UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 27, 2019

or

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

For the transition period from _____ to _____

Commission File Number : 001-35803

Mallinckrodt 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	(Trading Symbol(s))	Name of each exchange on which registered
Ordinary shares, par value $0.20 per share	MNK	New York Stock Exchange

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 ☒ No ☐

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

Large Accelerated Filer ☒ Accelerated Filer ☐ Non-accelerated Filer ☐ Smaller Reporting Company ☐ Emerging Growth Company ☐

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant (assuming solely for the purposes of this calculation that all directors and executive officers of the Registrant are "affiliates") as of June 28, 2019, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $764.7 million (based upon the closing price of $9.18 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 21, 2020 was 84,207,022.

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 27, 2019, are incorporated by reference into Part III of this report.

MALLINCKRODT PLC
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Presentation of Information

Unless the context requires otherwise, references to "Mallinckrodt plc," "Mallinckrodt," "we," "us," "our" and "the Company" refer to Mallinckrodt plc, an Irish public limited company, and its consolidated subsidiaries. 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 consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute 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.

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

- *Specialty Brands* includes innovative specialty pharmaceutical brands; and
- *Specialty Generics* includes niche specialty generic drugs and active pharmaceutical ingredients ("API(s)").

During fiscal 2019, we experienced a change in our reportable segments, which primarily served to move the results related to Amitiza® (lubiprostone) ("Amitiza") to the Specialty Brands segment from the Specialty Generics segment. All prior period segment information has been recast to reflect the realignment of our reportable segments on a comparable basis.

We continue to execute on our ongoing transformation to become an innovation-driven biopharmaceutical company focused on improving outcomes for underserved patients with severe and critical conditions. For further information on our products, refer to "Our Businesses and Products" within this Item 1. Business.

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.") and our Specialty Brands global external manufacturing operations are located in Dublin, Ireland. In addition, we have other locations in the United States ("U.S."), most notably our corporate shared services office in Hazelwood, Missouri, our Specialty Brands commercial headquarters in Bedminster, New Jersey, and our Specialty Generics headquarters and technical development center in Webster Groves, Missouri.

Our Businesses and Products

We manage our business in two reportable segments: Specialty Brands and Specialty Generics. Management measures and evaluates our operating segments based on segment net sales and operating income. Information regarding the product portfolios and business strategies of these segments is included in the following discussion.

Specialty Brands

Our business markets branded pharmaceutical products for autoimmune and rare diseases in the specialty areas of neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; analgesics and gastrointestinal products. Our diversified, in-line portfolio of both marketed and development products is focused on patients with significant unmet medical needs. In the past few years, we have expanded our 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 innovative new therapies and next-generation devices for our 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 27, 2019. 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 product portfolio:

- *Acthar® Gel (repository corticotropin injection) ("Acthar Gel")* is an injectable drug approved by the U.S. Food and Drug Administration ("FDA") for use in 19 indications. The product currently generates substantially all of its net sales from 11 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 keratitis and uveitis; add-on medicine for the short-term administration (to tide patients over an acute episode or exacerbation) in psoriatic arthritis (PsA); and ankylosing spondylitis. We may initiate commercial efforts for other approved indications where there is high unmet medical need. The currently approved indications of Acthar Gel are not subject to patent or other exclusivity.

  Since acquiring 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 five ongoing Company-sponsored studies for which the areas of focus include focal segmental glomerular sclerosis ("FSGS") (a nephrotic condition), MS, pulmonary sarcoidosis, keratitis and uveitis. We continue our efforts to extend the value of the product through product enhancements including the ongoing development of the Acthar self-injection device, which will create an easier and more patient-friendly application for single unit dosage indications, as well as through additional Phase 4 studies.

- *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 received approval in Australia for the treatment of perioperative pulmonary hypertension in adults in conjunction with cardiovascular surgery. Additionally, our Phase 4 registry assessing INOmax for treatment of pulmonary hypertension in premature (27 to 34 weeks) and term and near-term neonates showed positive results during the planned interim analysis with 86% of the 31 premature and 56 term and near-term patients showing a 25% or greater improvement in oxygenation index from baseline, or surrogate oxygenation index for patients who are not ventilated, during the treatment.

  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. Development continues for the next-generation INOmax device which is designed to 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 19 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.
- *Amitiza* is a leading global product in the branded constipation market. Amitiza is approved by the FDA for treatment of chronic idiopathic constipation in adults, irritable bowel syndrome with constipation in women 18 years of age and older, and opioid-induced constipation in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation. Amitiza is a chloride channel activator which increases fluid secretion and motility of the intestine, facilitating passage of stool. Roughly 40 million patients in the U.S. suffer from some form of chronic constipation. Of the branded products currently marketed, only Amitiza is approved for three constipation indications in the U.S.

  Prior to our acquisition of this product in February 2018, the prior owner had entered into an agreement with Par Pharmaceutical, Inc., et al. (collectively "Par") in connection with the settlement of patent litigation in the U.S. related to Amitiza. Under this agreement, Par was granted a non-exclusive license to market Par's generic version of lubiprostone 8 mcg and 24 mcg soft gelatin capsules in the U.S. for the indications approved for Amitiza beginning in fiscal 2021, or earlier under certain circumstances. Refer to Note 19 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 for further information regarding patent litigation in relation to Amitiza.
- *Pipeline products* - We have multiple products in various stages of development, which we believe will provide long-term organic growth and diversification. For a detailed description of the most significant development products in our pipeline, refer to the Research and Development ("R&D") section in this Item 1. Business.

Specialty Generics

Our Specialty Generics segment is focused on providing our customers high-quality specialty generic drugs and APIs. 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 two new products in fiscal 2020, 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 2019, we estimated that we received approximately 35.1% 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 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.

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

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

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 Acthar Gel, INOmax and Therakos.

The most significant development products in our pipeline are the following:

- *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 2019 we completed enrollment for the Phase 3 clinical study to evaluate the efficacy and safety of terlipressin (for injection) in subjects with HRS type 1, and announced positive top line results. The study met its primary endpoint of verified HRS type 1 reversal, as well as the statistical value requirements outlined in the FDA completed response letter. This Phase 3 clinical study was conducted under an FDA Special Protocol Assessment ("SPA"). We expect to submit the new drug application ("NDA") filing to the FDA in the first half of 2020.
- *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 enrolled 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. StrataGraft is among the first products to be designated as a Regenerative Medicine Advanced Therapy ("RMAT") by the FDA under the provisions of the 21st Century Cures Act. The RMAT designation allows for earlier and increased interactions with the FDA, including discussions of whether priority review and/or accelerated approval would be appropriate based on surrogate or intermediate endpoints that would be reasonably likely to predict long-term clinical benefit; or reliance upon data obtained from a meaningful number of sites. During fiscal 2019, we completed full enrollment for the Phase 3 clinical study and met both primary endpoints as well as the secondary end point evaluating the safety and efficacy of a single application of StrataGraft in the treatment of severe deep partial thickness burns. We expect to submit a biologics license application ("BLA") filing to the FDA in the first half of 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.
- *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, by way of a SPA, and plan to initiate the Phase 3 trial for the IV formulation of this development product in the first half of 2020. The Phase 2 oral trial is still ongoing.

- *SLN500* is a ribonucleic acid ("RNA") technology therapy currently in preclinical development designed to inhibit the complement cascade, a group of proteins that are involved in the immune system and play a role in the development of inflammation. These proteins are known to contribute to the pathogenesis of many diseases, including autoimmune diseases. In July 2019, we announced a collaboration with Silence Therapeutics plc to develop and commercialize SLN500, and an option for up to two additional assets with different complement protein targets.

Specialty Generics. 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 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 six 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.

To facilitate our development efforts, we have a multipurpose commercial production facility and pilot plant in St. Louis, Missouri, where we can test and scale our manufacturing processes for new products. This also allows us to more rapidly and economically develop certain drug product submissions, all under one roof at our pilot plant, with a limited amount of API or drug product. This facility was converted to dual purpose for both pilot and commercial manufacturing in 2018, and the first product to launch from this facility is expected in 2020.

Competition

Several of our Specialty Brands products do not face direct competition from similar products, but instead compete against alternative forms of treatment that a prescriber may utilize. For example, Acthar 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. 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. For example, there is now direct competition in the U.S. market for INOmax due to the recent U.S. Court of Appeals ruling. However, we believe INOmax's highly differentiated service offering and next generation presentation will help to mitigate the impact of competition longer term.

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 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.

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 in three separate indications for CIC, IBS-C and OIC.

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 Rhodes Pharmaceuticals LP, Teva Pharmaceutical Industries Ltd., Aurobindo Pharma Ltd., Amneal Pharmaceutical Ltd., Noramco, Inc. and Johnson Matthey 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 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.

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 or the product's associated customer service and delivery models. Acthar Gel is not subject to patent or other exclusivity. Acthar Gel's commercial durability therefore relies partially upon product-related trade secrets, confidentiality agreements and trademark and copyright laws. These items may not prevent competitors from independently developing similar technology or duplicating our product. Several of the other products in our Specialty Brands product portfolio, currently benefit from these forms of regulatory and patent-conferred exclusivity.

Patents are a key determinant of market exclusivity for most branded pharmaceuticals. Patents provide the innovator with the right to exclude others from practicing an invention related to the product. Patents may cover, among other things, the active ingredient(s), various uses of a drug product, pharmaceutical formulations, drug delivery mechanisms, and processes for (or intermediates useful in) the manufacture of products. Protection for individual products extends for varying periods in accordance with the expiration dates of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent, its scope of coverage and the availability of meaningful legal remedies in the country.

Many developed countries provide certain non-patent incentives for the development of pharmaceuticals. For example, the U.S., European Union ("E.U.") and Japan each provide for a minimum period of time after the approval of certain new drugs during which the regulatory agency may not rely upon the innovator's data to approve a competitor's generic copy. Regulatory exclusivity is also available in certain markets as incentives for research on new indications, orphan drugs (drugs that demonstrate promise for the diagnosis or treatment of rare diseases or conditions) and medicines that may be useful in treating pediatric patients. Regulatory exclusivity is independent of any patent rights and can be particularly important when a drug lacks broad patent protection. However, most regulatory forms of exclusivity do not prevent a competitor from gaining regulatory approval prior to the expiration of regulatory exclusivity on the basis of the competitor's own safety and efficacy data on its drug, even when that drug is identical to that marketed by the innovator.

We estimate the likely market exclusivity period for each of our branded products on a case-by-case basis. It is not possible to predict with certainty the length of market exclusivity for any of our branded products because of the complex interaction between patent and regulatory forms of exclusivity, the relative success or lack thereof by potential competitors' experience in product development and inherent uncertainties concerning patent litigation. There can be no assurance that a particular product will enjoy market exclusivity for the full period of time that we currently estimate or that the exclusivity will be limited to the estimate.

In addition to patents and regulatory forms of exclusivity, we also market products with trademarks. Trademarks have no effect on market exclusivity for a product, but are considered to have marketing value. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registrations of such trademarks are for fixed terms and subject to renewal as provided by the laws of the particular country.

Regulatory Matters

Quality Assurance Requirements

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

The FDA conducts pre-approval inspections of facilities engaged in the development, manufacture, processing, packaging, testing and holding of the drugs subject to NDAs and 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 dosage form, new combination, new formulation, new indication or 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, but where at least some of the information required for approval comes from studies not conducted by the applicant, 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 nor misleading. Manufacturers are required to file copies of all product-specific promotional materials with 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 drug product 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 NDA 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 2020, the user fee rate has been set at $2,942,970 for a 505(b)(1) NDA and $1,471,480 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 help the FDA fund the drug approval process. Under the Generic Drug User Fee Amendments of 2017, the fiscal 2020 user fee rate is set at $176,240 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 2020.

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 ("HCP(s)") who prescribe these opioid analgesics and to distribute educational materials on their safe use to prescribers and patients. In September 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 entities that hold FDA marketing authorizations for opioid products 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 2019, manufacturing and procurement quotas granted by the DEA were sufficient to meet our sales and inventory requirements on most products. In December 2019, the DEA continued to further reduce the manufacturing quota for the top six misused Schedule II opioids that may be manufactured in the U.S. in calendar year 2020. 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 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, 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 $75.9 million, $98.9 million and $91.6

million in fiscal 2019, 2018 and 2017, respectively. The fiscal 2019 decrease in provisions for Medicaid payments is due to a $12.6 million decrease in Specialty Generics coupled with a $10.4 million decrease associated with Acthar Gel. The fiscal 2018 increase in provisions for Medicaid payments is primarily attributable to a $14.8 million increase associated with Acthar Gel offset by $7.0 million decrease in Specialty Generics products. Our business was also impacted by the annual fee on branded prescription pharmaceutical manufacturers and recorded expense of $20.1 million, $18.4 million and $21.8 million in fiscal 2019, 2018 and 2017, 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 in this role reports 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 program's 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 19 to the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

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 ("GPO(s)") 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 10.0% of our total net sales in fiscal 2019, 2018 and 2017 were as follows:

	Fiscal Year		
	2019	2018	2017
CuraScript, Inc.	29.7%	35.2%	40.1%
AmerisourceBergen Corporation	10.2%	*	*

* Net Sales to this distributor were less than 10.0% of total net sales during the respective periods presented above.

No other customer accounted for 10.0% or more of our net sales in the above periods presented.

Manufacturing and Distribution

As of December 27, 2019, we had 11 manufacturing sites, including eight located in the U.S., as well as sites in Ireland and Japan, which handle production, assembly, quality assurance testing, packaging and sterilization of our products. Approximately 91.0%, 6.6% and 2.4% of our manufacturing production (as measured by cost of production) was performed within the U.S., Canada and Japan, respectively, in fiscal 2019.

As of December 27, 2019, we maintained distribution centers in ten 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 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 27, 2019. As of December 27, 2019, our backlog was 10.5% of net sales, more than half of which is expected to be recognized as revenue in fiscal 2020.

Seasonality

We have historically experienced fluctuations in our business resulting from seasonality. For example, 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. Further, we have also experienced fluctuations in net sales of Ofirmev resulting from ordering patterns of our hospital customers. 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 27, 2019, we had approximately 3,400 employees, approximately 1,600 of which support the Specialty Generics 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.

Information About Our Executive Officers

Set forth below are the names, ages as of February 1, 2020, and current positions of our executive officers.

Name	Age	Title
Mark Trudeau	58	President, Chief Executive Officer and Director
Bryan Reasons	51	Executive Vice President and Chief Financial Officer
Mark Casey	56	Executive Vice President and Chief Legal Officer
Hugh O'Neill	56	Executive Vice President and Chief Commercial Officer
Steven Romano, MD	60	Executive Vice President and Chief Scientific Officer
Ian Watkins	57	Executive Vice President and Chief Human Resources Officer

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

Mark Trudeau has been President, Chief Executive Officer and a director since June 2013. In anticipation of our spin transaction, Mr. Trudeau joined Covidien plc 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.

Bryan Reasons is our Executive Vice President and Chief Financial Officer. He has executive responsibility for the global finance function. Prior to joining Mallinckrodt in March 2019, Mr. Reasons served as Senior Vice President and Chief Financial Officer of Amneal Pharmaceuticals, Inc. ("Amneal") from May 2018 until January 2019 and as Senior Vice President, Finance and Chief Financial Officer of Impax Laboratories, Inc. ("Impax") from December 2012 until Amneal Pharmaceuticals LLC and Impax completed their business combination to form Amneal in May 2018. Mr. Reasons previously served as Impax's Acting Chief Financial Officer from June 2012 to December 2012 and as Impax's Vice President, Finance from January 2012 to June 2012. Prior to joining Impax in January 2012, he held various finance management positions at Cephalon, Inc. from 2005 to 2012 and at E. I. Du Pont De Nemours and Company from 2003 to 2005 and was at PricewaterhouseCoopers LLP from 1993 to 2003 last serving as senior manager. Mr. Reasons also serves as an independent board director and audit committee chair for both Aclaris Therapeutics, Inc. and Recro Pharma, Inc.

Mark Casey is our Executive Vice President and Chief Legal Officer, a role he assumed in August 2019. He joined Mallinckrodt in February 2018 as our General Counsel and 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, as well as the Company's Specialty Generics business. 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.

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. Dr. Romano also serves as a director of Silence Therapeutics plc.

Ian Watkins is our Executive Vice President and Chief Human Resources Officer. He has executive responsibility for organizational development, effectiveness and sustainability, talent acquisition, total rewards, human resources systems and service delivery and the Company's communications. He is also responsible for supporting the Board of Directors in their governance activities related to executive compensation, talent and succession management. Mr. Watkins joined Covidien's Pharmaceuticals business in September 2012 as the Chief Human Resources Officer. Mr. Watkins served as Vice President, Global Human Resources at Synthes, Inc. from June 2007 to September 2012, which was acquired by Johnson & Johnson. Mr. Watkins served as Senior Vice President, Human Resources from 2003 to 2006 for Andrx Corporation, which is now part of Allergan 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. Securities and Exchange Commission ("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.

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 Attorneys General and private persons seeking to hold us and others accountable for opioid misuse and abuse. As of February 25, 2020, the cases we are aware of include, but are not limited to, approximately 2,496 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 253 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers; approximately 110 cases filed by individuals; approximately six cases filed by schools and school boards; and 17 cases filed by the Attorneys General for New Mexico, Kentucky, Rhode Island, Georgia, Florida, Alaska, New York, Nevada, South Dakota, New Hampshire, Louisiana, Illinois, Mississippi, West Virginia, and Idaho, with Idaho being the only state Attorney General to file in federal as opposed to state court. As of February 25, 2020, the Mallinckrodt defendants in these cases consist of Mallinckrodt plc and the following subsidiaries of Mallinckrodt plc: Mallinckrodt Enterprises LLC, Mallinckrodt LLC, SpecGx LLC, Mallinckrodt Brand Pharmaceuticals Inc., Mallinckrodt Inc., MNK 2011 Inc. and Mallinckrodt Enterprises Holdings, Inc. However, there can be no assurance that plaintiffs will not assert claims against additional Mallinckrodt plc subsidiaries in the future. 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 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, together with the manner in which other defendants in those cases resolve opioid-related lawsuits and other actions, 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 if the Litigation Settlement (as defined below) is not consummated. 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, if the Litigation Settlement (as defined below) is not fully implemented or consummated, we 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. Any such potential liabilities or losses could also require us to seek financing, which may not be available on terms acceptable to us, or at all, when required. Such matters or the resolution thereof, or increase in accruals thereof, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

On February 25, 2020, we announced that we, certain of our subsidiaries operating the Specialty Generics business (the "Specialty Generics Subsidiaries") and certain other affiliates have reached an agreement in principle on the terms of a global settlement that would resolve all opioid-related claims against us, which we refer to herein as the "Litigation Settlement." The Litigation Settlement is subject to certain contingencies and may not go into effect in its current form or at all, as a result of which our business prospects may be adversely impacted. The Litigation Settlement contemplates the filing of voluntary petitions under Chapter 11 of the U.S. Bankruptcy Code ("Chapter 11") by the Specialty Generics Subsidiaries and the establishment of a trust for the benefit of plaintiffs holding opioid-related claims against Mallinckrodt (the "Opioid Claimant Trust"). Any bankruptcy of the Specialty Generics Subsidiaries (as contemplated by the Litigation Settlement or otherwise) would subject both the Specialty Generics Subsidiaries and us and our other subsidiaries to additional risks and uncertainties that could adversely affect our business prospects and ability to continue as a going concern, including, but not limited to by causing increased difficulty obtaining and maintaining commercial relationships on competitive terms with customers, suppliers and other counterparts; increased difficulty retaining and motivating key employees, as well as attracting new employees; diversion of management's time and attention to dealing with bankruptcy and restructuring activities rather than focusing exclusively on business operations; incurrence of substantial costs, fees and other expenses associated with bankruptcy proceedings; and loss of ability to maintain or obtain sufficient financing sources for operations or to fund any reorganization plan and meet future obligations. We would in that event also be subject to risks and uncertainties caused by the actions of creditors and other third parties who have interests that may be inconsistent with our plans. Furthermore, depending on developments with respect to the Litigation Settlement and other factors, it may be necessary or advisable for us and/or our subsidiaries other than the Specialty Generics Subsidiaries to seek to restructure our or their obligations in a bankruptcy proceeding. Such a bankruptcy could further exacerbate the foregoing risks.

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 (the "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. In April 2019, the State of New York passed its 2020 budget, which amended the OSA so that if the OSA decision is reversed on appeal, the OSA would apply only to the sale or distribution of certain opioids in New York for 2017 and 2018 and, effective July 1, 2019, imposed an excise tax on certain opioids. Furthermore, Rhode Island and Delaware have enacted opioid taxes, Minnesota and Maine have enacted increased licensure and registration fees and 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 additional 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.

The Litigation Settlement is subject to certain contingencies and may not go into effect in its current form or at all, as a result of which our business prospects may be adversely impacted.

The Litigation Settlement into which we have entered is neither final nor binding and there is no assurance that the necessary parties will agree to definitive documentation, that the contingencies to any agreement will be fulfilled or that any potential settlement agreement entered into by us will be on terms as favorable as the Litigation Settlement. In particular, the Litigation Settlement is subject to a number of conditions, many of which may not be satisfied. Among other things, we and the other parties to the Litigation Settlement do not intend to proceed with its implementation absent supermajority support and participation amongst the plaintiffs in the opioid cases, and there is no assurance that such support and participation will be obtained. As of February 25, 2020, our discussions regarding the Litigation Settlement have principally been with representatives of governmental entities that are plaintiffs in the opioid cases, rather than private plaintiffs such as hospitals and insurers. Furthermore, the Litigation Settlement is intended to be implemented through a filing by the Specialty Generics Subsidiaries of a pre-arranged bankruptcy case under Chapter 11, which will require confirmation of a plan of reorganization by a U.S. Bankruptcy Court. Confirmation of such a plan is uncertain and could be denied. Furthermore, subject to the satisfaction of the conditions to the Litigation Settlement, the consummation of the Litigation Settlement would become effective upon the emergence of the Specialty Generics Subsidiaries from Chapter 11 bankruptcy, the timing of which emergence is uncertain. The settlement process may use a significant portion of our resources and divert management's attention from our day-to-day operations, all of which could harm our business. Furthermore, the Litigation Settlement may not be implemented or consummated. In such circumstances, we would be subject to continued litigation with certain plaintiffs with opioid-related claims, including an expected New York state trial date commencing in March 2020, while the outcome of proceedings with the U.S. Department of Health and Human Services ("HHS") with respect to the Centers for Medicare & Medicaid Services ("CMS") reimbursement rates may remain uncertain. If the Litigation Settlement is not fully implemented or consummated, we or our subsidiaries may become subject to some or all of the liabilities that would have otherwise been settled, which could have a material and adverse effect on our business, financial condition, results of operations and cash flows. The failure of the Litigation Settlement may also lead to Mallinckrodt plc's subsequent bankruptcy, which would subject us to additional risks and uncertainties that could adversely affect our business prospects, as further described in the risk factor "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."

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 HHS, the FDA, the Federal Trade Commission (the "FTC") 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 FFDCA, 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. On or about March 8, 2019, the U.S. District Court for the Eastern District of Pennsylvania unsealed two qui tam actions involving the allegations under investigation by the USAO for the

Eastern District of Pennsylvania. The DOJ intervened in both actions, which have since been consolidated. In September 2019, we executed a settlement agreement to resolve the portion of the investigation and the litigation involving promotional practices for $15.4 million.

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. As discussed above, the USAO for the Eastern District of Pennsylvania is investigating this issue and the U.S. District Court for the Eastern District of Pennsylvania has unsealed two qui tam actions involving the allegations that are the subject of this investigation. 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 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.

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 Acthar Gel that occurred prior to our acquisition of the product. Acthar Gel represented 30.1% of our net sales for fiscal 2019. 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.

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 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 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 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.

Furthermore, 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. In May 2019, CMS issued a decision requiring that we revert to the base date average manufacturer price ("AMP") used to calculate Medicaid drug rebates for Acthar Gel. We subsequently filed suit in federal district court against the HHS and CMS seeking to hold unlawful and set aside this decision. We plan to vigorously defend our position. If we are unsuccessful in our efforts to set aside CMS's decision, Medicaid net sales of Acthar Gel could be substantially eliminated and our efforts to continue building on our investment in non-sales and marketing activities to modernize Acthar Gel could be significantly undermined.

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. See “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.”

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, in May 2019, CMS issued a decision requiring that we revert to the base date AMP used to calculate Medicaid drug rebates for Acthar Gel and 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.

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.

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 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.

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 not achieve the anticipated benefits of price increases enacted on our pharmaceutical products, which may adversely affect our business.

From time to time, we may initiate price increases on certain of our pharmaceutical products. There is no guarantee that our customers will be receptive to these price increases and continue to purchase the products at historical quantities. In addition, it is unclear how market participants will react to price increases. For example, following pricing actions in our Specialty Generics

segment in fiscal 2015, additional competitors entered the marketplace for several of these products and prices subsequently decreased 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 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 be unable to protect our intellectual property rights, intellectual property rights may be limited or we may be subject to claims that we infringe on the intellectual property rights of others.

We rely on a combination of patents, trademarks, trade secrets, proprietary know-how, market exclusivity gained from the regulatory approval process and other intellectual property to support our business strategy, most notably in relation to Acthar Gel, Ofirmev, INOmax, Therakos and Amitiza 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 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 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 Distribution, Inc. and Praxair, Inc. (collectively "Praxair") to prevent the marketing of its potential infringing nitric oxide drug product delivery system 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 appealed the decision to the Court of Appeals for the Federal Circuit, which upheld the lower court's decision on August 27, 2019. We filed a petition for en banc review at the Federal Circuit on September 26, 2019, which the Federal Circuit denied on November 19, 2019. 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. The Court of Appeals' decision with respect to the Praxair litigation 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 Bristol Myers Squibb ("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.

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.

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

Our net sales of 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. 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 FFDCA. This amendment introduced the requirement that drug manufacturers provide proof of the effectiveness (in addition to the previously required proof of safety) of their drugs in order to obtain FDA approval. As such, the FDA's original approval in 1952 was based on safety data as clinical trials evaluating efficacy were not then required. In the 1970s, the FDA reviewed the safety and efficacy of Acthar Gel during its approval of 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 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 Acthar Gel in treatment of IS, the FDA again reviewed evidence of safety and efficacy of Acthar Gel, and added the IS indication to the label of approved indications while maintaining approval of 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 Acthar Gel label, the FDA eliminated approximately 30 other indications from the label. The FDA review included a medical and scientific review of 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 Acthar Gel.

Accordingly, evidence of efficacy is largely based on physician's clinical experience with Acthar Gel and does not include clinical trials except for the MS and IS indications. We have initiated Phase 4 clinical trials to supplement the non-clinical evidence supporting the use of Acthar Gel in the treatment of the on-label indications of MS, RA, FSGS, symptomatic sarcoidosis, uveitis and systemic lupus erythematosus and have reported positive results from the open-label part of the Phase 4 clinical trials. The completion of such ongoing or future clinical trials to provide further evidence on the efficacy of 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 Acthar Gel to treat any of its approved indications. In addition, a clinical trial to evaluate the use of Acthar Gel to treat indications not on the current Acthar Gel label may not provide a basis to pursue adding such indications to the current Acthar Gel label. Furthermore, even if prescribed by a physician, third-party payers may implement restrictions on reimbursement of 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.

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.

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 19 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K. If any of these legal proceedings, inquiries or investigations were to result in an adverse outcome, the impact could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

With respect to product liability and clinical trial risks, in the ordinary course of business we are subject to liability claims and lawsuits, including potential class actions, alleging that our marketed products or products in development have caused, or could cause, serious adverse events or other injury. Any such claim brought against us, with or without merit, could be costly to defend and could result in an increase in our insurance premiums. We retain liability for $10.0 million per claim of the first $50.0 million of a loss in our primary liability policies and purchase an additional $120.0 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 27, 2019, it was probable that we would incur remediation costs in the range of $38.2 million to $86.9 million. We also concluded that, as of December 27, 2019, the best estimate within this range was $61.9 million. For further information on our environmental obligations, refer to Item 3. Legal Proceedings and Note 19 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K. Based upon information known to date, we believe our current capital and operating plans are adequate to address costs associated with the investigation, cleanup and potential remedial action for our known environmental matters.

While we have planned for future capital and operating expenditures to comply with environmental laws, our costs of complying with current or future environmental protection and health and safety laws and regulations, or our liabilities arising from past or future releases of, or exposures to, hazardous substances may exceed our estimates or could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. We may also be subject to additional environmental claims for personal injury or cost recovery actions for remediation of facilities in the future based on our past, present or future business activities.

Potential indemnification liabilities to Covidien pursuant to the separation and distribution agreement could materially adversely affect us.

In connection with the separation of the Company from Covidien (which was subsequently acquired by Medtronic plc) we entered into a separation and distribution agreement that provided for, among other things, the principal corporate transactions required to effect our separation from Covidien, certain conditions to the distribution of equity interests in the Company 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 imposes upon us certain indemnification obligations, which Covidien has asserted required us to indemnify Covidien for certain opioid-related claims brought against Covidien. 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. While the Litigation Settlement requires as a condition precedent that any of our indemnification liabilities to Covidien will be channeled to the Opioid Claimant Trust or otherwise resolved in a manner acceptable to us, there is no guarantee that such condition will be satisfied or that the Litigation Settlement will be effectuated on its current terms or at all.

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.

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 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.

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 supplies our products to many end user customers, CuraScript Inc. and AmerisourceBergen Corporation, accounted for 10.0% or more of our total net sales in 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 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 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 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 Acthar Gel may also be materially impacted by the decrease in the relatively small number of prescriptions written for Acthar Gel as compared to other products in our portfolio, given Acthar Gel's use in treating rare diseases. Any disruption in our ability to generate net sales from Acthar Gel could have an adverse impact 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 2018 and 2019, the DEA reduced the amount of opioid medication that may be manufactured in the United States by approximately 20% and 10%, respectively. For 2020, the DEA has reduced the amounts that may be produced of the eight most misused opioid molecules by approximately 13% compared to the 2019 amounts. Notably, hydrocodone and oxycodone quotas were reduced by 19% and 15%, respectively, and fentanyl quota was reduced by 31%. On September 13, 2019, the DEA proposed that benzylfentanyl and 4-anilinopiperidine be controlled as list I chemicals under the CSA. On September 17, 2019, the DEA proposed to designate norfentanyl as an immediate precursor (i.e., a substance from which another is formed) for

fentanyl and to make it a Schedule II controlled substance under the CSA. The DEA 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.

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.

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 U.K.'s exit from 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;
- exposure to potentially unfavorable movements in foreign currency exchange rates associated with international net sales and operating expense and intercompany debt financings; and
- potential negative impact of public health epidemics on employees, our supply chain and the global economy, such as the coronavirus currently impacting China and elsewhere.

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.

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.

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.

Past acquisitions have significantly increased our intangible assets, which were $7,018.0 million at December 27, 2019. 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 are subject to labor and employment laws and regulations, which could increase our costs and restrict our operations in the future.

