.0
Derivative hedge gains (losses)	2.7	(4.1)	0.2	(8.9)

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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. The fair value of the Company's reporting units is reconciled to its share price and market capitalization as a corroborative step. 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 claims, product liability matters, government investigations, environmental matters, employee disputes, contractual disputes and other commercial disputes, and other legal proceedings in the ordinary course of business as further discussed in Note 20. 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 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

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule was effective for all filings made on or after November 5, 2018. The Company has complied with all relevant disclosure requirements, with the exception of the expanded interim disclosure requirements for changes in shareholders' equity, which is required in the first interim reporting period after the effective date. The interim analysis of changes in shareholders' equity will be effective for the Company's quarterly reporting in the year ending December 27, 2019.

The Financial Accounting Standards Board ("FASB") issued ASU 2018-05, "Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118 (SEC Update)" in March 2018. This update adds SEC paragraphs pursuant to the SEC's Staff Accounting Bulletin ("SAB") 118, which provides guidance on accounting for the tax effects of the Tax Cuts and Jobs Act ("TCJA" or "U.S. Tax Reform") that was enacted in December 2017. SAB 118 provides a measurement period that should not extend beyond one year from the TCJA enactment date for companies to complete the accounting for the tax effects of the TCJA. The Company adopted this standard in fiscal 2018. See Note 9 for additional details of the Company's assessment of impact of this adoption.

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 Company adopted this standard in fiscal 2018 and will apply this standard to prospective modifications. The adoption of this standard did not result in any material changes to the consolidated financial statements.

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. The Company adopted this guidance in fiscal 2018 which required retroactive application resulting in the reclassification of the following:

	Fiscal Year Ended		Three Months Ended
	December 29, 2017	September 30, 2016	December 30, 2016
Cost of sales	$1.2	$ 2.6	$ 0.9
Selling, general and administrative expenses	71.2	11.6	47.2
Research and development expenses	0.4	1.0	0.1
Restructuring charges, net	—	0.6	—
Other income (expense), net	$72.8	$ 15.8	$ 48.2

The adoption of this standard did not result in any material changes to the consolidated financial statements.

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. The Company adopted this standard in fiscal 2018, which did not have a material impact to the consolidated financial statements.

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 by $47.3 million. 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 2016-01, "Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities," in January 2016. This update addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. Under the new guidance, equity investments, other than equity method investments, are to be measured at fair value with changes in fair value recognized through net income. The Company adopted this guidance in fiscal 2018, resulting in a $1.5 million increase to beginning retained earnings with an offsetting decrease to other accumulated comprehensive loss relating to the unrealized gain on its investment in Mesoblast Limited ("Mesoblast"). The adoption of this standard did not result in any material changes to the consolidated financial statements.

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 the 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(s); (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract(s); and (5) recognize revenue when (or as) the entity satisfies a performance obligation. 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 adopted ASU 2014-09 and its related amendments (collectively known as “ASC 606”) effective on December 30, 2017 using the modified retrospective transition approach. The adoption of ASC 606 represents a change in accounting principle that more closely aligns revenue recognition with the delivery of the Company's products and will provide financial statement readers with enhanced disclosures, which have been included in Note 5. The cumulative effect of applying the new standard to contracts not completed at December 30, 2017 was recorded as a $1.1 million increase, net of tax, to beginning retained earnings. The prior periods were not restated. The adoption of this standard did not result in any material changes to the consolidated financial statements.

Not Yet Adopted

The FASB issued ASU 2018-15, "Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract," in August 2018. This update aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The amendments in this update also require the entity (customer) to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. Upon adoption, the update will be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. This standard is effective for the Company in the first quarter of fiscal 2020; however, early adoption is permitted. The Company intends to adopt this standard in the first quarter of 2019 and does not believe the standard will have a material impact on the consolidated financial statements.

The FASB issued ASU 2018-02, "Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income," in February 2018. This update allows a reclassification from accumulated other comprehensive income ("AOCI") to retained earnings for the tax effects resulting from TCJA that are stranded in AOCI. This standard is effective for the Company in the first quarter of fiscal 2019. The Company has assessed the impact of this standard and determined the standard will not result in any material changes to the consolidated financial statements.

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 standard is effective for the Company in the first quarter of fiscal 2019. The Company has assessed the impact of this standard and determined the standard will not result in any material changes to the consolidated financial statements.

The FASB issued ASU 2016-13, "Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments," in June 2016. This update calls for financial assets to be measured at their net amount to be collected, or net of credit losses. Credit losses are to be measured on a probability weighted approach comprised of historical loss experience, current economic conditions, and reasonable and supportable forecasts. This standard is effective for the Company in the first quarter of fiscal 2020. The Company is assessing the impact of this guidance on the consolidated financial statements.

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 standard is effective for the Company in the first quarter of fiscal 2019. The FASB subsequently issued additional ASUs to clarify the guidance of ASU 2016-02. The ASUs issued include ASU 2018-01 "Leases: Land

Easement Practical Expedient for Transition to Topic 842;" ASU 2018-10 "Codification Improvements to Topic 842, Leases;" ASU 2018-11 "Leases (Topic 842: Targeted Improvements; and ASU 2018-20 "Leases (Topic 842): Narrow-Scope Improvements for Lessors." The Company has identified its population of lease agreements and embedded leases. The Company expects to elect the package of practical expedients, the lessor expedient, and the modified transition approach expedient. Although the Company is in process of finalizing the impact on its consolidated financial statements, it anticipates that the most significant change will be related to the Company recording additional assets and corresponding liabilities on the consolidated balance sheet for operating leases of approximately $85.0 million. This estimate may change depending on the Company's lease activity.

5. Revenue from Contracts with Customers

Product Sales Revenue

See Note 22 for presentation of the Company's net sales by product family.

Reserves for variable consideration

The following table reflects activity in the Company's sales reserve accounts:

	Rebates and Chargebacks	Product Returns	Other Sales Deductions	Total
Balance as of December 29, 2017	$ 327.4	$ 34.5	$ 14.7	$ 376.6
Provisions	2,281.3	39.3	66.9	2,387.5
Payments or credits	(2,254.4)	(39.8)	(64.5)	(2,358.7)
Balance as of December 28, 2018	$ 354.3	$ 34.0	$ 17.1	$ 405.4

Product sales transferred to customers at a point in time and over time accounted for 82.9% and 17.1% of net sales, respectively, for fiscal 2018.

Transaction price allocated to the remaining performance obligations

The following table includes estimated revenue from contracts extending greater than one year for certain of the Company's hospital products that are expected to be recognized in the future related to performance obligations that are unsatisfied or partially unsatisfied at December 28, 2018:

Fiscal 2019	$ 145.0
Fiscal 2020	127.3
Fiscal 2021	32.6
Thereafter	3.2

Costs to fulfill a contract

As of December 28, 2018, the total net book value of the devices used in the Company's portfolio of drug-device combination products, which are used in satisfying future performance obligations, was $28.4 million and are classified in property, plant and equipment, net, on the consolidated balance sheet. The associated depreciation expense recognized during fiscal 2018 was $7.4 million.

Product Royalty Revenues

In relation to the Company's acquisition of Sucampo on February 13, 2018, as discussed in further detail in Note 7, it acquired an arrangement under which the Company licenses certain rights to Amitiza to a third party in exchange for royalties on net sales of the product. The Company recognizes such royalty revenue as the related sales occur. The associated royalty revenue recognized during fiscal 2018 was $81.3 million.

Contract Liabilities

The following table reflects the balance of the Company's contract liabilities at the end of the respective periods:

	December 28, 2018	December 29, 2017
Accrued and other current liabilities	$ 20.4	$ 14.0
Other liabilities	15.1	6.6
Contract liabilities	$ 35.5	$ 20.6

Revenue recognized during fiscal 2018 from amounts included in contract liabilities at the beginning of the period was approximately $12.5 million.

6. Discontinued Operations and Divestitures

Discontinued Operations

The below businesses met the discontinued operations criteria and, accordingly, were included in discontinued operations for all periods presented.

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.

During fiscal 2018, the Company received a total of $15.0 million in contingent consideration related to the sale of the Nuclear Imaging business, consisting of a $6.0 million cash payment and the issuance of $9.0 million par value non-voting preferred equity certificates. The preferred equity certificates accrue interest at a rate of 10.0% per annum and are redeemable on the retirement date of July 27, 2025, or earlier if elected by the issuer, for cash at a price equal to the par value and any accrued but unpaid interest. The Company recorded a tax expense of $1.4 million associated with the $6.0 million contingent consideration cash payment. The $9.0 million in preferred equity certificates is presented as a non-cash investing activity on the consolidated statements of cash flows. The $13.6 million of contingent consideration received, net of tax, was recorded as income from discontinued operations.

The following table summarizes the financial results of the Nuclear Imaging business for respective periods 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**	**December 30, 2016**
Net sales	$31.6	$ 418.6	$ 99.4
Cost of sales	15.6	216.6	44.7
Selling, general and administrative	7.8	83.7	16.4
Restructuring charges, net	—	2.3	—
Other	(0.2)	5.7	0.2
Income from discontinued operations	8.4	110.3	38.1
Gain on disposal of discontinued operations	362.8	—	—
Income from discontinued operations, before income taxes	371.2	110.3	38.1
Income tax expense	5.2	49.0	15.3
Income from discontinued operations, net of tax	$366.0	$ 61.3	$ 22.8

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 respective periods:

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

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 2016 as presented in the consolidated statement of income:

Major line items constituting (loss) income from discontinued operations	**Fiscal Year Ended September 30, 2016**
Net sales	$ 61.0
Cost of sales	46.9
Selling, general and administrative	20.3
Other	1.2
Loss from discontinued operations	(7.4)
Gain on disposal of discontinued operations	95.3
Income from discontinued operations, before income taxes	87.9
Income tax benefit	(2.5)
Income from discontinued operations net of tax	$ 90.4

The Company incurred $1.6 million of capital expenditures related to the CMDS business that are included within the consolidated statement of cash flows for fiscal 2016.

Mallinckrodt Baker: During fiscal 2010, the Specialty Chemicals business (formerly known as "Mallinckrodt Baker") was sold because its products and customer base were not aligned with the Company's long-term strategic objectives. During fiscal 2018 and 2017, the Company recorded a loss, net of tax of $0.3 million and $0.6 million, respectively. During fiscal 2016 and the three months ended December 30, 2016, the Company recorded a gain, net of tax, of $3.0 million and $0.6 million, respectively. The gains and losses were primarily related to the indemnification obligations to the purchaser, which are discussed in Note 19.

Divestitures

PreveLeak/Recothrom: On March 16, 2018, the Company completed the sale of a portion of its Hemostasis business, inclusive of its PreveLeak™ Surgical Sealant ("PreveLeak") and RECOTHROM® Thrombin topical (Recombinant) ("Recothrom") products to Baxter International Inc. ("Baxter") for approximately $185.0 million, with a base payment of $153.0 million, inclusive of existing inventory and subject to a closing inventory adjustment, with the remainder in potential future milestones. Baxter assumed other expenses, including contingent liabilities associated with PreveLeak. During fiscal 2018, the Company recorded a pre-tax loss on the sale of $0.8 million, which excluded any potential proceeds from the potential future milestones and reflected a post-sale closing inventory adjustment of $13.7 million. The financial results of the PreveLeak and Recothrom operations 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 loss, the Company wrote off intangible assets of $49.9 million and goodwill of $51.5 million during the first quarter of fiscal 2018, from the Specialty Brands segment, ascribed to the PreveLeak and Recothrom operations. The remaining items included in the gain calculation are primarily attributable to inventory transferred, contingent consideration transferred and transaction costs incurred by the Company.

Intrathecal Therapy: 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 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. In fiscal 2018, the Company received $154.0 million from Piramal for the settlement of the aforementioned note receivable. 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.

During fiscal 2017, 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 $3.1 million and $6.5 million was included in accrued and other current liabilities on the consolidated balance sheets as of December 28, 2018 and December 29, 2017, respectively. The remaining items included in the gain calculation were attributable to inventory transferred and transaction costs incurred by the Company.

7. Acquisitions and License Agreements

Business Acquisitions

Sucampo Pharmaceuticals, Inc.

In February 2018, the Company acquired Sucampo through the acquisition of all the outstanding common stock of 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 a $600.0 million aggregate principal amount of senior secured term loan, a $900.0 million borrowing under the Company's revolving credit facility, as discussed further in Note 14, and cash on hand. Sucampo's primary commercialized product was Amitiza, a leading global product in the branded constipation market. Through this acquisition, the Company acquired VTS-270, a Phase 3 development product for Niemann-Pick Type C, a complicated, ultra-rare neurodegenerative disease that typically presents in childhood and is ultimately fatal. Also acquired was an option to exercise a collaborative agreement with Cancer Prevention Pharmaceuticals ("CPP") associated with the development of CPP-1X/sulindac, a Phase 3 development product for Familial Adenomatous Polyposis ("FAP"). Refer to the License Agreements section below for further information on the CPP agreement.

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 could be converted into $1,221 cash. As of December 28, 2018, the issued convertible debt of $300.0 million had been converted and paid in full by the Company.

Ocera Therapeutics, Inc.

In December 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"). Through this acquisition, the Company acquired Ocera’s primary development product MNK-6105/6106, an ammonia scavenger, which 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. Through this acquisition, the Company acquired InfaCare's development product stannsoporfin, a heme oxygenase inhibitor, which 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. See further discussion related to the stannsoporfin developmental product in Notes 13 and 21.

Stratatech Corporation

In August 2016, the Company acquired Stratatech Corporation ("Stratatech") 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"). Through this acquisition, the Company acquired Stratatech's development products including 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

In February 2016, the Company acquired three commercial stage topical hemostasis drugs from The Medicines Company ("the Hemostasis Acquisition") - Recothrom, 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 shifted its focus to the critical care, autoimmune and rare disease spaces, the Company sold the Recothrom and PreveLeak assets and discontinued marketing of Raplixa. See further discussion in Notes 6, 13, and 21.

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:

	Sucampo	**Ocera** [(1)]	**InfaCare** [(2)]	**Stratatech**	**Hemostasis** [(3)]
Acquisition Date	February 2018	December 2017	September 2017	August 2016	February 2016
Cash	$ 149.6	$ 1.0	$ 1.3	$ 0.2	$ 3.3
Accounts receivable	35.7	—	—	1.3	—
Inventory	153.2	—	—	—	94.6
Intangible assets	919.5	64.5	113.5	99.8	132.7
Goodwill (non-tax deductible) [(4)]	248.6	18.0	11.4	55.1	3.3
Other assets, current and non-current	25.8	0.4	0.1	1.9	7.9
Total assets acquired	1,532.4	83.9	126.3	158.3	241.8
Current liabilities	109.4	12.0	14.5	4.3	3.6
Other liabilities (non-current)	33.3	—	—	—	10.6
Deferred tax liabilities, net (non-current)	175.8	16.7	8.7	22.1	2.1
Contingent consideration (non-current)	—	12.8	35.0	54.9	52.0
Debt	366.3	—	30.0	1.0	—
Total liabilities assumed	684.8	41.5	88.2	82.3	68.3
Net assets acquired	$ 847.6	$ 42.4	$ 38.1	$ 76.0	$ 173.5

(1) Of the $42.4 million net assets acquired for Ocera, $40.5 million and $1.9 million was paid in fiscal 2017 and 2018, respectively.