We employ approximately 3,400 employees worldwide. Some of our employees are represented by labor organizations and national works councils. Our management believes that our employee relations are satisfactory. However, further organizing activities or collective bargaining may increase our employment-related costs and we may be subject to work stoppages and other labor disruptions. Moreover, if we are subject to employment-related claims, such as individual and class actions relating to alleged employment discrimination, wage-hour and labor standards issues, and such actions are successful in whole or in part, this may affect our ability to compete or have a material adverse effect on our business, financial condition and results of operations.

Our operations may be interrupted by the occurrence of a natural disaster or other catastrophic event at our facilities.

We depend on our manufacturing facilities, laboratories and equipment for the continued operation of our business. Our principal executive offices are located at a facility in Staines-Upon-Thames, U.K. and our Specialty Brands global manufacturing operations are located in Dublin, Ireland. In addition, we have other locations in the U.S., most notably our corporate shared services facility in Hazelwood, Missouri, our Specialty Brands commercial headquarters in Bedminster, New Jersey and our Specialty Generics headquarters and technical development center in Webster Groves, Missouri. As of December 27, 2019, we owned a total of ten facilities in the U.S., Ireland and Japan. We have 11 manufacturing sites: one in Ireland; two in Japan; and eight in the U.S. Although we have contingency plans in effect for natural disasters or other catastrophic events, these events could still disrupt our operations. Even though we carry business interruption insurance policies, we may suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies. Any natural disaster or catastrophic event at any of our facilities could have a significant negative impact on our business, financial condition and results of operations.

Risks Related to Our Indebtedness

Our substantial indebtedness could adversely affect our financial condition and prevent us from fulfilling our obligations and could further adversely affect our ability to consummate the Litigation Settlement.

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 27, 2019, total debt principal was $5,422.8 million, of which $634.5 million was classified as current, including $614.8 million aggregate principal amount of 4.875% senior unsecured notes that mature on April 15, 2020 (the "2020 Notes").

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.

As discussed in greater detail in "Debt and Capitalization" within Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report on Form 10-K, we have entered into certain agreements relating to potential financing and debt exchange transactions intended to address our near-term debt maturities. The transactions contemplated by these agreements are subject to a number of conditions. We cannot guarantee that we will satisfy all such conditions and, if we do not do so, we could experience heightened risks related to short-term liquidity constraints, which could adversely affect our ability to fulfill our financial obligations and jeopardize the consummation of the Litigation Settlement.

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.

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 or other indebtedness, those lenders or investors will be able to proceed against the collateral granted to them to secure that indebtedness. If the holders of our debt 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 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.

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.

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 27, 2019, we had $1,924.4 million outstanding variable-rate debt on our senior secured term loans and $900.0 million outstanding on our revolving credit facility. 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.

Despite current and anticipated indebtedness levels, we may still be able to incur 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.

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.

The phase out of LIBOR, or the replacement of LIBOR with a different reference rate, may adversely affect interest rates.

On July 27, 2017, the Financial Conduct Authority (the authority that regulates LIBOR) announced that it would phase out LIBOR by the end of 2021. It is unclear whether new methods of calculating LIBOR will be established such that it continues to exist after 2021, or if alternative rates or benchmarks will be adopted. Changes in the method of calculating LIBOR, or the replacement of LIBOR with an alternative rate or benchmark, may adversely affect interest rates and result in higher borrowing costs. This could materially and adversely affect our results of operations, cash flows and liquidity. We cannot predict the effect of the potential changes to LIBOR or the establishment and use of alternative rates or benchmarks.

Risks Related to Tax Matters

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.

On August 5, 2019, the Internal Revenue Service ("IRS") proposed an adjustment to the taxable income of Mallinckrodt Hospital Products Inc. (“MHP”) as a result of its findings in the audit of MHP's tax year ended September 26, 2014. MHP, formerly known as Cadence Pharmaceuticals, Inc. (“Cadence”), was acquired as a U.S. subsidiary on March 19, 2014. Following the acquisition of Cadence, we transferred certain rights and risks in Ofirmev® intellectual property (“Transferred IP”) to one of our wholly owned non-U.S. subsidiaries. The transfer occurred at a price (“Transfer Price”) determined in conjunction with our external advisors, in accordance with applicable Treasury Regulations and with reference to the $1,329.0 million taxable consideration we paid to the shareholders of Cadence. The IRS asserts the value of the Transferred IP exceeds the value of the acquired Cadence shares and, further, partially disallows our control premium subtraction. The proposed adjustment to taxable income of $871.0 million, excluding potential associated interest and penalties, is proposed as a multi-year adjustment and may result in a non-cash reduction of our U.S. Federal net operating loss carryforward of $782.0 million. We strongly disagree with the proposed increase to the Transfer Price and intend to contest it through all available administrative and judicial remedies, which may take a number of years to conclude. The final outcome cannot be reasonably quantified at this time, however, the proposed adjustment may be material. We believe our reserve for income tax contingencies is adequate.

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 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., Ireland, 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”) and Ireland's Budget 2019 published in October 2018 announcing changes to the corporate tax code including implementation of certain provisions of ATAD I. 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 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 has been ratified by both Ireland and the U.K., supersedes 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.

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 2019 Annual General Meeting is due to expire on the earlier of our 2020 Annual General Meeting or August 15, 2020 unless renewed by shareholders for a further period. We anticipate seeking the renewal of this authority at our 2020 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 2019 Annual General Meeting and is due to expire on the earlier of our 2020 Annual General Meeting or August 15, 2020, unless renewed for a further period. We anticipate seeking the renewal of this opt-out at our 2020 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 developments related to current litigation involving our Specialty Generics 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 initiate 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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal executive offices are located at a facility in Staines-Upon-Thames, U.K. and our Specialty Brands global external manufacturing operations are located in Dublin, Ireland. In addition, we have other locations in the U.S., most notably our corporate shared services facility in Hazelwood, Missouri, our Specialty Brands commercial headquarters in Bedminster, New Jersey and our Specialty Generics headquarters and technical development center in Webster Groves, Missouri. As of December 27, 2019, we owned a total of ten facilities in the U.S., Ireland and Japan. Our owned facilities consist of approximately 2.1 million square feet, and our

leased facilities consist of approximately 0.8 million square feet. We have 11 manufacturing sites: 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.

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

Opioid-Related Matters

Since 2017, multiple U.S. states, counties, a territory, other governmental persons or entities and private plaintiffs have filed lawsuits against certain entities of our Company, 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 our products. As of February 25, 2020, the cases we are aware of include, but are not limited to, approximately 2,496 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 253 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers; approximately 110 cases filed by individuals; approximately six cases filed by schools and school boards and 17 cases filed by the Attorneys General for New Mexico, Kentucky, Rhode Island, Georgia, Florida, Alaska, New York, Nevada, South Dakota, New Hampshire, Louisiana, Illinois, Mississippi, West Virginia, Puerto Rico, Ohio and Idaho, with Idaho being the only state Attorney General to file in federal as opposed to state court. As of February 25, 2020, the Mallinckrodt defendants in these cases consist of Mallinckrodt plc and the following subsidiaries of Mallinckrodt plc: Mallinckrodt Enterprises LLC, Mallinckrodt LLC, SpecGx LLC, Mallinckrodt Brand Pharmaceuticals Inc., Mallinckrodt Inc., MNK 2011 Inc., and Mallinckrodt Enterprises Holdings, Inc. Certain of the lawsuits have been filed as putative class actions. On November 22, 2019, the Delaware Attorney General filed a motion in the Superior Court of the State of Delaware to amend its complaint to add certain entities of our Company, which the Court granted on December 18, 2019. The Delaware Attorney General has not yet filed its amended complaint. The Hawaii Attorney General filed a complaint against us on June 3, 2019. On December 27, 2019, the First Circuit Court entered a written order dismissing the Hawaii Attorney General's claims against all defendants without prejudice, finding that the allegations in the State's complaint failed to give notice of the claims against the defendants.

Federal Lawsuits

Most pending federal 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, setting pre-trial deadlines and setting a trial date on October 21, 2019 for two cases originally filed in the Northern District of Ohio by Summit County and Cuyahoga County against opioid manufacturers, distributors, and pharmacies ("Track 1 Cases"). The counties claimed that opioid manufacturers' marketing activities changed the medical standard of care for treating both chronic and acute pain, which led to increases in the sales of their prescription opioid products. They also alleged that opioid manufacturers' and distributors' failure to maintain effective controls against diversion was a substantial cause of the opioid crisis.

Summit County filed a complaint on December 20, 2017, an amended complaint that added us on April 25, 2018, and a second amended complaint on May 18, 2018. The manufacturer defendants jointly moved to dismiss the second amended complaint on May 25, 2018. Judge Polster, who is presiding over the MDL, denied the motion on December 19, 2018. Summit County filed a third amended complaint on March 21, 2019, which alleges violations of RICO, the Ohio Corrupt Practices Act, statutory public nuisance, common law absolute public nuisance, negligence, common law fraud, violations of Injury Through Criminal Acts, unjust enrichment, and civil conspiracy. Summit County seeks damages including but not limited to actual damages, treble damages, equitable and/or injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, attorneys' fees, all costs and expenses of suit, and pre- and post-judgment interest. Cuyahoga County filed a complaint on October 27, 2017, and an amended complaint on April 25, 2018 that added us. Cuyahoga County filed a third amended complaint on May 10, 2019. The third amended complaint contains causes of action and damages similar to those in the Summit County litigation. In June 2019, the parties filed motions for summary judgment and Daubert motions in Summit County and Cuyahoga County. In August and September 2019, the MDL court ruled on the summary judgment and Daubert motions, granting some and denying most others, including Mallinckrodt's Motion for Partial Summary Judgment. On September 6, 2019, the Company announced that it had reached a settlement in principle with Summit

County and Cuyahoga County. The settlement fully resolves the Track 1 Cases against all named Mallinckrodt entities that were scheduled to go to trial in October 2019 in the MDL. The Track 1 Cases assert various claims related to the opioid business operated by SpecGx LLC. Under the agreement, we paid a total sum of $24.0 million in cash during the three months ended December 27, 2019. In addition, we will provide $6.0 million in generic products, including addiction treatment products, and also provide a $0.5 million payment in two years in recognition of the counties' time and expenses. Further, in the event of a comprehensive resolution of government-related opioid claims, we have agreed that the two plaintiff counties will receive the value they would have received under such a resolution, less the payments described above. All named Mallinckrodt entities were dismissed with prejudice from the lawsuit. The value of the settlement should not be extrapolated to any other opioid-related cases or claims. On October 21, 2019, the MDL court issued a Stipulated Dismissal Order dismissing the claims against the remaining manufacturers and distributors pursuant to a settlement agreement, and severing the claims against the remaining pharmacy defendant to be heard in a subsequent trial.

Judge Polster issued Suggestions of Remand for City and County of San Francisco, California and City of Chicago, Illinois. Both cases have been remanded, respectively, to the Northern District of California and the Northern District of Illinois. Additionally, all manufacturer defendants, including ourselves, were severed from the “Track Two” MDL cases, City of Huntington and Cabell County Commission, West Virginia. Those cases have subsequently been remanded to the Southern District of West Virginia.

We are also named in 234 similar state court cases in 31 states and Puerto Rico. These state court cases include actions filed by (1) state and territory attorneys general; (2) counties, cities, and other municipalities; (3) district attorneys; (4) hospitals and other health systems; (5) individuals; and (6) third-party payers. There are differences among these cases. For instance, counties and cities often seek to recoup governmental expenses related to public services, while hospitals and other health systems typically seek compensation for opioid-related medical services. These cases also contain different causes of action. For example, state attorneys general complaints often utilize consumer protection statutes whereas third-party payers tend to focus on claims of fraud and breach of implied warranties. Further, not all lawsuits name the same defendants - some name manufacturers and distributors, while others also include pharmacies, pain clinics, doctors, and/or other individuals as defendants.

On June 14, 2019, MDL plaintiffs filed a Notice of Motion and Motion for Certification of Rule 23(b)(3) Cities/Counties Negotiation Class. On July 9, 2019, the plaintiffs' executive committee filed an Amended Motion for Class Certification. In July 2019, parties and third parties filed responses and replies to plaintiffs' Amended Motion for Class Certification. A hearing on the Amended Motion took place on August 6, 2019. On September 11, 2019, the MDL court certified the Rule 23(b)(3) negotiation class. On September 25, 2019, certain Ohio cities and defendant distributors and pharmacies petitioned the Court of Appeals for the Sixth Circuit for permission to appeal the class certification decision, which the Court of Appeals allowed on November 8, 2019. The appeal is currently pending, and briefing began on February 7, 2020.

State Court Lawsuits

A. Lawsuits Filed by State and Territory Attorneys General

Sixteen of the seventeen state and territory attorneys general who have filed lawsuits against us, filed in their respective state courts. The New Mexico Attorney General was the first attorney general to file suit against us on December 20, 2017. The Ohio Attorney General's motion for leave to file an amended complaint that names certain entities of the Company was granted on February 24, 2020. In general, the state and territory attorneys general allege that opioid manufacturers engaged in fraudulent or misleading marketing activities that led to increases in the sales of their prescription opioid products. They also allege that opioid manufacturers and distributors failed to maintain effective controls against diversion and to identify, report, and halt suspicious orders. For example, on August 14, 2018, the New York Attorney General brought an action against Purdue in the coordinated opioid litigation in Suffolk County, New York. An amended complaint was filed on March 28, 2019, naming us, among other opioid manufacturers, distributors, and individuals. The amended complaint alleges state law violations of the New York State Finance Law, the New York Social Service Law, the New York General Business Law, the New York Controlled Substance Act, and the New York Executive Law, as well as public nuisance, fraud, gross negligence, willful misconduct, and unjust enrichment against us. The amended complaint seeks, among other remedies, declaratory judgment, injunctive relief, the creation of an abatement fund, damages, civil penalties, and the disgorgement of profits. Certain defendants, including us, filed motions to dismiss on May 31, 2019. The State of New York opposed the motions on July 31, 2019 and defendants filed their reply briefs on August 30, 2019. Oral argument on these motions was subsequently held on October 7, 2019, and the motions are still pending. Defendants filed motions for summary judgment on January 14, 2020 and those motions are still pending. While the New York Attorney General action is illustrative, there are differences between the cases filed by state and territory attorneys general. Each lawsuit contains different causes of action, including different common law claims and alleged violations of state-specific statutes. The lawsuits also contain different claims for damages. For instance, the Kentucky action seeks punitive damages, but the Florida action does not. Further, not all lawsuits name the same defendants - some name manufacturers and distributors, while others also include pharmacies and/or individuals as defendants. The New York Attorney General action is one of the three Track One cases naming us in New York with a liability-only trial currently scheduled to begin on March 20, 2020. For plaintiff the State of New York, the causes of action are limited to public nuisance, the New York Controlled Substance Act, and the New York Executive Law Section 63(12). Trial dates have also been set in Louisiana (September 14, 2020),

Alaska (January 4, 2021), Nevada (January 4, 2021), Rhode Island (January 19, 2021), New Mexico (September 7, 2021) and Georgia (January 24, 2022).

B. Lawsuits Filed by Cities, Counties, and Other Municipalities

There are currently more than 191 lawsuits against us filed by cities, counties, and other municipalities, pending in various state courts in 18 states. The earliest lawsuit that remains in state court was filed by the County of Northampton, Pennsylvania on December 28, 2017. In general, the complaints allege that opioid manufacturers engaged in fraudulent or misleading marketing activities that led to increases in the sales of their prescription opioid products. They also allege that opioid manufacturers and distributors failed to maintain effective controls against diversion and to identify, report, and halt suspicious orders. For example, on September 18, 2018, City of Reno filed a complaint in the Second Judicial District Court of Nevada and named us as a defendant, among other opioid manufacturers, distributors, and healthcare providers. An amended complaint was filed in December 3, 2018, following removal to and remand from the U.S. District Court for the District of Nevada. The amended complaint alleges violations of statutory public nuisance, common law public nuisance, negligence, negligent misrepresentation and unjust enrichment. City of Reno seeks damages including but not limited to, general and special damages, punitive damages, a fund for establishing a medical monitoring program, restitution and reimbursement, disgorgement, and attorneys' fees and costs. Defendants, including us, filed motions to dismiss on March 4, 2019. The state court heard oral argument on the motions to dismiss on January 7-8, 2020. On February 14, 2020, the court entered an order dismissing City of Reno's claim of negligent misrepresentation without leave to amend. The court also dismissed the negligence and unjust enrichment claims with leave to amend and allowed discovery to begin with respect to those claims. The court denied the motions as to the statutory and common law public nuisance claims. While the City of Reno action is illustrative, there are differences between the cases filed by cities, counties and other municipalities. These lawsuits contain different causes of action, including different common law claims and alleged violations of state-specific statutes. For example, municipalities in Maryland, Pennsylvania, and Virginia assert violations of their state consumer protection statutes, while many other states do not. The lawsuits also contain different claims for damages. For example, the City of Granite City and the County of Jersey, Illinois seek damages for particular public health expenditures, while municipalities in other states allege damages related more generally to costs for public services. Further, not all lawsuits name the same defendants - some name manufacturers and distributors, while others also include pharmacies and/or individuals as defendants.

In some jurisdictions, such as Arizona, California, Connecticut, Illinois, Massachusetts, New York, Pennsylvania, South Carolina, Texas, Utah and West Virginia, certain of the 191 state lawsuits filed by counties, cities and other municipalities have been consolidated or coordinated for pre-trial proceedings before a single court within their respective state court systems. The first coordinated proceeding was formed in New York on July 31, 2017. The most recent state consolidated proceeding was formed in Arizona on January 9, 2020. We are not named as a defendant in each case that may be pending in a particular state court MDL or coordinated proceeding. For example, approximately 44 cases filed by Texas plaintiffs, primarily cities and counties, are consolidated in the *In re: Texas Opioid Litigation*, No. 2018-63587, MDL No. 18-0358 (the "Texas MDL"), of which we are named in 13 cases. The Texas complaints generally allege violations of public nuisance, negligence, the Texas Controlled Substances Act, the Deceptive Trade Practices-Consumer Protection Act, unjust enrichment, common law fraud, and civil conspiracy, though there are differences among the complaints. Plaintiffs seek damages including but not limited to injunctive relief, economic and treble damages arising from alleged violations of the Texas Deceptive Trade Practices-Consumer Protection Act, civil penalties for violations of the Texas Controlled Substances Act, abatement of public nuisance, punitive and actual damages, restitution, and attorneys' fees. We have filed answers in certain cases. A hearing on bellwether selection and other trial scheduling matters occurred on July 26, 2019, in which eight bellwether counties and alternates were selected as candidates for four trials, the first two of which are scheduled to occur in January 2021 and April 2021. We are currently named in six out of the eight selected bellwether counties but plaintiffs may amend their complaints to add us to the other two cases. Since the bellwether candidates were selected on July 26, 2019, three of the eight bellwether cases have been removed to federal court and transferred to the federal MDL. No replacement bellwethers have been selected while those cases remain in federal court. At present, we are named in three of the five bellwether candidates that remain in state court, and all three of the bellwethers that have been removed, although we may still be amended into others. Pursuant to the Docket Control Order entered by the court on October 18, 2019, trials are scheduled to begin on January 19, 2021 and April 12, 2021. While the Texas MDL is illustrative, there are differences between the coordinated cases. Each states' coordinated proceedings contain different causes of action, including different common law claims and alleged violations of state-specific statutes. For example, municipalities in Arizona, Connecticut, Illinois, Massachusetts, New York, Pennsylvania, South Carolina, Texas and Utah assert violations of their state unfair or deceptive trade practices acts, while other plaintiffs do not. The lawsuits also contain different claims for damages. For example, some of the cases in the Texas MDL request exemplary and punitive damages for gross negligence, while other cases do not. Further, not all lawsuits name the same defendants-some name manufacturers and distributors, while others also include pharmacies and/or individuals as defendants. A Case Management Order has been entered in the New York consolidated cases in Suffolk County, which provides for two separate case tracks to proceed to discovery and ultimately to trial. We are named in the three Track One cases with a liability-only trial currently scheduled to begin on March 20, 2020. For the two Track One Counties, plaintiffs Suffolk County and Nassau County, the claims are limited to public nuisance. For the third plaintiff, the State of New York, the claims are limited to public nuisance, the New York Controlled Substances Act, and the New York Executive Law Section 63(12).

C. Lawsuits Filed by District Attorneys

Eight District Attorneys ("DAs") have also filed lawsuits in state court against us that remain in state court. In general, the DA suits filed in Tennessee allege that defendants engaged in false and deceptive promotion of opioids and contributed to the oversupply and diversion of those products. They also allege that defendants' actions caused high addiction rates, overdose deaths, and increased rates of neonatal abstinence syndrome. The DAs have initiated lawsuits against opioid manufacturers, distributors, prescribers, retailers, and other individuals. The DAs allege that defendants participated in an illegal opioids market and that plaintiffs suffered damages related to increased law enforcement and health care costs, expenses related to rehabilitation and addiction treatment, prosecution costs, and foster care expenses, among others. *Staubus et al. v. Purdue Pharma, LP et al.*, No. C-41916 was filed in the Circuit Court for Sullivan County on June 13, 2017 and amended on July 27, 2017 and February 15, 2018. We joined a motion to dismiss filed by the manufacturer defendants and filed a supplemental motion to dismiss regarding Company-specific claims on March 23, 2018. The court held a hearing on the motion to dismiss, in addition to other motions, on May 8, 2018. The court denied the motions to dismiss in an order filed on June 12, 2018. We filed an answer to the second amended complaint on June 29, 2018. The parties are currently engaged in discovery, and the court has set a trial date to begin on May 18, 2020. *Effler et al. v. Purdue Pharma, LP et al.*, No. 16596 was filed in the Circuit Court for Campbell County on September 29, 2017 and amended on October 6, 2017, January 10, 2018 and May 21, 2018. We joined a motion to dismiss filed by the manufacturer defendants on July 27, 2018. The court held a hearing on the motion to dismiss on October 4, 2018 and issued an order granting the manufacturer defendants' motion to dismiss on October 5, 2018. Plaintiffs filed a Notice of Appeal on November 1, 2018. We joined defendants-appellees' response brief which was filed on May 28, 2019. Plaintiff-appellants' filed their reply brief on July 11, 2019, and oral argument occurred on July 18, 2019. On September 11, 2019, the court granted plaintiffs' appeal, reversing the trial court's judgment and remanding the case for further proceedings. We filed a petition to appeal this ruling to the Tennessee Supreme Court on November 12, 2019. Plaintiffs filed their opposition brief on November 27, 2019. On February 24, 2020, the Tennessee Supreme Court denied the petition to appeal, and the case will proceed to discovery. *Dunaway et al. v. Purdue Pharma, LP et al., No. CCI-2018-cv-6347* was filed in the Circuit Court for Cumberland County on January 10, 2018 and amended on August 7, 2018. We joined a motion to dismiss filed by the manufacturer defendants on September 21, 2018. Plaintiffs filed a second amended complaint on April 1, 2019, adding new defendants. A distributor defendant removed the action on May 3, 2019, and the district court remanded the case on May 22, 2019. We joined a motion to dismiss filed by the manufacturer defendants on July 15, 2019. Plaintiffs' opposition to defendants' motions to dismiss was filed on September 30, 2019. Replies were filed on November 13, 2019, and oral argument is scheduled for April 6, 2020. On January 17, 2020, the Tennessee Attorney General's uncontested motion to intervene in *Dunaway* was granted. Other than *Staubus et al. v. Purdue Pharma, LP et al*., there are currently no trials set in these cases.

With respect to the DA lawsuits filed in Pennsylvania, the first lawsuit that remains in state court was filed by the Commonwealth of Pennsylvania by John T. Adams, District Attorney of Berks County in the Berks County Court of Common Pleas on October 16, 2019. The most recent DA lawsuit that remains in state court was filed by the Commonwealth of Pennsylvania, acting by and through Matthew D. Weintraub, the District Attorney of Bucks County in the Bucks County Court of Common Pleas on January 29, 2020. In general, these DA cases allege that opioid manufacturers engaged in fraudulent or misleading marketing activities that led to increased use of prescription opioid products. They also allege that distributors failed to maintain effective controls over the opioid distribution system and attempted to evade restrictions on opioid distribution. Plaintiffs in all four cases bring claims for alleged violations of the Pennsylvania Unfair Trade Practices and Consumer Protection Law and Civil Conspiracy. Plaintiffs in all four cases seek damages related to services associated with addiction, overdoses, adverse health conditions, emergency response, hospitalization, and public safety conditions allegedly attributable to the opioid products manufactured and distributed by defendants, among other relief. There are currently no trials set in these cases.

The final DA lawsuit that remains in state court was filed by Scott Ellington, the Second Judicial Circuit Prosecuting Attorney, on behalf of the State of Arkansas, counties, and cities in Arkansas, on March 19, 2018. The Company secured dismissal of the initial complaint without prejudice, and the case proceeded against other defendants. A third amended complaint was filed on January 29, 2020, which again names certain entities of the Company. The complaint generally alleges that opioid manufacturers engaged in fraudulent or misleading marketing activities that led to increased use of prescription opioid products. The complaint also alleges that the defendants failed to maintain effective controls over the opioid distribution system. Plaintiffs seek damages related to future abatement costs, compensatory, and punitive damages, among other relief. There is currently no trial set in this case.

D. Lawsuits Filed by Hospitals and Health Systems

Hospitals and other health systems have also filed lawsuits in state courts against us, and there are currently eight such lawsuits. The first lawsuit that remains in state court was filed by Nueces County and Nueces County Hospital District in Texas on July 3, 2018. The other seven lawsuits that remain in state court were filed by (1) Tucson Medical Center ("TMC") in Arizona on October 9, 2018; (2) various hospitals and other health systems in West Virginia on April 29, 2019; (3) various hospitals and other health systems in Arizona on June 18, 2019; (4) various hospitals and other health systems in Alabama on September 3, 2019; (5) various hospitals and other health systems in Florida on September 16, 2019; (6) Mobile County Board of Health and Family Oriented Primary Health Care Clinic in Alabama on October 15, 2019; and (7) Bexar County Hospital District d/b/a University Health System in Texas on November 26, 2019. The plaintiffs allege that opioid manufacturers have engaged in fraudulent or misleading marketing activities that led to increases in the sales of their opioid products. They also allege that opioid manufacturers and distributors failed to maintain effective

controls against diversion and to identify, report, and halt suspicious orders. For example, on October 9, 2018, TMC filed a complaint in the Pima County Superior Court, Arizona against us, among other opioid manufacturers and distributors. On July 15, 2019, TMC filed a First Amended Complaint, which asserts claims for negligence, wanton negligence, negligence per se, negligent marketing, negligent distribution, nuisance, unjust enrichment, fraud and deceit, civil conspiracy, fraudulent concealment, and violations of Arizona's RICO Act and Consumer Fraud Act. TMC seeks damages and costs. Defendants, including us, filed motions to dismiss the complaint, which were denied by the court on September 16, 2019. On February 7, 2020, TMC filed a Second Amended Complaint, removing certain named defendants. While the TMC action is illustrative, there are differences between these cases. Each lawsuit contains different causes of action, including different common law claims and alleged violations of state-specific statutes. Further, not all lawsuits name the same defendants. For example, TMC and the other Arizona plaintiffs name manufacturers, distributors and pharmacies as defendants, while the West Virginia, Florida and Alabama plaintiffs also include individuals as defendants. TMC is set for trial on March 16, 2021.

E. Lawsuits Filed by Individuals

Individuals have filed lawsuits in state courts against us, and there are currently six such lawsuits. The first lawsuit that remains in state court was initially filed by the Estate of Bruce Brockel in the Circuit Court of Mobile County, Alabama, on October 25, 2017, and amended to add us to plaintiff's first amended complaint on February 5, 2018. The most recent lawsuit that remains in state court was filed by plaintiff Elizabeth Lavoise, individually and as next of kin of Kyle Asher in St. Louis City Circuit Court in Missouri, on August 21, 2019. In general, these lawsuits allege that opioid manufacturers have engaged in fraudulent or misleading marketing activities that led to increases in the sales of their opioid products. They also allege that opioid manufacturers and distributors failed to maintain effective controls against diversion and to identify, report, and halt suspicious orders. Individual plaintiffs generally claim that they suffered damages related to increased healthcare costs, or wrongful death. For example, on December 5, 2018, the Estate of Bruce Brockel filed a third amended complaint in the Circuit Court of Mobile County, Alabama against us, among other prescription opioid manufacturers and individual doctors. The complaint contains a variety of causes of actions, including medical malpractice, negligence, wantonness, Alabama extended manufacturer's doctrine, fraud and misrepresentation, suppression and concealment, deceit, unjust enrichment and civil conspiracy. The plaintiff alleges that manufacturers engaged in the false and deceptive promotion of opioids, which led to the oversupply of opioids and caused decedent's death. The plaintiff seeks damages in an unspecified amount. We moved to dismiss the complaint on March 26, 2019. An opposition to the motion to dismiss was filed on April 25, 2019. The motion was denied on December 20, 2019. While the *Brockel* action is illustrative, there are differences among the cases filed by individuals. Many of these lawsuits contain different causes of action. For example, *Brockel* asserts a claim for civil conspiracy, while two of the individual actions filed in Missouri state court do not. One of the cases, *Robert Ruth*, is a putative class action, asserting claims on behalf of Missouri citizens who purchased or paid for health insurance policies. Further, not all lawsuits name the same defendants. For example, some lawsuits name only us as defendants, while others also include other manufacturers, pharmacies, and/or individuals. There are currently no trials set in these cases.

F. Lawsuits Filed by Third-Party Payers

Third-party payers, such as insurers, have also filed lawsuits in state courts against us. There are currently seven such lawsuits. The first lawsuit that remains in state court was filed by United Food and Commercial Workers (UFCW), Local 23 and Employers Health Fund in Pennsylvania on April 24, 2018. The most recent lawsuit that remains in state court, was filed by Steamfitters Local 449 Medical and Benefit Fund, on September 11, 2019. In general, plaintiffs allege that opioid manufacturers have engaged in fraudulent or misleading marketing activities that led to increases in the sales of their opioid products. They also allege that opioid manufacturers and distributors failed to maintain effective controls against diversion and to identify, report, and halt suspicious orders. Third-party payer plaintiffs claim that they paid costs for health issues stemming from opioid overuse.

The *Illinois Public Risk Fund* case asserts state law claims against the Company such as violations of the Illinois Consumer Fraud and Deceptive Business Practices Act, fraudulent misrepresentation, insurance fraud, negligence, public nuisance and unjust enrichment. *Fire and Police Retiree Health Care Fund*, filed in Bexar County District Court in Texas and transferred to the Texas MDL, asserts similar state law claims against us, including public nuisance, common law fraud, negligence, gross negligence, unjust enrichment, civil conspiracy and fraudulent concealment. The remaining five cases are in Pennsylvania state court, where they have all been consolidated in the coordinated proceedings in Delaware County, Pennsylvania. The Pennsylvania complaints assert state law claims such as violations of the Pennsylvania Unfair Trade Practices and Consumer Protection Law statute, public nuisance, negligence, unjust enrichment, common law fraud, breach of implied warranties, negligence per se, negligent misrepresentation, negligent marketing and civil conspiracy. The Court denied the manufacturer defendants' preliminary objections on October 30, 2019 and certain test cases are proceeding to discovery. There are differences between these cases. Certain of these lawsuits contain different causes of action. For example, a case filed by Carpenters Health and Welfare Fund of Philadelphia and Vicinity asserts a claim for public nuisance, while a case filed by the International Union of Painters and Allied Trades, District Council 21 Welfare Fund does not. The lawsuits also contain different claims for damages. For instance, *Carpenters Health* seeks a declaratory judgment regarding plaintiffs' public nuisance claims, but *Painters and Allied Trades* does not. Further, not all lawsuits name the same defendants - some name manufacturers, while at least one lawsuit includes individuals as defendants. There are currently no trials set in these cases.

On February 25, 2020, we, the Specialty Generics Subsidiaries and certain other affiliates announced an agreement in principle on the terms of a global settlement, which we refer to as the Litigation Settlement, that would resolve all opioid-related claims against us, the Specialty Generics Subsidiaries and our other subsidiaries. The Litigation Settlement contemplates the filing of voluntary petitions under Chapter 11 by the Specialty Generics Subsidiaries and the establishment of the Opioid Claimant Trust. Under the terms of the proposed settlement, which would become effective upon the Specialty Generics Subsidiaries' emergence from a contemplated Chapter 11 process, subject to court approval and other conditions, we would (1) make cash payments of $1,600.0 million in structured payments over eight years, beginning upon the Specialty Generics Subsidiaries' emergence from the completed Chapter 11 case, the substantial majority of which is expected to be contributed to the Opioid Claimant Trust and (2) issue warrants with an eight year term to the Opioid Claimant Trust exercisable at a strike price of $3.15 per share to purchase our ordinary shares that would represent approximately 19.99% of our fully diluted outstanding shares, including after giving effect to the exercise of the warrants (the "Settlement Warrants"). The Litigation Settlement into which we have entered is neither final nor binding and there is no assurance that the necessary parties will agree to definitive documentation, that the contingencies to any agreement will be fulfilled or that any potential settlement agreement entered into by us will be on terms as favorable as the Litigation Settlement. Among other things, the failure of the Litigation Settlement may lead to Mallinckrodt plc's subsequent bankruptcy, as a result of which we would be subject to additional risks and uncertainties that could adversely affect our business prospects and ability to continue as a going concern, as further described in Part II, Item 1A. "Risk Factors."

For further information regarding the Litigation Settlement, refer to Note 24 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.

Investigations and Other Inquiries

In addition to the lawsuits described above, certain entities of the Company have received subpoenas and civil investigative demands (“CIDs”) for information concerning the sale, marketing and/or distribution of prescription opioid medications and the Company's suspicious order monitoring programs, including from the DOJ and the Attorneys General for Missouri, New Hampshire, Kentucky, Washington, Alaska, South Carolina, Puerto Rico, New York, West Virginia, Indiana and the Divisions of Consumer Protection and Occupational and Professional Licensing of the Utah Department of Commerce, and the New York State Department of Financial Services. We have 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, we received a grand jury subpoena from the USAO for the Southern District of Florida for documents related to the distribution, marketing and sale of generic oxymorphone products. On April 17, 2019, we received a grand jury subpoena from the USAO for the Eastern District of New York (“EDNY”) for documents related to the sales and marketing of controlled substances, the policies and procedures regarding controlled substances, and other related documents. On June 4, 2019, we received a rider from the USAO for EDNY requesting additional documents regarding our anti-diversion program. We are responding or have responded to these subpoenas, CIDs and any informal requests for documents.

The Attorneys General for Kentucky, Alaska, New York, New Hampshire, West Virginia and Puerto Rico have subsequently filed lawsuits against us. Similar subpoenas and investigations may be brought by others or the foregoing matters may be expanded or result in litigation. Since these investigations and/or lawsuits 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, we filed suit in the U.S. District Court for the Southern District of New York against the State of New York, asking the court to declare New York State's OSA unconstitutional and to enjoin its enforcement. On December 19, 2018, the court declared the OSA unconstitutional and granted our motion for preliminary injunctive relief. On January 17, 2019, the State of New York appealed the court's decision. The appeal has been fully briefed and argued before the Second Circuit, and the parties are awaiting a decision. In April 2019, the State of New York passed its 2020 budget, which amended the OSA so that if the OSA decision is reversed on appeal, the OSA would apply only to the sale or distribution of certain opioids in New York for 2017 and 2018 and, effective July 1, 2019, imposed an excise tax on certain opioids.

U.S. Drug Enforcement Administration Investigation

In November 2011 and October 2012, we received subpoenas from the DEA requesting production of documents relating to our suspicious order monitoring program for controlled substances. The USAO for the Eastern District of Michigan investigated the possibility that we 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 we failed to maintain appropriate records and security measures with respect to

manufacturing of certain controlled substances at our Hobart facility during the period 2012-2013. In July 2017, we entered into a final settlement with the DEA and the USAOs for the Eastern District of Michigan and the Northern District of New York to settle these investigations. As part of the agreement, we paid $35.0 million in fiscal 2017 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 of our controlled substance products and to report to the DEA when we conclude 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, but we will continue utilizing all available transaction information to identify suspicious orders for reporting to the DEA beyond that date.

House Energy and Commerce Committee Investigation of Opioid Marketing and Distribution

In August 2018, we received a letter from the leaders of the Energy and Commerce Committee in the U.S. House of Representatives requesting a range of documents relating to our marketing and distribution of opioids. We completed our response to this letter in December 2018. We received a follow-up letter in January 2020 and provided the committee with a response. We are cooperating with the investigation.

See Notes 19 and 24 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 further description of the litigation, legal and administrative proceedings as of December 27, 2019.

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 84,207,022 shareholders of record of our ordinary shares as of February 21, 2020.

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 27, 2019, we repurchased 3,950 of our ordinary shares for 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)
September 28, 2019 to October 25, 2019	655	$ 2.25	—	$ 564.2
October 26, 2019 to November 29, 2019	3,295	3.43	—	564.2
November 30, 2019 to December 27, 2019	—	—	—	564.2
September 28, 2019 to December 27, 2019	**3,950**	**3.23**		

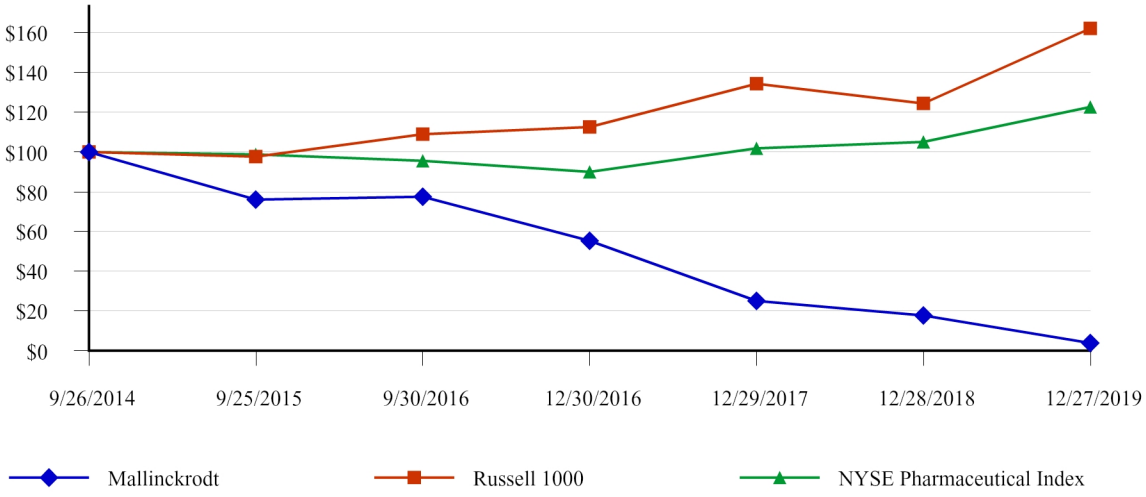
Performance Graph

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 26, 2014 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 27, 2019. Refer to Item 6. Selected Financial Data regarding the change in the Company's fiscal year end.

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.

Item 6. Selected Financial Data.

The consolidated statements of operations data for fiscal 2019, 2018 and 2017, and the consolidated balance sheet data as of December 27, 2019 and December 28, 2018 were derived from our consolidated financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K. The consolidated statements of operations for fiscal 2016 and 2015 and the three months ended December 30, 2016, and the consolidated balance sheet data as of December 29, 2017, December 30, 2016, September 30, 2016 and September 25, 2015 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]					Three Months Ended [2]
	December 27, 2019	December 28, 2018	December 29, 2017	September 30, 2016	September 25, 2015	December 30, 2016
Consolidated Statement of Operations Data:						
Net sales	$ 3,162.5	$ 3,215.6	$ 3,221.6	$ 3,380.8	$ 2,923.1	$ 829.9
Gross profit	1,421.4	1,471.2	1,657.5	1,857.6	1,624.4	446.7
Research and development expenses	349.4	361.1	276.9	261.2	202.7	66.1
Operating (loss) income[3]	(1,822.2)	(3,720.9)	492.9	633.1	362.4	(158.6)
(Loss) income from continuing operations before income taxes	(1,591.5)	(4,052.0)	61.6	233.4	107.3	(298.5)
(Loss) income from continuing operations	(1,007.2)	(3,621.9)	1,771.2	489.0	236.6	(176.8)
Share Data:						
Basic (loss) income from continuing operations per share	$ (12.00)	$ (43.12)	$ 18.13	$ 4.42	$ 2.03	$ (1.67)
Diluted (loss) income from continuing operations per share	(12.00)	(43.12)	18.09	4.39	2.00	(1.67)
Cash dividends per ordinary share	—	—	—	—	—	—
Consolidated Balance Sheet Data:						
Total assets	$ 10,338.9	$ 10,877.3	$ 15,280.9	$ 15,498.7	$ 16,404.1	$ 15,206.3
Total debt	5,374.8	6,091.6	6,734.6	6,045.0	6,496.3	6,152.0
Shareholders' equity	1,940.7	2,887.3	6,522.0	5,270.7	5,311.2	4,984.3

(1) We report our results based on a "52-53 week" year ending on the last Friday of December. 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 trends in financial condition and results of operations for fiscal 2019, 2018 and 2017.

(2) 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, 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"). Fiscal 2016 and 2015 covers the period from September 26, 2015 through September 30, 2016 and from September 27, 2014 through September 25, 2015, respectively.

(3) Fiscal 2019 includes the opioid-related litigation settlement charge of $1,643.4 million. Fiscal 2018 includes non-restructuring impairment charges of $3,893.1 million for goodwill and an IPR&D asset. For further information, refer to Notes 13 and 24 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.

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.

Overview

We are a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute 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.

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

- *Specialty Brands* includes innovative specialty pharmaceutical brands; and
- *Specialty Generics* includes niche specialty generic drugs and API(s).

During fiscal 2019, we experienced a change in our reportable segments, which primarily served to move the results related to Amitiza to the Specialty Brands segment from the Specialty Generics segment. All prior period segment information has been recast to reflect the realignment of our reportable segments on a comparable basis.

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

Significant Events

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 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. During fiscal 2019 and 2018, we incurred $56.2 million and $38.8 million in opioid defense costs, respectively, which are included in SG&A.

On September 30, 2019, we announced that Mallinckrodt plc, along with its wholly owned subsidiaries Mallinckrodt LLC and SpecGx LLC, executed a definitive settlement agreement and release with Cuyahoga and Summit Counties in Ohio in connection with the MDL Track 1 Cases. The settlement fully resolved the Track 1 Cases against all named Mallinckrodt entities that were scheduled to go to trial in October 2019 in the MDL. The Track 1 Cases asserted various claims related to the opioid business operated by SpecGx LLC. Under the agreement, we paid $24.0 million in cash in October 2019. In addition, we will provide $6.0 million in generic products, including addiction treatment products, and will also provide a $0.5 million payment in two years in recognition of the counties' time and expenses. Further, in the event of a comprehensive resolution of government-related opioid claims, we have agreed that the two plaintiff counties will receive the value they would have received under such a resolution, less the payments described above. All named Mallinckrodt entities were dismissed with prejudice from the lawsuit. The value of the settlement should not be extrapolated to any other opioid-related cases or claims.

Litigation Settlement

On February 25, 2020, we, the Specialty Generics Subsidiaries and certain other affiliates announced an agreement in principle on the terms of a global settlement that would resolve all opioid-related claims against us, the Specialty Generics Subsidiaries and our other subsidiaries. The Litigation Settlement has been reached with a court-appointed plaintiffs' executive committee representing the interests of thousands of plaintiffs in the MDL and is supported by a broad-based group of 47 state and U.S. Territory Attorneys General (the "Plaintiffs"). The Litigation Settlement contemplates the filing of voluntary petitions under Chapter 11 by the Specialty Generics Subsidiaries and the establishment of the Opioid Claimant Trust. Under the terms of the proposed settlement, which would become effective upon the Specialty Generics Subsidiaries' emergence from a contemplated Chapter 11 process, subject to court approval and other conditions, we would (1) make cash payments of $1,600.0 million in structured payments over eight years, beginning upon the Specialty Generics Subsidiaries' emergence from the completed Chapter 11 case, the substantial majority of which is expected to be contributed to the Opioid Claimant Trust and (2) issue warrants with an

eight year term to the Opioid Claimant Trust exercisable at a strike price of $3.15 per share to purchase our ordinary shares that would represent approximately 19.99% of our fully diluted outstanding shares, including after giving effect to the exercise of the warrants (the "Settlement Warrants"). As a result of the Litigation Settlement, we recorded a charge of $1,643.4 million attributed to the anticipated structured cash payments and the Settlement Warrants to be issued upon effectiveness of the settlement.

The court-supervised process is also expected to provide a fair, orderly, efficient and legally binding mechanism to resolve all opioid-related claims against the Company, Specialty Generics, and all of our other subsidiaries and related entities. Mallinckrodt plc and our Specialty Brands-related subsidiaries would not be part of the Chapter 11 filing. It is expected that Mallinckrodt plc would receive the benefit of a "channeling injunction" that would provide for the release of all opioid-related claims that have been or could have been asserted against Mallinckrodt plc or our subsidiaries related to Specialty Generics' manufacture and sale of opioids prior to the time the Specialty Generics Chapter 11 plan becomes effective. All of our subsidiaries, including Specialty Generics, are operating as normal and are expected to continue operating normally throughout the court-supervised process contemplated for Specialty Generics. We currently expect that the Specialty Generics Subsidiaries would continue to be an indirect, wholly owned subsidiary of Mallinckrodt plc during and following emergence from the contemplated court-supervised process. Further discussion of this Litigation Settlement is included in Note 24 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Separation

In fiscal 2016, the Board of Directors began to explore a range of strategic alternatives for our Specialty Generics business. Consistent with that strategy, on December 6, 2018, we announced our plans to spin off to our shareholders a new independent public company that would hold the Specialty Generics business. On August 6, 2019, based on market conditions and developments, including increasing uncertainties created by the opioid litigation, we announced the suspension of our previously announced plans to spin off the Specialty Generics business. Our long-standing goal remains to be an innovation-driven biopharmaceutical company focused on improving outcomes for underserved patients with severe and critical conditions. We hope that the Litigation Settlement will help resolve opioid uncertainties and we will continue to evaluate strategic options for the Specialty Generics business upon emergence from the contemplated Chapter 11 process.

During fiscal 2019 and 2018, we incurred $63.9 million and $6.0 million in separation costs, respectively. These costs, which are included in SG&A expenses, primarily relate to professional fees, incremental costs incurred to build out the corporate infrastructure of the previously planned Specialty Generics business, costs incurred as we work to resolve opioid uncertainties, as well as rebranding initiatives associated with the Specialty Brands ongoing transformation.

Silence Therapeutics

In July 2019, we entered into a license and collaboration agreement with Silence Therapeutics plc ("Silence") that will allow the companies to develop and commercialize ribonucleic acid interference ("RNAi") drug targets designed to inhibit the complement cascade, a group of proteins that are involved in the immune system and that play a role in the development of inflammation. These proteins are known to contribute to the pathogenesis of many diseases, including autoimmune disease.

During fiscal 2019, we paid $20.0 million upfront, which was recorded within R&D expense, and gained an exclusive worldwide license to Silence's C3 complement asset, SLN500, with options to license up to two additional complement-targeted assets in Silence's preclinical complement-directed RNAi development program. The agreement also includes additional payments to Silence of up to $10.0 million in research milestones for SLN500, in addition to funding for Phase 1 clinical development including good manufacturing practices. Silence will be responsible for preclinical activities, and for executing the development program of SLN500 until the end of Phase 1, after which we will assume clinical development and responsibility for global commercialization. If approved, Silence could receive up to $563.0 million in commercial milestone payments and tiered low double-digit to high-teen royalties on net sales for SLN500.

In addition to the aforementioned agreement, in July 2019 we acquired an equity investment of $5.0 million in Silence, which was valued at $26.2 million and included within other assets in the consolidated balance sheet as of December 27, 2019. The unrealized gain on this investment of $20.2 million was recognized in the fiscal 2019 consolidated statement of operations. Further information regarding this investment is included 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.

BioVectra

In November 2019, we completed the sale of BioVectra Inc. ("BioVectra") to an affiliate of H.I.G. Capital with total consideration of up to $250.0 million including an upfront payment of $135.0 million and contingent consideration of $115.0 million based on the long-term performance of the business. During fiscal 2019, the Company recorded a loss on the sale of $33.5 million, which excluded any potential proceeds from future milestones, in the event they are achieved. The financial results of BioVectra's operations are presented within continuing operations as this divestiture did not meet the criteria for discontinued operations classification.

Medicaid Lawsuit

In May 2019, we filed a lawsuit in federal district court against the HHS and CMS (together with the HHS, the "Agency"). This lawsuit is in response to a decision by CMS to require that we revert to the original base date AMP used to calculate Medicaid drug rebates for Acthar Gel, which has the practical effect of imposing a prospective reduction in Acthar Gel net sales of $90.0 million to $100.0 million, which corresponds with the approximate amount of annualized Medicaid net sales for Acthar Gel. While we believe that our lawsuit has strong factual and legal bases, as of December 27, 2019, the potential for retroactive non-recurring charges could range from zero to approximately $630.0 million. Further discussion of this matter is included in Note 19 to the Noted to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual report on Form 10-K.

Tax Matters

On August 5, 2019, the IRS proposed an adjustment to the taxable income of Mallinckrodt Hospital Products Inc. (“MHP”) as a result of its findings in the audit of MHP's tax year ended September 26, 2014. MHP, formerly known as Cadence Pharmaceuticals, Inc. (“Cadence”), was acquired as a U.S. subsidiary on March 19, 2014. Following the acquisition of Cadence, we transferred certain rights and risks in Ofirmev® intellectual property (“Transferred IP”) to one of our wholly owned non-U.S. subsidiaries. The transfer occurred at a price (“Transfer Price”) determined in conjunction with our external advisors, in accordance with applicable Treasury Regulations and with reference to the $1,329.0 million taxable consideration we paid to the shareholders of Cadence. The IRS asserts the value of the Transferred IP exceeds the value of the acquired Cadence shares and, further, partially disallows our control premium subtraction. The proposed adjustment to taxable income of $871.0 million, excluding potential associated interest and penalties, is proposed as a multi-year adjustment and may result in a non-cash reduction of our U.S. Federal net operating loss carryforward of $782.0 million. We strongly disagree with the proposed increase to the Transfer Price and intend to contest it through all available administrative and judicial remedies, which may take a number of years to conclude. The final outcome cannot be reasonably quantified at this time, however, the proposed adjustment may be material. We believe our reserve for income tax contingencies is adequate.

Reorganization of Intercompany Financing and Legal Entity Ownership

During fiscal 2019, we completed a reorganization of our intercompany financing and associated legal entity ownership in response to the changing global tax environment. As a result, during fiscal 2019, we recognized current income tax expense of $26.2 million and a deferred income tax benefit of $239.0 million with a corresponding reduction to net deferred tax liabilities. The reduction in net deferred tax liabilities was comprised of a decrease in interest-bearing deferred tax obligations, which resulted in the elimination of the December 28, 2018 balance of $227.5 million, a $29.7 million increase in various other net deferred tax liabilities, a $28.7 million increase to a deferred tax asset related to excess interest carryforwards and a $12.5 million increase to a deferred tax asset related to tax loss and credit carryforwards net of valuation allowances. The elimination of the interest-bearing deferred tax obligation also eliminated the annual Internal Revenue Code section 453A interest expense. The reorganization involved the interpretation of multi-jurisdictional tax laws and regulations, supported by third party opinions. Interpretation of tax laws can be inherently uncertain and can be subject to potential challenges by the relevant tax authorities, both of which were considered in assessing our reserves for uncertain tax positions.

Business Factors Influencing the Results of Operations

Specialty Brands

Net sales of Acthar Gel for fiscal 2019 decreased $157.4 million, or 14.2%, to $952.7 million driven primarily by continued reimbursement challenges impacting new and returning patients and continued payer scrutiny on overall specialty pharmaceutical spending. This was partially offset by continued strength in Ofirmev, INOmax and Therakos and an increase in net sales related to Amitiza, which was acquired in the first quarter of 2018.

Research and Development

We devote significant resources to R&D of products and proprietary drug technologies. During fiscal 2019, we incurred R&D expenses of $349.4 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.

We have completed the Phase 3 clinical studies for two of our development programs, terlipressin for the treatment of HRS type 1 and StrataGraft for the treatment of deep partial thickness burns, both of which had positive top line results. We expect to submit to the FDA the NDA filing for terlipressin and the BLA filing for StrataGraft in the first half of 2020. Upon approval we would be responsible for a one-time milestone payment related to terlipressin of $12.5 million. As part of the contingent consideration included in our acquisition of StrataGraft, we are responsible for a $20.0 million payment upon submission and another $20.0 million upon approval.

Non-restructuring Impairment Charges

During the three months ended June 28, 2019, we recognized a full impairment on our in-process research and development ("IPR&D") asset related to stannsoporfin of $113.5 million as we are no longer pursuing this development product.

During the three months ended December 27, 2019, we recognized a full impairment on our IPR&D asset related to VTS-270 of $274.5 million, primarily driven by continued regulatory challenges. The Company will continue to engage with the FDA and assess future opportunities for the development program.

Specialty Generics

After experiencing contraction over the last several years, the Specialty Generics business returned to growth in fiscal 2019, as compared to 2018, primarily driven by share recapture in specialty generic products, partially offset by opioid market contraction. Net sales from the Specialty Generics segment were $738.7 million for fiscal 2019 compared to $718.9 million for fiscal 2018.

Results of Operations

Fiscal Year Ended December 27, 2019 Compared with Fiscal Year Ended December 28, 2018

Net Sales

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

	Fiscal Year		Percentage Change
	2019	2018	
U.S.	$ 2,765.6	$ 2,834.5	(2.4)%
Europe, Middle East and Africa	281.8	256.8	9.7
Other	115.1	124.3	(7.4)
Net sales	$ 3,162.5	$ 3,215.6	(1.7)

Net sales in fiscal 2019 decreased $53.1 million, or 1.7%, to $3,162.5 million, compared with $3,215.6 million in fiscal 2018. This decrease was driven by our Specialty Brands segment primarily due to Acthar Gel, as the brand continues to face reimbursement challenges impacting new and returning patients while navigating continued 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, as well as a decrease in net sales from BioVectra largely driven by the sale of this business in November 2019. These decreases were partially offset by continued strength in Ofirmev, INOmax and Therakos and the increase in net sales related to Amitiza, which was acquired in the first quarter of 2018. In addition, we continue to experience increased net sales in the Specialty Generics segment due to share recapture in specialty generic products, partially offset by opioid market contraction. 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 Loss

Gross profit. Gross profit for fiscal 2019 decreased $49.8 million, or 3.4%, to $1,421.4 million, compared with $1,471.2 million in fiscal 2018, due in part to the $53.1 million decrease in net sales, as discussed above. Gross profit margin was 44.9% for fiscal 2019, compared with 45.8% in fiscal 2018. The decrease in gross profit and gross profit margin was primarily attributable to a change in product mix driven by the decrease in Acthar Gel net sales and an additional $107.3 million of amortization for the Ofirmev intangible asset resulting from a change in amortization method on day 1 of fiscal 2019, as discussed further in Note 13 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. The additional amortization was partially offset by a decrease in the amortization of the inventory fair value adjustment related to Amitiza, which was fully amortized during the first quarter of 2019.

Selling, general and administrative expenses. SG&A expenses for fiscal 2019 were $831.0 million, compared with $834.1 million for fiscal 2018, a decrease of $3.1 million, or 0.4%. This decrease is attributable to cost benefits gained from restructuring actions, including lower employee compensation costs and a $60.2 million decrease in the fair value of our contingent consideration liabilities in fiscal 2019, compared to a $50.2 million decrease in fiscal 2018. These decreases were partially offset by a $57.9 million increase in separation costs, an increase in legal expense, primarily related to opioid defense costs, and an increase in legal settlements driven by the $28.2 million charge associated with the settlement of the MDL Track 1 Cases during fiscal 2019. As a percentage of our net sales, SG&A expenses were 26.3% and 25.9% in fiscal 2019 and 2018, respectively.

Research and development expenses. R&D expenses decreased $11.7 million, or 3.2%, to $349.4 million in fiscal 2019, compared with $361.1 million in fiscal 2018. This decrease was driven by the completion of certain development programs, partially offset by the $20.0 million upfront payment made to Silence during fiscal 2019. The Company continues to focus current R&D activities on performing clinical studies and publishing clinical and non-clinical experiences and evidence that support health economic activities and patient outcomes. As a percentage of our net sales, R&D expenses were 11.0% and 11.2% in fiscal 2019 and 2018, respectively.

Restructuring and related charges, net. During fiscal 2019, we recognized a net benefit of $1.7 million of restructuring and related charges, net. During fiscal 2019, we finalized the settlement of the contract termination costs related to the production of Raplixa resulting in a $14.1 million reversal of the associated restructuring reserve that was previously established in fiscal 2018. This was partially offset by restructuring charges related to employee severance and benefits. 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. The remaining $103.0 million primarily related to the estimated contract termination costs related to the production of Raplixa, exiting certain facilities and employee severance and benefits.

Non-restructuring impairment charges. Non-restructuring impairment charges were $388.0 million for fiscal 2019 resulting from the $274.5 million full impairment related to our VTS-270 intangible asset and the $113.5 million full impairment related to our stannsoporfin intangible asset, both as previously discussed. 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.

Losses on divestiture. During fiscal 2019, we completed the sale of BioVectra for a loss of $33.5 million. 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 loss of $0.8 million.

Opioid-related litigation settlement charge. During fiscal 2019, we recorded a charge of $1,643.4 million attributed to the anticipated structured cash payments and the Settlement Warrants to be issued upon effectiveness of the settlement. For further information, refer to Note 24 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.

Non-Operating Items

Interest expense and interest income. During fiscal 2019 and fiscal 2018, net interest expense was $299.5 million and $362.0 million, respectively. This $62.5 million decrease was attributable to a lower average outstanding debt balance during fiscal 2019 that yielded a decrease in interest expense of $26.6 million, a $23.7 million decrease in interest accrued on deferred tax liabilities associated with our previously outstanding installment notes and the recognition of an $8.6 million benefit to interest expense during fiscal 2019 due to a lapse of certain statute of limitations. For further information, refer to Note 19 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. Additionally, non-cash interest expense decreased by $2.4 million over the comparable period. Interest income increased to $9.5 million during fiscal 2019, compared to $8.2 million during fiscal 2018, primarily related to interest on preferred equity certificates received as contingent consideration associated with the sale of the Nuclear Imaging business.

Gains on debt extinguishment, net. During fiscal 2019 and 2018, we recorded gains on debt extinguishment, net, of $466.6 million and $8.5 million, respectively. During fiscal 2019 we completed a private exchange of our senior unsecured notes resulting in a gain of $377.4 million, net of the write-off of associated deferred financing fees of $4.9 million. For further information, refer to Note 14 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. Fiscal 2019 also included a gain of $98.6 million on debt repurchases that aggregated to a total principal amount of $492.1 million, partially offset by the write-off of associated deferred financing fees of $9.4 million. Fiscal 2018 included a gain of $12.7 million on debt repurchases that aggregated to a total principal amount of $81.8 million, partially offset by the write-off of associated deferred financing fees of $4.2 million.

Other income, net. During fiscal 2019 and 2018, we recorded other income, net, of $63.6 million and $22.4 million, respectively. This was primarily driven by a $23.5 million increase in royalty income related to our license agreement with Advanced Accelerator Applications ("AAA") for net sales of their Lutathera product. In addition, we recorded an unrealized gain on investment of $20.2 million related to our equity investment in Silence. 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. During fiscal 2019, we recognized an income tax benefit of $584.3 million on a loss from continuing operations before income taxes of $1,591.5 million. The fiscal 2019 income tax benefit was comprised of $21.8 million of current tax expense and $606.1 million of deferred tax benefit, which was predominantly related to previously acquired intangibles, the opioid-related litigation settlement charge, the generation of tax loss and credit carryforwards net of valuation allowances, the non-restructuring impairment charge, as well as the reorganization of our intercompany financing and associated legal entity ownership, which eliminated the interest-bearing deferred tax obligation. During 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.

Our effective tax rate was 36.7% and 10.6% for fiscal 2019 and 2018, respectively. Our effective tax rate for fiscal 2019 was most significantly impacted by the recognition of $212.8 million tax benefit associated with the reorganization of our intercompany financing and associated legal entity ownership. Further impacts include receiving $211.9 million of tax benefit associated with the $1,643.4 million opioid-related litigation settlement charge, $71.9 million of tax benefit associated with the $386.3 million of restructuring costs and non-restructuring impairment charges, $18.7 million of tax benefit associated with accrued income tax liabilities and uncertain tax positions, $13.5 million of tax benefit primarily associated with U.S. tax credits, $11.4 million of tax benefit associated with separation costs of $63.9 million, $10.2 million of tax expense associated with a gain on debt extinguishment of $466.6 million, $8.0 million of tax benefit associated with a legal settlement charge of $28.2 million, $7.6 million of tax expense associated with $60.2 million of income from the decrease in the fair value of contingent consideration liabilities and zero tax impact associated with a $33.5 million loss associated with the sale of BioVectra. Any remaining impacts were related to the impact of recent acquisitions. 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 a $0.8 million 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.

Income from discontinued operations, net of income taxes. We recorded income of $10.7 million and $14.9 million on discontinued operations, net of income taxes, during fiscal 2019 and 2018, respectively. During fiscal 2019 and 2018, the income from discontinued operations included $9.0 million and $13.6 million of income, net of tax, respectively, from the receipt of contingent consideration related to the sale of the Nuclear Imaging business. The remaining amounts in both periods represented various post-sale adjustments associated with our previous divestitures.