(2) During fiscal 2018, the Company reduced the contingent consideration liability related to this acquisition to zero through the recognition of a $35.0 million fair value adjustment. Refer to Note 21 for further information.

(3) During fiscal 2017, the Company recorded a non-restructuring impairment charge relating to its Raplixa intangible asset and reduced the associated contingent consideration liability. During fiscal 2018, the Company sold its Recothrom and PreveLeak assets to Baxter. Refer to Notes 6, 13 and 21, respectively, for further information.

(4) Refer to Note 13 for further information relating to the full goodwill impairment recorded in fiscal 2018.

The following reconciles the total consideration to net assets acquired:

Sucampo	**Ocera** [(1)]	**InfaCare**	**Stratatech**	**Hemostasis**

Total consideration, net of cash	$ 698.0	$ 63.4	$ 71.8	$ 130.7	$ 222.2
Plus: cash assumed in acquisition	149.6	1.0	1.3	0.2	3.3
Total consideration	847.6	64.4	73.1	130.9	225.5
Less: non-cash contingent consideration	—	(22.0)	(35.0)	(54.9)	(52.0)
Net assets acquired	$ 847.6	$ 42.4	$ 38.1	$ 76.0	$ 173.5

(1) $1.9 million of the total consideration, net of cash was paid in fiscal 2018, subsequent to the Company's December 11, 2017 acquisition date.

Intangible assets acquired consist of the following:

Acquisition	Intangible Asset Acquired	Amount	Amortization Period	Discount Rate	Segment
Sucampo	Completed technology - Amitiza	$ 634.0	9 years	14.0 %	Specialty Generics and Amitiza
Sucampo	Completed technology - Other	11.0	8 years	14.0 %	Specialty Generics and Amitiza
Sucampo	In-process research and development - VTS-270	274.5	Non-Amortizable	15.0 %	Specialty Brands
Ocera	In-process research and development - MNK-6105/6106	64.5	Non-Amortizable	15.5 %	Specialty Brands
InfaCare	In-process research and development - stannsoporfin	113.5	Non-Amortizable	13.5 %	Specialty Brands
Stratatech	In-process research and development - StrataGraft	99.8	Non-Amortizable	16.5 %	Specialty Brands
Hemostasis	Completed technology - Raplixa (1)	73.0	15 years	17.0 %	Specialty Brands
Hemostasis	Completed technology - Recothrom (2)	42.7	13 years	16.0 %	Specialty Brands
Hemostasis	Completed technology - PreveLeak (2)	17.0	13 years	17.0 %	Specialty Brands

(1) During fiscal 2017, the Company recorded a non-restructuring impairment charge relating to the Raplixa intangible asset. Refer to Note 13 for further information.

(2) During fiscal 2018, the Company sold the Recothrom and PreveLeak assets to Baxter. Refer to Note 6 for further information.

The fair value of the intangible assets was 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 Food and Drug Administration ("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.

Financial Results

The amount of net sales and operating losses included in the Company's fiscal 2018 consolidated statement of income related to the Sucampo Acquisition were $190.5 million and $369.1 million, respectively. Included within Sucampo's results was $62.9 million of amortization associated with intangibles recognized from this acquisition and $118.8 million of expense associated with fair value adjustments of acquired inventory. During fiscal 2018, 2017 and 2016 and the three months ended December 30, 2016, the Company in total recognized $120.8 million, $10.1 million, $24.3 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 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Sucampo	$5.2	$ 4.2	$ —	$ —
Ocera	0.5	0.9	—	—
InfaCare	—	1.2	—	—
Stratatech	—	—	3.7	—
Hemostasis	—	—	2.7	0.1
Other	0.1	0.1	0.5	—
Total acquisition-related costs	$5.8	$ 6.4	$ 6.9	$ 0.1

License Agreements

CPP

In April 2018, the Company exercised the option under its collaborative agreement with CPP to negotiate terms of an exclusive license to commercialize CPP-1X/sulindac in North America. In addition, the Company provided CPP with a $10.0 million upfront

R&D payment for expenses related to the FAP pivotal trial incurred during the "Negotiation Period," or the period from the exercise date through the execution of such license agreement. CPP shall return to the Company any portion of the R&D payment that is not utilized during the Negotiation Period. Of the $10.0 million upfront payment, $7.3 million was utilized during fiscal 2018 and recorded as R&D expense within the consolidated statements of income. The remaining $2.7 million was included in prepaid expenses and other current assets on the consolidated balance sheet as of December 28, 2018.

In August 2018, the license agreement with CPP was executed and the Company paid $5.0 million upfront with cash on hand and gained exclusive rights to develop and commercialize the product in North America, if approved. The agreement includes additional payments of up to $185.0 million dependent on developmental, regulatory and sales milestones, subject to reduction up to $15.0 million related to amounts provided by the Company in advance of entering into this agreement, and provides for both parties' reimbursement of R&D expenses from future profits. Following the commercialization of the product, CPP and the Company will share profits in accordance with the agreement. The Company will manage the development of the product in North America.

Xenon Gas for Inhalation

In October 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 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 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. During fiscal 2018, the Company paid a milestone payment of $5.0 million related to the first patient enrolled in a Phase 3 trial. The initial $10.0 million upfront cash payment and the $5.0 million milestone payment were both recorded within R&D expense during fiscal 2017 and fiscal 2018, respectively. Of the remaining $20.0 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 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 as of March 31, 2017. This intangible asset was fully amortized as of December 29, 2017 as the nine month exclusivity period had ended. During fiscal 2018, all of the Company's shares were sold for gross proceeds of $25.5 million resulting in a $3.4 million gain being recognized within other income (expense), net within the consolidated statement of income.

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 Bristol-Myers Squibb Company ("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 made the final milestone payment of $15.0 million in fiscal 2018. In addition, the Company is obligated to pay royalties on sales of the product. During fiscal 2018, 2017, 2016 and the three months ended December 30, 2016, the Company paid royalties of $76.9 million, $53.9 million, $46.3 million and $14.7 million, respectively, which were recorded within cost of sales on the consolidated statements of income.

Assertio Therapeutics, Inc. (formerly known as Depomed, Inc.)
In 2009, the Company licensed worldwide rights to utilize Assertio Therapeutics, Inc. (formerly known as Depomed, Inc.) 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 2018, approximately $22.0 million of these payments have been made by the Company, and as of December 28, 2018, the Company has no remaining obligations

under this arrangement. During fiscal 2014, upon approval by the FDA for XARTEMIS™ XR (oxycodone HCl and acetaminophen) extended release tablets CII ("Xartemis"), 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.

Advanced Accelerator Applications

In 2007, the Company's Nuclear Imaging business entered into a license agreement with BioSynthema, Inc. ("BioSynthema"), which was subsequently amended in 2010 when Advanced Accelerator Applications ("AAA") acquired BioSythema. Pursuant to the amended agreement, upon the first commercial sale of Lutathera® ("Lutathera"), AAA is to provide the Company with a royalty based on net sales of the product through January 1, 2020. In early 2018, the FDA approved Lutathera for treatment of gastroenteropancreatic neuroendocrine tumors and commercial sales commenced. During fiscal 2018, in relation to this agreement, the Company recognized royalty income of $15.5 million, which was recognized within other income (expense), net in the consolidated statement of income.

8. 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. As of December 28, 2018, the 2013 Mallinckrodt Program is 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 included actions across the Specialty Brands and Specialty Generics and Amitiza segments, as well as within corporate functions. As of December 28, 2018, the 2016 Mallinckrodt Program is substantially complete.

In February 2018, the Company's Board of Directors approved a $100.0 million to $125.0 million restructuring program ("the 2018 Mallinckrodt Program") that is of similar design as the 2016 Mallinckrodt Program. The utilization of the 2018 Mallinckrodt Program commenced upon substantial completion of the 2016 Mallinckrodt Program. There is no specified time period associated with the 2018 Mallinckrodt Program.

In addition to the 2018, 2016 and the 2013 Mallinckrodt Programs, 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 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Specialty Brands	$52.2	$ 25.4	$ 23.3	$ 2.6
Specialty Generics and Amitiza	29.0	7.7	3.4	0.8
Corporate	27.0	3.3	10.9	1.9
Restructuring and related charges, net	108.2	36.4	37.6	5.3
Less: accelerated depreciation	(5.2)	(5.2)	(4.9)	(1.5)
Restructuring charges, net	$103.0	$ 31.2	$ 32.7	$ 3.8
Charges in other income (expense) [1]	$—	$ —	$ 0.6	$ —

(1) Charges incurred under restructuring programs related to pension that were reclassified to other income (expense), net due to the adoption of ASU 2017-07.

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

	Fiscal Year Ended			Three Months Ended
	December 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
2018 Mallinckrodt Program	$5.2	$ —	$ —	$ —
2016 Mallinckrodt Program	71.6	36.2	8.3	5.2
2013 Mallinckrodt Program	—	(0.7)	25.6	—
Acquisition programs	31.4	0.9	3.7	0.1
Total programs	108.2	36.4	37.6	5.3
Less: non-cash charges, including accelerated depreciation and impairments	(5.2)	(5.2)	(4.9)	(1.5)
Total charges expected to be settled in cash	$103.0	$ 31.2	$ 32.7	$ 3.8
Charges in other income (expense) [1]	$—	$ —	$ 0.6	$ —

(1) Charges incurred under restructuring programs related to pension that were reclassified to other income (expense) due to the adoption of ASU 2017-07.

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

	2018 Mallinckrodt Program	2016 Mallinckrodt Program	2013 Mallinckrodt Program	Acquisition Programs	Total
Balance at September 25, 2015	$ —	$ —	$ 8.0	$ 10.0	$18.0
Charges from continuing operations	—	6.4	24.0	5.0	35.4
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]	—	—	(0.7)	—	(0.7)
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	—	0.3	—	—	0.3
Balance at December 29, 2017	—	14.7	—	0.8	15.5
Charges from continuing operations	2.2	76.9	—	29.9	109.0
Changes in estimate from continuing operations	—	(5.3)	—	(0.7)	(6.0)
Cash payments	—	(23.4)	—	(22.2)	(45.6)
Reclassifications	—	(1.9)	—	—	(1.9)
Balance at December 28, 2018	$ 2.2	$ 61.0	$ —	$ 7.8	$71.0

(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 2018, 2016 and 2013 Mallinckrodt Programs are as follows:

	2018 Mallinckrodt Program	2016 Mallinckrodt Program	2013 Mallinckrodt Program
Specialty Brands	$ 3.0	$ 81.7	$ 18.8
Specialty Generics and Amitiza	—	14.6	18.3
Discontinued Operations	—	—	69.9
Corporate	2.2	25.9	17.7
	$ 5.2	$ 122.2	$ 124.7

In fiscal 2018, the Company discontinued the marketing of Raplixa after an evaluation of strategic options and incurred restructuring expenses of $51.1 million under the 2016 Mallinckrodt Program, consisting primarily of contract termination costs related to the production of Raplixa. Amounts paid in the future may differ from the amount currently recorded.

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

9. Income Taxes

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the TCJA. The TCJA reduces the U.S. federal corporate statutory rate from 35% to 21%, requires companies to pay a one-time transition tax on certain undistributed earnings of foreign subsidiaries of U.S. entities and creates new taxes on certain foreign sourced earnings. As of December 28, 2018, the Company has completed its accounting for all of the tax effects of the TCJA.

During fiscal 2017 the Company recorded a deferred tax benefit of $444.8 million for the provisional estimate of the remeasurement of its net U.S. deferred tax liabilities for the reduction in the U.S. federal corporate statutory tax rate to 21%. The provisional estimate was 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. During fiscal 2018, on the basis of additional analysis related to certain tax calculations, the Company recognized an additional deferred tax benefit of $8.5 million, impacting the effective tax rate by 0.2%.

The one-time transition tax under the TCJA is based upon the amount of post-1986 cumulative undistributed earnings of certain of the Company's subsidiaries which was deferred from U.S. income tax under previous U.S. law. During fiscal 2017, the Company estimated this item would not result in any current or future tax. During fiscal 2018, no adjustments to the one-time transition tax have been made.

TCJA subjects a U.S. shareholder to current tax on global intangible low-taxed income (“GILTI”) earned by certain foreign subsidiaries. The FASB Staff *Question & Answer Topic 740 No. 5, Accounting for Global Intangible Low-Taxed Income*, states that an entity can make an accounting policy election to either recognize deferred taxes for temporary differences expected to reverse as GILTI in future years or provide for the tax expense related to GILTI in the year the tax is incurred. The Company has elected to recognize the tax on GILTI as a period expense in the period the tax is incurred.

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

	Fiscal Year Ended			Three Months Ended
	December 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
U.K.	$ (233.7)	$ (165.9)	$ (275.3)	$ (97.4)
Non-U.K.	(3,818.3)	227.5	508.7	(201.1)

Total	$ (4,052.0)	$ 61.6	$ 233.4	$ (298.5)

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

	Fiscal Year Ended			Three Months Ended
	December 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Current:				
U.K.	$(0.2)	$0.4	$0.3	$—
Non-U.K.	113.0	37.7	120.5	82.0
Current income tax provision	112.8	38.1	120.8	82.0
Deferred:				
U.K.	1.4	0.6	0.7	(0.5)
Non-U.K.	(544.3)	(1,748.3)	(377.1)	(203.2)
Deferred income tax benefit	(542.9)	(1,747.7)	(376.4)	(203.7)
Total	$(430.1)	$(1,709.6)	$(255.6)	$(121.7)

The fiscal 2018 U.K. current income tax provision reflects a tax benefit of $8.5 million from utilization of net operating loss carryforwards. The fiscal 2018 non-U.K. current income tax provision reflects a tax benefit of $13.7 million from utilization of net operating loss carryforwards.

The fiscal 2017 U.K. current income tax provision reflects a tax benefit of $14.3 million from utilization of net operating loss carryforwards. The fiscal 2017 non-U.K. current income tax provision reflects a tax benefit of $57.2 million from utilization of net operating loss carryforwards 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 U.S. credit utilization is comprised of credit carryforwards and credits 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 loss carryforwards. The fiscal 2016 non-U.K. current income tax provision reflects a tax benefit of $29.2 million from utilization of net operating loss carryforwards 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 loss carryforwards. The U.S. credit utilization is comprised of credit carryforwards and credits generated during fiscal 2016.

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 loss carryforwards and $2.0 million of U.S. credits. The U.S. credit utilization is comprised of credit carryforwards and credits generated during the three months ended December 30, 2016.