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		
	2018	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 Acthar Gel as the brand continued to face reimbursement challenges impacting new and returning patients 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 the strength in Ofirmev, INOmax and Therakos and the acquisition of the Amitiza product in the first quarter of 2018. The Specialty Generics segment experienced increased competition and customer consolidation, which 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 (Loss) 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 the inventory fair value adjustment 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. These decreases were partially offset by increased legal fees and provisions for settlement agreements. As a percentage of our net sales, SG&A expenses were 25.9% and 26.4% of net sales for fiscal 2018 and 2017, respectively.

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. This increase was partially offset by lower spend in the Specialty Generics segment. R&D activities focused on performing clinical studies and publishing clinical and non-clinical experiences and evidence to 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 the estimated contract termination costs related to the production of Raplixa, exiting certain facilities and employee severance and benefits. 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.

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 discussed. Non-restructuring impairment charges were $63.7 million for fiscal 2017 related to the Raplixa intangible asset.

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 loss of $0.8 million. In fiscal 2017, we recorded a $56.6 million 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 included an increase of $48.1 million due to our higher average outstanding debt balance in fiscal 2018 following the close of the Sucampo Pharmaceuticals Inc. ("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 Cut and Jobs Act of 2017 ("TCJA") that reduced the interest-bearing U.S. deferred tax liabilities balance during late fiscal 2017.

Gains on debt extinguishment, net. During fiscal 2018 we recorded an $8.5 million gain consisting of a $12.7 million gain on debt repurchases that aggregated to a total principal amount of $81.8 million, partially offset by a $4.2 million write-off of associated deferred financing fees. During fiscal 2017 we recorded a gain of $8.3 million consisting of a $9.4 million gain on debt repurchases that aggregated to a total principal amount of $66.9 million, partially offset by a $1.1 million write-off of associated deferred financing fees.

Other income (expense), net. During fiscal 2018 and 2017, we recorded other income, net, of $22.4 million and other expense, net, of $75.1 million, respectively. Fiscal 2018 included royalty income of $15.5 million and 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 and a $10.0 million charge associated with the refinancing of our term loan. 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 a $0.8 million 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 a $56.6 million 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.

Business Segment Results

Management measures and evaluates our operating segments based on segment net sales and operating income. Management excludes corporate expenses from segment operating income. In addition, certain amounts that management considers to be non-recurring or non-operational are excluded from segment operating income because management evaluates the operating results of

the segments excluding such items. These items include, but are not limited to, 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 (loss) income and in the reconciliations presented below. Selected information by business segment is as follows:

Fiscal Year Ended December 27, 2019 Compared with Fiscal Year Ended December 28, 2018

Net Sales

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

	Fiscal Year		
	2019	2018	Percentage Change
Specialty Brands	$ 2,423.8	$ 2,496.7	(2.9)%
Specialty Generics	738.7	718.9	2.8
Net sales	$ 3,162.5	$ 3,215.6	(1.7)

Specialty Brands. Net sales for fiscal 2019 decreased $72.9 million, or 2.9%, to $2,423.8 million, compared with $2,496.7 million for fiscal 2018. This decrease was primarily driven by a $157.4 million, or 14.2%, decrease in Acthar Gel net sales driven primarily by continued reimbursement challenges impacting new and returning patients and continued payer scrutiny on overall specialty pharmaceutical spending, a $13.7 million, or 40.4%, decrease in Other product sales primarily attributable to the sale of Recothrom during the first quarter of 2018 and a $13.0 million or 24.5% decrease in net sales related to BioVectra, which was sold in November 2019. These decreases were partially offset by continued strength in Ofirmev, INOmax, and Therakos, as well as an increase in net sales related to Amitiza, which was acquired in the first quarter of 2018.

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

	Fiscal Year		
	2019	2018	Percentage Change
U.S.	$ 2,164.3	$ 2,246.7	(3.7)%
Europe, Middle East and Africa	161.4	144.2	11.9
Other	98.1	105.8	(7.3)
Net sales	$ 2,423.8	$ 2,496.7	(2.9)

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

	Fiscal Year		
	2019	2018	Percentage Change
Acthar Gel	$ 952.7	$ 1,110.1	(14.2)%
INOmax	571.4	542.7	5.3
Ofirmev	384.0	341.9	12.3
Therakos	246.9	231.2	6.8
Amitiza	208.5	183.8	13.4
BioVectra	40.1	53.1	(24.5)
Other	20.2	33.9	(40.4)
Specialty Brands	$ 2,423.8	$ 2,496.7	(2.9)

Specialty Generics. Net sales for fiscal 2019 increased $19.8 million, or 2.8%, to $738.7 million, compared to $718.9 million for fiscal 2018. The increase in net sales was driven by increased net sales of $10.4 million or 15.8% and $8.8 million or 13.3% for hydrocodone-related products and oxycodone-related products, respectively, along with an increase of $8.7 million or 2.5% related to net sales of other controlled substances. These increases were partially offset by decreased net sales of $5.3 million or 10.5% related to other product net sales primarily due to decreases from our supply agreement with the acquirer of our contrast media and delivery systems ("CMDS") business.

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

	Fiscal Year		
	2019	2018	Percentage Change
U.S.	$ 601.3	$ 587.8	2.3%
Europe, Middle East and Africa	120.4	112.6	6.9
Other	17.0	18.5	(8.1)
Net sales	$ 738.7	$ 718.9	2.8

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

	Fiscal Year		
	2019	2018	Percentage Change
Hydrocodone (API) and hydrocodone-containing tablets	$ 76.3	$ 65.9	15.8%
Oxycodone (API) and oxycodone-containing tablets	74.9	66.1	13.3
Acetaminophen (API)	189.9	192.7	(1.5)
Other controlled substances	352.5	343.8	2.5
Other	45.1	50.4	(10.5)
Specialty Generics	$ 738.7	$ 718.9	2.8

Operating (Loss) Income

Operating income by segment and as a percentage of segment net sales for fiscal 2019 and 2018 is shown in the following table (dollars in millions):

	Fiscal Year			
	2019		2018	
Specialty Brands [1]	$ 1,174.5	48.5%	$ 1,093.1	43.8%
Specialty Generics	108.1	14.6	89.3	12.4
Segment operating income	1,282.6	40.6	1,182.4	36.8
Unallocated amounts:				
Corporate and allocated expenses	(137.8)		(155.8)	
Intangible asset amortization	(853.4)		(740.2)	
Restructuring and related charges, net [2]	1.7		(108.2)	
Non-restructuring impairment charges	(388.0)		(3,893.1)	
Separation costs	(63.9)		(6.0)	
R&D upfront payment [3]	(20.0)		—	
Opioid-related litigation settlement charge [4]	(1,643.4)		—	
Total operating loss	$ (1,822.2)		$ (3,720.9)	

(1) Includes $10.0 million and $118.8 million of inventory fair-value step up expense, primarily related to Amitiza during fiscal 2019 and 2018, respectively.
(2) Includes restructuring-related accelerated depreciation.
(3) Represents R&D expense incurred related to an upfront payment made to Silence in connection with the license and collaboration agreement entered into in July 2019.
(4) For further information, refer to Note 24 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.

Specialty Brands. Operating income for fiscal 2019 increased $81.4 million to $1,174.5 million, compared with $1,093.1 million for fiscal 2018. Operating margin increased to 48.5% for fiscal 2019, compared with 43.8% for fiscal 2018. The increase in operating income and margin includes a $39.4 million increase in gross profit primarily driven by an additional $110.8 million of expense recorded during fiscal 2018 related to the inventory fair value adjustment for Amitiza, which was fully amortized in the first quarter of 2019. The increase in operating income and margin was also attributable to a $19.4 million decrease in R&D spending and a $23.3 million decrease in SG&A expenses compared to fiscal 2018, primarily due to cost benefits gained from restructuring actions, including lower employee compensation costs. These changes were partially offset by changes in product mix, primarily driven by the decrease in Acthar Gel net sales.

Specialty Generics. Operating income for fiscal 2019 increased $18.8 million to $108.1 million, compared with $89.3 million for fiscal 2018. Operating margin increased to 14.6% for fiscal 2019, compared with 12.4% for fiscal 2018. The increase in operating income and margin was impacted by a $21.2 million increase in gross profit primarily due to product mix as well as a $13.2 million decrease in R&D spending, partially offset by a $15.6 million increase in SG&A primarily due to higher legal expense related to opioid litigation defense costs and increased consulting and professional fees.

Corporate and allocated expenses. Corporate and allocated expenses were $137.8 million and $155.8 million for fiscal 2019 and 2018, respectively. Fiscal 2019 included a $33.5 million loss on the divestiture of BioVectra and a $28.2 million charge associated with the settlement of the MDL Track 1 Cases, partially offset by a $60.2 million decrease in the fair value of our contingent consideration liabilities. Fiscal 2018 included a $50.2 million decrease in the fair value of our contingent consideration liabilities, as well as an $11.8 million reduction in the accrual associated with our Lower Passaic River, New Jersey environmental remediation liability. The remaining decrease was primarily driven by cost benefits gained from restructuring actions, including lower employee compensation costs, partially offset by increased professional fees.

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		
	2018	2017	Percentage Change
Specialty Brands	$ 2,496.7	$ 2,352.0	6.2%
Specialty Generics	718.9	869.6	(17.3)
Net sales	$ 3,215.6	$ 3,221.6	(0.2)

Specialty Brands. Net sales for fiscal 2018 increased $144.7 million, or 6.2%, to $2,496.7 million, compared with $2,352.0 million for fiscal 2017. This increase was primarily driven by net sales of $183.8 million from Amitiza acquired in the first quarter of fiscal 2018 coupled with 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. These increases were partially offset by a decrease in Acthar Gel net sales of $85.0 million, or 7.1%, driven by the residual impact of previously reported patient withdrawal issues from fiscal 2017 while navigating growing payer scrutiny on overall specialty pharmaceutical spending and a decrease of $45.7 million, or 57.4%, in sales of Other products. The decrease in Other product sales was primarily attributable to a $42.9 million decrease in net sales related to the sale of Recothrom during the first quarter of 2018 and a $7.8 million decrease in net sales related to the sale of the Intrathecal Therapy business during the first quarter of 2017.

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

	Fiscal Year		
	2018	2017	Percentage Change
U.S.	$ 2,246.7	$ 2,216.9	1.3%
Europe, Middle East and Africa	144.2	73.0	97.5
Other	105.8	62.1	70.4
Net sales	$ 2,496.7	$ 2,352.0	6.2

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

	Fiscal Year		
	2018	2017	Percentage Change
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
Amitiza	183.8	—	—
BioVectra	53.1	54.7	(2.9)
Other	33.9	79.6	(57.4)
Specialty Brands	$ 2,496.7	$ 2,352.0	6.2

Specialty Generics. Net sales for fiscal 2018 decreased $150.7 million, or 17.3%, to $718.9 million, compared with $869.6 million for fiscal 2017. The decrease in net sales was driven by decreases of $21.9 million, or 24.9%, and $19.4 million, or 22.7%, in net sales of oxycodone-related products and hydrocodone-related products, respectively. These decreases were due to increased competition and customer consolidation, which 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 $48.4 million, or 49.0%, primarily due to a $33.8 million decrease from our supply agreement with the acquirer of our CMDS business. These decreases were partially offset by an increase of $7.2 million in net sales of acetaminophen products compared to fiscal 2017.

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

	Fiscal Year		
	2018	2017	Percentage Change
U.S.	$ 587.8	$ 682.1	(13.8)%
Europe, Middle East and Africa	112.6	169.3	(33.5)
Other	18.5	18.2	1.6
Net sales	$ 718.9	$ 869.6	(17.3)

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

	Fiscal Year		
	2018	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
Other controlled substances	343.8	412.0	(16.6)
Other	50.4	98.8	(49.0)
Specialty Generics	$ 718.9	$ 869.6	(17.3)

Operating (Loss) Income

Operating 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			
	2018		2017	
Specialty Brands [1]	$ 1,093.1	43.8%	$ 1,146.3	48.7%
Specialty Generics	89.3	12.4	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 fiscal 2018.
(2) Includes restructuring-related accelerated depreciation.

Specialty Brands. Operating income for fiscal 2018 decreased $53.2 million to $1,093.1 million, compared with $1,146.3 million for fiscal 2017. Operating margin decreased to 43.8% for fiscal 2018, compared with 48.7% for fiscal 2017. The decrease in operating income was impacted by an increase of $95.7 million in R&D expenses related to the increased investment in our pipeline products. This was partially offset by a decrease of $42.8 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 and advertising and promotion fees and various minor increases and decreases.

Specialty Generics. Operating income for fiscal 2018 decreased $177.1 million to $89.3 million, compared with $266.4 million for fiscal 2017. Operating margin decreased to 12.4% for fiscal 2018, compared with 30.6% for fiscal 2017. The decrease in operating income was impacted by a $134.4 million decrease in gross profit, primarily due to the previously discussed decrease in net sales of oxycodone-related products, hydrocodone-related products and other controlled substances due to channel consolidation and increased pricing pressure. The decrease in operating income was also impacted by a $51.4 million increase in SG&A expenses, primarily due to higher legal expense related to opioid litigation defense costs and higher professional fees, partially offset by lower employee compensation costs and stock compensation expense.

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 $50.2 million decrease in the fair value of our contingent consideration liabilities. Fiscal 2017 included a $56.6 million 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 employee compensation costs, lower professional fees 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, cash paid in connection with acquisitions and licensing agreements and cash received as a result of our divestitures. We have historically generated and expect to continue to generate positive cash flows 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 and access to capital markets will provide adequate resources to fund our working capital needs, capital expenditures and strategic investments for the foreseeable future.

As previously discussed, on February 25, 2020, we announced the Litigation Settlement. If the Litigation Settlement is not fully implemented or consummated, we or our subsidiaries may become subject to some or all of the liabilities that would have otherwise been settled, which could have a material and adverse effect on our business, financial condition, results of operations and cash flows. Further information on these risks are described in Part I, Item 1A. "Risk Factors".

Furthermore, from time to time, we may seek to enter into certain transactions to extend the maturities of our outstanding indebtedness. For example, on February 25, 2020, we announced certain financing activities that are aimed at addressing our near-term debt maturities, as discussed further in "Debt and Capitalization" within this Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

In fiscal 2020, we intend to fund capital expenditures with cash generated from operations. At December 27, 2019, we had capital expenditure commitments of $1.0 million.

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

	Fiscal Year		
	2019	2018	2017
Net cash provided by (used in):			
Operating activities	$ 742.9	$ 665.5	$ 727.3
Investing activities	(8.3)	(480.3)	318.4
Financing activities	(280.1)	(1,095.0)	(130.2)
Effect of currency exchange rate changes on cash	0.6	(1.8)	2.5
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 455.1	$ (911.6)	$ 918.0

Operating Activities

Net cash provided by operating activities of $742.9 million for fiscal 2019 included a loss from continuing operations, as adjusted for non-cash items including a $466.6 million gain on debt extinguishment, net and a $388.0 million adjustment for non-cash impairment charges, both as previously discussed. The loss from continuing operations adjusted for non-cash items was offset by a $1,451.6 million inflow from net changes in working capital, primarily driven by the portion of the opioid-related litigation settlement liability related to the structured cash payments of $1,600.0 million with the remaining $43.4 million related to the Settlement Warrants reflected as a non-cash item. This was partially offset by a $161.5 million net outflow from other assets and liabilities primarily driven by cash outflows related to separation costs, one time legal settlement payments of $24.0 million and $15.4 million related to the settlement of the MDL Track 1 Cases and the Questcor Pharmaceuticals, Inc. (“Questcor”) DOJ settlement, respectively, a $26.5 million decrease in accrued restructuring charges, a $16.3 million decrease in payroll related accruals and decreases in other accrual balances attributable to cost benefits gained from restructuring actions.

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 discussed, 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.

Investing Activities

Net cash used in investing activities of $8.3 million for fiscal 2019 was primarily attributable to capital expenditures of $133.0 million, partially offset by $95.1 million in proceeds received related to the sale of BioVectra, net of cash, as well as proceeds from other long-term asset disposals.

Net cash used in investing activities of $480.3 million for fiscal 2018 was primarily attributable to cash outflows related to the Sucampo acquisition of $698.0 million and capital expenditures of $127.0 million, partially offset by the $159.0 million of proceeds received, net of transaction costs, from the divestiture of a portion of the Hemostasis business, inclusive of the PreveLeak and Recothrom products; proceeds received of $154.0 million related to the note receivable from the purchaser of the Intrathecal Therapy business that 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.

Net cash provided by investing activities of $318.4 for fiscal 2017 included $576.9 million of proceeds received from the divestiture of the Nuclear Imaging and Intrathecal Therapy businesses during fiscal 2017, partially offset by capital expenditures of $186.1 million; payments, net of cash acquired, of $36.8 million 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.

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 $280.1 million for fiscal 2019, compared with $1,095.0 million for fiscal 2018. The $814.9 million decrease was primarily attributable to a $748.5 million decrease in debt repayments and a $54.9 million decrease in shares repurchased. The significant components of our current year debt repayments included aggregate debt repayments of $286.4 million on our variable-rate term loans, open market debt repurchases that aggregated to a total principal amount of $492.1 million and a repayment of $250.0 million on the receivable securitization program. These repayments were partially offset by a net draw of $680.0 million on our revolving credit facility.

Net cash used in financing activities was $1,095.0 million for fiscal 2018, compared with $130.2 million 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.

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 2019, we repurchased debt that aggregated to a principal amount of $492.1 million.

As of December 27, 2019, total debt principal was $5,422.8 million compared with $6,156.7 million as of December 28, 2018, with total debt reduction of $733.9 million during fiscal 2019. Total debt principal at December 27, 2019 is comprised of the following:

	December 27, 2019
Variable-rate instruments:	
Term loan due September 2024	$ 1,520.8
Term loan due February 2025	403.6
Revolving credit facility	900.0
Fixed-rate instruments	2,598.4
Debt principal	$ 5,422.8

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 27, 2019, our fixed-rate instruments had a weighted-average interest rate of 6.0% and pay interest at various dates throughout the fiscal year. As of December 27, 2019, we were fully drawn on our $900.0 million revolving credit facility.

In December 2019, upon the terms and conditions set forth in a confidential offering memorandum dated November 5, 2019, Mallinckrodt International Finance S.A. and Mallinckrodt CB LLC (the "Issuers") completed private offers to exchange (the "2019 Exchange Offers") (i) $83.2 million 2020 Notes issued by the Issuers for $70.2 million of new 10.00% Second Lien Senior Secured Notes due April 2025 to be issued by the Issuers (the "2025 Notes") and (ii) $52.9 million of the 5.75% senior unsecured notes due August 2022 (the "2022 Notes"), $216.4 million of the 4.75% senior unsecured notes due April 2023, $144.7 million of the 5.625% senior unsecured notes due October 2023 (the "October 2023 Notes") and $208.9 million of the 2025 Notes issued by the Issuers (collectively, and together with the 2020 Notes, the "Existing Notes") for $252.7 million of 2025 Notes. The 2019 Exchange Offers were accounted for as a debt extinguishment, which resulted in the extinguishment of $383.2 million of principal of Existing Notes and the transfer of $322.9 million of Existing Notes to the 2025 Notes. The exchanges also resulted in the capitalization of $10.1 million of deferred financing fees related to the 2025 Notes. In conjunction with the exchanges, we recorded a gain on debt extinguishment of $377.4 million primarily associated with retiring a portion of our Existing Notes at less than face value, net of the write-off of associated deferred financing fees of $4.9 million.

As of December 27, 2019, $634.5 million of our total debt is classified as current as these payments are due within the next fiscal year, including $614.8 million of the 2020 Notes. On February 25, 2020, we announced certain financing activities that are aimed at addressing our near term-debt maturities. We and the Issuers have entered into a support agreement with certain of our existing term lenders, as well as certain of our existing noteholders, as new lenders, relating to an amendment to our existing credit agreement on terms consistent with an agreed term sheet (the "Amendment"), which, if effected on the terms contemplated by the term sheet, will (i) provide for a commitment to provide a new $800.0 million term loan with a four-year term and (ii) implement certain other amendments on the terms described in the term sheet. The proceeds of the new term loan will be used to fund the redemption or repayment of all of our outstanding 2020 Notes, and additionally to partially repay loans and terminate corresponding commitments under the revolving credit facility in respect of revolving lenders who agree to extend their loans and commitments to March 2024. The amendments to the existing credit agreement would provide for, among other things, certain changes to the covenants, including the financial covenant, a rate increase of 100 basis points for existing term loans, and an increase in amortization on the existing term loans. Conditions to the effectiveness of the Amendment, include, among other things, (i) the consent by certain thresholds of the existing term lenders and revolving lenders (which condition has not yet been satisfied as of this date) and (ii) the commencement of an exchange offer with respect to our 2022 Notes pursuant to the Exchange Agreement (as described below). However, we cannot guarantee that we will satisfy the conditions, and in such event, we could experience heightened risks related to short-term liquidity constraints, which could adversely affect our ability to fulfill our other financial obligations and jeopardize the consummation of the Litigation Settlement.

We and the Issuers entered into a support and exchange agreement with Aurelius Capital Master, Ltd., Franklin Advisers, Inc. and Capital Research and Management Company (the "Exchange Agreement") pursuant to which, among other things, the Issuers agreed to use commercially reasonable efforts to commence, by no later than March 20, 2020, a private offer to exchange any and all of the 2022 Notes held by such noteholders for an equal principal amount of new second lien secured notes (such new notes, the "Exchange Offer Notes" and, such private offer to exchange, the "2022 Exchange Offer") at a rate of $1,000 of Exchange Offer Notes for every $1,000 of 2022 Notes exchanged, subject to the terms and conditions set forth in the Exchange Agreement. Pursuant to the Exchange Agreement, the Issuers also agreed to use commercially reasonable efforts to commence, by no later than March 20, 2020, a solicitation of consents from holders of the 2022 Notes to certain amendments to eliminate or waive substantially all of the restrictive covenants contained in the 2022 Notes and the applicable indenture, and eliminate certain events of default, modify covenants regarding mergers and the transfer of assets, and modify and eliminate certain other provisions, including covenants regarding future guarantors and certain provisions relating to defeasance (such solicitation of consents, the "2022 Consent Solicitation"). The closing of the 2022 Exchange Offer will be conditioned on, among other things, the absence of events materially and adversely affecting the ability to implement the Litigation Settlement, and the funding of the new term loans and the effectiveness of the Amendment. The noteholders have agreed to tender in the 2022 Exchange Offer all of their 2022 Notes, deliver their consents in the 2022 Consent Solicitation and, if the aggregate principal amount of Exchange Offer Notes issued pursuant to the 2022 Exchange Offer is less than approximately $610.3 million (the "Exchange Cap"), exchange the outstanding October 2023 Notes held by the noteholders party to the Exchange Agreement for an amount of Exchange Offer Notes equal to the excess, if any, by which the Exchange Cap exceeds the aggregate principal amount of Exchange Offer Notes to be issued pursuant to the 2022 Exchange Offer, at a rate of $900 of Exchange Offer Notes for every $1,000 of October 2023 Notes exchanged by each noteholder. The noteholders collectively hold approximately $271.0 million aggregate principal amount of the 2022 Notes and approximately $255.0 million aggregate principal amount of the October 2023 Notes. Additionally, pursuant to the Exchange Agreement, the noteholders have consented, in their capacity as holders of the 2020 Notes, to the adoption of an amendment to the 2020 Notes and the indenture governing the 2020 Notes to provide for the reduction of the optional redemption notice period from 30 days to three business days. The 2022 Exchange Offer will be subject to

the satisfaction or waiver of certain conditions, and the failure to consummate the 2022 Exchange Offer could adversely affect the implementation and consummation of the Litigation Settlement.

The risks associated with the failure to consummate the Litigation Settlement are further described in the risk factor “The Litigation Settlement is subject to certain contingencies and may not go into effect in its current form or at all, as a result of which our business prospects may be adversely impacted.” in Part I, Item 1A. "Risk Factors."

As of December 27, 2019, 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 $1,940.7 million at December 27, 2019 compared with $2,887.3 million at December 28, 2018. The decrease in shareholders' equity is primarily attributed to the fiscal 2019 net loss.

From time to time, the Company's Board of Directors have authorized share repurchase programs. We did not make any share repurchases during fiscal 2019, compared to $55.2 million in fiscal 2018, due to our shift to debt reduction as one of our primary focuses of our capital allocation strategy for fiscal 2019. For further information, refer to Note 16 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.

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, while executing disciplined capital allocation. 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 27, 2019 (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	$ 5,422.8	$ 634.5	$ 1,560.1	$ 2,135.0	$ 1,093.2
Interest on long-term debt obligations [1]	1,083.2	268.5	483.7	301.6	29.4
Operating lease obligations [2]	104.2	23.5	31.6	21.0	28.1
Purchase obligations [3]	73.4	63.4	3.4	3.3	3.3
Total contractual obligations	$ 6,683.6	$ 989.9	$ 2,078.8	$ 2,460.9	$ 1,154.0

(1) Interest on long-term debt obligations are projected for future periods using interest rates in effect as of December 27, 2019. Certain of these projected interest payments may differ in the future based on changes in market interest rates.

(2) Refer to Note 12 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K for further information.

(3) 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 $2,219.1 million, primarily consisting of the opioid-related litigation settlement liability of $1,643.4 million and 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, other than the opioid-related settlement liability discussed in Note 24 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, 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 27, 2019, we have accrued $69.3 million for these potential payments, of which $11.5 million is considered to be long-term. For further information on our contingent consideration arrangements, refer to Note 20 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

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 2019, we received royalty income of $39.0 million and preferred equity certificates of $9.0 million. 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 5 and 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.

We are obligated to pay royalties under certain agreements with third parties. During fiscal 2019, 2018 and 2017, we made payments under these arrangements of $95.7 million, $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 net sales generated 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 27, 2019, was $227.1 million. Payment of these liabilities is uncertain and, even if payments are determined to be necessary, they are subject to the timing of rulings by the Internal Revenue Service related to tax positions we take. For further information on income tax related matters, refer to Note 8 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

As of December 27, 2019, we had net unfunded pension and postretirement benefit obligations of $27.0 million and $40.5 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 2020, but may elect to make voluntary contributions to our defined pension plans or our postretirement benefit plans during fiscal 2020. We settled all outstanding obligations associated with our six U.S. qualified pension plans during 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 27, 2019, we believe that it is probable that we will incur investigation and remediation costs of approximately $61.9 million, of which $1.9 million is included in accrued and other current liabilities on our consolidated balance sheet at December 27, 2019. Note 19 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K provides additional information regarding environmental matters.

Legal Proceedings

We are subject to various legal proceedings and claims, including present and former operations, including those described in Part I, Item 3. Legal Proceedings and 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, which are incorporated by reference into this Part II, Item 7. We believe these legal proceedings and claims likely will be resolved over an extended period of time. Although it is not feasible to predict the outcome of these matters, we believe, unless otherwise indicated, given the information currently available, that their ultimate resolution should not have a material adverse effect on our business, financial condition, results of operations and cash flows.

Guarantees

In disposing of assets or businesses, we have historically provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to the assets, environmental risks involved in the sale of real estate, liability to investigate and remediate environmental contamination at waste disposal sites and manufacturing facilities, and unidentified tax liabilities related to periods prior to disposition. 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 18 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

As of December 27, 2019, we had various other letters of credit and guarantee and surety bonds totaling $35.2 million and restricted cash of $12.8 million held in segregated accounts primarily to collateralize surety bonds for the Company's environmental liabilities.

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 GPOs 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 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 sale 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 that 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 we are entitled based on the terms of the contract. The amount of variable consideration that 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 as of 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 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
Provisions	2,347.3	22.2	68.2	2,437.7
Payments or credits	(2,405.8)	(27.8)	(72.1)	(2,505.7)
Balance as of December 27, 2019	$ 295.8	$ 28.4	$ 13.2	$ 337.4

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 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

Total provisions for fiscal 2019 increased $50.2 million compared with fiscal 2018. The increase in rebates and chargebacks of $66.0 million primarily related to an increase in $49.3 million in the Specialty Generics segment as our distributors incurred higher chargebacks as compared to our direct customers, coupled with a $16.7 million increase in Specialty Brands. Provisions for returns decreased $17.1 million driven the Specialty Generics segment primarily related to discontinuation of select products in fiscal 2019, and other sales deductions increased by $1.3 million from fiscal 2018 to fiscal 2019.

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 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, 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 sheets and expensed to cost of sales over the useful life of the equipment.

Product Royalty Revenues

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 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.

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

For additional information, refer to 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.

Goodwill and Other Intangible Assets

During fiscal 2018, our annual goodwill impairment analysis resulted in the recognition of a full goodwill impairment of $3,672.8 million related to our Specialty Brands reporting unit. As a result, we did not have a goodwill balance during fiscal 2019. Prior to this full impairment, we tested goodwill on the first day of the fourth quarter of each year for impairment or whenever events or changes in circumstances indicated that the carrying value may not be recoverable. 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. 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.

Intangible assets include completed technology, licenses, trademarks and IPR&D. Intangible assets acquired in a business combination are recorded at fair value, while intangible assets acquired in other transactions are recorded at cost. Finite-lived intangible assets are amortized, generally using the straight-line method over five to thirty years. 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. 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. 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. Indefinite-lived intangible assets are tested annually 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. The fair value of the intangible asset is estimated using an income approach, using similar assumptions as used in our goodwill valuation. 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.

For more information on our goodwill and intangible impairment analyses and the results thereof, refer to Notes 2 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

For acquisitions that meet the criteria for business combination accounting, the amounts paid 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 that 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.

Certain asset acquisitions or license agreements may not meet the criteria for a business combination. We account for these transactions as an asset acquisition and recognize the identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquired entity. Any initial up-front payments incurred in connection with the acquisition or licensing of IPR&D product candidates that do not meet the definition of a business are treated as research and development 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 operations. The determination of fair value is dependent upon a number of factors, which include projections of future revenues, the probability of successfully 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 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.

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 19 of Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K. Accruals recorded for various contingencies, including legal proceedings, self-insurance and other claims, are based on judgment, the probability of losses and, where applicable, the consideration of opinions of internal and/or external legal counsel, internal and/or external technical consultants and actuarially determined estimates. When a range is established but a best estimate cannot be made, we record the minimum loss contingency amount. These estimates are often initially developed substantially earlier than the ultimate loss is known, and the estimates are reevaluated each accounting period as additional information becomes available. When we are initially unable to develop a best estimate of loss, we record the minimum amount of loss, which could be zero. As information becomes known, additional loss provisions are recorded when either a best estimate can be made or the minimum loss amount is increased. When events result in an expectation of a more favorable outcome than previously expected, our best estimate is changed to a lower amount. We record receivables from third-party insurers up to the amount of the related liability when we have determined that existing insurance policies will provide reimbursement. In making this determination, we consider applicable deductibles, policy limits and the historical payment experience of the insurance carriers. Receivables are not netted against the related liabilities for financial statement presentation.