During fiscal years 2018, 2017, and 2016 net cash payments for income taxes was $12.4 million, $73.4 million and $165.4 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 $1.0 million, $1.8 million and $1.0 million for the fiscal years 2018, 2017 and 2016, 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 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
(Benefit) provision for income taxes at U.K. statutory income tax rate [1]	$ (770.1)	$ 11.7	$ 46.6	$ (59.7)
Adjustments to reconcile to income tax provision:				
Rate difference between U.K. and non-U.K. jurisdictions [2] [4]	(235.7)	(219.9)	(249.3)	(123.0)
Valuation allowances, nonrecurring	—	(3.7)	2.1	—
Adjustments to accrued income tax liabilities and uncertain tax positions	60.1	5.1	(14.9)	0.9
Interest and penalties on accrued income tax liabilities and uncertain tax positions	13.1	0.2	(16.4)	(0.1)
Investment in partnership	—	—	—	(12.7)
Credits, principally research and orphan drug [3]	(25.9)	(13.8)	(33.7)	(0.7)
Impairments non deductible	788.7	—	—	75.3
Permanently nondeductible and nontaxable items	7.2	6.4	7.9	1.6
Pension plan settlement, release of tax effects lodged in other comprehensive income	—	(2.4)	—	—
Divestitures [7]	(2.7)	18.2	—	—
U.S. Tax Reform [5]	(8.5)	(456.9)	—	—
Legal Entity Reorganization [6]	(256.0)	(1,054.8)	—	—
Other	(0.3)	0.3	2.1	(3.3)
Benefit for income taxes	$ (430.1)	$ (1,709.6)	$ (255.6)	$ (121.7)

(1) The statutory tax rate reflects the U.K. statutory tax rate of 19% for fiscal 2018 and 2017 and 20% for fiscal 2016 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 2018, the research and orphan drug credits increased in conjunction with the Company's increased investment in qualified research. 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.

(4) 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 reporting unit.

(5) For fiscal 2018, the Company completed its analysis of the TCJA and recognized an additional tax benefit. Other line items, to the extent U.S. related, are reflected at the current U.S. statutory income tax rate of 21%. For fiscal 2017, the benefit reflects the redetermination of the Company’s end of year net deferred tax liabilities as a result of the new U.S. statutory income tax rate of 21%. Other line items, to the extent U.S. related, are reflected at the former U.S. statutory income tax rate of 35%.

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

(7) During fiscal 2018, the Company completed the sale of a portion of its Hemostasis business. During fiscal 2017, the Company completed the sale of the Intrathecal Therapy Business.

The rate difference between U.K. and non-U.K. jurisdictions changed from $219.9 million of tax benefit to $235.7 million of tax benefit for fiscal 2017 to fiscal 2018, respectively. The $15.8 million increase in the tax benefit included a $90.3 million increase attributable to the non-restructuring impairment charges in fiscal 2018, a $22.2 million increase attributable to the divestiture of the Intrathecal Therapy business in fiscal 2017 and of the PreveLeak and Recothrom assets in fiscal 2018; partially offset by decreases of $80.2 million to the tax benefit attributable to the impact of U.S. Tax Reform, an $11.8 million decrease related to recent acquisitions, and a $4.7 million decrease attributable to changes in operating income and fiscal 2017 one-time items that did not recur in fiscal 2018.

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.

During fiscal 2018, the Company initiated a reorganization of its intercompany financing and associated legal entity ownership in response to the changing global tax environment. As a result, the Company recognized current income tax expense of $25.5 million and a deferred income tax benefit of $281.5 million with a corresponding reduction to net deferred tax liabilities. The

reduction in net deferred tax liabilities is comprised of a $310.6 million decrease in interest-bearing deferred tax obligations, a $58.9 million increase in deferred tax liabilities associated with its investment in partnership, a $58.9 million decrease in deferred tax liabilities predominately associated with intangible assets, a $39.7 million increase related to a change in valuation allowances, a $9.3 million decrease in various other net deferred tax liabilities and a $1.3 million decrease associated with generation of tax loss and credit carryforwards.

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

	Fiscal Year Ended			Three Months Ended
	December 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Balance at beginning of period	$182.5	$ 118.7	$ 89.2	$ 114.8
Additions related to current year tax positions	19.6	79.9	63.8	5.0
Additions related to prior period tax positions	125.1	0.3	10.8	—
Reductions related to prior period tax positions	(32.7)	(13.6)	(37.8)	(1.1)
Reductions related to disposition transactions	—	—	(6.6)	—
Settlements	(2.0)	—	(2.6)	—
Lapse of statute of limitations	(4.8)	(2.8)	(2.0)	—
Balance at end of period	$287.7	$ 182.5	$ 114.8	$ 118.7

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

	December 28, 2018	December 29, 2017
Accrued and other current liabilities	$ 1.0	$ 1.5
Other income tax liabilities	189.9	82.6
Deferred income taxes (non-current liability)	96.8	98.4
	$ 287.7	$ 182.5

Included within total unrecognized tax benefits at December 28, 2018, December 29, 2017, September 30, 2016 and December 30, 2016, were $275.8 million, $180.8 million, $113.1 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 2018, the Company recorded $33.2 million of additional interest and penalties through tax provision and acquisition accounting and decreased accrued interest by $3.2 million related to prior period reductions, settlements and lapse of statute of limitations. During fiscal 2017, 2016 and the three months ended December 30, 2016, the Company had net interest and penalties activity of zero, an increase of $1.9 million and a decrease of $0.2 million, respectively. The total amount of accrued interest and penalties related to uncertain tax positions was $37.1 million, $7.1 million, $7.4 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 $136.9 million. Interest and penalties could decrease by up to $32.8 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 28, 2018	December 29, 2017

Income taxes payable	$ 25.0	$ 15.8
Other income tax liabilities	228.0	94.1
	$ 253.0	$ 109.9

Tax receivables and payments associated with deferred intercompany transactions are included in the following consolidated balance sheet captions in the amounts shown:

	December 28, 2018	December 29, 2017
Other assets	$ 3.0	$ —
Prepaid expenses and other current assets	16.2	6.1
	$ 19.2	$ 6.1

Certain of the Company's subsidiaries continue to be subject to examination by the IRS for tax years as early as 2014. As of December 28, 2018, the primary unresolved issue relates to transfer pricing, which could have a significant impact to the consolidated financial statements if not resolved favorably. The Company believes its allowances for income tax contingencies are adequate. The Company has not received a proposed assessment for the unresolved issues and does not expect a final resolution of these issues in the next 12 months. In addition, the earliest open years for state tax jurisdictions are 2009 and 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 28, 2018	December 29, 2017
Deferred tax assets:		
Accrued liabilities and reserves	$ 56.3	$ 62.7
Tax loss and credit carryforwards	1,987.8	1,734.5
Intangible assets	757.7	575.1
Other	204.6	113.3
	3,006.4	2,485.6
Deferred tax liabilities:		
Intangible assets	(264.7)	(181.0)
Interest-bearing deferred tax obligations	(227.5)	(553.5)
Investment in partnership	(170.2)	(108.8)
Other	(42.9)	(47.0)
	(705.3)	(890.3)
Net deferred tax asset before valuation allowances	2,301.1	1,595.3
Valuation allowances	(2,604.9)	(2,267.9)
Net deferred tax liability	$ (303.8)	$ (672.6)

The deferred tax asset valuation allowances of $2,604.9 million and $2,267.9 million at December 28, 2018 and December 29, 2017, respectively, relate primarily to the uncertainty of the utilization of certain deferred tax assets, driven by U.K. and 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.

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

	December 28, 2018	December 29, 2017
Other assets	$ 20.5	$ 16.4
Deferred income taxes (non-current liability)	(324.3)	(689.0)
Net deferred tax liability	$ (303.8)	$ (672.6)

Non-current deferred tax liability decreased from $689.0 million at December 29, 2017 to $324.3 million at December 28, 2018, primarily due to $281.5 million of decreases associated with the deferred tax benefit recognized

from the reorganization of the Company's intercompany financing and associated legal entity ownership, $135.9 million of decreases predominately related to the generation of net operating losses and other operational activity, $49.1 million of decreases related to impairments, $28.9 million of decreases associated with the amortization of intangibles, $23.6 million of decreases associated with inventory step up amortization, $8.5 million of decreases associated with the impact of U.S. Tax Reform and $6.5 million of decreases related to reductions of deferred tax assets associated with legal settlements. These decreases are partially offset by $169.3 million of increases related to recent acquisitions.

The sale of a portion of the Hemostasis business, inclusive of the PreveLeak and Recothrom products, was completed on March 16, 2018. This divestiture resulted in a net deferred tax liability decrease of $2.7 million. A significant component of this decrease includes a decrease of $2.7 million of deferred tax liability associated with inventories. In addition, there was a decrease of $1.5 million associated with other deferred tax assets, a decrease of $2.7 million of deferred tax assets associated with tax loss and credit carryforwards, and a decrease of $4.2 million of deferred tax assets associated with intangible assets, all of which were offset by a reduction in valuation allowance of $8.4 million.
The Sucampo Acquisition resulted in a net deferred tax liability increase of $175.8 million. Significant components of this increase include $179.3 million of deferred tax liabilities associated with intangible assets and a $25.7 million deferred tax liability associated with inventories. The increase in deferred tax liabilities is partially offset by $25.1 million of deferred tax assets associated with tax loss and credit carryforwards, and various other net deferred tax assets of $4.1 million.
The Company refined its acquisition accounting estimate associated with the measurement of its acquired Ocera net deferred tax liabilities in fiscal 2018, resulting in a decrease to the acquired net deferred tax liabilities from $23.2 million to $16.7 million prior to recording the impact from the TCJA.
As of December 28, 2018, the Company had approximately $1,817.8 million of net operating loss carryforwards in certain non-U.K. jurisdictions measured at the applicable statutory rates, of which $1,484.4 million have no expiration and the remaining $333.4 million will expire in future years through 2039. The Company had $108.2 million of U.K. net operating loss carryforwards measured at the applicable statutory rates at December 28, 2018, which have no expiration date.
As of December 28, 2018, the Company also had $61.8 million of tax credits available to reduce future income taxes payable, primarily in jurisdictions within the U.S., of which $4.6 million have no expiration and the remainder will expire in future years through 2039.
As of December 28, 2018, the Company’s financial reporting basis in international subsidiaries that may be subject to tax was in excess of its corresponding tax basis by $41.6 million. Such excess amount is considered to be indefinitely reinvested and it is not practicable to determine the cumulative amount of tax liability that would arise if this indefinitely reinvested amount were realized due to a variety of factors including the complexity of the Company’s legal entity structure as well as the timing, extent, and nature of any hypothetical realization. The net increase, as compared to the period ending December 29, 2017, was attributable to the finalization of the impacts of the TCJA as well as income and losses attributed to current year activity. The Company has recorded a deferred tax liability of $9.1 million for amounts not considered to be indefinitely reinvested.

10. (Loss) Earnings per Share

Basic (loss) earnings per share is computed by dividing net (loss) income by the number of weighted-average shares outstanding during the period. Diluted (loss) earnings 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 (loss) earnings per share by application of the treasury stock method.
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 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
(Loss) earnings per share numerator:				
(Loss) income from continuing operations attributable to common shareholders	$(3,621.9)	$1,771.2	$489.0	$(176.8)
Income from discontinued operations	14.9	363.2	154.7	23.6
Net (loss) income attributable to common shareholders	$(3,607.0)	$2,134.4	$643.7	$(153.2)
(Loss) earnings per share denominator:				
Weighted-average shares outstanding - basic	84.0	97.7	110.6	105.7
Impact of dilutive securities	—	0.2	0.9	—
Weighted-average shares outstanding - diluted	84.0	97.9	111.5	105.7
Basic (loss) earnings per share attributable to common shareholders:				
(Loss) income from continuing operations	$(43.12)	$18.13	$4.42	$(1.67)
Income from discontinued operations	0.18	3.72	1.40	0.22
Net (loss) income attributable to common shareholders	$(42.94)	$21.85	$5.82	$(1.45)
Diluted (loss) earnings per share attributable to common shareholders:				
(Loss) income from continuing operations	$(43.12)	$18.09	$4.39	$(1.67)
Income from discontinued operations	0.18	3.71	1.39	0.22
Net (loss) income attributable to common shareholders	$(42.94)	$21.80	$5.77	$(1.45)

The computation of diluted earnings per share for fiscal 2018, 2017, 2016 and the three months ended December 30, 2016, excludes approximately 3.3 million, 4.2 million, 1.7 million and 2.4 million, respectively, of equity award shares because the effect would have been anti-dilutive. As the Company incurred a net loss in fiscal 2018 and 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.

11. Inventories

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

	December 28, 2018	December 29, 2017
Raw materials and supplies	$ 69.2	$ 70.0
Work in process	167.6	167.1
Finished goods	85.5	103.3
Inventories	$ 322.3	$ 340.4

12. 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 28, 2018	December 29, 2017
Land	$ 43.9	$ 44.0
Buildings	379.5	355.5
Capitalized software	130.8	109.0
Machinery and equipment	1,137.3	1,123.8
Construction in process	244.7	209.7
	1,936.2	1,842.0
Less: accumulated depreciation	(954.2)	(875.2)

Property, plant and equipment, net	$ 982.0	$ 966.8

Depreciation expense for continuing operations was as follows:

	Fiscal Year Ended			Three Months Ended
	December 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Depreciation expense	$111.9	$ 113.8	$ 113.3	$ 27.5

13. Goodwill and Intangible Assets

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

	December 28, 2018		December 29, 2017	
	Gross Carrying amount	Accumulated Impairment	Gross Carrying amount	Accumulated Impairment
Specialty Brands	$3,672.8	$ (3,672.8)	$3,482.7	$ —
Specialty Generics	207.0	(207.0)	207.0	(207.0)
Total	$3,879.8	($3,879.8)	$3,689.7	$ (207.0)

During the fiscal year ended December 28, 2018, the gross carrying value of goodwill in the Specialty Brands segment increased by $190.1 million. The increase was primarily attributable to the Sucampo Acquisition, which yielded $248.6 million of goodwill, partially offset by $51.5 million of goodwill ascribed to the sale of a portion of the Company's Hemostasis business, inclusive of the PreveLeak and Recothrom products. The remaining change in goodwill was related to purchase accounting adjustments during the twelve month measurement period for previous acquisitions.

Goodwill Impairment Analysis

Fiscal Year ended December 28, 2018

The Company performed its annual goodwill impairment analysis for the Specialty Brands reporting unit as of the first day of the fourth quarter. The Company’s 2018 annual assessment first considered its internally developed future cash flows, which reflect the Company's overall strategy, future growth and value proposition. There continues to be a disparity between the Company's anticipated future performance and present uncertainty reflected in its market capitalization, driven by a sustained decrease in its share price. The Company continues to believe that its share price has been adversely affected primarily by uncertainties regarding patient withdrawal issues impacting net sales of H.P. Acthar® Gel ("H.P. Acthar Gel"), ongoing Inomax® ("Inomax") patent litigation and the perceived value of its various pipeline products. Given the passage of time since first experiencing a substantial decline in its share price during the three months ended December 29, 2017 and the fact that the aforementioned uncertainties are not expected to be resolved in the near-term, the Company's annual goodwill impairment analysis resulted in the recognition of a full goodwill impairment of $3,672.8 million.

For purposes of the 2018 goodwill impairment assessment 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. The projections of future cash flows were discounted based on a weighted average cost of capital of 12.5% 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 cash flows. 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.

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 were expected to compete with the Company's methylphenidate HCl extended-release tablets USP (CII) ("Methylphenidate ER") products and at that time one competitor had 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. 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 28, 2018		December 29, 2017	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortizable:				
Completed technology	$10,467.9	$ 2,980.6	$9,882.8	$ 2,260.8
License agreements	120.1	70.1	177.1	121.1
Trademarks	81.9	18.1	82.1	14.5
Customer relationships	27.5	14.1	29.5	12.2
Other	—	—	8.6	8.6
Total	$10,697.4	$ 3,082.9	$10,180.1	$ 2,417.2
Non-Amortizable:				
Trademarks	$35.0		$35.0	
In-process research and development	633.3		577.1	
Total	$668.3		$612.1	

The Company recorded impairment charges totaling $220.3 million, $63.7 million, $16.9 million, and $7.3 million during fiscal 2018, 2017, 2016 and the three months ended December 30, 2016, respectively. The fiscal 2018 and 2017 impairment charges primarily related to the MNK-1411 and Raplixa intangible assets respectively, and were a result of lower than previously anticipated pricing assumptions and commercial opportunities, respectively, for the products. The fiscal 2016 impairment charge primarily related to IPR&D assets acquired as part of the CNS Therapeutics acquisition in fiscal 2013, and resulted from delays in anticipated FDA approval, higher than expected development costs and lower than previously anticipated commercial opportunities. The impairment charge recorded during the three months ended December 30, 2016 related to the impairment of licenses associated with the Xartemis product upon the Company's election to discontinue the product. The valuation method used to approximate fair value in each of these periods was based on the estimated discounted cash flows for the respective asset.

Stannsoporfin

On May 3, 2018, in a joint meeting, the FDA's Gastrointestinal Drugs Advisory Committee and Pediatric Advisory Committee (the "Advisory Committee") recommended that the risk benefit profile of the Company's stannsoporfin IPR&D product does not support approval for the treatment of newborns ≥35 weeks of gestational age with indicators of hemolysis who are at risk of developing hyperbilirubinemia (severe jaundice).

On August 9, 2018, the Company received a complete response letter from the FDA related to its new drug application ("NDA") for stannsoporfin. In the letter, the FDA provided guidance regarding areas of further evaluation

for resubmitting the stannsoporfin NDA for the treatment of newborns ≥35 weeks of gestational age with indicators of hemolysis who are at risk of developing hyperbilirubinemia. While the timing of the development program has shifted outward, the Company continues to have conversations with the FDA to determine the best path forward. The Company will continue to assess the impact of any changes to planned revenue or earnings on the fair value of the associated IPR&D asset of $113.5 million included within intangible assets, net on the consolidated balance sheet as of December 28, 2018. Refer to Note 21 for the associated impact on the Company's contingent consideration liability related to stannsoporfin.

VTS-270

VTS-270 is the Company's development product to treat Niemann-Pick Type C, a complicated, ultra-rare neurodegenerative disease that typically presents in childhood and is ultimately fatal. The results of the Company's recently completed registration trial for the product did not show a statistically significant separation from placebo. Neither the VTS-270 nor the placebo arm showed disease progression as would be expected for a neurodegenerative condition over 52 weeks of observation. The Company is in the process of evaluating this portion of the study in order to ensure the data was properly captured and of the highest quality. The FDA indicated to the Company at a Type A meeting in August 2018 that their view on the potential approvability will be based on the totality of data, not a single study or endpoint. Accordingly, the Company's review of the data from the Phase 2b/3 trial, including the longer term open label portion, continues to proceed and is being assessed in combination with several other available data sources. The Company expects that a better understanding of the potential benefit of VTS-270 will emerge as it carefully considers the totality of data available and continues to work with the primary investigators and the FDA to determine the best path forward. The Company will continue to assess the impact of any changes to planned revenue or earnings on the fair value of the associated IPR&D asset of $274.5 million included within intangible assets, net, on the consolidated balance sheet as of December 28, 2018.

Finite-lived intangible asset amortization expense within continuing operations is as follows:

	Fiscal Year Ended			Three Months Ended
	December 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Amortization expense	$ 740.2	$ 694.5	$ 700.1	$ 175.7

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

Fiscal 2019	$ 748.4
Fiscal 2020	748.0
Fiscal 2021	747.8
Fiscal 2022	620.8
Fiscal 2023	584.8

14. Debt

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

	December 28, 2018		December 29, 2017	
	Principal	Unamortized Discount and Debt Issuance Costs	Principal	Unamortized Discount and Debt Issuance Costs
Current maturities of long-term debt:				
3.50% notes due April 2018	$—	$ —	$300.0	$ 0.2
Term loan due September 2024	16.4	0.2	14.0	0.3
Term loan due February 2025	6.0	0.1	—	—
Other	0.3	—	0.2	—
Total current debt	22.7	0.3	314.2	0.5
Long-term debt:				
4.875% notes due April 2020	700.0	3.2	700.0	5.7
Variable-rate receivable securitization due July 2020	250.0	0.4	200.0	0.7
9.50% debentures due May 2022	10.4	—	10.4	—
5.75% notes due August 2022	835.2	7.0	884.0	9.5
8.00% debentures due March 2023	4.4	—	4.4	—
4.75% notes due April 2023	500.2	3.5	526.5	4.5
5.625% notes due October 2023	731.4	8.0	738.0	9.7
Term loan due September 2024	1,597.4	19.8	1,837.2	26.7
Term loan due February 2025	591.0	10.7	—	—
5.50% notes due April 2025	692.1	7.7	692.1	9.0
Other	1.9	—	—	—
Revolving credit facility	220.0	4.5	900.0	5.9
Total long-term debt	6,134.0	64.8	6,492.6	71.7
Total debt	$6,156.7	$ 65.1	$6,806.8	$ 72.2

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 a $600.0 million aggregate principal amount of 4.75% senior unsecured notes due April 2023 ("the 2013 Notes"). Mallinckrodt plc has fully and unconditionally guaranteed the 2013 Notes on an unsecured and unsubordinated basis. The 2013 Notes are subject to an indenture which contains covenants limiting the ability of MIFSA, its restricted subsidiaries (as defined in the 2013 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 2013 Notes at any time, and some of the 2013 Notes from time to time, at a redemption price equal to the principal amount of the 2013 Notes redeemed plus a make-whole premium. The Company pays interest on the 2013 Notes semiannually in arrears on April 15th and October 15th of each year, which commenced on October 15, 2013. In April 2018, the Company's $300.0 million aggregate principal amount of 3.50% senior unsecured notes, which were issued in tandem with the 2013 Notes with similar terms, matured and were repaid with cash on hand.

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 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 on or after August 1, 2017 at specified redemption prices. 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 of net proceeds from certain asset sales. These obligations are subject to certain qualifications and exceptions. The Company pays interest on the 2022 Notes semiannually in arrears on February 1st and August 1st of each year, which commenced on February 1, 2015.

In April 2015, in connection with the Company's acquisition of Ikaria, Inc. ("Ikaria"), MIFSA and MCB issued $700.0 million aggregate principal amount of 4.875% senior unsecured notes due April 2020 ("the 2020 Notes") and $700.0 million aggregate principal amount of 5.50% senior unsecured notes due April 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 (as defined below), which following the acquisition of Ikaria 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. The Issuers are obligated to offer to repurchase the Ikaria Notes (a) at a price of 101% of their respective principal amount plus accrued and unpaid interest, if any, as a result of certain change of control events and (b) at a price of 100% of their respective principal amount plus accrued and unpaid interest of net proceeds from certain 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.

In September 2015, in connection with the Company's acquisition of Therakos, Inc. ("Therakos"), MIFSA and MCB issued $750.0 million aggregate principal amount of 5.625% senior unsecured notes due October 2023 (the “2023 Notes”). The 2023 Notes are guaranteed by Mallinckrodt plc and each of its subsidiaries under the 2017 Facilities (as defined below), which following the acquisition of Therakos, 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. As of October 15, 2018, issuers may call some or all of the 2023 Notes at specified redemption prices. The issuers may also redeem all, but not less than all, of the 2023 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 2023 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) at a price of 100% of their principal amount plus accrued and unpaid interest of net proceeds from certain 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.

In February 2017, MIFSA and MCB refinanced the March 2014 and August 2014 term loans, both of which were due March 2021 ("the Existing Term Loans"). The Company accounted for the term loan refinancing as a debt modification, which resulted in a $10.0 million charge included within the other expense line in the consolidated statement of income. The refinanced term loan had an initial aggregate principal amount of $1,865.0 million, is due September 2024 and bears 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 September 2024. In January 2018, the Company made a $225.0 million prepayment on the 2017 Term Loan. In making this payment, the Company satisfied certain obligations included within external debt agreements to reinvest proceeds from the sale of assets and businesses within the year of the respective transaction or use the proceeds to pay down debt.

In conjunction with the term loan refinancing, MIFSA and MCB entered into a $900.0 million revolving credit facility that matures on February 28, 2022 ("the 2017 Revolving Credit Facility"). The 2017 Revolving Credit Facility bears

interest at LIBOR plus 2.25% and contains a $50.0 million letter of credit provision, of which none had been issued as of December 28, 2018. Unused commitments on the 2017 Revolving Credit Facility are subject to an annual commitment fee, which was 0.275% as of December 28, 2018, and the fee applied to outstanding letters of credit is based on the interest rate applied to borrowings. 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.

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. Mallinckrodt Securitization may, from time to time, obtain up to $250.0 million in third-party borrowings secured by certain receivables. Loans under the Receivable Securitization bear interest (including facility fees) at a rate equal to one month

LIBOR rate plus a margin of 0.90%. Unused commitments on the Receivables Securitization are subject to an annual commitment fee of 0.40%. 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.

In February 2018, in connection with the Sucampo Acquisition, MIFSA and MCB issued a $600.0 million senior secured term loan due February 2025. The variable-rate loan bears an interest rate of LIBOR plus 3.00% basis points and was issued with a discount of 0.25%. The incremental term loan requires quarterly principal amortization payments in an amount equal to 0.25% of the original principal balance of the incremental 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, 2018.

As of December 28, 2018, the applicable interest rate and outstanding borrowings on the Company's variable-rate debt instruments were as follows:

	Applicable interest rate		Outstanding borrowings
Term loan due September 2024	5.14	%	$ 1,613.8
Term loan due February 2025	5.62	%	597.0
Variable-rate receivable securitization	3.22	%	250.0
Revolving credit facility	4.64	%	220.0

The aggregate amounts of debt maturing during the next five fiscal years are as follows:

Fiscal 2019	$ 22.7
Fiscal 2020	972.7
Fiscal 2021	28.2
Fiscal 2022	1,088.2
Fiscal 2023	1,258.6

15. 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 other income (expense) during fiscal 2017. During fiscal 2018, the Company received a refund of $3.4 million of the initial cash contribution, recorded as other income (expense), net within the consolidated statement of income.

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 28, 2018, U.S. plans represented 36% 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 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Service cost	$0.2	$ 1.4	$ 1.8	$ 0.8
Interest cost	0.6	2.3	13.2	2.0
Expected return on plan assets	—	(1.3)	(16.7)	(2.3)
Amortization of net actuarial loss	0.5	2.7	11.3	3.5
Amortization of prior service cost	0.1	0.2	—	0.1
Loss on plan settlements	0.1	71.1	8.1	45.0
Curtailment gain	—	(1.0)	—	—
Net periodic benefit cost	$1.5	$ 75.4	$ 17.7	$ 49.1

	Postretirement Benefits			
	Fiscal Year Ended			Three Months Ended
	December 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Service cost	$—	$ —	$ 0.1	$ 0.1
Interest cost	1.5	1.7	2.0	0.4
Amortization of net actuarial loss	0.1	—	—	—
Amortization of prior service credit	(2.1)	(2.0)	(2.1)	(0.5)
Gain on plan settlements	(0.7)	(0.9)	—	—
Net periodic benefit credit	$(1.2)	$ (1.2)	$ —	$ —

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 28, 2018	December 29, 2017	December 28, 2018	December 29, 2017
Change in benefit obligations:				
Projected benefit obligations at beginning of year	$27.8	$ 257.4	$45.6	$ 47.5
Service cost	0.2	1.4	—	—
Interest cost	0.6	2.3	1.5	1.7
Actuarial loss (gain)	0.7	(9.0)	(3.9)	0.2
Benefits and administrative expenses paid	(1.6)	(9.4)	(2.7)	(2.9)
Plan settlements	(0.8)	(217.0)	(0.7)	(0.9)
Currency translation	(0.8)	2.1	—	—
Projected benefit obligations at end of year	26.1	27.8	39.8	45.6
Change in plan assets:				
Fair value of plan assets at beginning of year	—	161.0	—	—
Actual return on plan assets	—	0.3	—	—
Employer contributions	2.4	68.0	2.7	2.9
Benefits and administrative expenses paid	(1.6)	(9.4)	(2.7)	(2.9)
Plan settlements	(0.8)	(217.0)	—	—

Net transfer out	—	(2.9)	—	—
Fair value of plan assets at end of year	—	—	—	—
Funded status at end of year	$(26.1)	$ (27.8)	$(39.8)	$ (45.6)

	Pension Benefits		Postretirement Benefits	
	December 28, 2018	December 29, 2017	December 28, 2018	December 29, 2017
Amounts recognized on the consolidated balance sheet:				
Current liabilities	$(2.0)	$ (2.4)	$(3.4)	$ (3.9)
Non-current liabilities	(24.1)	(25.4)	(36.4)	(41.7)
Net amount recognized on the consolidated balance sheet	$(26.1)	$ (27.8)	$(39.8)	$ (45.6)
Amounts recognized in accumulated other comprehensive loss consist of:				
Net actuarial (loss) gain	$(8.4)	$ (8.6)	$0.9	$ (3.0)
Prior service (cost) credit	(0.4)	(0.5)	8.1	10.2
Net amount recognized in accumulated other comprehensive loss	$(8.8)	$ (9.1)	$9.0	$ 7.2

The estimated amounts that will be amortized from accumulated other comprehensive loss into net periodic benefit cost (credit) in fiscal 2019 are as follows:

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

	December 28, 2018	December 29, 2017
Pension plans with accumulated benefit obligations in excess of plan assets:		
Accumulated benefit obligation	$ 25.6	$ 27.3

The accumulated benefit obligation 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 U.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
	December 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016	December 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Discount rate	3.3%	3.0%	3.9%	2.2%	1.9%	1.8%	2.0%	1.3%
Expected return on plan assets	— %	3.5%	5.8%	3.5%	— %	— %	2.0%	— %
Rate of compensation increase	— %	— %	— %	— %	2.5%	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
	December 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016	December 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Discount rate	4.0%	3.3%	2.3%	3.0%	2.0%	1.9%	1.3%	1.8%
Rate of compensation increase	— %	— %	— %	— %	2.5%	2.5%	— %	0.3%

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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
	December 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Net periodic benefit cost	3.4%	3.7%	4.0%	3.2%
Benefit obligations	4.1%	3.4%	3.2%	3.8%

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

	December 28, 2018	December 29, 2017
Healthcare cost trend rate assumed for next fiscal year	6.3%	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	(0.2)

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 2018 and 2017, the Company made $2.4 million and $68.0 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 2019	$ 2.0	$ 3.5
Fiscal 2020	1.7	3.4
Fiscal 2021	1.7	3.2
Fiscal 2022	1.6	3.1

Fiscal 2023	1.6	3.0
Fiscal 2024 - 2028	7.4	13.4

Defined Contribution Retirement Plans

The Company maintains one active tax-qualified 401(k) retirement plan and one active non-qualified deferred compensation plan in the U.S. The 401(k) retirement plan provides for an automatic Company contribution of three percent of an eligible employee's pay, with an additional Company matching contribution generally equal to 50% of each employee's elective contribution to the plan up to six percent of the employee's eligible pay. The deferred compensation plan permits eligible employees to defer a portion of their compensation. Total defined contribution expense related to continuing operations was $25.3 million, $25.2 million, $25.3 million and $4.2 million for fiscal 2018, 2017, 2016 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 21 provides additional information regarding the debt and equity securities. The carrying value of the 118 life insurance contracts held by these trusts was $58.4 million and $58.1 million at December 28, 2018 and December 29, 2017, respectively. These contracts had a total death benefit of $142.9 million and $145.8 million at December 28, 2018 and December 29, 2017, respectively. However, there are outstanding loans against the policies amounting to $43.8 million and $44.5 million at December 28, 2018 and December 29, 2017, respectively.