Income Taxes

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

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

We 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 50.0% 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.

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

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

Our operations include activities in the U.S. and countries outside of the U.S. These operations expose us to a variety of market risks, including the effects of changes in interest rates and currency exchange rates. We monitor and manage these financial exposures as an integral part of our overall risk management program 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 27, 2019, our outstanding debt included $1,924.4 million variable-rate debt on our senior secured term loans and $900.0 million variable-rate debt on our revolving credit facility. Assuming a one percent increase in the applicable interest rates, in excess of applicable minimum floors, annual interest expense for fiscal 2019 would increase by approximately $28.2 million.

The remaining outstanding debt as of December 27, 2019 is fixed-rate debt. Changes in market interest rates generally affect the fair value of fixed-rate debt, but do not impact earnings or cash flows.

Currency Risk

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

The consolidated statement of operations 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. The aggregate potential unfavorable impact from a hypothetical 10.0% adverse change in foreign exchange rates was $1.4 million as of December 27, 2019, with all other variables held constant. 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.

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 (the "Company") as of December 27, 2019 and December 28, 2018, the related consolidated statements of operations, comprehensive operations, changes in shareholders' equity, and cash flows for the fiscal years ended December 27, 2019, December 28, 2018 and December 29, 2017 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 27, 2019 and December 28, 2018, and the results of its operations and its cash flows for the fiscal years ended December 27, 2019, December 28, 2018 and December 29, 2017, 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 27, 2019, 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 25, 2020, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Income Taxes - Legal Entity Reorganization - Refer to Note 8 to the financial statements

Critical Audit Matter Description

The Company completed a reorganization of its intercompany financing and associated legal entity ownership in response to the changing global tax environment, resulting in a $26.2 million current tax expense and a $239.0 million deferred income tax benefit. The reorganization involved the interpretation of multi-jurisdictional tax laws and regulations, supported by third-party tax opinions. Interpretation of tax laws can be inherently uncertain and can be subject to potential challenges by the relevant tax authorities, both of which were considered in assessing its reserves for uncertain tax positions.

We identified the income taxes associated with the legal entity reorganization as a critical audit matter because of the significant judgments made by management and the complex nature of the reorganization, particularly related to the interpretation of multi-jurisdictional tax laws and regulations. This required a high degree of auditor judgment and an increased extent of effort, including the

need to involve our tax specialists when performing audit procedures to evaluate the Company's interpretation of tax laws and regulations for multiple jurisdictions.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the income taxes associated with the legal entity reorganization included the following, among others:

- We tested the effectiveness of management's controls over income taxes, including those over the legal entity reorganization and the interpretation of tax laws and regulations.
- With the assistance of our tax specialists, we evaluated the income taxes associated with the legal entity reorganization by performing the following:
  - Obtaining management and third-party tax opinions or memoranda regarding the analysis of relevant tax laws and regulations and evaluating whether the analysis was consistent with our interpretation.
  - Evaluating the appropriateness of management's conclusions with respect to reserves for uncertain tax positions associated with the legal entity reorganization.
  - Testing the underlying calculations and allocations supporting the tax expense and benefit recorded.

Commitments and Contingencies - Opioid Litigation Settlement - Refer to Notes 19 and 24 to the financial statements

Critical Audit Matter Description

On February 25, 2020, the Company announced that it has reached an agreement in principle on the terms of a global settlement that would resolve all opioid-related claims against the Company and its subsidiaries ("Litigation Settlement") for $1,600.0 million in cash payments over eight years and the issuance of warrants to purchase ordinary shares of the Company that would represent approximately 19.99% of the Company's fully diluted outstanding shares. The Litigation Settlement contemplates the filing of voluntary petitions under Chapter 11 of the U.S. Bankruptcy Code ("Chapter 11") by certain subsidiaries of Mallinckrodt plc operating the Specialty Generics business (the "Specialty Generics Subsidiaries"). The Litigation Settlement payments and the issuance of warrants are effective upon the emergence from the contemplated Chapter 11 process and are conditioned upon, among other things, bankruptcy court approval of the bankruptcy plan effectuating the Litigation Settlement, the emergence of the Specialty Generics Subsidiaries from bankruptcy and other material terms.

The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. As a result of the Litigation Settlement, the Company recorded an accrual of $1,600.0 million related to the cash payments and $43.4 million related to the warrants in the consolidated balance sheet as of December 27, 2019, with a corresponding non-cash charge to the consolidated statement of operations as a component of operating expenses.

We identified the opioid-related litigation settlement liability and disclosures as a critical audit matter because of the significant judgments made by management to assess the complex terms of the Litigation Settlement in order to determine the measurement and recognition of the estimated loss. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate the reasonableness of management's conclusions.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the opioid-related litigation settlement liability and disclosures included the following, among others:

- We tested the effectiveness of controls over the Litigation Settlement, which included review and approval of the accounting and related disclosures.
- We requested and received written responses from the Company's external legal counsel regarding opioid litigation and the Litigation Settlement.
- We evaluated the Company's conclusions regarding the recognition and measurement of the opioid-related litigation settlement by obtaining management's documented accounting treatment and evaluating the accounting based on the terms of the Litigation Settlement and the applicable accounting principles generally accepted in the United States of America.
- We evaluated the Company's disclosures for consistency with our knowledge of the Litigation Settlement.

/s/ DELOITTE & TOUCHE LLP
St. Louis, Missouri
February 25, 2020

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

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

	Fiscal Year		
	2019	**2018**	**2017**
Net sales	$ 3,162.5	$ 3,215.6	$ 3,221.6
Cost of sales	1,741.1	1,744.4	1,564.1
Gross profit	1,421.4	1,471.2	1,657.5
Selling, general and administrative expenses	831.0	834.1	849.7
Research and development expenses	349.4	361.1	276.9
Restructuring charges, net	(1.7)	103.0	31.2
Non-restructuring impairment charges	388.0	3,893.1	63.7
Losses (gains) on divestiture	33.5	0.8	(56.9)
Opioid-related litigation settlement charge (Note 24)	1,643.4	—	—
Operating (loss) income	(1,822.2)	(3,720.9)	492.9
Interest expense	(309.0)	(370.2)	(369.1)
Interest income	9.5	8.2	4.6
Gains on debt extinguishment, net	466.6	8.5	8.3
Other income (expense), net	63.6	22.4	(75.1)
(Loss) income from continuing operations before income taxes	(1,591.5)	(4,052.0)	61.6
Benefit from income taxes	(584.3)	(430.1)	(1,709.6)
(Loss) income from continuing operations	(1,007.2)	(3,621.9)	1,771.2
Income from discontinued operations, net of tax expense of $1.7, $1.4, and $5.4	10.7	14.9	363.2
Net (loss) income	$ (996.5)	$ (3,607.0)	$ 2,134.4
Basic (loss) earnings per share (Note 9):			
(Loss) income from continuing operations	$ (12.00)	$ (43.12)	$ 18.13
Income from discontinued operations	0.13	0.18	3.72
Net (loss) income	$ (11.88)	$ (42.94)	$ 21.85
Basic weighted-average shares outstanding	83.9	84.0	97.7
Diluted (loss) earnings per share (Note 9):			
(Loss) income from continuing operations	$ (12.00)	$ (43.12)	$ 18.09
Income from discontinued operations	0.13	0.18	3.71
Net (loss) income	$ (11.88)	$ (42.94)	$ 21.80
Diluted weighted-average shares outstanding	83.9	84.0	97.9

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
CONSOLIDATED STATEMENTS OF COMPREHENSIVE OPERATIONS
(in millions)

	Fiscal Year		
	2019	**2018**	**2017**
Net (loss) income	$ (996.5)	$ (3,607.0)	$ 2,134.4
Other comprehensive income (loss), net of tax			
Currency translation adjustments	18.3	(12.2)	11.3
Unrecognized gain on derivatives, net of tax expense of $0.6, $0.2, and $0.3	1.8	0.7	1.0
Unrecognized (loss) gain on benefit plans, net of tax (benefit) expense of $(1.1), $0.5, and $30.8	(4.2)	1.6	45.8
Unrecognized gain on investments	—	—	1.5
Total other comprehensive income (loss), net of tax	15.9	(9.9)	59.6
Comprehensive (loss) income	$ (980.6)	$ (3,616.9)	$ 2,194.0

See Notes to Consolidated Financial Statements.

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

	December 27, 2019	December 28, 2018
Assets		
Current Assets:		
Cash and cash equivalents	$ 790.9	$ 348.9
Accounts receivable, less allowance for doubtful accounts of $4.0 and $5.0	577.5	623.3
Inventories	312.1	322.3
Prepaid expenses and other current assets	150.2	132.7
Total current assets	1,830.7	1,427.2
Property, plant and equipment, net	896.5	982.0
Intangible assets, net	7,018.0	8,282.8
Other assets	593.7	185.3
Total Assets	$ 10,338.9	$ 10,877.3
Liabilities and Shareholders' Equity		
Current Liabilities:		
Current maturities of long-term debt	$ 633.6	$ 22.4
Accounts payable	139.8	147.5
Accrued payroll and payroll-related costs	105.2	124.0
Accrued interest	62.9	77.6
Accrued and other current liabilities	485.4	572.2
Total current liabilities	1,426.9	943.7
Long-term debt	4,741.2	6,069.2
Opioid-related litigation settlement liability (Note 24)	1,643.4	—
Pension and postretirement benefits	62.4	60.5
Environmental liabilities	60.0	59.7
Deferred income taxes	11.0	324.3
Other income tax liabilities	227.1	228.0
Other liabilities	226.2	304.6
Total Liabilities	8,398.2	7,990.0
Shareholders' Equity:		
Preferred shares, $0.20 par value, 500,000,000 authorized; none issued or outstanding	—	—
Ordinary A shares, €1.00 par value, 40,000 authorized; none issued or outstanding	—	—
Ordinary shares, $0.20 par value, 500,000,000 authorized; 93,459,206 and 92,705,747 issued; 84,105,786 and 83,323,877 outstanding	18.7	18.5
Ordinary shares held in treasury at cost, 9,353,420 and 9,381,870	(1,615.7)	(1,617.4)
Additional paid-in capital	5,562.5	5,528.2
Retained deficit	(2,016.9)	(1,017.7)
Accumulated other comprehensive loss	(7.9)	(24.3)
Total Shareholders' Equity	1,940.7	2,887.3
Total Liabilities and Shareholders' Equity	$ 10,338.9	$ 10,877.3

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in millions)

	Fiscal Year		
	2019	**2018**	**2017**
Cash Flows From Operating Activities:			
Net (loss) income	$ (996.5)	$ (3,607.0)	$ 2,134.4
Adjustments to reconcile net cash provided by operating activities:			
Depreciation and amortization	951.1	852.1	808.3
Share-based compensation	33.8	34.6	59.2
Deferred income taxes	(604.3)	(541.5)	(1,744.1)
Non-cash impairment charges	388.0	3,893.1	63.7
Inventory provisions	18.0	37.9	34.1
Losses (gains) on divestiture	33.5	0.8	(418.1)
Gain on debt extinguishment, net	(466.6)	(8.5)	(8.3)
Other non-cash items	(65.7)	(42.4)	(13.1)
Changes in assets and liabilities, net of the effects of acquisitions:			
Accounts receivable, net	31.6	(145.8)	(16.2)
Inventories	(23.1)	63.1	(23.6)
Accounts payable	6.7	24.6	(25.8)
Income taxes	(2.1)	99.0	(34.2)
Opioid-related litigation settlement liability	1,600.0	—	—
Other	(161.5)	5.5	(89.0)
Net cash from operating activities	742.9	665.5	727.3
Cash Flows From Investing Activities:			
Capital expenditures	(133.0)	(127.0)	(186.1)
Acquisitions, net of cash acquired	—	(699.9)	(76.3)
Proceeds from divestiture, net of cash	95.1	313.0	576.9
Other	29.6	33.6	3.9
Net cash from investing activities	(8.3)	(480.3)	318.4
Cash Flows From Financing Activities:			
Issuance of external debt	695.0	690.3	1,465.0
Repayment of external debt	(945.1)	(1,693.6)	(917.2)
Debt financing costs	(10.1)	(12.1)	(12.7)
Proceeds from exercise of share options	0.6	1.0	4.1
Repurchase of shares	(2.6)	(57.5)	(651.7)
Other	(17.9)	(23.1)	(17.7)
Net cash from financing activities	(280.1)	(1,095.0)	(130.2)
Effect of currency rate changes on cash	0.6	(1.8)	2.5
Net change in cash, cash equivalents and restricted cash	455.1	(911.6)	918.0
Cash, cash equivalents and restricted cash at beginning of period	367.5	1,279.1	361.1
Cash, cash equivalents and restricted cash at end of period	$ 822.6	$ 367.5	$ 1,279.1
Cash and cash equivalents at end of period	$ 790.9	$ 348.9	$ 1,260.9
Restricted cash included in other long-term assets at end of period	31.7	18.6	18.2
Cash, cash equivalents and restricted cash at end of period	$ 822.6	$ 367.5	$ 1,279.1
Supplemental Disclosures of Cash Flow Information:			
Cash paid for interest	$ 314.2	$ 309.7	$ 339.1
Cash paid for income taxes, net	30.7	12.4	73.4

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 (Deficit)	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Number	Par Value	Number	Amount				
Balance as of 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 as of 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 as of December 28, 2018	92.7	$ 18.5	9.4	$ (1,617.4)	$ 5,528.2	$ (1,017.7)	$ (24.3)	$ 2,887.3
Impact of accounting standard adoptions	—	—	—	—	—	(0.5)	0.5	—
Net loss	—	—	—	—	—	(996.5)	—	(996.5)
Currency translation	—	—	—	—	—	—	18.3	18.3
Change in derivatives, net of tax	—	—	—	—	—	—	1.8	1.8
Minimum pension liability, net of tax	—	—	—	—	—	—	(4.2)	(4.2)
Share options exercised	—	—	—	—	0.6	—	—	0.6
Vesting of restricted shares	0.8	0.2	0.2	(2.6)	(0.1)	—	—	(2.5)
Share-based compensation	—	—	—	—	33.8	—	—	33.8
Reissuance of Treasury shares	—	—	(0.2)	4.3	—	(2.2)	—	2.1
Balance at December 27, 2019	93.5	$ 18.7	9.4	$ (1,615.7)	$ 5,562.5	$ (2,016.9)	$ (7.9)	$ 1,940.7

See Notes to Consolidated Financial Statements.

1. Background and Basis of Presentation

Background

Mallinckrodt plc is a global business of multiple wholly owned subsidiaries (collectively, "Mallinckrodt" or "the Company") that develop, manufacture, market and distribute 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.

The Company operates in two reportable segments, which are further described below:

- *Specialty Brands* includes innovative specialty pharmaceutical brands; and
- *Specialty Generics* includes niche specialty generic drugs and active pharmaceutical ingredients "("API(s)").

The Company is incorporated in Ireland, with its principal executive offices located in the United Kingdom ("U.K."). The Company 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 50.0% 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.

During fiscal 2019, the Company experienced a change in its reportable segments, which primarily served to move the results related to Amitiza® (lubiprostone) ("Amitiza") to the Specialty Brands segment from the Specialty Generics segment. All prior period segment information has been recast to reflect the realignment of the Company's reportable segments on a comparable basis.

Certain prior-period amounts on the consolidated financial statements have been reclassified to conform to current-period presentation.

Fiscal Year

The Company reports its results based on a "52-53 week" year ending on the last Friday of December. Fiscal 2019, 2018 and 2017 each consisted of 52 weeks. Unless otherwise indicated, fiscal 2019, 2018 and 2017 refer to the Company's fiscal years ended December 27, 2019, December 28, 2018 and December 29, 2017, respectively.

2. 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 sale of the Company's 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 that 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 that 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, 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 have a term of 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 operations. 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

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 operations. 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.

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		
	2019	2018	2017
Shipping costs	$ 17.6	$ 12.8	$ 13.9

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.

From time to time, the Company has entered into licensing or collaborative agreements with third parties from time to time to develop a new drug candidate or intellectual property asset. These agreements may include R&D, marketing, promotion and selling activities to be performed by one or all parties involved. These collaborations generally include upfront, milestone and royalty or profit sharing payments contingent upon future events tied to the developmental and commercial success of the asset. In general, upfront and milestone payments made to third parties under these agreements are expensed as incurred up to the point of regulatory approval of the product. Milestone payments made to third parties upon 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) income ("AOCI"). From time to time, the Company has entered into derivative instruments to mitigate the exposure of movements in certain of these foreign currency transactions. Gains and losses resulting from foreign currency transactions are included in net (loss) income.

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 with 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 is stated at cost. Major renewals and improvements are capitalized, while routine maintenance and repairs are expensed as incurred. Depreciation for property, plant and equipment, 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.

Leases

The Company assesses all contracts at inception to determine whether a lease exists. The Company leases office space, manufacturing and warehousing facilities, equipment and vehicles, which are generally operating leases. Leases with an initial term of 12 months or less are not recorded on the consolidated balance sheet; the Company recognizes lease expense for these leases on a straight-line basis over the lease term. The Company has lease agreements with lease and non-lease components, which are accounted for separately. The Company's lease agreements generally do not contain variable lease payments or any material residual value guarantees.

Lease assets and liabilities are recognized based on the present value of the future minimum lease payments over the lease term as of the commencement date. As the Company's leases do not generally provide an implicit rate, the Company utilized its incremental borrowing rate based on the information available at commencement date in determining the present value of future lease payments. The Company used the incremental borrowing rate as of December 29, 2018 for leases that commenced prior to that date. Most leases include one or more options to terminate or renew, with renewal terms that can extend the lease term from one to five years. The exercise of lease renewal options is at the Company's sole discretion. Termination and renewal options are included within the lease assets and liabilities only to the extent they are reasonably certain. Refer to Note 3 for further information regarding the adoption of the lease accounting standard in fiscal 2019.

Acquisitions

Amounts paid for acquisitions that meet the criteria for business combination accounting 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 that 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.

Certain asset acquisitions or license agreements may not meet the criteria for a business combination. The Company accounts for these transactions as asset acquisitions and recognizes the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquired entity. Any initial up-front payments incurred in connection with the acquisition or licensing of IPR&D product candidates that do not meet the definition of a business are treated as R&D expense.

Goodwill and Other Intangible Assets

During fiscal 2018, the Company's annual goodwill impairment analysis resulted in the recognition of a full goodwill impairment of $3,672.8 million related to the Specialty Brands reporting unit. As a result, the Company did not have a goodwill balance during fiscal 2019. Prior to this full impairment, the Company tested goodwill on the first day of the fourth quarter of each year for impairment or whenever events or changes in circumstances indicated that the carrying value may not be recoverable. 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 estimated useful lives of the assets. The estimated useful lives of the Company's intangible assets as of December 27, 2019 were the following:

Completed technology	8	to	25 years
License agreements			30 years
Trademarks	22	to	30 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 asset group, with their carrying value. The fair value of the intangible asset, or asset group, is estimated using an income approach. If the fair value is less than the carrying value of the intangible asset, or asset group, 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 19. 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 the Company's Board of Directors 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 50.0% 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. Refer to Note 8 for further information regarding the classification of such amounts in the consolidated balance sheets.

3. Recently Issued Accounting Standards

Adopted

The Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2018-02, "Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income," in February 2018. This ASU allows for a reclassification from AOCI to retained earnings for the stranded tax effects arising from the change in the reduction of the U.S. federal statutory income tax rate from 35.0% to 21.0%. The Company adopted this

standard as of day 1 of fiscal 2019, which resulted in a reclassification between AOCI and retained deficit of $0.5 million and had no impact on the Company's results of operations or financial position.

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 statement of operations separately from the service cost component and outside a subtotal of income from operations, if one is presented. The Company adopted this standard as of day 1 of fiscal 2018 which required retroactive application resulting in the reclassification of the following:

	Fiscal Year
	2017
Cost of sales	$ 1.2
Selling, general and administrative expenses	71.2
Research and development expenses	0.4
Other income (expense), net	$ 72.8

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

The FASB issued ASU 2016-02, "Leases," in February 2016. This ASU 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. The FASB subsequently issued additional ASUs to clarify the guidance of ASU 2016-02 ("Topic 842"), as amended. The Company adopted this standard as of day 1 of fiscal 2019 utilizing the modified transition approach expedient which allows an entity to elect not to recast its comparative periods in the period of adoption. In addition, the Company elected to use the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed the Company to carry forward the historical lease classification. The Company also elected the hindsight practical expedient to determine the lease term for existing leases. Adoption of the new standard resulted in the recording of additional lease assets and corresponding liabilities of $83.1 million and $99.7 million, respectively, as of December 29, 2018. Refer to Note 12 for further details on the Company's leases.

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 standard in fiscal 2018, resulting in a $1.5 million increase to beginning retained earnings with an offsetting decrease to AOCI 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.

4. Revenue from Contracts with Customers

Product Sales Revenue

See Note 21 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
Provisions	2,347.3	22.2	68.2	2,437.7
Payments or credits	(2,405.8)	(27.8)	(72.1)	(2,505.7)
Balance as of December 27, 2019	$ 295.8	$ 28.4	$ 13.2	$ 337.4

Product sales transferred to customers at a point in time and over time were as follows:

	Fiscal Year	
	2019	2018
Product sales transferred at a point in time	81.8%	82.9%
Product sales transferred over time	18.2	17.1

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 were unsatisfied or partially unsatisfied as of December 27, 2019:

Fiscal 2020	$ 191.5
Fiscal 2021	95.5
Fiscal 2022	35.7
Thereafter	6.2

Costs to fulfill a contract

As of December 27, 2019 and 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 $26.5 million and $28.4 million, respectively, and was classified in property, plant and equipment, net, on the consolidated balance sheets. The associated depreciation expense recognized during fiscal 2019 and 2018 was $6.7 million and $7.4 million, respectively.

Product Royalty Revenues

As part of the Company's acquisition of Sucampo Pharmaceuticals, Inc. ("Sucampo") in fiscal 2018, as discussed in further detail in Note 6, 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 royalty rates consist of several tiers ranging from 18.0% to 26.0% with the royalty rate resetting every year. The associated royalty revenue recognized during both fiscal 2019 and 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 27, 2019	December 28, 2018
Accrued and other current liabilities	$ 5.6	$ 20.4
Other liabilities	0.6	15.1
Contract liabilities	$ 6.2	$ 35.5

Revenue recognized during fiscal 2019 and 2018 from amounts included in contract liabilities at the beginning of the period was approximately $13.7 million and $12.5 million inclusive of the Company's wholly owned subsidiary BioVectra Inc. ("BioVectra), prior to the completion of the sale of this business in November 2019.

5. Discontinued Operations and Divestitures

Discontinued Operations

Nuclear Imaging: In January 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. This business met the discontinued operations criteria and, accordingly, was included in discontinued operations for all periods presented.

The Company received a total of $9.0 million and $15.0 million in contingent consideration related to the sale of the Nuclear Imaging business during fiscal 2019 and 2018, respectively, consisting primarily of the issuance of $9.0 million par value non-voting preferred equity certificates in both fiscal 2019 and 2018, with an additional $6.0 million cash payment in fiscal 2018. 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 receipt of the preferred equity certificates are presented as a non-cash investing activity on the consolidated statements of cash flows for fiscal 2019 and 2018.

The following table summarizes the financial results of the Nuclear Imaging business as presented in the consolidated statement of operations, prior to the completion of the sale of this business in January 2017:

	Fiscal Year
Major line items constituting income from discontinued operations	**2017**
Net sales	$ 31.6
Cost of sales	15.6
Selling, general and administrative expenses	7.8
Other	(0.2)
Income from discontinued operations	8.4
Gain on disposal of discontinued operations	362.8
Income from discontinued operations, before income taxes	371.2
Income tax expense	5.2
Income from discontinued operations, net of tax	$ 366.0

The Company incurred $0.3 million of capital expenditures related to the Nuclear Imaging business that are included within the consolidated statement of cash flows for fiscal 2017.

Divestitures

The below businesses did not meet the criteria for discontinued operations classification and accordingly were included in continuing operations for all periods presented.

BioVectra: In November 2019, the Company completed the sale of its wholly owned subsidiary BioVectra to an affiliate of H.I.G. Capital for total consideration of up to $250.0 million, including an upfront payment of $135.0 million and contingent consideration of $115.0 million based on long-term performance of the business. During fiscal 2019, the Company recorded a loss on the sale of $33.5 million, which excluded any potential proceeds from future milestones, in the event they are achieved.

PreveLeak/Recothrom: In March 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 loss on the sale of $0.8 million, which excluded any potential proceeds from future milestones, in the event they are achieved and reflected a post-sale closing inventory adjustment of $13.7 million.

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 fiscal 2018, from the Specialty Brands segment, ascribed to the PreveLeak and Recothrom operations. The remaining items included in the calculation of the loss are primarily attributable to inventory transferred, contingent consideration transferred and transaction costs incurred by the Company.

Intrathecal Therapy: In March 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 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.

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 $2.1 million and

$3.1 million was included in accrued and other current liabilities on the consolidated balance sheets as of December 27, 2019 and December 28, 2018, respectively. The remaining items included in the gain calculation were attributable to inventory transferred and transaction costs incurred by the Company.

6. 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").

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. The issued convertible debt of $300.0 million had been converted and paid in full by the Company during fiscal 2018.

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

In September 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. The InfaCare Acquisition was funded with cash on hand.

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 [1]	Ocera [2]	InfaCare [3]
Acquisition Date	February 2018	December 2017	September 2017
Cash	$ 149.6	$ 1.0	$ 1.3
Accounts receivable	35.7	—	—
Inventory	153.2	—	—
Intangible assets	919.5	64.5	113.5
Goodwill (non-tax deductible) [4]	248.6	18.0	11.4
Other assets, current and non-current	25.8	0.4	0.1
Total assets acquired	1,532.4	83.9	126.3
Current liabilities	109.4	12.0	14.5
Other liabilities (non-current)	33.3	—	—
Deferred tax liabilities, net (non-current)	175.8	16.7	8.7
Contingent consideration (non-current)	—	12.8	35.0
Debt	366.3	—	30.0
Total liabilities assumed	684.8	41.5	88.2
Net assets acquired	$ 847.6	$ 42.4	$ 38.1

(1) During fiscal 2019, the Company recognized a full impairment of the IPR&D asset related to VTS-270 of $274.5 million. Refer to Note 13 for further information.

(2) 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.

(3) During fiscal 2019, the Company recognized a full impairment of the IPR&D asset related to stannsoporfin of $113.5 million. 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 13 and 21 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
Total consideration, net of cash	$ 698.0	$ 63.4	$ 71.8
Plus: cash assumed in acquisition	149.6	1.0	1.3
Total consideration	847.6	64.4	73.1
Less: non-cash contingent consideration	—	(22.0)	(35.0)
Net assets acquired	$ 847.6	$ 42.4	$ 38.1

(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 Brands
Sucampo	Completed technology - Other [1]	11.0	8 years	14.0	Specialty Brands
Sucampo	In-process research and development - VTS-270 [2]	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 [3]	113.5	Non-Amortizable	13.5	Specialty Brands

(1) During fiscal 2019, the intellectual property related to this intangible asset was sold, and therefore is no longer reflected in the Company's consolidated balance sheet as of December 27, 2019.

(2) During fiscal 2019, the Company recognized a full impairment of the IPR&D asset related to VTS-270 of $274.5 million.

(3) During fiscal 2019, the Company recognized a full impairment of the IPR&D asset related to stannsoporfin of $113.5 million.

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 U.S. 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 was not deductible for U.S. income tax purposes.

Financial Results - The amount of net sales and operating losses included in the Company's fiscal 2019 consolidated statement of operations related to the Sucampo Acquisition were $217.2 million and $210.6 million, respectively, as compared to $190.5 million and $369.1 million included in the Company's 2018 consolidated statement of operations, respectively. Included within the Sucampo operating results was the full impairment of the VTS-270 intangible asset in fiscal 2019 and a charge for the goodwill allocated to Sucampo at the time of acquisition as a result of the full goodwill impairment in fiscal 2018. Also included within the fiscal 2019 and 2018 results was $70.9 million and $62.9 million of amortization associated with intangibles recognized from this acquisition, respectively, and $10.0 million and $118.8 million of expense associated with fair value adjustments of acquired inventory, respectively. During fiscal 2019, 2018, and 2017, the Company in total recognized $10.0 million, $120.8 million, and $10.1 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	
Acquisition-related costs	**2018**	**2017**
Sucampo	$ 5.2	$ 4.2
Ocera	0.5	0.9
InfaCare	—	1.2
Other	0.1	0.1
Total acquisition-related costs	$ 5.8	$ 6.4

License Agreements

Silence Therapeutics

In July 2019, the Company entered into a license and collaboration agreement with Silence Therapeutics plc ("Silence") that will allow the companies to develop and commercialize ribonucleic acid interference ("RNAi") drug targets designed to inhibit the complement cascade, a group of proteins that are involved in the immune system and that play a role in the development of inflammation. These proteins are known to contribute to the pathogenesis of many diseases, including autoimmune disease. Under the terms of the agreement, the Company will obtain an exclusive worldwide license to Silence's C3 complement asset, SLN500, with options to license up to two additional complement-targeted assets in Silence's preclinical complement-directed RNAi development program. Silence will be responsible for preclinical activities, and for executing the development program of each asset until the end of Phase 1, after which the Company will assume clinical development and responsibility for global commercialization.

During fiscal 2019, the Company provided Silence an upfront payment of $20.0 million with cash on hand, which was recorded within R&D expense, and gained an exclusive worldwide license to Silence's C3 complement asset, SLN500, with options to license up to two additional complement-targeted assets in Silence's preclinical complement-directed RNAi development program. Silence is also eligible to receive up to $10.0 million in research milestones for SLN500, in addition to funding for Phase 1 clinical development including good manufacturing practices (GMP) manufacturing. Silence will be responsible for preclinical activities, and for executing the development program of SLN500 until the end of Phase 1, after which the Company will assume clinical development and responsibility for global commercialization. If approved, Silence could receive up to $563.0 million in commercial milestone payments and tiered low double-digit to high-teen royalties on net sales for SLN500.

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 have entered 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. 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 operations.

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 2019, 2018 and 2017, the Company paid royalties of $69.8 million, $76.9 million and $53.9 million, respectively, which were recorded within cost of sales on the consolidated statements of operations.

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 BioSynthema. 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 2019 and 2018, in relation to this agreement, the Company recognized royalty income of $39.0 million and $15.5 million, respectively, which was recognized within other income (expense), net in the consolidated statements of operations.

7. Restructuring and Related Charges

During fiscal 2018, 2016 and 2013, the Company launched restructuring programs designed to improve its cost structure. Charges of $100.0 million to $125.0 million were provided for under each program. Each program generally commences upon substantial completion of the previous program. In addition to the aforementioned restructuring programs, the Company has taken restructuring actions to generate synergies from its acquisitions.