The Company has insurance contracts which serve as collateral for certain of the Company's non-U.S. pension plan benefits, which totaled $8.0 million and $8.8 million at December 28, 2018 and December 29, 2017, respectively. These amounts were also included in other assets on the consolidated balance sheets.

16. 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 28, 2018. 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

From time to time, the Company's Board of Directors have authorized share repurchase programs. The details of such programs are as follows:

	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	—	—	—	—
Fiscal 2018	3,610,968	55.2	—	—	—	—	—	—
Remaining amount available		$ 564.2		$ —		$ —		$ —

The March 2017 Program has no time limit or expiration date, and the Company currently expects to fully utilize the program.

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 zero, $5.1 million, $2.3 million and $0.4 million to acquire shares in connection with equity-based awards in fiscal 2018, 2017, 2016 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.

17. Share Plans

Total share-based compensation cost from continuing operations was $34.6 million, $58.5 million, $41.4 million and $10.6 million for fiscal 2018, 2017, 2016 and the three months ended December 30, 2016, respectively. These amounts are generally included within SG&A expenses in the consolidated statements of income. The Company recognized a related tax benefit associated with this expense of zero, $11.0 million, $13.1 million and $3.6 million in fiscal 2018, 2017, 2016 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

The Company has adopted and amended its Mallinckrodt Pharmaceuticals Stock and Incentive Plan over the years which 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 maximum number of common shares to be issued as Awards, subject to adjustment as provided under the terms of the respective plans are as follows:

	Maximum Number of Common Shares to be Issued as Awards (in millions)
2013 Plan	5.7
2015 Plan	17.8
2018 Plan	26.8

As of December 28, 2018, all equity awards held by the Company's employees were converted from equity awards issued by Questcor Pharmaceuticals, Inc. ("Questcor"), acquired during fiscal 2014, or granted under the aforementioned plans.

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 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		
Granted	3,159,521	13.92		
Exercised	(39,949)	32.00		
Expired/Forfeited	(756,505)	52.63		
Outstanding at December 28, 2018	7,007,051	38.74	4.8	$ 6.5
Vested and non-vested expected to vest as of December 28, 2018	6,114,782	39.94	7.6	$ 5.5
Exercisable at December 28, 2018	2,414,968	55.24	4.9	0.1

As of December 28, 2018, there was $29.6 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 2.4 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 2018, 2017, 2016 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 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Expected share price volatility	38 %	36 %	31 %	35 %
Risk-free interest rate	2.64 %	2.00 %	1.74 %	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	$ 5.32	$ 18.36	$ 22.82	$ 20.04

In fiscal 2018, 2017, 2016 and the three months ended December 30, 2016, the total intrinsic value of options exercised was $0.2 million, $1.4 million, $15.3 million and $0.3 million, respectively, and the related tax benefit was $0.1 million, $0.5 million, $5.7 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 is determined based on the market value of the Company's shares on the date of grant for periods after the Company's separation from Covidien plc ("Covidien") in fiscal 2013.
RSU activity is as follows:

	Shares	Weighted-Average Grant-Date Fair Value
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
Granted	1,222,568	14.58
Exercised	(433,354)	57.93
Expired/Forfeited	(209,879)	44.38
Non-vested at December 28, 2018	1,685,101	29.54

The total fair value of Mallinckrodt RSU awards granted during fiscal 2018 was $17.8 million. The total vest date fair value of Mallinckrodt RSUs vested during fiscal 2018 was $25.1 million. As of December 28, 2018, there was $29.6 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 2.2 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 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
Granted	770,714	13.80
Forfeited	(89,614)	59.18
Vested	(24,022)	98.27
Non-vested at December 28, 2018	1,161,529	28.61

(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 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Expected stock price volatility	57%	48%	41%	48%
Peer group stock price volatility	39%	40%	36%	40%
Correlation of returns	2%	17%	24%	17%

The weighted-average grant-date fair value per share of PSUs granted was $13.80 in fiscal 2018. As of December 28, 2018, there was $12.6 million of unrecognized compensation cost related to PSUs, which is expected to be recognized over a weighted-average period of 1.9 years.

Restricted stock awards. Recipients of restricted stock awards ("RSAs") pertain solely to converted awards from Questcor, 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 were subject to accelerated vesting as prescribed by the terms of the original award based on a change in control, and all of which have vested as of December 28, 2018. Restrictions on RSAs lapse upon normal retirement, death or disability of the employee. The grant-date fair value of RSAs, adjusted for estimated forfeitures, was recognized as expense on a straight-line basis over the service period. The weighted average grant-date fair value per share was $70.88.

	Shares
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
Vested	(3,970)
Forfeited	(705)
Non-vested at December 28, 2018	—

The total vest date fair value of Mallinckrodt restricted share awards vested during fiscal 2018 was $0.2 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.

18. Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss are as follows:

	Currency Translation	Unrecognized Loss on Derivatives	Unrecognized (Loss) Gain on Benefit Plans	Unrecognized Gain on Equity Securities [1]	Accumulated Other Comprehensive Loss [1]
Balance at December 30, 2016	$ (19.5)	$ (5.7)	$ (47.3)	$ —	$ (72.5)
Other comprehensive income, net	16.0	—	5.2	1.5	22.7
Reclassification from other comprehensive (loss) income	(4.7)	1.0	40.6	(1.5)	35.4
Balance at December 29, 2017	(8.2)	(4.7)	(1.5)	—	(14.4)
Other comprehensive (loss) income, net	(12.2)	—	3.1	—	(9.1)
Reclassification from other comprehensive income (loss)	—	0.7	(1.5)	—	(0.8)
Balance at December 28, 2018	$ (20.4)	$ (4.0)	$ 0.1	$ —	$ (24.3)

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The following summarizes reclassifications from accumulated other comprehensive loss:

	Amount Reclassified From Accumulated Other Comprehensive Loss		
	December 28, 2018	December 29, 2017	Line Item in the Consolidated Statement of Income
Currency translation	$ —	$ (4.7)	
Amortization of unrealized loss on derivatives	0.9	1.3	Interest expense
Income tax provision	(0.2)	(0.3)	Provision for income taxes
Net of income taxes	0.7	1.0	
Amortization of pension and post-retirement benefit plans:			
Net actuarial loss	0.6	2.7	(1)
Prior service credit	(2.0)	(1.9)	(1)
Disposal of discontinued operations	—	(3.1)	
Plan settlements	(0.6)	70.2	(1)
Total before tax	(2.0)	67.9	
Income tax effect	0.5	(27.3)	Provision for income taxes
Net of income taxes	(1.5)	40.6	
Recognized gain on equity securities [2]	—	(1.5)	
Total reclassifications for the period	$ (0.8)	$ 35.4	

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19. Guarantees

In disposing of assets or businesses, the Company has from time to time 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 the 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 28, 2018 and December 29, 2017 was $14.6 million and $14.9 million, of which $11.8 million and $12.1 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 28, 2018 and December 29, 2017. As of December 28, 2018, 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 $18.6 million and $18.3 million remained in other assets on the consolidated balance sheets at December 28, 2018 and December 29, 2017, respectively.

The Company has recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 20.

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.
As of December 28, 2018, the Company had various other letters of credit and guarantee and surety bonds totaling $38.7 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.

20. Commitments and Contingencies

The Company has purchase obligations related to commitments to purchase certain goods and services. At December 28, 2018, such obligations were as follows:

Fiscal 2019	$ 110.3
Fiscal 2020	43.5
Fiscal 2021	2.2
Fiscal 2022	2.1
Fiscal 2023	1.7

The Company is subject to various legal proceedings and claims, including patent infringement claims, product liability matters, personal injury, environmental matters, employment disputes, contractual disputes and other commercial disputes, including those described below. The Company believes that these legal proceedings and claims likely will be resolved over an extended period of time. Although it is not feasible to predict the outcome of these matters, the Company believes, unless indicated below, given the information currently available, that their ultimate resolution will not have a material adverse effect on its financial condition, results of operations and cash flows.

Governmental Proceedings

Opioid Related Matters

Since 2017, multiple U.S. states, counties, other governmental persons or entities and private plaintiffs have filed lawsuits against certain Mallinckrodt entities, as well as various other manufacturers, distributors, pharmacies, pharmacy benefit managers, individual doctors and/or others, asserting claims relating to defendants’ alleged sales, marketing, distribution, reimbursement, prescribing, dispensing and/or other practices with respect to prescription opioid medications, including certain of the Company's products. As of February 26, 2019, the cases of which the Company is aware include, but are not limited to, approximately 1,487 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 104 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers; approximately 15 cases filed by individuals and 6 cases filed by the Attorneys General for New Mexico, Kentucky, Rhode Island. Georgia, Florida, and Alaska. Certain of the lawsuits have been filed as putative class actions.
Many of the lawsuits have been coordinated in a federal multi-district litigation (“MDL”) pending in the U.S. District Court for the Northern District of Ohio. The MDL court has issued a series of case management orders permitting motion practice addressing threshold legal issues in certain cases, allowing discovery and setting a trial date in October 2019 for two cases originally filed in the Northern District of Ohio.
Other lawsuits remain pending in various state courts. In some jurisdictions, such as Connecticut, Illinois, New York, Pennsylvania and Texas, certain state court cases have been coordinated for pretrial proceedings before a single court within their respective state court systems. State cases are generally at the pleading and/or discovery stage.
The lawsuits assert a variety of claims, including, but not limited to, public nuisance, negligence, civil conspiracy, fraud, violations of the Racketeer Influenced and Corrupt Organizations Act (“RICO”) or similar state laws, violations

of state Controlled Substances Acts or state False Claims Acts, product liability, consumer fraud, unfair or deceptive trade practices, false advertising, insurance fraud, unjust enrichment and other common law and statutory claims arising from defendants' manufacturing, distribution, marketing and promotion of opioids and seek restitution, damages, injunctive and other relief and attorneys' fees and costs. The claims generally are based on alleged misrepresentations and/or omissions in connection with the sale and marketing of prescription opioid medications and/or an alleged failure to take adequate steps to prevent abuse and diversion.

The Company intends to vigorously defend itself against these lawsuits and similar lawsuits that may be brought by others. Since these lawsuits are in early stages, the Company is unable to predict outcomes or estimate a range of reasonably possible losses.

In addition to the lawsuits described above, certain Mallinckrodt entities have received subpoenas and civil investigative demands ("CID(s)") for information concerning the sale, marketing and/or distribution of prescription opioid medications, including from U.S. Department of Justice ("DOJ") and the Attorneys General for Missouri, New Hampshire, Kentucky, Washington, Alaska, South Carolina, Puerto Rico and New York. Our 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. 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 distribution, marketing and sale of generic oxymorphone products. The Company is in the process of responding to these subpoenas, CIDs and any informal requests for documents.

On August 2, 2018, Energy and Commerce Committee leaders in the U.S. House of Representatives sent a letter to one of Mallinckrodt's subsidiaries requesting information about that subsidiary's efforts to monitor opioid sales for suspicious orders. The subsidiary has responded to this letter.

Similar subpoenas and investigations may be brought by others or the foregoing matters may be expanded or result in litigation. Since these investigations are in early stages, we are unable to predict outcomes or estimate a range of reasonably possible losses.

New York State Opioid Stewardship Act. On October 24, 2018, the Company filed suit in the United States District Court for the Southern District of New York against the State of New York, asking the court to declare New York State's Opioid Stewardship Act ("OSA") unconstitutional and to enjoin its enforcement. On December 19, 2018, the court declared the OSA unconstitutional and granted the Company's motion for preliminary injunctive relief. On January 17, 2019, the State of New York appealed the Court's decision. The Company intends to vigorously assert its position in this matter.

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 and agreed, as part of a Memorandum of Agreement ("MOA"), to utilize all available transaction information to identify suspicious orders of any Mallinckrodt controlled substance product and to report to the DEA when it concludes that chargeback data or other information indicates that a downstream registrant poses a risk of diversion, among other things. The MOA remains in effect until July 10, 2020.

Other Matters

U.S. House Committee Investigation. In January 2019, the Company along with 11 other pharmaceutical companies, received a letter from the U.S. House Committee on Oversight and Reform requesting information relating to the Company's pricing strategy for H.P. Acthar Gel and related matters. The Company is cooperating with the Committee investigation.

Florida Civil Investigative Demand. In February 2019, the Company received a CID from the U.S. Attorney's Office for the Middle District of Florida. The demand relates to documents related to alleged payments to healthcare providers in Florida and whether those payments violated the Anti-Kickback Statute. The Company is in the process of responding to this demand for documents and intends to cooperate with the investigation.

Boston Civil Investigative Demand. In January 2019, the Company received a CID from the U.S. Attorney's Office for the District of Massachusetts for documents related to the Company's participation in the Medicaid Drug Rebate Program. The Company is in the process of responding to this demand for documents, and intends to cooperate with the investigation.

Generic Pricing Subpoena. In March 2018, the Company received a grand jury subpoena issued by the U.S. District Court for the Eastern District of Pennsylvania pursuant to which the Antitrust Division of the DOJ is seeking documents regarding generic products and pricing, communications with generic competitors and other related matters. The Company is in the process of responding to this subpoena, and the Company intends to cooperate fully in the investigation.

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 responded to these requests. In December 2018, the Company entered into a final settlement with the Texas Attorney General's Office to resolve all potential claims in the investigation and recorded a corresponding expense, which is included in SG&A in the consolidated statement of income.