Net restructuring and related charges by segment were as follows:

	Fiscal Year		
	2019	2018	2017
Specialty Brands	$ (13.7)	$ 54.6	$ 25.4
Specialty Generics	10.0	5.3	7.7
Corporate	2.0	48.3	3.3
Restructuring and related charges, net	(1.7)	108.2	36.4
Less: accelerated depreciation	—	(5.2)	(5.2)
Restructuring charges, net	$ (1.7)	$ 103.0	$ 31.2

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

	Fiscal Year		
	2019	2018	2017
2018 Program	$ 9.8	$ 5.2	$ —
2016 Program	(10.6)	71.6	36.2
2013 Program	—	—	(0.7)
Acquisition programs	(0.9)	31.4	0.9
Total programs	(1.7)	108.2	36.4
Less: non-cash charges, including accelerated depreciation	—	(5.2)	(5.2)
Total charges expected to be settled in cash	$ (1.7)	$ 103.0	$ 31.2

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 Program	2016 Program	2013 Program	Acquisition Programs	Total
Balance as of 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 as of 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 as of December 28, 2018	2.2	61.0	—	7.8	71.0
Charges from continuing operations	11.2	4.0	—	0.1	15.3
Changes in estimate from continuing operations	(1.4)	(14.6)	—	(1.0)	(17.0)
Cash payments	(9.3)	(13.1)	—	(2.4)	(24.8)
Reclassifications [1]	—	(5.0)	—	(4.3)	(9.3)
Currency translation	—	(1.0)	—	—	(1.0)
Balance as of December 27, 2019	$ 2.7	$ 31.3	$ —	$ 0.2	$ 34.2

(1) Represents the reclassification of lease liabilities, net to lease liabilities and lease assets, which are reflected within other liabilities and other assets on the consolidated balance sheet, due to the adoption of ASU 2016-02.

As of December 27, 2019, net restructuring and related charges incurred cumulative to date were as follows:

	2018 Program [1]	2016 Program	2013 Program
Specialty Brands	$ 3.0	$ 68.1	$ 18.8
Specialty Generics	10.0	14.6	18.3
Discontinued Operations	—	—	69.9
Corporate	2.0	28.9	17.7
	$ 15.0	$ 111.6	$ 124.7

(1) There is no specified time period associated with this restructuring program.

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 Program, consisting primarily of estimated contract termination costs related to the production of Raplixa. During fiscal 2019, the Company finalized the settlement of these contract termination costs.

All of the restructuring reserves were included in accrued and other current liabilities on the Company's consolidated balance sheets. Amounts paid in the future may differ from the amount currently recorded.

8. Income Taxes

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

	Fiscal Year		
	2019	2018	2017
U.K.	$ (75.3)	$ (233.7)	$ (165.9)
Non-U.K.	(1,516.2)	(3,818.3)	227.5
Total	$ (1,591.5)	$ (4,052.0)	$ 61.6

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

	Fiscal Year		
	2019	2018	2017
Current:			
U.K.	$ 0.1	$ (0.2)	$ 0.4
Non-U.K.	21.7	113.0	37.7
Current income tax provision	21.8	112.8	38.1
Deferred:			
U.K.	(1.1)	1.4	0.6
Non-U.K.	(605.0)	(544.3)	(1,748.3)
Deferred income tax benefit	(606.1)	(542.9)	(1,747.7)
Total	$ (584.3)	$ (430.1)	$ (1,709.6)

The fiscal 2019 U.K. current income tax provision reflects a tax benefit of $1.2 million from utilization of net operating loss carryforwards. The fiscal 2019 non-U.K. current income tax provision reflects a tax benefit of $0.9 million from utilization of net operating loss carryforwards.

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.

During fiscal years 2019, 2018, and 2017, net cash payments for income taxes was $30.7 million, $12.4 million, and $73.4 million.

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		
	2019	2018	2017
Provision (benefit) for income taxes at U.K. statutory income tax rate [1]	$ (302.4)	$ (770.1)	$ 11.7
Adjustments to reconcile to income tax provision:			
Rate difference between U.K. and non-U.K. jurisdictions [2]	(206.3)	(235.7)	(219.9)
Valuation allowances, nonrecurring [3]	61.7	—	(3.7)
Adjustments to accrued income tax liabilities and uncertain tax positions	(12.4)	60.1	5.1
Interest and penalties on accrued income tax liabilities and uncertain tax positions	(6.3)	13.1	0.2
Credits, principally research and orphan drug [4]	(13.5)	(25.9)	(13.8)
Impairments non deductible	—	788.7	—
Permanently nondeductible and nontaxable items [3]	98.1	7.2	6.4
Pension plan settlement, release of tax effects lodged in other comprehensive income	—	—	(2.4)
Divestitures [5]	9.6	(2.7)	18.2
U.S. Tax Reform [6]	—	(8.5)	(456.9)
Legal Entity Reorganization [7]	(212.8)	(256.0)	(1,054.8)
Other	—	(0.3)	0.3
Benefit for income taxes	$ (584.3)	$ (430.1)	$ (1,709.6)

(1) The statutory tax rate reflects the U.K. statutory tax rate of 19.0% for all periods presented.

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

(3) For fiscal 2019, the nonrecurring valuation allowances and permanently nondeductible and nontaxable item were primarily driven by the impact from the opioid-related litigation settlement charge. Refer to Note 24 for further discussion.

(4) During fiscal 2019 and 2018, the research and orphan drug credits decreased primarily as a result of the impact of the Tax Cut and Jobs Act of 2017 ("TCJA") and increased in conjunction with the Company's increased investment in qualified research, respectively.

(5) The Company completed the sale of its wholly owned subsidiary BioVectra in November 2019, a portion of its Hemostasis business during fiscal 2018 and the Intrathecal Therapy Business during fiscal 2017.

(6) 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 21.0%. 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 21.0%. Other line items, to the extent U.S. related, are reflected at the former U.S. statutory income tax rate of 35.0%.

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

The rate difference between U.K. and non-U.K. jurisdictions changed from $235.7 million of tax benefit to $206.3 million of tax benefit for fiscal 2018 to fiscal 2019, respectively. The $29.4 million decrease in the tax benefit included a $101.0 million decrease attributable to the non-restructuring impairment charges, a $45.8 million decrease attributable to changes in operating income, a $20.2 million decrease attributable to divestitures; partially offset by an increase of $76.7 million attributable to the gain on debt extinguishment and $60.9 million attributable to the opioid-related settlement charge.

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 divestitures; 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.

During fiscal 2019, the Company completed 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 $26.2 million and a deferred income tax benefit of $239.0 million with a corresponding reduction to net deferred tax liabilities. The reduction in net deferred tax liabilities was comprised of a decrease in interest-bearing deferred tax obligations which resulted in the elimination of the December 28, 2018 balance of $227.5 million, a $29.7 million increase in various other net deferred tax liabilities, a $28.7 million increase to a deferred tax asset related to excess interest carryforwards and a $12.5 million increase to a deferred tax asset related to tax loss and credit carryforwards net of valuation allowances. The elimination of the interest-bearing deferred tax obligation also eliminated the annual Internal Revenue Code section 453A interest expense. The reorganization involved the interpretation of multi-jurisdictional tax laws and regulations, supported by third party opinions. Interpretation of tax laws can be inherently uncertain and can be subject to potential challenges by the relevant tax authorities, both of which were considered in assessing its reserves for uncertain tax positions.

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

	Fiscal Year		
	2019	2018	2017
Balance at beginning of period	$ 287.7	$ 182.5	$ 118.7
Additions related to current year tax positions	123.5	19.6	79.9
Additions related to prior period tax positions	19.2	125.1	0.3
Reductions related to prior period tax positions	(5.7)	(32.7)	(13.6)
Settlements	(1.0)	(2.0)	—
Lapse of statute of limitations	(25.1)	(4.8)	(2.8)
Balance at end of period	$ 398.6	$ 287.7	$ 182.5

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

	December 27, 2019	December 28, 2018
Other assets	$ 204.7	$ —
Accrued and other current liabilities	—	1.0
Other income tax liabilities	193.9	189.9
Deferred income taxes (non-current liability)	—	96.8
	$ 398.6	$ 287.7

Included within total unrecognized tax benefits as of December 27, 2019, December 28, 2018, and December 29, 2017, were $395.9 million, $275.8 million, and $180.8 million, respectively, of unrecognized tax benefits, which if favorably settled would benefit the effective tax rate, of which up to $20.0 million in each year may be reported in discontinued operations. The remaining unrecognized tax benefits for each period would be offset by the write-off of related other tax assets, if recognized. During fiscal

2019, the Company recorded $14.4 million of additional interest through tax provision and decreased accrued interest and penalties by $18.6 million related to prior period reductions, settlements and lapse of statute of limitations. During fiscal 2018 and 2017, the Company had a net increase of interest and penalties activity of $30.0 million and a net interest and penalties activity of zero, respectively. The total amount of accrued interest and penalties related to uncertain tax positions was $32.9 million, $37.1 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 $99.5 million. Interest and penalties could decrease by up to $21.7 million.

Certain of the Company's subsidiaries continue to be subject to examination by the IRS for tax years as early as 2014. On August 5, 2019, the IRS proposed an adjustment to the taxable income of Mallinckrodt Hospital Products Inc. (“MHP”) (formerly known as Cadence Pharmaceuticals, Inc.) as a result of its findings in the audit of MHP's tax year ended September 26, 2014. The proposed adjustment to taxable income of $871.0 million, excluding potential associated interest and penalties, is proposed as a multi-year adjustment and may result in a non-cash reduction of the Company's U.S. Federal net operating loss carryforward of $782.0 million. The Company strongly disagrees with the proposed adjustment and intends to contest it through all available administrative and judicial remedies, which may take a number of years to conclude. See Note 19 for further details. 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.

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 27, 2019	December 28, 2018
Accrued and other current liabilities	$ 15.0	$ 25.0
Other income tax liabilities	227.1	228.0
	$ 242.1	$ 253.0

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

	December 27, 2019	December 28, 2018
Other assets	$ 3.1	$ 3.0
Prepaid expenses and other current assets	8.0	16.2
	$ 11.1	$ 19.2

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 asset (liability) at the end of each fiscal year were as follows:

	December 27, 2019	December 28, 2018
Deferred tax assets:		
Tax loss and credit carryforwards	$ 2,263.4	$ 1,987.8
Intangible assets	981.2	757.7
Opioid-related litigation settlement liability	273.7	—
Excess interest	81.5	71.4
Other	200.4	189.5
	3,800.2	3,006.4
Deferred tax liabilities:		
Intangible assets	(139.4)	(264.7)
Interest-bearing deferred tax obligations	—	(227.5)
Investment in partnership	(178.9)	(170.2)
Other	(46.3)	(42.9)
	(364.6)	(705.3)
Net deferred tax asset before valuation allowances	3,435.6	2,301.1
Valuation allowances	(3,131.5)	(2,604.9)
Net deferred tax assets (liability)	$ 304.1	$ (303.8)

The deferred tax asset valuation allowances of $3,131.5 million and $2,604.9 million as of December 27, 2019 and December 28, 2018, 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, intangible assets and the opioid-related settlement liability. 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 27, 2019	December 28, 2018
Other assets	$ 315.1	$ 20.5
Deferred income taxes (non-current liability)	(11.0)	(324.3)
Net deferred tax asset (liability)	$ 304.1	$ (303.8)

The net deferred tax liability decreased from $303.8 million as of December 28, 2018 to a non-current deferred tax asset of $304.1 million as of December 27, 2019, primarily due to $239.0 million of decreases associated with the deferred tax benefit recognized from a completed reorganization of its intercompany financing and associated legal entity ownership in response to the changing global tax environment, $211.9 million of decreases related to the opioid-related settlement charge, $69.0 million of decreases related to non-restructuring impairment charges, $37.8 million of decreases associated with the amortization of intangibles and $50.2 million of decreases predominately related to the generation of net operating losses and other operational activity.

The sale of BioVectra was completed in November 2019. This divestiture resulted in a net deferred tax liability decrease of $3.1 million. Significant components of this decrease includes a decrease of $2.7 million of deferred tax liability associated with fixed assets and $2.2 million of deferred tax liability associated with intangible assets, partially offset by an increase of $1.3 million associated with other deferred tax assets and $0.5 million of deferred tax assets associated with tax loss and credit carryforwards.

As of December 27, 2019, the Company had approximately $2,084.0 million of net operating loss carryforwards in certain non-U.K. jurisdictions measured at the applicable statutory rates, of which $1,378.2 million have no expiration and the remaining $705.8 million will expire in future years through 2040. The Company had $115.1 million of U.K. net operating loss carryforwards measured at the applicable statutory rates at December 27, 2019, which have no expiration date.

As of December 27, 2019, the Company also had $64.3 million of tax credits available to reduce future income taxes payable, primarily in jurisdictions within the U.S., of which $2.6 million have no expiration and the remainder will expire in future years through 2040.

As of December 27, 2019, the Company's financial reporting basis in international subsidiaries that may be subject to tax was in excess of its corresponding tax basis by $17.0 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 decrease, as compared to fiscal 2018, was attributable to the divestiture of BioVectra as well as income and losses attributed to current year activity. The Company has recorded a deferred tax liability of $7.6 million for amounts not considered to be indefinitely reinvested.

9. (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 is 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.

The weighted-average number of shares outstanding used in the computations of basic and diluted (loss) earnings per share were as follows (*in millions*):

	Fiscal Year		
	2019	2018	2017
Basic	83.9	84.0	97.7
Dilutive impact of restricted share units and share options	—	—	0.2
Diluted	83.9	84.0	97.9

The computation of diluted weighted-average shares outstanding for fiscal 2019, 2018 and 2017 excluded approximately 6.3 million, 3.3 million and 4.2 million, respectively, shares of equity award because the effect would have been anti-dilutive.

10. Inventories

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

	December 27, 2019	December 28, 2018
Raw materials	$ 62.7	$ 69.2
Work in process	166.5	167.6
Finished goods	82.9	85.5
Inventories	$ 312.1	$ 322.3

11. Property, Plant and Equipment

The gross carrying amount and accumulated depreciation of property, plant and equipment were comprised of the following at the end of each period:

	December 27, 2019	December 28, 2018
Land	$ 43.4	$ 43.9
Buildings	363.6	379.5
Capitalized software	142.2	130.8
Machinery and equipment	1,157.0	1,137.3
Construction in process	193.9	244.7
	1,900.1	1,936.2
Less: accumulated depreciation	(1,003.6)	(954.2)
Property, plant and equipment, net	$ 896.5	$ 982.0

Depreciation expense was as follows:

	Fiscal Year		
	2019	2018	2017
Depreciation expense	$ 97.7	$ 111.9	$ 113.8

12. Leases

Lease assets and liabilities related to the Company's operating leases are reported in the following consolidated balance sheet captions:

	December 27, 2019
Other assets	$ 83.5
Accrued and other current liabilities	$ 19.2
Other liabilities	70.2
Total lease liabilities	$ 89.4

Dependent on the nature of the leased asset, lease expense is included within cost of sales or SG&A. The primary components of lease expense were as follows:

	Fiscal Year 2019
Lease cost:	
Operating lease cost	$ 21.3
Short-term lease cost	3.5
Total lease cost	$ 24.8

Prior to the adoption of Topic 842, rental expense under facility, vehicle and equipment operating leases was $24.8 million and $30.4 million for fiscal 2018 and 2017, respectively.

Lease terms and discount rates were as follows:

	December 27, 2019
Weighted-average remaining lease term (in years) - operating lease	6.6
Weighted-average discount rate - operating leases	3.8%

Maturities of operating lease liabilities as of December 27, 2019 were as follows:

Fiscal 2020	$ 22.7
Fiscal 2021	17.9
Fiscal 2022	13.7
Fiscal 2023	12.1
Fiscal 2024	8.9
Thereafter	28.1
Total lease payments	103.4
Less: Interest	(14.0)
Present value of lease liabilities	$ 89.4

Other supplemental cash flow information related to leases were as follows:

	Fiscal Year 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 23.2
Lease assets obtained in exchange for lease obligations:	
Operating leases	7.3

13. Goodwill and Intangible Assets

2018 Goodwill Impairment Analysis

During fiscal 2018, the Company's annual goodwill impairment analysis resulted in the recognition of a full goodwill impairment of $3,672.8 million related to the Specialty Brands reporting unit. 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. At the time of this analysis there continued 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 determined that its share price had been adversely affected primarily by uncertainties regarding patient withdrawal issues impacting net sales of Acthar® Gel ("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 were not expected to be resolved in the near-term, the Company determined that its goodwill was fully impaired.

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.

Intangible Assets

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

	December 27, 2019		December 28, 2018	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortizable:				
Completed technology	$ 10,456.9	$ 3,822.8	$ 10,467.9	$ 2,980.6
License agreements	120.1	74.1	120.1	70.1
Trademarks	77.7	20.1	81.9	18.1
Customer relationships	—	—	27.5	14.1
Total	$ 10,654.7	$ 3,917.0	$ 10,697.4	$ 3,082.9
Non-Amortizable:				
Trademarks	$ 35.0		$ 35.0	
In-process research and development	245.3		633.3	
Total	$ 280.3		$ 668.3	

The Company recorded impairment charges totaling $388.0 million, $220.3 million and $63.7 million during fiscal 2019, 2018 and 2017, respectively. 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. During the three months ended December 27, 2019, the Company recognized a full impairment on its IPR&D asset related to VTS-270 of $274.5 million, primarily driven by continued regulatory challenges. The

Company will continue to engage in dialogue with the FDA and assess future opportunities for this development program. Also during the three months ended June 28, 2019, the Company recognized a full impairment on its IPR&D asset related to stannsoporfin of $113.5 million as the Company is no longer pursuing this development program. The fiscal 2018 and 2017 impairment charges primarily relate to the MNK-1411 and Raplixa intangible assets, respectively, and were a result of lower than previously anticipated pricing assumptions and commercial opportunities, respectively.

Ofirmev®

Since the Company's acquisition of Ofirmev in March 2014, the related completed technology intangible asset had been amortized using the straight-line method over a useful life of eight years. As the product nears loss of exclusivity, the Company is better positioned to reliably determine the pattern in which the remaining economic benefits of the intangible asset are consumed. As a result, during the three months ended March 29, 2019, the Company concluded that the sum of the years digits method, an accelerated method of amortization, would more accurately reflect the consumption of the economic benefits over the remaining useful life of the asset. This change in amortization method resulted in additional amortization expense of $107.3 million during fiscal 2019, which impacted basic earnings per share for the respective periods by $1.28 per share.

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

	Fiscal Year		
	2019	2018	2017
Amortization expense	$ 853.4	$ 740.2	$ 694.5

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

Fiscal 2020	$ 754.2
Fiscal 2021	657.6
Fiscal 2022	585.1
Fiscal 2023	581.1
Fiscal 2024	581.1

14. Debt

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

	December 27, 2019		December 28, 2018	
	Principal	Unamortized Discount and Debt Issuance Costs	Principal	Unamortized Discount and Debt Issuance Costs
Current maturities of long-term debt:				
4.875% senior notes due April 2020	$ 614.8	$ 0.6	$ —	$ —
Term loan due September 2024	15.6	0.2	16.4	0.2
Term loan due February 2025	4.1	0.1	6.0	0.1
Other	—	—	0.3	—
Total current debt	634.5	0.9	22.7	0.3
Long-term debt:				
4.875% senior notes due April 2020	—	—	700.0	3.2
Variable-rate receivable securitization due July 2020	—	—	250.0	0.4
9.50% debentures due May 2022	10.4	—	10.4	—
5.75% senior notes due August 2022	610.3	3.7	835.2	7.0
8.00% debentures due March 2023	4.4	—	4.4	—
4.75% senior notes due April 2023	133.7	0.8	500.2	3.5
5.625% senior notes due October 2023	514.7	4.4	731.4	8.0
Term loan due September 2024	1,505.2	15.5	1,597.4	19.8
Term loan due February 2025	399.5	6.1	591.0	10.7
5.50% senior notes due April 2025	387.2	3.6	692.1	7.7
10.00% senior notes due April 2025	322.9	9.9	—	—
Other	—	—	1.9	—
Revolving credit facility	900.0	3.1	220.0	4.5
Total long-term debt	4,788.3	47.1	6,134.0	64.8
Total debt	$ 5,422.8	$ 48.0	$ 6,156.7	$ 65.1

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 April 2023 Notes"). Mallinckrodt plc has fully and unconditionally guaranteed the April 2023 Notes on an unsecured and unsubordinated basis. The April 2023 Notes are subject to an indenture which contains covenants limiting the ability of MIFSA, its restricted subsidiaries (as defined in the April 2023 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 April 2023 Notes at any time, and some of the April 2023 Notes from time to time, at a redemption price equal to the principal amount of the April 2023 Notes redeemed plus a make-whole premium. The Company pays interest on the April 2023 Notes semiannually in arrears on April 15th and October 15th of each year, which commenced on October 15, 2013.

In August 2014, MIFSA and Mallinckrodt CB LLC ("MCB") ("the Issuers") issued $900.0 million aggregate principal amount of 5.75% senior unsecured notes due August 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 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 2025 Notes prior to April 15, 2020 by paying a “make-whole” premium. The Issuers may redeem some or all of the (i) 2020 Notes 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 “October 2023 Notes”). The October 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 October 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 October 2023 Notes and could cause a cross-default that could result in the acceleration of other indebtedness of the Company. The issuers may call some or all of the October 2023 Notes at specified redemption prices. The issuers may also redeem all, but not less than all, of the October 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 October 2023 Notes. The Issuers are obligated to offer to repurchase the October 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 October 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 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 operations. 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 2019, the Company made a $25.0 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 "Revolving Credit Facility"). The 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 27, 2019. Unused commitments on the Revolving Credit Facility are subject to an annual commitment fee, which was 0.275% as of December 27, 2019, and the fee applied to outstanding letters of credit is based on the interest rate applied to borrowings. The Revolving Credit Facility added certain wholly owned subsidiaries of the Company as borrowers, in addition to MIFSA and MCB.

The 2017 Term Loan and 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.

In July 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 PNC Bank, National Association, as administrative agent, and Mallinckrodt LLC, a wholly owned subsidiary of the Company, as initial servicer (the "Servicer"). Loans under the Receivable Securitization bore interest (including facility fees) at a rate equal to one month LIBOR rate plus a margin of 0.90%. In July 2019, the Company repaid $200.0 million of outstanding obligations. Upon payment in full of such outstanding obligations under the Receivable Securitization, the $250.0 million receivables securitization program was automatically terminated (including (i) the Receivable Securitization, (ii) the Amended and Restated Purchase and Sale Agreement,

dated as of July 28, 2017 (as amended, the "Purchase and Sale Agreement"), among certain wholly owned subsidiaries of the Company, the Servicer, and Mallinckrodt Securitization, (iii) the Sale Agreements (together, the "Sale Agreements"), between Mallinckrodt LLC and certain subsidiaries of the Company and (iv) all agreements and documents entered into in connection therewith, and all security interests, liens or other rights securing the receivables securitization program were automatically released and terminated. Certain indemnification and other obligations in the Receivable Securitization, the Purchase and Sale Agreement, the Sale Agreements and the documents related thereto, which by their terms expressly survive termination of such documents, will survive the termination of Mallinckrodt Securitization's receivables securitization program.

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 "2018 Term Loan"). 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. In February 2019, the Company made a $175.0 million prepayment on the term loan due February 2025. 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 December 2019, upon the terms and conditions set forth in a confidential offering memorandum dated November 5, 2019, the Issuers, completed private offers to exchange (the "2019 Exchange Offers") (i) $83.2 million of the 2020 Notes issued by the Issuers for $70.2 million of new 10.00% Second Lien Senior Secured Notes due April 2025 to be issued by the Issuers (the "2025 Notes") and (ii) $52.9 million of the 2022 Notes, $216.4 million of the April 2023 Notes, $144.7 million of the October 2023 Notes and $208.9 million of the 2025 Notes issued by the Issuers (collectively, and together with the 2020 Notes, the "Existing Notes") for $252.7 million of 2025 Notes. The 2025 Notes are subject to an indenture that contains customary covenants and events of default (subject in certain cases to customary grace and cure periods). The 2025 Notes are secured by a second lien security interest in all collateral that currently secures Mallinckrodt plc's senior secured notes, subject to certain exceptions. The 2025 Notes are guaranteed by each entity that currently guarantees Mallinckrodt plc's senior secured notes, subject to certain exceptions. The Issuers may redeem any or all of the 2025 Notes at any time at specified redemption prices. The Issuers are obligated to (a) offer to repurchase all of the 2025 Notes at a price of 101% of their principal amount plus accrued and unpaid interest, if any, upon the occurrence of certain change of control events and (b) offer to repurchase 2025 Notes with the net proceeds of certain asset sales at a price equal to 100% of their principal amount plus accrued and unpaid interest, if any. These obligations are subject to certain qualifications and exceptions.

The Company accounted for the 2019 Exchange Offers as a debt extinguishment, which resulted in the extinguishment of $383.2 million of principal of Existing Notes and the transfer of $322.9 million of Existing Notes to 2025 Notes. The exchanges also resulted in the capitalization of $10.1 million of deferred financing fees related to the 2025 Notes. In conjunction with the exchanges, the Company recorded a gain on debt extinguishment of $377.4 million primarily associated with retiring a portion of its Existing Notes at less than face value, net of the write-off of associated deferred financing fees of $4.9 million.

As of December 27, 2019, 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	4.85%	$ 1,520.8
Term loan due February 2025	4.91	403.6
Revolving credit facility	4.23	900.0

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

Fiscal 2020	$ 634.5
Fiscal 2021	19.7
Fiscal 2022	1,540.4
Fiscal 2023	672.5
Fiscal 2024	1,462.5

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.

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 27, 2019, U.S. plans represented 35.0% 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			Postretirement Benefits		
	Fiscal Year			Fiscal Year		
	2019	2018	2017	2019	2018	2017
Service cost	$ 0.1	$ 0.2	$ 1.4	$ —	$ —	$ —
Interest cost	0.7	0.6	2.3	1.6	1.5	1.7
Expected return on plan assets	—	—	(1.3)	—	—	—
Amortization of net actuarial loss	0.5	0.5	2.7	—	0.1	—
Amortization of prior service cost	0.2	0.1	0.2	(2.1)	(2.1)	(2.0)
Loss (gain) on plan settlements	—	0.1	71.1	—	(0.7)	(0.9)
Curtailment gain	—	—	(1.0)	—	—	—
Net periodic benefit cost (credit)	$ 1.5	$ 1.5	$ 75.4	$ (0.5)	$ (1.2)	$ (1.2)

The following table represents the changes in benefit obligations 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 27, 2019	December 28, 2018	December 27, 2019	December 28, 2018
Change in benefit obligations:				
Projected benefit obligations at beginning of year	$ 26.1	$ 27.8	$ 39.8	$ 45.6
Service cost	0.1	0.2	—	—
Interest cost	0.7	0.6	1.6	1.5
Actuarial loss (gain)	2.3	0.7	1.7	(3.9)
Benefits and administrative expenses paid	(1.7)	(1.6)	(2.6)	(2.7)
Plan settlements	(0.2)	(0.8)	—	(0.7)
Currency translation	(0.3)	(0.8)	—	—
Projected benefit obligations at end of year	$ 27.0	$ 26.1	$ 40.5	$ 39.8

The accumulated benefit obligation for pension plans with projected benefit obligations in excess of plan assets do not significantly differ from the amounts recognized on the consolidated balance sheet, as noted in the table above, since all of the Company's U.S. pension plans are frozen.

	Pension Benefits		Postretirement Benefits	
	December 27, 2019	December 28, 2018	December 27, 2019	December 28, 2018
Amounts recognized on the consolidated balance sheet:				
Current liabilities	$ (1.8)	$ (2.0)	$ (3.3)	$ (3.4)
Non-current liabilities	(25.2)	(24.1)	(37.2)	(36.4)
Net amount recognized on the consolidated balance sheet	$ (27.0)	$ (26.1)	$ (40.5)	$ (39.8)
Amounts recognized in accumulated other comprehensive loss consist of:				
Net actuarial (loss) gain	$ (10.1)	$ (8.4)	$ (0.8)	$ 0.9
Prior service (cost) credit	(0.2)	(0.4)	5.9	8.1
Net amount recognized in accumulated other comprehensive loss	$ (10.3)	$ (8.8)	$ 5.1	$ 9.0

The estimated amounts that will be amortized from accumulated other comprehensive loss into net periodic benefit cost (credit) in fiscal 2020 are as follows:

	Pension Benefits	Postretirement Benefits
Amortization of net actuarial loss	$ 0.7	$ —
Amortization of prior service cost (credit)	0.1	(2.1)

Actuarial Assumptions

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

	U.S. Plans			Non-U.S. Plans		
	Fiscal Year			Fiscal Year		
	2019	2018	2017	2019	2018	2017
Discount rate	4.0%	3.3%	3.0%	2.0%	1.9%	1.8%
Rate of compensation increase	—%	—%	—%	2.5%	2.5%	2.5%

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

	U.S. Plans			Non-U.S. Plans		
	Fiscal Year			Fiscal Year		
	2019	2018	2017	2019	2018	2017
Discount rate	2.8%	4.0%	3.3%	1.3%	2.0%	1.9%
Rate of compensation increase	—%	—%	—%	2.5%	2.5%	2.5%

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.

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

	Fiscal Year		
	2019	2018	2017
Net periodic benefit credit	4.1%	3.4%	3.7%
Benefit obligations	3.0%	4.1%	3.4%

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

	December 27, 2019	December 28, 2018
Healthcare cost trend rate assumed for next fiscal year	5.8%	6.3%
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

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 2019 and 2018, the Company made $1.9 million and $2.4 million in contributions, respectively, to the Company's pension plans.

Expected Future Benefit Payments

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

	Pension Benefits	Postretirement Benefits
Fiscal 2020	$ 1.8	$ 3.4
Fiscal 2021	1.7	3.2
Fiscal 2022	1.6	3.0
Fiscal 2023	1.6	2.9
Fiscal 2024	1.6	2.8
Fiscal 2025 - 2029	7.2	12.6

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 50.0% 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 $21.9 million, $25.3 million, and $25.2 million for fiscal 2019, 2018 and 2017, respectively.

Rabbi Trusts and Other Investments

The Company maintains several rabbi trusts, the assets of which are used to pay retirement benefits. The rabbi trust assets are subject to the claims of the Company's creditors in the event of the Company's insolvency. Plan participants are general creditors of the Company with respect to these benefits. The trusts primarily hold life insurance policies and debt and equity securities, the value of which is included in other assets on the consolidated balance sheets. Note 20 provides additional information regarding the debt and equity securities. During fiscal 2019, a portion of these policies were liquidated. The carrying value of the 62 and 118 life insurance contracts held by these trusts was $43.8 million and $58.4 million as of December 27, 2019 and December 28, 2018, respectively. These contracts had a total death benefit of $94.0 million and $142.9 million at December 27, 2019 and December 28, 2018, respectively. However, there are outstanding loans against the policies amounting to $23.6 million and $43.8 million at December 27, 2019 and December 28, 2018, respectively.

The Company has insurance contracts that serve as collateral for certain of the Company's non-U.S. pension plan benefits. These insurance contracts totaled $7.3 million and $8.0 million at December 27, 2019 and December 28, 2018, respectively. These amounts were 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 27, 2019. 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, as set forth below:

	March 2017 Repurchase Program [1]		March 2016 Repurchase Program	
	Number of Shares	Amount	Number of Shares	Amount
Authorized repurchase amount		$ 1,000.0		$ 350.0
Repurchases:				
Three months ended December 30, 2016 [2]	—	—	1,501,676	84.0
Fiscal 2017	13,490,448	380.6	5,366,741	266.0
Fiscal 2018	3,610,968	55.2	—	—
Fiscal 2019	—	—	—	—
Remaining amount available		$ 564.2		$ —

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

(2) On May 17, 2016, the Company's Board of Directors 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, 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").

The Company also repurchases shares from certain employees in order to satisfy employee tax withholding requirements in connection with the vesting of restricted shares. In addition, the Company repurchases shares to settle certain option exercises. The Company spent $2.6 million, zero and $5.1 million to acquire shares in connection with equity-based awards in fiscal 2019, 2018 and 2017, respectively.

Treasury Shares

During fiscal 2017, the Company canceled approximately 26.5 million treasury shares. Irish law requires a company's treasury share value to represent less than 10.0% 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 was $33.8 million, $34.6 million and $58.5 million for fiscal 2019, 2018 and 2017, respectively. These amounts are generally included within SG&A expenses in the consolidated statements of operations. The Company recognized a related tax benefit associated with this expense of $1.2 million, zero and $11.0 million in fiscal 2019, 2018 and 2017, 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

Over the years, the Company has adopted and amended its Mallinckrodt Pharmaceuticals Stock and Incentive Plan, 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 were 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 27, 2019, 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 was as follows:

	Share Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of 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 as of 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 as of December 28, 2018	7,007,051	38.74		
Granted	1,378,175	22.09		
Exercised	(45,324)	20.67		
Expired/Forfeited	(1,449,202)	34.80		
Outstanding as of December 27, 2019	6,890,700	36.39	1.6	$ —
Vested and non-vested expected to vest as of December 27, 2019	6,376,302	37.58	7.1	$ —
Exercisable as of December 27, 2019	3,349,227	49.80	1.2	—

As of December 27, 2019, there was $20.9 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 2019, 2018 and 2017, along with the weighted-average grant-date fair value, were as follows:

	Fiscal Year		
	2019	2018	2017
Expected share price volatility	45.8%	38.2%	36.0%
Risk-free interest rate	2.2%	2.6%	2.0%
Expected annual dividend per share	—%	—%	—%
Expected life of options (in years)	5.3	5.3	5.3
Fair value per option	$ 9.66	$ 5.32	$ 18.36

In fiscal 2019, 2018 and 2017, the total intrinsic value of options exercised was $0.3 million, $0.2 million and $1.4 million, respectively, and the related tax benefit was $0.1 million, $0.1 million and $0.5 million, respectively.

Restricted share units. Recipients of restricted share units ("RSUs") have no voting rights and receive dividend equivalent units that 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.

RSU activity was as follows:

	Shares	Weighted-Average Grant-Date Fair Value
Non-vested as of 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 as of 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 as of December 28, 2018	1,685,101	29.54
Granted	755,180	20.13
Exercised	(713,274)	35.29
Expired/Forfeited	(307,987)	24.81
Non-vested as of December 27, 2019	1,419,020	22.68

The total fair value of Mallinckrodt RSUs granted during fiscal 2019 was $15.2 million. The total vest date fair value of Mallinckrodt RSUs vested during fiscal 2019 was $25.2 million. As of December 27, 2019, there was $20.6 million of total unrecognized compensation cost related to non-vested RSUs granted, which is expected to be recognized over a weighted-average period of 2.3 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 0.0% to 200.0%, of the award granted.

PSU activity was as follows [1]:

	Shares	Weighted-Average Grant-Date Fair Value
Non-vested as of December 30, 2016	265,648	$ 88.51
Granted	348,963	51.73
Forfeited	(48,606)	107.00
Vested	(61,554)	62.65
Non-vested as of December 29, 2017	504,451	64.44
Granted	770,714	13.80
Forfeited	(89,614)	59.18
Vested	(24,022)	98.27
Non-vested as of December 28, 2018	1,161,529	28.61
Granted	448,363	32.46
Forfeited	(414,387)	30.54
Non-vested as of December 27, 2019	1,195,505	23.85

(1) The number of shares disclosed within this table are at the target number of 100.0%.

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		
	2019	2018	2017
Expected stock price volatility	55.2%	56.9%	47.5%
Peer group stock price volatility	41.3%	39.1%	39.9%
Correlation of returns	47.8%	2.1%	17.0%

The weighted-average grant-date fair value per share of PSUs granted during fiscal 2019 was $32.46. As of December 27, 2019, there was $10.5 million of unrecognized compensation cost related to PSUs, which is expected to be recognized over a weighted-average period of 1.8 years.

Restricted stock awards. Recipients of restricted stock awards ("RSAs") pertained solely to converted awards from Questcor, which were converted at identical terms to their original award. 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 as of December 30, 2016	14,868
Vested	(7,970)
Forfeited	(2,223)
Non-vested as of December 29, 2017	4,675
Vested	(3,970)
Forfeited	(705)
Non-vested as of December 28, 2018	—

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 15.0% 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 by utilizing treasury stock accumulated by the Company. The ESPP was suspended effective June 30, 2019 and remains unavailable as of December 27, 2019.

18. 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 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 resolutions 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 27, 2019 and December 28, 2018 was $15.0 million and $14.6 million, respectively, of which $12.3 million and $11.8 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 27, 2019 and December 28, 2018. As of December 27, 2019, 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 $18.9 million and $18.6 million remained in restricted cash, included in other long-term assets on the consolidated balance sheets at December 27, 2019 and December 28, 2018, respectively.

The Company has recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 19.

The Company is also liable for product performance; however the Company believes, given the information currently available, that the ultimate resolution of any such claims will not have a material adverse effect on its financial condition, results of operations and cash flows.

As of December 27, 2019, the Company had various other letters of credit, guarantees and surety bonds totaling $35.2 million and restricted cash of $12.8 million held in segregated accounts primarily to collateralize surety bonds for the Company's environmental liabilities.

19. Commitments and Contingencies

The Company has purchase obligations related to commitments to purchase certain goods and services. At December 27, 2019, such obligations were as follows:

Fiscal 2020	$	63.4
Fiscal 2021		1.7
Fiscal 2022		1.7
Fiscal 2023		1.7
Fiscal 2024		1.6

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, a territory, other governmental persons or entities and private plaintiffs have filed lawsuits against certain entities of the Company, 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 25, 2020, the cases the Company is aware of include, but are not limited to, approximately 2,496 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 253 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers; approximately 110 cases filed by individuals; approximately six cases filed by schools and school boards; and 17 cases filed by the Attorneys General for New Mexico, Kentucky, Rhode Island, Georgia, Florida, Alaska, New York, Nevada, South Dakota, New Hampshire, Louisiana, Illinois, Mississippi, West Virginia, Puerto Rico, Ohio, and Idaho, with Idaho being the only state Attorney General to file in federal as opposed to state court. As of February 25, 2020, the Mallinckrodt defendants in these cases consist of Mallinckrodt plc and the following subsidiaries of Mallinckrodt plc: Mallinckrodt Enterprises LLC, Mallinckrodt LLC, SpecGx LLC, Mallinckrodt Brand Pharmaceuticals Inc., Mallinckrodt Inc., MNK 2011 Inc., and Mallinckrodt Enterprises Holdings, Inc. On November 22, 2019, the Delaware Attorney General filed a motion in the Superior Court of the State of Delaware to amend its complaint to add certain entities of the Company, which the Court granted on December 18, 2019. The Delaware Attorney General has not yet filed its amended complaint. The Hawaii Attorney General filed a complaint against the Company on June 3, 2019. On December 27, 2019, the First Circuit Court entered a written order dismissing the Hawaii Attorney General's claims against all defendants without prejudice, finding that the allegations in the State's complaint failed to give notice of the claims against the defendants. Certain of the lawsuits have been filed as putative class actions.

Most pending federal 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, setting pre-trial deadlines and setting a trial date on October 21, 2019 for two cases originally filed in the Northern District of Ohio by Summit County and Cuyahoga County against opioid manufacturers, distributors, and pharmacies ("Track 1 Cases"). The counties claimed that opioid manufacturers' marketing activities changed the medical standard of care for treating both chronic and acute pain, which led to increases in the sales of their prescription opioid products. They also alleged that opioid manufacturers' and distributors' failure to maintain effective controls against diversion was a substantial cause of the opioid crisis. On September 30, 2019, the Company announced that Mallinckrodt plc, along with its wholly owned subsidiaries Mallinckrodt LLC and SpecGx LLC, had executed a definitive settlement agreement and release with Cuyahoga and Summit Counties in Ohio. The settlement fully resolves the Track 1 cases against all named Mallinckrodt entities that were scheduled to go to trial in October 2019 in the MDL. Under the agreement, the Company paid $24.0 million in cash on October 1, 2019. In addition, the Company will provide $6.0 million in generic products, including addiction treatment products, and will also provide a $0.5 million payment in two years in recognition of the counties' time and expenses. Further in the event of a comprehensive resolution of government-related opioid claims, the Company has agreed that the two plaintiff counties will receive the value they would have received under such a resolution, less the payments described above. All named Mallinckrodt entities were dismissed with prejudice from the lawsuit. The value of the settlement should not be extrapolated to any other opioid-related cases or claims. On October 21, 2019, the MDL court issued a Stipulated Dismissal Order dismissing the claims against the remaining manufacturers and distributors pursuant to a settlement agreement, and severing the claims against the remaining pharmacy defendant to be heard in a subsequent trial. Judge Polster issued Suggestions of Remand for City and County of San Francisco, California and City of Chicago, Illinois. Additionally, all manufacturer defendants, including us, were severed from the “Track Two” MDL cases, City of Huntington and Cabell County Commission, West Virginia. Those cases have subsequently been remanded to the Southern District of West Virginia.

Other lawsuits remain pending in various state courts. In some jurisdictions, such as Arizona, California, Connecticut, Illinois, Massachusetts, New York, Pennsylvania, South Carolina, Texas, Utah and West Virginia, certain of the 234 state lawsuits have been consolidated or coordinated for pre-trial 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, negligence, negligent misrepresentation, 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 diversion.

Subsequent to December 27, 2019, the Company announced an agreement in principle on the terms of a global settlement of all opioid-related claims against the Company and its subsidiaries. See Note 24 for further information.

In addition to the lawsuits described above, certain entities of the Company have received subpoenas and civil investigative demands ("CID(s)") for information concerning the sale, marketing and/or distribution of prescription opioid medications and the Company's suspicious order monitoring programs, including from the U.S. Department of Justice ("DOJ") and the Attorneys General for Missouri, New Hampshire, Kentucky, Washington, Alaska, South Carolina, Puerto Rico, New York, West Virginia, Indiana, the Divisions of Consumer Protection and Occupational and Professional Licensing of the Utah Department of Commerce, and the New York State Department of Financial Services. The Company has been contacted by the coalition of State Attorneys General investigating the role manufacturers and distributors may have had in contributing to the increased use of opioids in the U.S. 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. On April 17, 2019, the Company received a grand jury subpoena from the USAO for the Eastern District of New York ("EDNY") for documents related to the sales and marketing of controlled substances, the policies and procedures regarding controlled substances, and other related documents. On June 4, 2019, the Company received a rider from the USAO for EDNY requesting additional documents regarding the Company's anti-diversion program. The Company is responding or has responded to these subpoenas, CIDs and any informal requests for documents.

In August 2018, the Company received a letter from the leaders of the Energy and Commerce Committee in the U.S. House of Representatives requesting a range of documents relating to its marketing and distribution of opioids. The Company completed its response to this letter in December 2018. The Company received a follow-up letter in January 2020 and provided the committee a response. The Company is cooperating with the investigation.

The Attorneys General for Kentucky, Alaska, New York, New Hampshire, West Virginia and Puerto Rico have subsequently filed lawsuits against the Company. Similar subpoenas and investigations may be brought by others or the foregoing matters may be expanded or result in litigation. Since these investigations and/or lawsuits are in early stages, the Company is 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 U.S. 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 appeal has been fully briefed and argued before the Second Circuit, and the parties are awaiting a decision. In April 2019, the State of New York passed its 2020 budget, which amended the OSA so that if the OSA decision is reversed on appeal, the OSA would apply only to the sale or distribution of certain opioids in New York for 2017 and 2018 and, effective July 1, 2019, imposed an excise tax on certain opioids.

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

SEC Subpoena. In August 2019, the Company received a subpoena from the U.S. Securities and Exchange Commission ("SEC") for documents related to the Company's disclosure of its dispute with the U.S. Department of Health and Human Services ("HHS") and Centers for Medicare & Medicaid Services ("CMS" and together with HHS, the "Agency") concerning the base date average manufacturer price ("AMP") under the Medicaid Drug Rebate Program for Mallinckrodt's Acthar® Gel (repository corticotropin injection) ("Acthar Gel"), which is now the subject of litigation between the Company and the Agency (see *Medicaid Lawsuit* below). The Company is cooperating with the SEC's investigation.

Medicaid Lawsuit. In May 2019, the Company filed a lawsuit under the Administrative Procedure Act ("APA") in federal district court for the District of Columbia against the Agency. The dispute involves the base date AMP under the Medicaid Drug Rebate Program for Acthar Gel. A drug's "base date AMP" is used to calculate the Medicaid rebate amount payable by the drug's manufacturer to state Medicaid agencies when the drug is prescribed to Medicaid beneficiaries. At issue in the lawsuit is whether FDA's 2010 approval of a new drug application for use of Acthar Gel in treating infantile spasms rendered Acthar Gel eligible for a new base date AMP, as indicated by CMS's written communications in 2012. In May 2019, CMS indicated that if the Company failed to revert to use of the original base date AMP in its calculation of Acthar Medicaid rebates, CMS would identify the Company as being out of compliance with its Medicaid Drug Rebate Program reporting requirements, among other potential actions, triggering certain negative consequences. As such, the Company filed a lawsuit alleging (i) that CMS has violated the Medicaid drug rebate statute, (ii) that CMS has violated its own regulations defining "single source drug," (iii) that CMS has failed to adequately explain its change in position based on two letters that CMS sent Questcor Pharmaceuticals Inc. ("Questcor") in 2012 regarding the base date AMP for Acthar Gel, (iv) that CMS failed to give the Company fair notice of its latest position, and (v) that CMS should be prohibited from applying its new position retroactively. The court held a hearing regarding this matter on August 2, 2019 and the court took the matter under advisement. While the Company believes that its lawsuit has strong factual and legal bases, as of December 27, 2019, the potential for retroactive non-recurring charges could range from zero to approximately $630.0 million.

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 for documents related to alleged payments to healthcare providers in Florida and whether those payments violated the Anti-Kickback Statute. The Company is cooperating with the investigation.

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 Acthar Gel and related matters. The Company is cooperating with the Committee's 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 cooperating 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 intends to cooperate 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 payments to charitable foundations, the provision of financial and other support by charitable foundations to patients receiving Acthar Gel, and related matters. The Company responded to these requests and continues to cooperate 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 operations.

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 Application ("ANDA") for Methylphenidate ER. On October 21, 2016, the U.S. 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.

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 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 Acthar Gel. Questcor subsequently was 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 pertaining to Acthar Gel. The current investigation also relates to Questcor's provision of financial and other support to patients, including through charitable foundations and related matters. On March 9, 2015, the Company received a "No Action" letter from the SEC regarding its review of the Company's promotional practices related to Acthar Gel. On or about March 8, 2019, the U.S. District Court for the Eastern District of Pennsylvania unsealed two *qui tam* actions involving the allegations under investigation by the USAO for the Eastern District of Pennsylvania. The DOJ intervened in both actions, which were later consolidated. In September 2019, the Company executed a settlement agreement with the DOJ for $15.4 million and finalized settlements with the three *qui tam* plaintiffs. These settlements were paid during the three months ended September 27, 2019 and resolve the portion of the investigation and litigation involving Questcor's promotional practices related to Acthar Gel.

On or about June 4, 2019, the DOJ filed its Complaint in Intervention in the litigation, alleging claims under the federal False Claim Act based on Questcor's relationship with and donations to an independent charitable patient co-pay foundation. The Company disagrees with the DOJ's characterization of the facts and applicable law. On January 22, 2020, the court denied the Company's motion to dismiss the Complaint in Intervention. The Company intends to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit.

Patent Litigation

Amitiza Patent Litigation: Zydus Pharmaceuticals (USA) Inc. In January 2020, Sucampo GmbH, Sucampo Pharmaceuticals, Inc., Sucampo Pharma Americas LLC 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 Zydus Pharmaceuticals (USA) Inc. (“Zydus”) alleging that Zydus infringed U.S. Patent Nos. 7,795,312, 8,026,393, 8,338,639, 8,748,481 and 8,779,187 following receipt of a December 2019 notice from Zydus 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: 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 nitric oxide drug product delivery system. 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 its nitric oxide drug product delivery system. The infringement claims in the second suit were 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 added to the FDA Orange Book that was submitted by Praxair regarding its ANDA for its nitric oxide drug product delivery system.

Trial for 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 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. The appeal decision, issued on August 27, 2019, substantively affirmed the District Court decision with respect to the invalidity of the heart failure (HF) patents and the non-infringement of the delivery system infrared (DSIR) patents. The Company filed a petition for en banc review at the Federal Circuit on September 26, 2019, which the Federal Circuit denied on November 19, 2019. There has been limited commercial launch activity by Praxair. The Company intends to continue its efforts 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. An adverse final outcome in the appeal of the Praxair litigation decision (or a broad at-risk launch by Praxair prior to the final appellate decision) could result in the broader-scale 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: Altan Pharma Ltd. In March 2019, Mallinckrodt Hospital Products Inc. and Mallinckrodt Hospital Products IP Limited, both subsidiaries of the Company, and New Pharmatop LP, the current owner of the U.S. patents licensed exclusively by the Company, filed suit in the U.S. District Court for the District of Delaware against Altan Pharma Ltd. ("Altan") alleging that Altan infringed U.S. Patent No. 6,992,218, U.S. Patent No. 9,399,012, U.S. Patent No. 9,610,265 and U.S. Patent No. 9,987,238 following receipt of a February 2019 notice from Altan concerning its submission of a new drug application, containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev. On August 29, 2019, the parties entered into a settlement agreement under which Altan was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its New Drug Application (NDA) on or after December 6, 2020, or earlier under certain circumstances.

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.

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, 2019, 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.

Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV v. Pharmascience Inc. and SpecGx LLC. In December 2019, Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV (collectively “Janssen”) filed suit in the U.S. District Courts for the Districts of New Jersey and Delaware against the Company and Pharmascience Inc. (“Pharmascience”) relating to the collaboration between Company and Pharmascience that resulted in Pharmascience's ANDA submission, containing a Paragraph IV patent certification, with the FDA for a competing version of Invega Sustenna. Janssen alleges that the Company and Pharmascience infringe U.S. Patent No. 9,439,906. The Company intends to vigorously defend its position.

Commercial and Securities Litigation

City of Marietta Litigation. On February 6, 2020, the City of Marietta, Georgia filed a putative civil class action complaint against the Company in the U.S. District Court for the Northern District of Georgia relating to the price of Acthar Gel. The complaint, which pleads one claim for unjust enrichment, purports to be brought on behalf of third-party payers and their beneficiaries and people without insurance in the United States and its Territories that paid for Acthar from four years prior to the filing of the Complaint until the date of trial. The case is captioned *City of Marietta v. Mallinckrodt ARC LLC*. Marietta alleges that it has paid $2.0 million to cover the cost of an Acthar Gel prescription of an employee and that the Company has been unjustly enriched as a result. The Company intends to vigorously defend itself in this matter.

Shareholder Derivative Litigation (Brandhorst). In September 2019, a purported shareholder of the Company's stock filed a shareholder derivative complaint in the United States District Court for the District of Columbia against the Company, as nominal defendant, as well as its Chief Executive Officer ("CEO") Mark Trudeau, its former Chief Financial Officer ("CFO") Matthew K. Harbaugh, its Executive Vice President Hugh O'Neill, and the following members of the Company's Board of Directors: Angus Russell, David Carlucci, J. Martin Carroll, David Norton, JoAnn Reed and Kneeland Youngblood (collectively with Trudeau,

Harbaugh and O'Neill, the "Individual Defendants"). The lawsuit is captioned *Lynn Brandhorst, derivatively on behalf of nominal defendant Mallinckrodt PLC v. Mark Trudeau et al.* and relies on the allegations from the putative class action securities litigation that was filed against the Company and certain of its officers in January 2017, captioned *Patricia A. Shenk v. Mallinckrodt plc, et al*. described further below. The complaint asserts claims for contribution, breaches of fiduciary duty, unjust enrichment, abuse of control, and gross mismanagement, and is premised on allegations that the Individual Defendants caused the Company to make the allegedly false or misleading statements at issue in the *Shenk* lawsuit. The complaint seeks damages in an unspecified amount and corporate governance reforms. On November 20, 2019, this matter was stayed by agreement of the parties pending resolution of the *Shenk* lawsuit below. The Company and the Individual Defendants intend to vigorously defend themselves in this matter.

Humana Litigation. In August 2019, Humana Inc. filed a lawsuit against the Company in the U.S. District Court for the Central District of California alleging violations of federal and state antitrust laws; racketeering ("RICO") violations under 18 U.S.C. § 1962(c); conspiracy to violate RICO under 18 U.S.C. § 1962(d); violations of state unfair competition, consumer fraud and deceptive trade practice laws; state insurance fraud; tortious interference with contract; and unjust enrichment related to the pricing of Acthar Gel. Humana alleges that it paid more than $700.0 million for Acthar Gel and seeks undisclosed damages from 2011 through present. The case alleges similar facts as those alleged in the *MSP* and *Rockford* matters below, and includes references to allegations at issue in a pending *qui tam* action against the Company in the U.S. District Court for the Eastern District of Pennsylvania (see *Questcor Subpoena* above) and is proceeding as *Humana Inc. v. Mallinckrodt ARD LLC*. The Company intends to vigorously defend itself in this matter, and on October 28, 2019, moved to dismiss the complaint. The Company's motion to dismiss remains pending.

Putative Class Action Securities Litigation (Strougo). In July 2019, a putative class action lawsuit was filed against the Company, its CEO Mark Trudeau, its CFO Bryan M. Reasons, its former Interim CFO George A. Kegler and its former CFO Matthew K. Harbaugh, in the U.S. District Court for the Southern District of New York, captioned *Barbara Strougo v. Mallinckrodt plc, et al*. The complaint purports to be brought on behalf of all persons who purchased or otherwise acquired Mallinckrodt's securities between February 28, 2018 and July 16, 2019. The lawsuit generally alleges that the defendants made false and misleading statements in violation of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder related to the Company's clinical study designed to assess the efficacy and safety of its Acthar Gel in patients with amyotrophic lateral sclerosis. The lawsuit seeks monetary damages in an unspecified amount. The Company intends to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit.

Putative Class Action Litigation - Steamfitters Local Union No. 420. In July, 2019, Steamfitters Local Union No. 420 filed a putative class action lawsuit against the Company and United BioSource Corporation in the U.S. District Court for the Eastern District of Pennsylvania, proceeding as *Steamfitters Local Union No. 420 v. Mallinckrodt ARD, LLC et al.* The complaint makes similar allegations as those alleged in related state and federal actions that were filed by the same plaintiff's law firm in Illinois, Pennsylvania, Tennessee and Maryland (now dismissed; see *WCBE* below), and includes references to allegations at issue in a pending qui tam actions against the Company in the U.S. District Court for the Eastern District of Pennsylvania (see *Questcor Subpoena* above). In particular, the complaint alleges RICO violations under 18 U.S.C. § 1962(c); conspiracy to violate RICO under 18 U.S.C. § 1962(c); violations of the Pennsylvania (and other states) Unfair Trade Practices and Consumer Protection laws; negligent misrepresentation; aiding and abetting/conspiracy; and unjust enrichment. The complaint also seeks declaratory and injunctive relief. On December 19, 2019, the court denied the Company's motion to dismiss the complaint. The Company intends to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit.

Acument Global. In May 2019, Acument Global Technologies, Inc., filed a non-class complaint against the Company and other defendants in Tennessee state court alleging violations of Tennessee Consumer Protection Laws, unjust enrichment, fraud and conspiracy to defraud. The case alleges similar facts as those alleged in the *MSP* and *Rockford* matters below, and is captioned *Acument Global Technologies, Inc., v. Mallinckrodt ARD Inc., et al.* The Company intends to vigorously defend itself in this matter, and on July 29, 2019, moved to dismiss the complaint. The Company's motion to dismiss remains pending.

Washington County Board of Education ("WCBE"). In May 2019, WCBE filed a non-class complaint against the Company and other defendants in Maryland state court alleging violations of Maryland Consumer Protection Act, negligent misrepresentation, fraud, unjust enrichment and conspiracy to defraud. The case, which was removed to the U.S. District Court for the District of Maryland on June 24, 2019, alleges similar facts as those alleged in the *MSP* and *Rockford* matters discussed below. On January 4, 2020, the court dismissed the complaint.

Local 542. In May 2018, the International Union of Operating Engineers Local 542 filed a non-class complaint against the Company and other defendants in Pennsylvania state court alleging improper pricing and distribution of Acthar Gel, in violation of Pennsylvania's Unfair Trade Practices and Consumer Protection Law, aiding and abetting, unjust enrichment and negligent misrepresentation. The case alleges similar facts as the *MSP* and *Rockford* matters below, and is captioned *Int'l Union of Operating Engineers Local 542 v. Mallinckrodt ARD Inc., et al.* Plaintiff filed an amended complaint on August 27, 2018, the Company's objections to which were denied by the court. The Company intends to continue to vigorously defend itself in this matter. On January 22, 2020, the court stayed further proceedings in this case given the overlap with the *Rockford* and *MSP* cases discussed below.

Grifols. In March 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. During 2019, the Company entered into a settlement for this matter and appropriate reserves were recorded.

Putative Class Action Litigation (MSP). In October 2017, a putative class action lawsuit was filed against the Company and United BioSource Corporation in the U.S. District Court for the Central District of California. Pursuant to a motion filed by the defendants, the case was transferred to the U.S. District Court for the Northern District of Illinois in January 2018, and is currently proceeding as *MSP Recovery Claims, Series II, LLC, et al. v. Mallinckrodt ARD, Inc., et al.* The Company filed a motion to dismiss on February 23, 2018, which was granted on January 25, 2019 with leave to amend. MSP filed the operative First Amended Class Action Complaint on April 10, 2019, in which it asserts claims under federal and state antitrust laws and state consumer protection laws and names additional defendants. 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 ("Synacthen") and reaching anti-competitive agreements with the other defendants by selling Acthar Gel through an exclusive distribution network. The complaint purports to be brought on behalf of all third-party payers, or their assignees, in the U.S. and its territories, who have, as indirect purchasers, in whole or in part, paid for, provided reimbursement for, and/or possess the recovery rights to reimbursement for the indirect purchase of Acthar Gel from August 1, 2007 to present. The Company moved to dismiss the First Amended Class Action Complaint on May 24, 2019. The Company's motion to dismiss remains pending.

Employee Stock Purchase Plan (ESPP) Securities Litigation. In July 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 CEO Mark C. Trudeau, its former CFO Matthew K. Harbaugh, 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 *Shenk* lawsuit below. 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* lawsuit below.

Putative Class Action Litigation (Rockford). In April 2017, a putative class action lawsuit was filed against the Company and United BioSource Corporation 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 to, among other things, 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 Acthar Gel from August 2007 to the present. Plaintiff alleges violations of federal antitrust and RICO laws, as well as various state law claims in connection with the distribution and sale of Acthar Gel. On January 22, 2018, the Company filed a motion to dismiss the Second Amended Complaint, which was granted in part on January 25, 2019, dismissing one of two named plaintiffs and all claims with the exception of Plaintiff's federal and state antitrust claims. The remaining allegation in the case is that the Company engaged in anti-competitive acts to artificially raise and maintain the price of Acthar Gel. To this end, Plaintiff alleges that the Company unlawfully maintained a monopoly in a purported ACTH product market by acquiring the U.S. rights to Synacthen and conspired with the other named defendants by selling Acthar Gel through an exclusive distributor. The Company intends to continue to vigorously defend itself in this matter. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit.

Putative Class Action Securities Litigation (Shenk). In January 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 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 Acthar Gel revenues, and the exposure of 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, its CEO and former 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 Acthar Gel. On August 30, 2018, the lead plaintiff voluntarily dismissed the claims against Mr. O'Neill without prejudice. The Company filed a motion to dismiss the complaint which was granted in part, and denied in part by the court on July 30, 2019. The Company intends to vigorously defend itself in this matter.

Generic Price Fixing Litigation

Generic Pharmaceutical Antitrust MDL. In August 2016, a multidistrict litigation was established in the Eastern District of Pennsylvania relating to allegations of antitrust violations with respect to generic pharmaceutical pricing (the "Generic Pricing MDL"). Plaintiffs in the Generic Pricing MDL, captioned *In re: Generic Pharmaceuticals Pricing Antitrust Litigation*, allege a conspiracy of price-fixing and customer allocation among generic drug manufacturers beginning in or around July 2009. Since its establishment, the Generic Pricing MDL has expanded to encompass dozens of pharmaceutical companies and more than 100 generic pharmaceutical drugs. The Company was recently named in three cases associated with this litigation. A status conference is due to be held on March 12, 2020.

1199SEIU National Benefit Fund Litigation. In December 2019, a putative class action lawsuit was filed against the Company and more than thirty other pharmaceutical manufacturers in the U.S. District Court for the Eastern District of Pennsylvania, captioned *1199SEIU National Benefit Fund et al. v. Actavis Holdco U.S., Inc., et al.* The complaint purports to be brought on behalf of all persons and entities that indirectly purchased, paid, or provided reimbursement for the purchase of defendants' generic drugs, other than for resale, from July 1, 2009, to the present. The lawsuit generally alleges that defendants conspired to allocate customers and fix prices for generic pharmaceutical drugs beginning in July 2009. The complaint seeks monetary damages and injunctive relief based on violations of Sections 1 and 3 of the Sherman Act and various state antitrust, consumer protection, and unjust enrichment claims. The Company intends to vigorously defend itself in this matter.

César Castillo, Inc., Litigation. In February 2020, a putative class action lawsuit was filed against the Company and more than thirty other pharmaceutical manufacturers in the U.S. District Court for the Eastern District of Pennsylvania, captioned *César Castillo, Inc., et al. v. Actavis Holdco U.S., Inc., et al.* The lawsuit purports to be brought on behalf of all persons or entities that directly purchased certain generic drugs from defendants or from one of defendants' direct customers-where the direct customer is alleged to be a completely involved co-conspirator-between July 1, 2009, and the present. The complaint has similar allegations as the *1199SEIU National Benefit Fund* litigation and seeks damages for violations of Sections 1 and 3 of the Sherman Act. The Company intends to vigorously defend itself in this matter.