MNK 2011 Inc. (formerly known as Mallinckrodt Inc.) v. U.S. Food and Drug Administration and United States of America. In November 2014, the FDA reclassified the Company's Methylphenidate ER in the Orange Book: Approved Drug Products with Therapeutic Equivalence ("the Orange Book"). In November 2014, the Company filed a Complaint in the U.S. District Court for the District of Maryland Greenbelt Division against the FDA and the United States (the "MD Complaint") for judicial review of the FDA's reclassification. In July 2015, the court granted the FDA's motion to dismiss with respect to three of the five counts in the MD Complaint and granted summary judgment in favor of the FDA with respect to the two remaining counts (the "MD Order"). On October 18, 2016, the FDA initiated proceedings, proposing to withdraw approval of the Company's Abbreviated New Drug Applications ("ANDA") for Methylphenidate ER. On October 21, 2016, the United States Court of Appeals for the Fourth Circuit issued an order placing the Company's appeal of the MD Order in abeyance pending the outcome of the withdrawal proceedings. The parties exchanged documents and in April 2018, the Company filed its submission in support of its position in the withdrawal proceedings. A potential outcome of the withdrawal proceedings is that the Company's Methylphenidate ER products may lose their FDA approval and have to be withdrawn from the market.

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 Subpoena. 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 responded to these requests, and continues to cooperate fully in the investigation.

Questcor Subpoena. 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 was also 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

Amitiza Patent Litigation: Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc. In October 2018, Sucampo AG, Sucampo Pharmaceuticals, Inc. and Sucampo Pharma LLC, all subsidiaries of the Company, and Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA, Inc., and Takeda Pharmaceuticals America, Inc. (collectively "Takeda," the exclusive licensee under the patents in litigation) filed suit in the U.S. District Court for the District of New Jersey against Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc. (collectively “Sun”) alleging that Sun infringed U.S. Patent Nos. 7,795,312, 8,026,393, 8,097,653, 8,338,639, 8,389,542, 8,748,481 and 8,779,187 following receipt of a September 2018 notice from Sun concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of Amitiza. The Company intends to vigorously enforce its intellectual property rights relating to Amitiza.

Amitiza Patent Litigation: Teva Pharmaceuticals USA, Inc. In September 2017, Sucampo AG and Sucampo Pharmaceuticals, Inc., both subsidiaries of the Company, and Takeda filed suit in the U.S. District Court for the District of New Jersey against Teva

Pharmaceuticals USA, Inc. ("Teva") alleging that Teva infringed U.S. Patent Nos. 6,414,016, 6,982,283, 7,795,312, 8,026,393, 8,071,613, 8,097,653, 8,338,639, 8,389,542 and 8,748,481 following receipt of an August 2017 notice from Teva concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of Amitiza. On June 28, 2018, the parties entered into a settlement agreement under which Teva was granted the non-exclusive right to market a competing lubiprostone product in the U.S. under its ANDA on or after January 1, 2023, or earlier under certain circumstances.

Amitiza Patent Litigation: Amneal Pharmaceuticals, LLC. In April 2017, Sucampo AG and Sucampo Pharmaceuticals, Inc., both subsidiaries of the Company, and Takeda filed suit in the U.S. District Court for the District of New Jersey against Amneal Pharmaceuticals, LLC ("Amneal") alleging that Amneal infringed U.S. Patent Nos. 6,982,283, 8,026,393, 8,097,653, 8,338,639 and 8,389,542 following receipt of a March 2017 notice from Amneal concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of Amitiza. On June 28, 2018, the parties entered into a settlement agreement under which Amneal was granted the non-exclusive right to market a competing lubiprostone product in the U.S. under its ANDA on or after January 1, 2023, or earlier under certain circumstances.

Amitiza Patent Litigation: Par and DRL. Settlement and License Agreements were entered into with Anchen Pharmaceuticals, Inc., Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively "Par") and Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively "DRL") to settle Paragraph IV patent litigation with each of Par and DRL. Under the terms of the Par settlement dated September 30, 2014, Par was granted a non-exclusive license and right to market a competing generic of Amitiza on or after January 1, 2021, or earlier under certain circumstances. Under the terms of the DRL settlement dated September 14, 2016, DRL was granted a non-exclusive license and right to market a competing generic of Amitiza on or after January 1, 2023, or earlier under certain circumstances.

Inomax Patent Litigation: Praxair Distribution, Inc. and Praxair, Inc. (collectively "Praxair"). In February 2015, INO Therapeutics LLC and Ikaria, Inc., both 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 the Praxair litigation 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. The oral arguments in the appeal occurred on February 6, 2019. Praxair received FDA approval of their ANDA for their Noxivent nitric oxide and clearance of their 510(k) for their NOxBOXi device on October 2, 2018. An adverse outcome in the appeal of the Praxair litigation decision (or a decision by Praxair to launch at-risk prior to the appellate decision) could result in the launch of a competitive nitric oxide product before the expiration of the last of the listed patents on May 3, 2036 (November 3, 2036 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 believed the claim held valid by the PTAB describes and encompasses a 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 in January 2018. The Federal Circuit decision was issued May 16, 2018 and held all claims unpatentable (invalid).
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, both 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. On May 7, 2018 the parties entered into a settlement agreement under which Aurobindo was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its ANDA on or after December 6, 2020, or earlier under certain circumstances.

Ofirmev Patent Litigation: B. Braun Medical Inc. In April 2017, Mallinckrodt Hospital Products Inc. and Mallinckrodt IP, both 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 NDA, containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev. On October 3, 2018, the parties entered into a settlement agreement under which B. Braun was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its ANDA on or after December 6, 2020, or earlier under certain circumstances.

Ofirmev Patent Litigation: InnoPharma Licensing LLC and InnoPharma, Inc. In September 2014, Cadence and Mallinckrodt IP, both 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"). 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. Group), (collectively "Agila"). In December 2014, Cadence and Mallinckrodt IP, both subsidiaries of the Company, and Pharmatop 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. 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 (collectively, "Jazz") filed suit in the U.S. District Court for the District of New Jersey against the Company alleging that the Company infringed U.S. Patent Nos. 7,668,730, 7,765,106, 7,765,107, 7,895,059, 8,457,988, 8,589,182, 8,731,963, 8,772,306, 9,050,302, and 9,486,426 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. On June 4, 2018, the parties entered into a settlement agreement under which the Company was granted the non-exclusive right to market a competing sodium oxybate product in the U.S. under its ANDA on or after December 31, 2025, or earlier under certain circumstances.

Shire Development LLC, Shire LLC and Shire US, Inc. v. SpecGx LLC. In May 2018, Shire Development LLC, Shire LLC and Shire US, Inc. (collectively “Shire”) filed suit in the U.S. District Court for the District of Delaware against the Company alleging that the Company infringed U.S. Patent Nos. 6,913,768, 8,846,100, and 9,173,857 following receipt of an April 2018 notice from the Company concerning its submission of an ANDA, containing a Paragraph IV patent certification with the FDA for a competing version of Mydayis. On January 28, 2018, the parties entered into a

settlement agreement under which the Company was granted the non-exclusive right to market a competing generic version of Mydayis in the U.S. under its ANDA on or after May 10, 2023 (or November 10, 2023 if any pediatric exclusivity is granted by the FDA with respect to the Mydayis product), or earlier under certain circumstances.

Commercial and Securities Litigation

Grifols. On March 13, 2018, Grifols initiated arbitration against the Company, alleging breach of a Manufacturing and Supply Agreement entered into between the Company's predecessor-in-interest, Cadence Pharmaceuticals Inc., and Grifols. The Company intends to vigorously defend itself in this matter.

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 (Rockford). 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 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.

Local 542. On May 25, 2018, the International Union of Operating Engineers Local 542 filed a complaint against the Company and other defendants alleging improper pricing and distribution of H.P. Acthar Gel, in violation of Pennsylvania's Unfair Trade Practices and Consumer Protection Law, aiding and abetting, unjust enrichment and negligent misrepresentation. Plaintiff filed an amended complaint on August 27, 2018. 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 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 former 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, through 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. Stipulated co-lead plaintiffs were approved by the court on March 1, 2018. Co-Lead Plaintiffs filed an amended complaint on June 4, 2018 having a class period of July 14, 2014 to November 6, 2017. On July 6, 2018, this matter was stayed by agreement of the parties pending resolution of the *Shenk* matter below.

Putative Class Action Securities Litigation (Shenk). 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. Lead plaintiff was designated by the court on March 9, 2018. Lead plaintiff filed a consolidated complaint on May 18, 2018, alleging a class period from July 14, 2014 to November 6, 2017, the Company, its CEO, its former CFO, and Executive Vice President, Hugh O'Neill, as defendants, and containing similar claims, but further alleging misstatements regarding payer reimbursement restrictions for H.P.

Acthar Gel. On August 30, 2018, the lead plaintiff voluntarily dismissed the claims against Mr. O'Neill without prejudice. The Company intends to vigorously defend itself in 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 28, 2018, it was probable that it would incur remediation costs in the range of $36.4 million to $86.5 million. The Company also concluded that, as of December 28, 2018, the best estimate within this range was $61.8 million, of which $2.1 million was included in accrued and other current liabilities and the remainder was included in environmental liabilities on the consolidated balance sheet at December 28, 2018. 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.

Lower Passaic River, New Jersey. The Company and approximately 70 other companies (“Cooperating Parties Group” or “CPG”) are parties to a May 2007 Administrative Order on Consent ("AOC") with the Environmental Protection Agency ("EPA") to perform a remedial investigation and feasibility study ("RI/FS") of the 17-mile stretch known as the Lower Passaic River ("the River") Study Area. The Company's potential liability stems from former operations at Lodi and Belleville, New Jersey.

In April 2014, the EPA issued a revised Focused Feasibility Study ("FFS"), with remedial alternatives to address cleanup of the lower 8-mile stretch of the River. The EPA estimated the cost for the remediation alternatives ranged from $365.0 million to $3.2 billion and the EPA's preferred approach had an estimated cost of $1.7 billion.

In April 2015, the CPG presented a draft of the RI/FS of the River to the EPA that included alternative remedial actions for the entire 17-mile stretch of the River.

On March 4, 2016, the EPA issued the Record of Decision ("ROD") for the lower 8 miles of the River with a slight modification on its preferred approach and a revised estimated cost of $1.38 billion. On October 5, 2016, the EPA announced that Occidental Chemicals Corporation ("OCC") had entered into an agreement to develop the remedial design.

On August 7, 2018, the EPA finalized a buyout offer of $280,600 with the Company, limited to its former Lodi facility, for the lower 8 miles of the River. During the three months ended September 28, 2018, the Company reduced the accrual associated with this matter by $11.8 million to $26.2 million, which represents the Company's estimate of its remaining liability related to the River.

Despite the issuance of the revised FFS and ROD by the EPA, the RI/FS by the CPG, and the cash out settlement by the EPA there are many uncertainties associated with the final agreed-upon remediation, potential future liabilities 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.

Occidental Chemical Corp. v. 21st Century Fox America, Inc. The Company and approximately 120 other companies were named as defendants in a lawsuit filed on June 30, 2018, by OCC, in which OCC seeks cost recovery and contribution for past and future costs in response to releases and threatened releases of hazardous substances into the lower 8 miles of the River. A former Mallinckrodt facility located in Jersey City, NJ (located in Newark Bay) and the former Belleville facility were named in the suit. Due to an indemnification agreement with AVON Inc., Mallinckrodt has tendered the liability for the Jersey City site to AVON Inc. and they have accepted. The Company retains a share of the liability for this suit related to the Belleville facility. A motion to dismiss several of the claims has been submitted to the court. 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.

Mallinckrodt Veterinary, Inc., Millsboro, Delaware. The Company previously operated a facility in Millsboro, Delaware ("the Millsboro Site") where various animal healthcare products were manufactured. 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, have assumed responsibility for the Millsboro Site cleanup under the Alternative Superfund Program administered by the EPA. The companies have entered into three 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. 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.
Crab Orchard National Wildlife Refuge Superfund Site, near Marion, Illinois. Between 1967 and 1982, International Minerals and Chemicals Corporation ("IMC"), a predecessor in interest to the Company, leased portions of the Additional and Uncharacterized Sites ("AUS") Operable Unit at the Crab Orchard Superfund Site ("the CO Site") from the government and manufactured various explosives for use in mining and other operations. In March 2002, the Department of Justice, the U.S. Department of the Interior and the 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 CO Site, to compel General Dynamics to perform the RI/FS for the AUS Operable Unit. General Dynamics negotiated an AOC with the Government Agencies to conduct an extensive RI/FS at the CO 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 costs associated with alleged contamination of soils and groundwater resulting from historic operations, and the parties have entered into a non-binding mediation process. 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 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.

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 28, 2018, there were approximately 11,700 asbestos-related cases pending against the Company.
The Company estimates pending asbestos claims, claims that were incurred but not reported and related insurance recoveries, which are recorded on a gross basis in the consolidated balance sheets. The Company's estimate of its liability for pending and future claims is based on claims experience over the past five years and covers claims either currently filed or expected to be filed over the next seven years. The Company believes that it has adequate amounts recorded related to these matters. While it is not possible at this time to determine with certainty the ultimate outcome of these asbestos-related proceedings, the Company believes, given the information currently available, that the ultimate resolution of all known and anticipated future claims, after taking into account amounts already accrued, along with recoveries from insurance, will not have a material adverse effect on its financial condition, results of operations and cash flows.

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 acquisition of Ikaria and Therakos.

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. During fiscal 2018, the Company received payment on the note receivable and settled all installment sale provisions related to its sale of the Intrathecal Therapy business.

As of December 28, 2018, the Company had an aggregate $227.5 million of interest-bearing U.S. deferred tax liabilities associated with outstanding installment notes compared to $553.5 million at December 29, 2017. The decrease of $326.0 million is primarily attributed to the Company's reorganization of its intercompany financing and associated legal entity ownership, which occurred during fiscal 2018. See Note 9 for further details regarding this reorganization. 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 $23.7 million, $69.3 million, $73.8 million and $15.9 million for fiscal 2018, 2017, 2016 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 of its legal entity ownership.

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 $56.0 million and $46.0 million as of December 28, 2018 and December 29, 2017, respectively. 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.

Refer to Note 25 for further information subsequent to December 28, 2018 regarding the Company's interest-bearing deferred tax obligation.

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 $24.8 million, $30.4 million, $23.9 million and $7.2 million for fiscal 2018, 2017, 2016 and the three months ended December 30, 2016, respectively.

The following is a schedule of minimum lease payments for non-cancelable leases as of December 28, 2018:

	Operating Leases
Fiscal 2019	$ 22.3
Fiscal 2020	16.4
Fiscal 2021	12.8
Fiscal 2022	10.6
Fiscal 2023	10.3
Thereafter	39.2
Total minimum lease payments	$ 111.6

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 has completed its examination of all tax returns filed by Covidien through 2012. The only open audits for these tax years relate to tax returns filed in various state jurisdictions. 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.

The Company continues to be subject to examination by the IRS for tax years 2014 to 2017. As of December 28, 2018, the primary unresolved issue relates to transfer pricing, which could have a significant impact to the consolidated financial statements if not resolved favorably. The Company believes its allowances for income tax contingencies are adequate. The Company has not received a proposed assessment for unresolved issues and although possible, does not expect a final resolution of these issues in the next 12 months. See Note 9 for further information.

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.

21. 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 28, 2018	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	$ 33.1	$ 22.4	$ 10.7	$ —
Equity securities	—	—	—	—
	$ 33.1	$ 22.4	$ 10.7	$ —
Liabilities:				
Deferred compensation liabilities	$ 38.5	$ —	$ 38.5	$ —
Contingent consideration and acquired contingent liabilities	151.4	—	—	151.4
	$ 189.9	$ —	$ 38.5	$ 151.4

	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	—	—
	$ 58.1	$ 46.7	$ 11.4	$ —
Liabilities:				
Deferred compensation liabilities	$ 42.7	$ —	$ 42.7	$ —
Contingent consideration and acquired contingent liabilities	246.4	—	—	246.4
	$ 289.1	$ —	$ 42.7	$ 246.4

Debt and equity securities held in rabbi trusts. Debt securities held in the rabbi trusts 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 trusts primarily consist of U.S. common stocks, which are valued using quoted market prices reported on nationally recognized securities exchanges.

Equity securities. Equity securities consisted of shares in Mesoblast, for which quoted prices are available in an active market; therefore, the investment was classified as level 1 and is valued based on quoted market prices reported on a nationally recognized securities exchange. During fiscal 2018, the Company sold all its shares for gross proceeds of $25.5 million resulting in a $3.4 million gain being recognized within other income (expense), net within the consolidated statement of income.

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 13 to the consolidated financial statements.
Contingent consideration and acquired contingent liabilities. As of December 28, 2018, the Company maintains various contingent consideration and acquired contingent liabilities associated with the acquisitions of Questcor, Stratatech, and Ocera.
In August 2014, the Company recorded acquired contingent liabilities of $195.4 million from the acquisition of Questcor. 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 MNK-1411 ("Synacthen") from Novartis and their acquisition of BioVectra. The fair value of these contingent consideration obligations at December 28, 2018 and December 29, 2017 were $76.2 million and $111.8 million, respectively.
Under the terms of the license agreement with Novartis, the Company made a $25.0 million payment in fiscal 2018, and is obligated to make annual payments of $25.0 million subsequent to fiscal 2018 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 28, 2018, the total remaining payments under the license agreement shall not exceed $115.0 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%.
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 StrataGraft. The Company assesses the likelihood of and timing of making such payments. The fair value of the contingent payments was measured based on the net present value of a probability-weighted assessment. The Company determined the fair value of the contingent consideration associated with the Stratatech Acquisition to be $53.7 million and $53.5 million at December 28, 2018 and December 29, 2017, respectively.
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 intravenous ("IV") and oral formulations of MNK-6105 and MNK-6106, which represent the IV and oral formulations, respectively, and sales-based milestones associated with MNK-6105 and MNK-6106. The Company determined the fair value of the contingent consideration based on an option pricing model to be $21.5 million and $22.0 million as of December 28, 2018 and December 29, 2017, respectively.
Prior to December 28, 2018, the Company maintained various contingent consideration and acquired contingent liabilities associated with the Hemostasis Acquisition and InfaCare Acquisition.
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, respectively. During fiscal 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. The Company paid $12.0 million related to the FDA approval milestone of PreveLeak during the three months

ended March 30, 2018. On March 16, 2018, the Company sold a portion of the Hemostasis business, inclusive of the Recothrom and PreveLeak products to Baxter and the remaining contingent consideration liability balance of $12.1 million was transferred upon sale.

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. Due to recent developments and discussions with the FDA, as discussed in further detail in Note 13, the timing of the development program is expected to shift outward. During fiscal 2018, the Company recognized a $35.0 million fair value adjustment due to this shift in timing and its impact on the achievement of milestones per the purchase agreement. The fair value of the contingent consideration based on an option pricing model was determined to be zero and $35.0 million as of December 28, 2018 and December 29, 2017, respectively.

Of the total fair value of the contingent consideration of $151.4 million, $34.1 million was classified as current and $117.3 million was classified as non-current in the consolidated balance sheet as of December 28, 2018. The following table summarizes the fiscal 2018 activity for contingent consideration:

Balance at December 29, 2017	$246.4
Disposal of business	(12.1)
Payments	(37.0)
Accretion expense	4.3
Fair value adjustment	(50.2)
Balance at December 28, 2018	$151.4

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 28, 2018 and December 29, 2017:

- 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 $18.6 million and $18.3 million as of December 28, 2018 and December 29, 2017, 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). During fiscal 2018, the Company received $154.0 million from Piramal for settlement of the aforementioned note receivable.
- The Company received a portion of consideration as part of contingent earn-out payments related to the sale of the Nuclear Imaging business in the form of preferred equity certificates during fiscal 2018. These securities are classified as held-to-maturity and are carried at amortized cost, which approximates fair value, of $9.0 million at December 28, 2018 (level 3). These securities are included in other assets on the consolidated balance sheet.
- 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 $66.4 million and $67.0 million at December 28, 2018 and December 29, 2017, respectively. These contracts are included in other assets on the consolidated balance 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 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. 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 fair value of the "other" loan is based on the present value of future cash flows under the terms of the agreement with future cash flows and interest rates as significant assumptions, and therefore classified as level 3.

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 28, 2018		December 29, 2017	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Level 1:				
3.50% notes due April 2018	$—	$—	$300.0	$299.1
4.875% notes due April 2020	700.0	676.6	700.0	675.2
Variable-rate receivable securitization due July 2020	250.0	250.0	200.0	200.0
5.75% notes due August 2022	835.2	713.6	884.0	804.8
4.75% notes due April 2023	500.2	336.7	526.5	412.4
5.625% notes due October 2023	731.4	557.0	738.0	628.8
5.50% notes due April 2025	692.1	479.1	692.1	564.5
Revolving credit facility	220.0	220.0	900.0	900.0
Level 2:				
9.50% debentures due May 2022	10.4	9.7	10.4	10.9
8.00% debentures due March 2023	4.4	3.8	4.4	4.4
Term loan due September 2024	1,613.8	1,472.4	1,851.2	1,848.7
Term loan due February 2025	597.0	548.0	—	—
Level 3:				
Other	2.2	2.2	—	—
Total Debt	$6,156.7	$5,269.1	$6,806.6	$6,348.8

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 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
CuraScript, Inc.	35%	40%	38%	43%
McKesson Corporation	*	*	12%	10%

* 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 28, 2018	December 29, 2017
AmerisourceBergen Corporation	26%	15%
McKesson Corporation	22%	26%
CuraScript, Inc.	13%	14%
Cardinal Health, Inc.	*	11%

* Gross accounts receivables from these distributors were less than 10% of total gross accounts receivable during the respective periods presented above.

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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 28, 2018		December 29, 2017		September 30, 2016		December 30, 2016	
H.P. Acthar Gel	35	%	37	%	34	%	39	%
Inomax	17	%	16	%	14	%	14	%

22. Segment and Geographical Data

As a result of the planned Separation, the Company reassessed its segments based on the financial information viewed by the Chief Executive Officer, the Company's chief operating decision maker ("CODM"), for the purposes of making resource allocation decisions and assessing the performance of the business. The Company has identified two reportable segments that align with the operations of the two independent publicly traded companies anticipated post-separation: (1) Specialty Brands and (2) Specialty Generics and Amitiza, which are further described below:

- *Specialty Brands* includes innovative specialty pharmaceutical brands; and
- *Specialty Generics and Amitiza* includes niche specialty generic drugs products, APIs and Amitiza.

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

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, 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 CODM 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 $10.9 billion and $15.3 billion at December 28, 2018 and December 29, 2017, respectively.

Selected information by business segment is as follows:

	Fiscal Year Ended			Three Months Ended
	December 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Net sales:				
Specialty Brands	$2,306.2	$2,352.0	$2,288.8	$600.1
Specialty Generics and Amitiza	909.4	869.6	1,092.0	229.8
Net sales	$3,215.6	$3,221.6	$3,380.8	$829.9
Operating income:				
Specialty Brands	$1,077.4	$1,146.3	$1,060.7	$295.2
Specialty Generics and Amitiza	105.0	266.4	444.7	64.6
Segment operating income	1,182.4	1,412.7	1,505.4	359.8
Unallocated amounts:				
Corporate and allocated expenses [1]	(155.8)	(125.2)	(117.7)	(123.1)
Intangible asset amortization	(740.2)	(694.5)	(700.1)	(175.7)
Restructuring and related charges, net [2]	(108.2)	(36.4)	(37.6)	(5.3)
Non-restructuring impairments	(3,893.1)	(63.7)	(16.9)	(214.3)
Separation costs [3]	(6.0)	—	—	—
Operating income	$(3,720.9)	$492.9	$633.1	$(158.6)
Depreciation and amortization [4]:				
Specialty Brands	$696.0	$712.0	$715.7	$178.2
Specialty Generics and Amitiza	156.1	96.3	97.9	25.0
	$852.1	$808.3	$813.6	$203.2

(1) Includes administration expenses and certain compensation, environmental and other costs not charged to the Company's operating segments.
(2) Includes restructuring-related accelerated depreciation.
(3) Represents costs incurred related to the separation of the Company’s Specialty Generics and Amitiza segment, which are included in selling, general and administrative expenses.
(4) 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 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
H.P. Acthar Gel	$1,110.1	$1,195.1	$1,160.4	$325.4
Inomax	542.7	505.2	474.3	118.3
Ofirmev	341.9	302.5	284.3	72.5
Therakos	231.2	214.9	207.6	47.4
BioVectra	53.1	54.7	49.5	7.4
Other [1]	27.2	79.6	112.7	29.1
Specialty Brands	2,306.2	2,352.0	2,288.8	600.1
Hydrocodone (API) and hydrocodone-containing tablets	65.9	85.3	146.5	23.2
Oxycodone (API) and oxycodone-containing tablets [1]	66.1	88.0	139.9	27.2
Acetaminophen (API) [1]	192.7	185.5	169.1	40.8
Amitiza [2]	183.8	—	—	—

Other controlled substances [1]	343.8	412.0	543.9	117.4
Other [1], [3]	57.1	98.8	92.6	21.2
Specialty Generics and Amitiza	909.4	869.6	1,092.0	229.8
Net Sales	$ 3,215.6	$ 3,221.6	$ 3,380.8	$ 829.9

(1) Prior year amounts have been reclassified to conform to current year presentation.
(2) Amitiza net sales consist of both product and royalty net sales. Refer to Note 5 for further details on Amitiza's revenues.

(3) Includes 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 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Net sales [1]:				
U.S.	$ 2,834.5	$ 2,899.0	$ 3,095.4	$ 763.7
Europe, Middle East and Africa	256.8	242.3	211.8	52.8
Other	124.3	80.3	73.6	13.4
	$ 3,215.6	$ 3,221.6	$ 3,380.8	$ 829.9

	Fiscal Year Ended	
	December 28, 2018	December 29, 2017
Long-lived assets [2]:		
U.S.	$ 770.7	$ 788.5
Europe, Middle East and Africa [3]	146.7	127.0
Other	76.8	63.5
	$ 994.2	$ 979.0

(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 $145.2 million and $126.0 million as of December 28, 2018 and December 29, 2017, respectively.

23. Selected Quarterly Financial Data (Unaudited)

A summary of quarterly financial information for fiscal 2018 and 2017 is as follows:

	For the Quarter Ended [1]			
	March 30, 2018	June 29, 2018	September 28, 2018	December 28, 2018
Net sales	$755.3	$825.5	$ 799.9	$ 834.9
Gross profit [2]	347.5	394.0	366.4	363.3
(Loss) income from continuing operations [3]	(20.9)	3.2	114.2	(3,718.4)
Income (loss) from discontinued operations	2.9	12.4	(0.4)	—
Net (loss) income	(18.0)	15.6	113.8	(3,718.4)
Basic (loss) earnings per share from continuing operations [4]	$(0.24)	$0.04	$ 1.37	$ (44.64)
Diluted (loss) earnings per share from continuing operations [4]	(0.24)	0.04	1.34	(44.64)

	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 [2]	419.8	416.1	400.6	421.0
Income from continuing operations [3]	28.9	70.6	64.3	1,607.4
Income (loss) 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 [4]	$0.28	$0.72	$ 0.66	$ 17.43
Diluted earnings per share from continuing operations [4]	0.28	0.72	0.66	17.40

(1) The Specialty Generics Disposal Group was included within discontinued operations during the first three quarters of fiscal 2018, and has subsequently been recast to be included within continuing operations. In accordance with U.S. GAAP, depreciation and amortization are not recorded during the period in which a disposal group is classified as held-for-sale, thus the Company's financial results during the first three quarters of fiscal 2018 did not include $17.7 million and $6.8 million of depreciation and amortization expense, respectively, related to the Specialty Generics Disposal Group. During the fourth quarter of 2018, the Specialty Generics Disposal Group was reclassified to held and used and measured at its carrying amount before it was classified as held-for-sale, adjusted for depreciation and amortization expense that would have been recognized had the disposal group been continuously classified as held and used. The total adjustment of $24.5 million was reflected in loss from continuing operations during the fourth quarter of 2018, the period in which the held-for-sale criteria were no longer met.

(2) Financial data for each period has been adjusted to reflect the change in accounting for pension and postretirement costs with the adoption of ASU 2017-07. See Note 4 for further information.

(3) (Loss) income from continuing operations for the quarter ended December 28, 2018 reflects impairment charges for goodwill and an IPR&D asset. See Note 13 for further information. Income from continuing operations for the quarter ended December 29, 2017 reflects one-time effects for the completion of the reorganization of the Company's legal entity ownership and the impact of the TCJA.

(4) 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.

24. Condensed Consolidating Financial Statements

MIFSA is an indirectly 100%-owned subsidiary of Mallinckrodt plc 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 2013 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 2013 Notes,

MIFSA as issuer of the 2013 Notes and the operating companies that represent assets of MIFSA. There are no subsidiary guarantees related to the 2013 Notes.

Set forth below are the condensed consolidating balance sheets as of December 28, 2018 and December 29, 2017 and condensed consolidating statements of comprehensive income and cash flows for the fiscal three years ended December 28, 2018 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 28, 2018
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Assets					
Current Assets:					
Cash and cash equivalents	$ 0.4	$ 140.8	$ 207.7	$ —	$ 348.9
Accounts receivable, net	—	—	623.3	—	623.3
Inventories	—	—	322.3	—	322.3
Prepaid expenses and other current assets	3.9	0.2	128.6	—	132.7
Notes receivable	—	—	—	—	—
Intercompany receivable	131.1	29.2	1,087.9	(1,248.2)	—
Total current assets	135.4	170.2	2,369.8	(1,248.2)	1,427.2
Property, plant and equipment, net	—	—	982.0	—	982.0
Goodwill	—	—	—	—	—
Intangible assets, net	—	—	8,282.8	—	8,282.8
Investment in subsidiaries	2,481.6	25,506.1	8,362.1	(36,349.8)	—
Intercompany loan receivable	497.7	—	12,343.0	(12,840.7)	—
Other assets	—	—	185.3	—	185.3
Total Assets	$ 3,114.7	$ 25,676.3	$ 32,525.0	$ (50,438.7)	$ 10,877.3
					—
Liabilities and Shareholders' Equity					
Current Liabilities:					
Current maturities of long-term debt	$ —	$ 22.1	$ 0.3	$ —	$ 22.4
Accounts payable	0.1	—	147.4	—	147.5
Accrued payroll and payroll-related costs	—	—	124.0	—	124.0
Accrued interest	—	48.7	28.9	—	77.6
Income taxes payable	—	—	25.0	—	25.0
Accrued and other current liabilities	0.6	0.4	546.2	—	547.2
Intercompany payable	226.7	827.8	193.7	(1,248.2)	—
Total current liabilities	227.4	899.0	1,065.5	(1,248.2)	943.7
Long-term debt	—	3,566.9	2,502.3	—	6,069.2
Pension and postretirement benefits	—	—	60.5	—	60.5
Environmental liabilities	—	—	59.7	—	59.7
Deferred income taxes	—	—	324.3	—	324.3
Other income tax liabilities	—	—	228.0	—	228.0
Intercompany loans payable	—	12,840.7	—	(12,840.7)	—
Other liabilities	—	7.6	297.0	—	304.6
Total liabilities	227.4	17,314.2	4,537.3	(14,088.9)	7,990.0
Shareholders' equity	2,887.3	8,362.1	27,987.7	(36,349.8)	2,887.3
Total Liabilities and Shareholders' Equity	$ 3,114.7	$ 25,676.3	$ 32,525.0	$ (50,438.7)	$ 10,877.3

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
Prepaid expenses and other current assets	1.0	0.2	82.9	—	84.1
Notes receivable	—	—	154.0	—	154.0
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
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
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
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 STATEMENT OF COMPREHENSIVE INCOME
Fiscal year ended December 28, 2018
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Net sales	$ —	$ —	$ 3,215.6	$ —	$ 3,215.6
Cost of sales	2.0	—	1,742.4	—	1,744.4
Gross (loss) profit	(2.0)	—	1,473.2	—	1,471.2
Selling, general and administrative expenses	38.8	0.7	794.6	—	834.1
Research and development expenses	4.7	—	356.4	—	361.1
Restructuring charges, net	—	—	103.0	—	103.0
Non-restructuring impairment charges	—	—	3,893.1	—	3,893.1
Loss on divestiture	—	—	0.8	—	0.8
Operating loss	(45.5)	(0.7)	(3,674.7)	—	(3,720.9)
Interest expense	(7.8)	(460.8)	(63.4)	161.8	(370.2)
Interest income	9.5	2.5	158.0	(161.8)	8.2
Other income, net	9.9	8.7	12.3	—	30.9
Intercompany interest and fees	(18.5)	(0.1)	18.6	—	—
Equity in net income of subsidiaries	(3,561.0)	(2,726.0)	(3,170.9)	9,457.9	—
Loss from continuing operations before income taxes	(3,613.4)	(3,176.4)	(6,720.1)	9,457.9	(4,052.0)
Benefit from income taxes	(6.4)	(5.4)	(418.3)	—	(430.1)
Loss from continuing operations	(3,607.0)	(3,171.0)	(6,301.8)	9,457.9	(3,621.9)
Income from discontinued operations, net of income taxes	—	0.1	14.8	—	14.9
Net loss	(3,607.0)	(3,170.9)	(6,287.0)	9,457.9	(3,607.0)
Other comprehensive loss, net of tax	(9.9)	(9.9)	(20.5)	30.4	(9.9)
Comprehensive loss	$ (3,616.9)	$ (3,180.8)	$ (6,307.5)	$ 9,488.3	$ (3,616.9)

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	—	1,561.5	—	1,564.1
Gross (loss) profit	(2.6)	—	1,660.1	—	1,657.5
Selling, general and administrative expenses	59.5	0.7	789.5	—	849.7
Research and development expenses	5.1	—	271.8	—	276.9
Restructuring charges, net	—	—	31.2	—	31.2
Non-restructuring impairments	—	—	63.7	—	63.7
Gains on divestiture	—	—	(56.9)	—	(56.9)
Operating (loss) income	(67.2)	(0.7)	560.8	—	492.9
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)	(85.4)	—	(66.8)
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	—	—	1,523.2	—	1,523.2
Gross profit	—	—	1,857.6	—	1,857.6
Selling, general and administrative expenses	51.3	0.8	861.6	—	913.7
Research and development expenses	—	—	261.2	—	261.2
Restructuring charges, net	—	—	32.7	—	32.7
Non-restructuring impairments	—	—	16.9	—	16.9
Operating (loss) income	(51.3)	(0.8)	685.2	—	633.1
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	(108.1)	—	(16.4)
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

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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	—	—	383.2	—	383.2
Gross profit	—	—	446.7	—	446.7
Selling, general and administrative expenses	13.4	0.2	307.5	—	321.1
Research and development expenses	—	—	66.1	—	66.1
Restructuring charges, net	—	—	3.8	—	3.8
Non-restructuring impairments	—	—	214.3	—	214.3
Operating loss	(13.4)	(0.2)	(145.0)	—	(158.6)
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	(51.6)	—	(49.1)
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)

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MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS
Fiscal year ended December 28, 2018
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Cash Flows From Operating Activities:					
Net cash from operating activities	$ 438.9	$ 80.1	$ 1,702.5	$ (1,556.0)	$ 665.5
Cash Flows From Investing Activities:					
Capital expenditures	—	—	(127.0)	—	(127.0)
Acquisitions, net of cash acquired	—	—	(699.9)	—	(699.9)
Proceeds from disposal of discontinued operations, net of cash	—	—	313.0	—	313.0
Intercompany loan investment	(385.6)	(90.1)	(502.0)	977.7	—
Investment in subsidiary	—	(220.0)	—	220.0	—
Proceeds from sale of subsidiary	—	—	—	—	—
Acquisition of subsidiary	—	—	—	—	—
Other	—	—	33.6	—	33.6
Net cash from investing activities	(385.6)	(310.1)	(982.3)	1,197.7	(480.3)
Cash Flows From Financing Activities:					
Issuance of external debt	—	600.0	90.3	—	690.3
Repayment of external debt and capital leases	—	(1,289.4)	(404.2)	—	(1,693.6)
Debt financing costs	—	(12.1)	—	—	(12.1)
Proceeds from exercise of share options	1.0	—	—	—	1.0
Intercompany loan borrowings	—	977.7	—	(977.7)	—
Intercompany dividends	—	(814.2)	(741.8)	1,556.0	—
Capital contribution	—	—	220.0	(220.0)	—
Repurchase of shares	(57.5)	—	—	—	(57.5)
Other	2.9	—	(26.0)	—	(23.1)
Net cash from financing activities	(53.6)	(538.0)	(861.7)	358.3	(1,095.0)
Effect of currency rate changes on cash	—	—	(1.8)	—	(1.8)
Net decrease in cash, cash equivalents and restricted cash	(0.3)	(768.0)	(143.3)	—	(911.6)
Cash, cash equivalents and restricted cash at beginning of period	0.7	908.8	369.6	—	1,279.1
Cash, cash equivalents and restricted cash at end of period	$ 0.4	$ 140.8	$ 226.3	$ —	$ 367.5
Cash and cash equivalents at end of period	$ 0.4	$ 140.8	$ 207.7	$ —	$ 348.9
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	—	—	18.6	—	18.6
Cash, cash equivalents and restricted cash at end of period	$ 0.4	$ 140.8	$ 226.3	$ —	$ 367.5

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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, 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	—
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 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

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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, 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

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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, 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

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25. Subsequent Events

Reorganization of Intercompany Financing and Legal Entity Ownership

On January 26, 2019, the Company completed a reorganization of its intercompany financing and associated legal entity ownership in response to the changing global tax environment. The Company initiated the reorganization during the three months ended September 28, 2018 and continued the reorganization during the three months ended December 28, 2018.

During the three months ending March 29, 2019, the Company expects to recognize a net income tax benefit of $125.0 million to $175.0 million which will serve to reduce its net deferred tax liabilities by a similar amount. The reduction to net deferred tax liabilities is expected to be comprised predominantly of the elimination of the December 28, 2018 balance of interest-bearing U.S. deferred tax liabilities of $227.5 million offset by a decrease to other deferred tax assets. The elimination of the interest-bearing deferred tax obligation will also eliminate the annual Internal Revenue Code section 453A interest expense.

During fiscal 2018, the Company recognized current income tax expense of $25.5 million and a deferred income tax benefit of $281.5 million with a corresponding reduction to net deferred tax liabilities. See Note 9 for further details regarding the fiscal 2018 impact.

Financing Activities

On December 31, 2018, the Company made a $25.0 million voluntary prepayment on its outstanding term loan due September 2024 and $5.6 million of quarterly principal amortization payments on its outstanding term loans.

On February 14, 2019, the Company made a $175.0 million voluntary prepayment on its outstanding term loan due February 2025.

Subsequent to fiscal 2018 and up through the date of this filing, the Company repurchased fixed-rate debt that aggregated to a principal amount of $75.0 million.

Commitments and Contingencies

Certain litigation matters occurred in fiscal 2018 or prior, but had subsequent updates through the date of this report. See further discussion in Note 20 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 28, 2018. Based on that evaluation, our CEO and CFO concluded that, as of that date, our disclosure controls and procedures were not effective due to the material weakness in internal control over financial reporting described below. Notwithstanding this material weakness, management believes the Company's consolidated financial statements in this Annual Report on Form 10-K fairly present, in all material respects, our financial position, results of operations and cash flows as of the dates, and for the periods presented, in conformity with GAAP.

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 GAAP. 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 GAAP, 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 28, 2018. 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.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

During fiscal 2018, the Company did not design and maintain sufficiently precise or effective review and approval controls over the future cash flow forecasts used to develop certain management estimates, including those related to goodwill and other intangible assets. Management concluded that this control deficiency represents a material

weakness. This material weakness did not result in a material misstatement to the Company's financial statements or disclosures.

Management's Plans for Remediation

Management has already taken steps, and will take additional steps, to remediate the material weakness, including the development of enhanced procedures governing oversight and evaluation of future cash flow forecasts used to develop certain management estimates, including those related to goodwill and other intangible assets. Management believes the additional control procedures, when implemented and validated, will fully remediate this material weakness.

The remediation efforts are intended both to address the identified material weakness and to enhance our overall financial control environment. Management is committed to continuous improvement of the Company's internal control over financial reporting and will continue to diligently review the Company's internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 28, 2018 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 28, 2018, 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, because of the effect of the material weakness identified below on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 28, 2018, 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 28, 2018 and December 29, 2017, the related consolidated statements of income, comprehensive income, changes in shareholders' equity, and cash flows, for the fiscal years ended December 28, 2018, December 29, 2017 and September 30, 2016 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 26, 2019, expressed an unqualified opinion on those financial statements.

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.

Material Weakness

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company’s annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment: The Company did not design and maintain sufficiently precise or effective review and approval controls over future cash flow forecasts used to develop certain management estimates, including those related to goodwill and other intangible assets. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the consolidated financial statements as of and for the year ended December 28, 2018, of the Company, and this report does not affect our report on such financial statements.

/s/ DELOITTE & TOUCHE LLP
St. Louis, Missouri
February 26, 2019

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 28, 2018. 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 28, 2018.

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 28, 2018.

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 28, 2018.

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 28, 2018.

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 Statements of Income for the fiscal year ended December 28, 2018, December 29, 2017 and September 30, 2016 and the three months ended December 30, 2016
- Consolidated Statements of Comprehensive Income for the fiscal year ended December 28, 2018, December 29, 2017 and September 30, 2016 and the three months ended December 30, 2016
- Consolidated Balance Sheets as of December 28, 2018 and December 29, 2017
- Consolidated Statements of Cash Flows for the fiscal year ended December 28, 2018, December 29, 2017 and September 30, 2016 and the three months ended December 30, 2016
- Consolidated Statements of Changes in Shareholders' Equity for the period from September 25, 2015 to December 28, 2018
- 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 28, 2018	$ 3.9	$3.8	$ —	$(2.7)	$5.0
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
Sales reserve accounts:					
Fiscal year ended December 28, 2018	$ 376.6	$2,387.5	$ —	$(2,358.7)	$405.4
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
Tax valuation allowance:					
Fiscal year ended December 28, 2018	$ 2,267.9	$332.8	$ 4.2	$—	$2,604.9
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

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.

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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 26, 2019 By: /s/ George A. Kegler
George A. Kegler
Executive Vice President and Chief Financial Officer, Interim
(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 26, 2019
/s/ George A. Kegler George A. Kegler	Executive Vice President and Chief Financial Officer, Interim *(principal financial officer)*	February 26, 2019
/s/ Kathleen A. Schaefer Kathleen A. Schaefer	Senior Vice President, Finance and Corporate Controller *(principal accounting officer)*	February 26, 2019
/s/ Angus C. Russell Angus C. Russell	Chairman of the Board of Directors	February 26, 2019
/s/ David R. Carlucci David R. Carlucci	Director	February 26, 2019
/s/ J. Martin Carroll J. Martin Carroll	Director	February 26, 2019
/s/ Paul R. Carter Paul R. Carter	Director	February 26, 2019
/s/ David Y. Norton David Y. Norton	Director	February 26, 2019
/s/ JoAnn A. Reed JoAnn A. Reed	Director	February 26, 2019
/s/ Anne C. Whitaker Anne C. Whitaker	Director	February 26, 2019
/s/ Kneeland C. Youngblood, M.D. Kneeland C. Youngblood, M.D.	Director	February 26, 2019
/s/ Joseph A. Zaccagnino	Director	February 26, 2019

Joseph A. Zaccagnino

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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	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).
2.3	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).
2.4	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 3.1 to the Company's Current Report on Form 8-K filed March 1, 2017).
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 (incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2017).
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	First Amendment to the Amended and Restated Note Purchase Agreement, dated as of January 11, 2019, by and 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 servicer.
10.12	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.À 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).
10.13	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).
10.14	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).
10.15	Form of Deed of Indemnification by and between Mallinckrodt plc and Directors and Secretary (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed July 1, 2013).
10.16	Form of Indemnification Agreement by and between Mallinckrodt Brand Pharmaceuticals, Inc. and Directors and Secretary (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed July 1, 2013).
10.17*	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).
10.18*	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).
10.19*	Mallinckrodt Pharmaceuticals Stock and Incentive Plan (incorporated by reference to Appendix A to the Company's Proxy Statement filed April 4, 2018.)
10.20*	Form of 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).

10.21*	Form of 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).
10.22*	Form of 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*	Form of 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*	Form of Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Performance Unit Award.
10.25*	Mallinckrodt Pharmaceuticals Supplemental Savings and Retirement Plan (incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2017).
10.26*	Letter Agreement, dated November 16, 2018, by and between Mallinckrodt plc and George Kegler (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 6, 2018).
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 Interim 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 Interim 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 28, 2018 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. The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.

*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.