The Kroger Co. Litigation. In February 2020, a proposed amended complaint filed in the U.S. District Court for the Eastern District of Pennsylvania named the Company and several other pharmaceutical manufacturers as new defendants in an action captioned *The Kroger Co., et al. v. Actavis Holdco U.S., Inc. et al.* The lawsuit is brought by several entities that purportedly purchased generic drugs directly from defendants. The proposed amended complaint seeks monetary damages and injunctive relief for violations of Section 1 of the Sherman Antitrust Act, and is premised on facts similar to those alleged in the *1199SEIU National Benefit Fund* and *César Castillo* litigations. The motion for leave to file the proposed amended complaint remains pending.

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 27, 2019, it was probable that it would incur remediation costs in the range of $38.2 million to $86.9 million. The Company also concluded that, as of December 27, 2019, the best estimate within this range was $61.9 million, of which $1.9 million was included in accrued and other current liabilities and the remainder was included in environmental liabilities on the consolidated balance sheet as of December 27, 2019. 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 in June 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 was denied by 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 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 27, 2019, there were approximately 11,800 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 Acthar Gel intangible assets during the three months ended December 26, 2014. The installment sale transaction resulted in a taxable gain. In accordance with Internal Revenue Code Section 453A ("Section 453A") the gain is considered taxable in the period in which installment payments are received. During the three months ended December 25, 2015, the Company entered into similar transactions with certain intangible assets acquired in the acquisitions of Ikaria and Therakos.

During fiscal 2019, the Company completed its reorganization of its intercompany financing and associated legal entity ownership. As a result, the Company had no remaining interest-bearing U.S. deferred tax liabilities as of December 27, 2019, compared to $227.5 million as of December 28, 2018. See Note 8 for further details regarding this reorganization. The GAAP calculation of interest associated with these deferred tax liabilities was subject to variable interest rates. The Company recognized interest expense associated with these deferred tax liabilities of $23.7 million, and $69.3 million for fiscal 2018 and 2017, respectively. Fiscal 2017 included 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 $47.4 million and $56.0 million as of December 27, 2019 and December 28, 2018, respectively. The decrease of $8.6 million was recognized as a benefit to interest expense during fiscal 2019 due to a lapse of certain statute of limitations. Further 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 operations.

Tax Matters

The Company continues to be subject to examination by the IRS for tax years 2014 to 2018. On August 5, 2019, the IRS proposed an adjustment to the taxable income of MHP as a result of its findings in the audit of MHP's tax year ended September 26, 2014. MHP, formerly known as Cadence Pharmaceuticals, Inc. (“Cadence”), was acquired by the Company as a U.S. subsidiary on March 19, 2014. Following the acquisition of Cadence, the Company transferred certain rights and risks in Ofirmev intellectual property (“Transferred IP”) to a wholly owned non-U.S. subsidiary of the Company. The transfer occurred at a price (“Transfer Price”) determined in conjunction with the Company's external advisors, in accordance with applicable Treasury Regulations and with reference to the $1,329.0 million taxable consideration paid by the Company to the shareholders of Cadence. The IRS asserts the value of the Transferred IP exceeds the value of the acquired Cadence shares and, further, partially disallows the Company's control premium subtraction. The proposed adjustment to taxable income of $871.0 million, excluding potential associated interest and penalties, is proposed as a multi-year adjustment and may result in a non-cash reduction of the Company's U.S. Federal net operating loss carryforward of $782.0 million. The Company strongly disagrees with the proposed increase to the Transfer Price and intends to contest it through all available administrative and judicial remedies, which may take a number of years to conclude. The final outcome

cannot be reasonably quantified at this time, however, the proposed adjustment may be material. The Company believes its reserve for income tax contingencies is adequate. See Note 8 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.

20. Financial Instruments and Fair Value Measurements

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

Level 1— observable inputs such as quoted prices in active markets for identical assets or liabilities;

Level 2— significant other observable inputs that are observable either directly or indirectly; and

Level 3— significant unobservable inputs in which there is little or no market data, which requires the Company to develop its own assumptions.

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

	December 27, 2019	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	$ 30.6	$ 21.0	$ 9.6	$ —
Equity securities	26.2	26.2	—	—
	$ 56.8	$ 47.2	$ 9.6	$ —
Liabilities:				
Deferred compensation liabilities	$ 39.2	$ —	$ 39.2	$ —
Contingent consideration and acquired contingent liabilities	69.3	—	—	69.3
	$ 108.5	$ —	$ 39.2	$ 69.3

	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	$ —
	$ 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

Debt and equity securities held in rabbi trusts. Debt securities held in 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 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 consist of shares in Silence, for which quoted prices are available in an active market; therefore, the investment is classified as level 1 and is valued based on quoted market prices reported on an internationally recognized securities exchange.

In July 2019, the Company remitted $5.0 million of consideration to Silence in exchange for equity shares. As part of this equity investment, the Company took a non-executive Director seat on the Silence Board of Directors. The Company's investment in Silence qualifies for equity method accounting given its ability to exercise significant influence; however, the Company elected the fair value method to account for its investment in Silence. During fiscal 2019, the Company recognized an unrealized gain of $20.2 million related to this investment within other income (expense), net in the consolidated statement of operations.

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.

Contingent consideration and acquired contingent liabilities. As of December 27, 2019, the Company maintains various contingent consideration and acquired contingent liabilities associated with the acquisitions of Questcor, Stratatech Corporation ("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. Under the terms of the license agreement with Novartis, the Company made a $25.0 million payment in fiscal 2019 and is obligated to make annual payments of $25.0 million subsequent to fiscal 2019 until such time that the Company obtains FDA approval of Synacthen and makes a $25.0 million payment upon obtaining FDA approval of Synacthen. 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%. The Company determined the fair value of these contingent consideration obligations associated with the acquisition of Questcor at December 27, 2019 and December 28, 2018 was $24.5 million and $76.2 million, respectively.

As part of the acquisition of Stratatech in August 2016, 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 at each balance sheet date. 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 acquisition of Stratatech to be $29.0 million and $53.7 million at December 27, 2019 and December 28, 2018, 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 and oral formulations of MNK-6105 and MNK-6106 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 $15.8 million and $21.5 million as of December 27, 2019 and December 28, 2018, respectively.

Of the total fair value of the contingent consideration of $69.3 million, $57.8 million was classified as current and $11.5 million was classified as non-current in the consolidated balance sheet as of December 27, 2019. The following table summarizes the fiscal 2019 activity for contingent consideration:

Balance as of December 28, 2018	$	151.4
Payments		(25.0)
Accretion expense		3.1
Fair value adjustment		(60.2)
Balance as of December 27, 2019	$	69.3

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 27, 2019 and December 28, 2018:

- 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 of three months or less, as cash and cash equivalents (level 1). The fair value of restricted cash was equivalent to its carrying value of $31.7 million and $18.6 million as of December 27, 2019 and December 28, 2018, (level 1), respectively, which was included in other assets on the consolidated balance sheets.
- 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 2019 and 2018. These securities are classified as held-to-maturity and are carried at amortized cost, which approximates fair value (level 3), of $18.9 million and $9.0 million as December 27, 2019 and December 28, 2018, respectively. These securities are included in other assets on the consolidated balance sheets.
- The Company's life insurance contracts are carried at cash surrender value, which is based on the present value of future cash flows under the terms of the contracts (level 3). Significant assumptions used in determining the cash surrender value include the amount and timing of future cash flows, interest rates and mortality charges. The fair value of these contracts approximates the carrying value of $51.1 million and $66.4 million at December 27, 2019 and December 28, 2018, respectively. These contracts are included in other assets on the consolidated balance sheets.
- The carrying value of the Company's revolving credit facility approximates the fair value due to the short-term nature of this instrument and is therefore classified as level 1. The Company's 4.75%, 4.875%, 5.50%, 5.625%, 5.75% and 10.00% 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 following table presents the carrying values and estimated fair values of the Company's debt as of the end of each period:

	December 27, 2019		December 28, 2018	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Level 1:				
4.875% senior notes due April 2020	$ 614.8	$ 480.0	$ 700.0	$ 676.6
Variable-rate receivable securitization due July 2020	—	—	250.0	250.0
5.75% senior notes due August 2022	610.3	251.0	835.2	713.6
4.75% senior notes due April 2023	133.7	53.7	500.2	336.7
5.625% senior notes due October 2023	514.7	193.2	731.4	557.0
5.50% senior notes due April 2025	387.2	135.5	692.1	479.1
10.00% senior notes due April 2025	322.9	253.8	—	—
Revolving credit facility	900.0	900.0	220.0	220.0
Level 2:				
9.50% debentures due May 2022	10.4	5.4	10.4	9.7
8.00% debentures due March 2023	4.4	2.0	4.4	3.8
Term loan due September 2024	1,520.8	1,240.0	1,613.8	1,472.4
Term loan due February 2025	403.6	326.2	597.0	548.0
Level 3:				
Other	—	—	2.2	2.2
Total Debt	$ 5,422.8	$ 3,840.8	$ 6,156.7	$ 5,269.1

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 10.0% or more of the Company's total net sales:

	Fiscal Year		
	2019	2018	2017
CuraScript, Inc.	29.7%	35.2%	40.1%
AmerisourceBergen Corporation	10.2%	*	*

* Net sales to this distributor were less than 10.0% of total net sales during the respective periods presented above.

The following table shows accounts receivable attributable to distributors that accounted for 10.0% or more of the Company's gross accounts receivable at the end of each period:

	December 27, 2019	December 28, 2018
AmerisourceBergen Corporation	31.3%	25.7%
McKesson Corporation	15.3%	21.9%
CuraScript, Inc.	12.1%	13.1%

The following table shows net sales attributable to products that accounted for 10.0% or more of the Company's total net sales:

	Fiscal Year		
	2019	2018	2017
Acthar Gel	30.1%	34.5%	37.1%
INOmax	18.1%	16.9%	15.7%
Ofirmev	12.1%	10.6%	*

* Net sales from this product were less than 10.0% of total net sales during the respective period presented above.

21. Segment and Geographical Data

The Company operates in two reportable segments, which are further described below:

- *Specialty Brands* includes innovative specialty pharmaceutical brands; and
- *Specialty Generics* includes niche specialty generic drugs and API(s).

All prior period segment information has been recast to reflect the realignment of the Company's reportable segments on a comparable bases, as previously discussed in Note 1.

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 (loss) income and in the following reconciliations presented below.

Management manages assets on a total company basis, not by operating segment. The Company's chief operating decision maker does not regularly review any asset information by operating segment and, accordingly, the Company does not report asset information by operating segment. Total assets were approximately $10,338.9 million and $10,877.3 million at December 27, 2019 and December 28, 2018, respectively.

Selected information by business segment was as follows:

	Fiscal Year		
	2019	2018	2017
Net sales:			
Specialty Brands	$ 2,423.8	$ 2,496.7	$ 2,352.0
Specialty Generics	738.7	718.9	869.6
Net sales	3,162.5	3,215.6	3,221.6
Operating (loss) income:			
Specialty Brands	$ 1,174.5	$ 1,093.1	$ 1,146.3
Specialty Generics	108.1	89.3	266.4
Segment operating income	1,282.6	1,182.4	1,412.7
Unallocated amounts:			
Corporate and unallocated expenses [1]	(137.8)	(155.8)	(125.2)
Intangible asset amortization	(853.4)	(740.2)	(694.5)
Restructuring and related charges, net [2]	1.7	(108.2)	(36.4)
Non-restructuring impairment charges	(388.0)	(3,893.1)	(63.7)
Separation costs [3]	(63.9)	(6.0)	—
R&D upfront payment [4]	(20.0)	—	—
Opioid-related litigation settlement charge [5]	(1,643.4)	—	—
Operating (loss) income	$ (1,822.2)	$ (3,720.9)	$ 492.9
Depreciation and amortization:			
Specialty Brands	$ 862.4	$ 762.5	$ 712.0
Specialty Generics	88.7	89.6	96.3
	$ 951.1	$ 852.1	$ 808.3

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

(2) Includes restructuring-related accelerated depreciation.

(3) Represents costs incurred related to the separation of the Company's Specialty Generics segment, inclusive of costs related to the suspended spin-off of that business and rebranding costs associated with the Specialty Brands ongoing transformation, all of which are included in SG&A.

(4) Represents R&D expense incurred related to an upfront payment made to Silence in connection with the license and collaboration agreement entered into in July 2019. See Note 6 for further information.

(5) Subsequent to December 27, 2019, the Company announced an agreement in principle on the terms of a global settlement of all opioid-related claims against the Company and its subsidiaries. See Note 24 for further information.

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

	Fiscal Year		
	2019	2018	2017
Acthar Gel	$ 952.7	$ 1,110.1	$ 1,195.1
INOmax	571.4	542.7	505.2
Ofirmev	384.0	341.9	302.5
Therakos	246.9	231.2	214.9
Amitiza [1]	208.5	183.8	—
BioVectra [2]	40.1	53.1	54.7
Other	20.2	33.9	79.6
Specialty Brands	2,423.8	2,496.7	2,352.0
Hydrocodone (API) ad hydrocodone-containing tablets	76.3	65.9	85.3
Oxycodone (API) and oxycodone-containing tablets	74.9	66.1	88.0
Acetaminophen (API)	189.9	192.7	185.5
Other controlled substances	352.5	343.8	412.0
Other	45.1	50.4	98.8
Specialty Generics	738.7	718.9	869.6
Net Sales	$ 3,162.5	$ 3,215.6	$ 3,221.6

(1) Amitiza net sales consist of both product and royalty net sales. Refer to Note 4 for further details on Amitiza's revenues.

(2) In November 2019, the Company completed the sale of BioVectra. Refer to Note 5 for further details.

Selected information by geographic area was as follows:

	Fiscal Year		
	2019	2018	2017
Net sales [1]:			
U.S.	$ 2,765.6	$ 2,834.5	$ 2,899.0
Europe, Middle East and Africa	281.8	256.8	242.3
Other	115.1	124.3	80.3
	$ 3,162.5	$ 3,215.6	$ 3,221.6
Long-lived assets [2]:			
U.S.	$ 734.3	$ 770.7	
Europe, Middle East and Africa [3]	169.9	146.7	
Other	4.8	76.8	
	$ 909.0	$ 994.2	

(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 $168.4 million and $145.2 million as of December 27, 2019 and December 28, 2018, respectively.

22. Selected Quarterly Financial Data (Unaudited)

A summary of quarterly financial information for fiscal 2019 and 2018 is as follows:

	For the Quarter Ended			
	March 29, 2019	June 28, 2019	September 27, 2019	December 27, 2019
Net sales	$ 790.6	$ 823.3	$ 743.7	$ 804.9
Gross profit	335.1	388.9	324.3	373.1
Income (loss) from continuing operations [1]	155.2	(0.5)	(0.9)	(1,161.0)
(Loss) income from discontinued operations	(0.3)	7.3	(0.2)	3.9
Net income (loss)	154.9	6.8	(1.1)	(1,157.1)
Basic earnings (loss) per share from continuing operations [2]	$ 1.86	$ (0.01)	$ (0.01)	$ (13.80)
Diluted earnings (loss) per share from continuing operations [2]	1.83	(0.01)	(0.01)	(13.80)

	For the Quarter Ended [3]			
	March 30, 2018	June 29, 2018	September 28, 2018	December 28, 2018
Net sales	$ 755.3	$ 825.5	$ 799.9	$ 834.9
Gross profit	347.5	394.0	366.4	363.3
(Loss) income from continuing operations [4]	(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 [2]	$ (0.24)	$ 0.04	$ 1.37	$ (44.64)
Diluted (loss) earnings per share from continuing operations [2]	(0.24)	0.04	1.34	(44.64)

(1) Loss from continuing operations for the quarter ended December 27, 2019 reflects the opioid-related litigation settlement charge of $1,643.4 million. See Note 24 for further information.

(2) 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.

(3) The "Specialty Generics Disposal Group" was included within discontinued operations during the first three quarters of fiscal 2018, and was subsequently recast to be included within continuing operations during the fourth quarter of 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 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 fiscal 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 fiscal 2018, the period in which the held-for-sale criteria were no longer met. 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; (2) certain of the Company's non-promoted brands business; and (3) the Company's post-divestiture supply agreement with the acquirer of the contrast media and delivery systems ("CMDS") business.

(4) Loss 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.

23. Condensed Consolidating Financial Statements

MIFSA is an indirectly 100.0%-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 April 2023 Notes, which are fully and unconditionally guaranteed by Mallinckrodt plc. The following information provides the composition of the Company's comprehensive operations, assets, liabilities, equity and cash flows by relevant group within the Company: Mallinckrodt plc as guarantor of the April 2023 Notes, MIFSA as issuer of the April 2023 Notes and the operating companies that represent assets of MIFSA. There are no subsidiary guarantees related to the April 2023 Notes.

Set forth below are the condensed consolidating balance sheets as of December 27, 2019 and December 28, 2018 and condensed consolidating statements of comprehensive operations and cash flows for the fiscal three years ended December 27, 2019. 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 27, 2019
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Assets					
Current Assets:					
Cash and cash equivalents	$ 0.8	$ 124.7	$ 665.4	$ —	$ 790.9
Accounts receivable, net	—	—	577.5	—	577.5
Inventories	—	—	312.1	—	312.1
Prepaid expenses and other current assets	9.0	0.3	140.9	—	150.2
Intercompany receivable	138.8	31.8	249.1	(419.7)	—
Total current assets	148.6	156.8	1,945.0	(419.7)	1,830.7
Property, plant and equipment, net	—	—	896.5	—	896.5
Intangible assets, net	—	—	7,018.0	—	7,018.0
Investment in subsidiaries	1,602.0	7,457.6	2,812.0	(11,871.6)	—
Intercompany loan receivable	416.5	—	1,782.8	(2,199.3)	—
Other assets	—	—	593.7	—	593.7
Total Assets	$ 2,167.1	$ 7,614.4	$ 15,048.0	$ (14,490.6)	$ 10,338.9
Liabilities and Shareholders' Equity					—
Current Liabilities:					
Current maturities of long-term debt	$ —	$ 614.2	$ 19.4	$ —	$ 633.6
Accounts payable	0.1	—	139.7	—	139.8
Accrued payroll and payroll-related costs	—	—	105.2	—	105.2
Accrued interest	—	29.4	33.5	—	62.9
Accrued and other current liabilities	2.3	0.4	482.7	—	485.4
Intercompany payable	180.6	10.5	228.6	(419.7)	—
Total current liabilities	183.0	654.5	1,009.1	(419.7)	1,426.9
Long-term debt	—	1,946.4	2,794.8	—	4,741.2
Pension and postretirement benefits	—	—	62.4	—	62.4
Environmental liabilities	—	—	60.0	—	60.0
Deferred income taxes	—	—	11.0	—	11.0
Other income tax liabilities	—	—	227.1	—	227.1
Opioid-related litigation settlement liability	43.4	—	1,600.0	—	1,643.4
Intercompany loans payable	—	2,199.3	—	(2,199.3)	—
Other liabilities	—	2.2	224.0	—	226.2
Total liabilities	226.4	4,802.4	5,988.4	(2,619.0)	8,398.2
Shareholders' equity	1,940.7	2,812.0	9,059.6	(11,871.6)	1,940.7
Total Liabilities and Shareholders' Equity	$ 2,167.1	$ 7,614.4	$ 15,048.0	$ (14,490.6)	$ 10,338.9

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
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
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
Accrued and other current liabilities	0.6	0.4	571.2	—	572.2
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 STATEMENT OF COMPREHENSIVE OPERATIONS
Fiscal year ended December 27, 2019
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Net sales	$ —	$ —	$ 3,162.5	$ —	$ 3,162.5
Cost of sales	1.9	—	1,739.2	—	1,741.1
Gross (loss) profit	(1.9)	—	1,423.3	—	1,421.4
Selling, general and administrative expenses	43.9	1.6	785.5	—	831.0
Research and development expenses	5.2	—	344.2	—	349.4
Restructuring charges, net	—	—	(1.7)	—	(1.7)
Non-restructuring impairment charges	—	—	388.0	—	388.0
Loss on divestiture	4.2	—	29.3	—	33.5
Opioid-related litigation settlement charge	43.4	—	1,600.0	—	1,643.4
Operating loss	(98.6)	(1.6)	(1,722.0)	—	(1,822.2)
Interest expense	(5.8)	(282.1)	(235.9)	214.8	(309.0)
Interest income	9.8	1.3	213.2	(214.8)	9.5
Gains on debt extinguishment, net	—	420.9	45.7	—	466.6
Other income, net	9.2	—	54.4	—	63.6
Intercompany interest and fees	(20.4)	(0.1)	20.5	—	—
Equity in net income of subsidiaries	(895.8)	(933.4)	(787.0)	2,616.2	—
Loss from continuing operations before income taxes	(1,001.6)	(795.0)	(2,411.1)	2,616.2	(1,591.5)
Benefit from income taxes	(5.1)	(2.6)	(576.6)	—	(584.3)
Loss from continuing operations	(996.5)	(792.4)	(1,834.5)	2,616.2	(1,007.2)
Income from discontinued operations, net of income taxes	—	5.4	5.3	—	10.7
Net loss	(996.5)	(787.0)	(1,829.2)	2,616.2	(996.5)
Other comprehensive income, net of tax	15.9	15.9	30.0	(45.9)	15.9
Comprehensive loss	$ (980.6)	$ (771.1)	$ (1,799.2)	$ 2,570.3	$ (980.6)

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE OPERATIONS
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 impairments	—	—	3,893.1	—	3,893.1
Gains 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
Gains on debt extinguishment, net	—	8.5	—	—	8.5
Other income (loss), net	9.9	0.2	12.3	—	22.4
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 OPERATIONS
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
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
Gains on debt extinguishment, net	—	8.3	—	—	8.3
Other income (expense), net	20.3	(10.0)	(85.4)	—	(75.1)
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 CASH FLOWS
Fiscal year ended December 27, 2019
(in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Cash Flows From Operating Activities:					
Net cash from operating activities	$ (65.9)	$ 46.8	$ 765.8	$ (3.8)	$ 742.9
Cash Flows From Investing Activities:					
Capital expenditures	—	—	(133.0)	—	(133.0)
Proceeds from divestiture, net of cash	—	—	95.1	—	95.1
Intercompany loan investment	91.1	—	(1,124.0)	1,032.9	—
Investment in subsidiary	—	(975.4)	—	975.4	—
Other	—	—	29.6	—	29.6
Net cash from investing activities	91.1	(975.4)	(1,132.3)	2,008.3	(8.3)
Cash Flows From Financing Activities:					
Issuance of external debt	—	—	695.0	—	695.0
Repayment of external debt	—	(135.2)	(809.9)	—	(945.1)
Debt financing costs	—	(10.1)	—	—	(10.1)
Proceeds from exercise of share options	0.6	—	—	—	0.6
Intercompany loan borrowings	(24.9)	1,057.8	—	(1,032.9)	—
Intercompany dividends	—	—	(3.8)	3.8	—
Capital contribution	—	—	975.4	(975.4)	—
Repurchase of shares	(2.6)	—	—	—	(2.6)
Other	2.1	—	(20.0)	—	(17.9)
Net cash from financing activities	(24.8)	912.5	836.7	(2,004.5)	(280.1)
Effect of currency rate changes on cash	—	—	0.6	—	0.6
Net change in cash, cash equivalents and restricted cash	0.4	(16.1)	470.8	—	455.1
Cash, cash equivalents and restricted cash at beginning of period	0.4	140.8	226.3	—	367.5
Cash, cash equivalents and restricted cash at end of period	$ 0.8	$ 124.7	$ 697.1	$ —	$ 822.6
Cash and cash equivalents at end of period	$ 0.8	$ 124.7	$ 665.4	$ —	$ 790.9
Restricted cash included in other long-term assets at end of period	—	—	31.7	—	31.7
Cash, cash equivalents and restricted cash at end of period	$ 0.8	$ 124.7	$ 697.1	$ —	$ 822.6

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 divestiture, 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	—
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	—	(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 change 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 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

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 change 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 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

24. Subsequent Events

Commitments and Contingencies

Certain litigation matters occurred in fiscal 2019 or prior but had subsequent updates through the date of this report. See further discussion below and in Note 19 to the consolidated financial statements.

Opioid-Related Matters

On February 25, 2020, the Company announced that it has reached an agreement in principle on the terms of a global settlement that would resolve all opioid-related claims against the Company and its subsidiaries (“Litigation Settlement”). The Litigation Settlement has been reached with a court-appointed plaintiffs' executive committee representing the interests of thousands of plaintiffs in the MDL and is supported by a broad-based group of 47 state and U.S. Territory Attorneys General (the "Plaintiffs"). The Litigation Settlement contemplates the filing of voluntary petitions under Chapter 11 of the U.S. Bankruptcy Code (“Chapter 11”) by certain subsidiaries of Mallinckrodt plc operating the Specialty Generics business (the “Specialty Generics Subsidiaries”) and the establishment of a trust for the benefit of plaintiffs holding opioid-related claims against the Company (the “Opioid Claimant Trust”). Subject to the Settlement Closing (as defined below), the Company has agreed to the payment of certain structured payments to the Opioid Claimant Trust. Pursuant to the terms of a channeling injunction and third-party release, which are subject to court approval, all persons or entities asserting opioid-related claims against the Company would recover solely from the Opioid Claimant Trust on account of such claims. All other claims against, and equity interests in, the Specialty Generics Subsidiaries will be unimpaired and it is expected that all contracts to which the Specialty Generics Subsidiaries are party will be assumed. The Litigation Settlement also provides for:

- the payment of $300.0 million upon Specialty Generics' emergence from the completed Chapter 11 case;
- the payment to the Opioid Claimant Trust of additional cash totaling $1,300.0 million, consisting of $200.0 million on each of the first and second anniversaries of emergence and $150.0 million on each of the third through eighth anniversaries of emergence; and
- the issuance of warrants ("Settlement Warrants") upon emergence from the contemplated Chapter 11 process to the Opioid Claimant Trust to purchase ordinary shares of the Company with an eight year term at a strike price of $3.15 per ordinary share that would represent approximately 19.99% of the Company's fully diluted outstanding shares, including after giving effect to the exercise of the warrants, provided that such warrants may not be exercised during any calendar quarter in a quantity that would exceed 5.0% of the number of shares outstanding.

The consummation of the Litigation Settlement (such consummation, the "Settlement Closing") is conditioned upon, among other things, bankruptcy court approval of the bankruptcy plan effectuating the Litigation Settlement, the emergence of the Specialty Generics Subsidiaries from bankruptcy and:

- the exchange of the 2020 Notes and the 2022 Notes into new secured notes on terms reasonably satisfactory to the Company;
- the coordination of the action filed by the State of New York against the Company to allow the Specialty Generics Subsidiaries sufficient time to arrange for pre-arranged filings under Chapter 11;
- the support and participation of a supermajority of all claimants with opioid-related claims, including a future claims representative (if one is deemed necessary by the Company in consultation with an ad hoc committee of certain Supporting Claimants or their representatives (the "AHC")), against the Company on terms satisfactory to the Company;
- the resolution of U.S. Department of Justice civil and criminal claims against the Company on reasonable terms;
- the agreement by and between the Company and the Supporting Claimants to an injunction governing the sale and distribution of opioids by the Specialty Generics Subsidiaries, compliance with which is expected to protect the Company from further opioid-related liability, on terms satisfactory to the Company, with such terms to be binding on the Specialty Generics Subsidiaries and any buyers thereof or successors thereto;
- the treatment of potential indemnification claims of Covidien plc on terms satisfactory to the Company and the AHC;
- the disclosure by the Company of a subset of its litigation documents to be made publicly available as part of an industry-wide document disclosure program, subject to scope and protocols to be negotiated by the parties’ informed representatives;
- the entry of a judgment between the Company and the CMS and the entry by the Company into any other legal judgments or settlements, each on such terms and at such levels as may be acceptable to the Company, such that the Company is able to make all payments required under the terms of the Litigation Settlement;

- the resolution and settlement of certain outstanding intercompany indebtedness between the Specialty Generics Subsidiaries and the Company's other subsidiaries and the entry into a shared services agreement between the Specialty Generics Subsidiaries and certain other subsidiaries of the Company, as the case may be, in each case on terms reasonably satisfactory to the Company, subject to consent of the AHC;
- a rights offering or a shareholder vote to satisfy any applicable legal requirements relating to the issuance of the warrants, in a manner reasonably acceptable to the Company and the AHC; and
- the satisfaction such other conditions as may be mutually agreed to by the Company and the AHC.

Although the term sheet relating to the Litigation Settlement had included a reference to the Company making an exchange offer for the 2020 Notes, the Company currently plans to enter into the Amendment (as defined below), and to use the proceeds of the new term loan to refinance the 2020 Notes, in lieu of any exchange offer for the 2020 Notes.

As a result of the Litigation Settlement, the Company recorded an accrual for this contingency of $1,600.0 million related to the structured cash payments and $43.4 million related to the Settlement Warrants in the consolidated balance sheet as of December 27, 2019, with a corresponding non-cash charge to the consolidated statement of operations as a component of operating expenses.

The fair value of the Settlement Warrants to be issued upon the Settlement Closing 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 term assumption is based on the contractual term of the Settlement Warrants, including the maximum exercise restriction of 5.0% per calendar quarter, which resulted in the valuation of four separate tranches. 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 term assumed. The estimated fair value for the Settlement Warrants will be subject to revaluation at each balance sheet date with any changes in fair value recorded as a non-cash gain or (loss) in the consolidated statements of operations until the Settlement Warrants are issued, at which point they will be recorded as equity or as a liability based upon the facts and circumstances at the time of issuance.

The key assumptions used to estimate the fair value of the Settlement Warrants as of December 27, 2019 were as follows:

Expected share price volatility		54.4%
Weighted-average risk-free rate		1.8%
Expected annual dividend per share		—%
Weighted-average expected term (in years)		7.6
Share price	$	3.45

Financing Activities

Support and Exchange Agreement

On February 25, 2020, the Company and the Issuers entered into a support and exchange agreement with Aurelius Capital Master, Ltd., Franklin Advisers, Inc. and Capital Research and Management Company (collectively, the "Noteholder Parties", and such agreement, the "Exchange Agreement") pursuant to which, among other things, the Issuers agreed to use commercially reasonable efforts to commence, by no later than March 20, 2020, a private offer to exchange any and all of the 2022 Notes held by such noteholders for an equal principal amount of new second lien secured notes (such new notes, the "Exchange Offer Notes" and, such private offer to exchange, the "2022 Exchange Offer") at a rate of $1,000 of Exchange Offer Notes for every $1,000 of 2022 Notes exchanged. Pursuant to the Exchange Agreement, the Issuers also agreed to use commercially reasonable efforts to commence, by no later than March 20, 2020, a solicitation of consents from holders of the 2022 Notes to certain amendments to eliminate or waive substantially all of the restrictive covenants contained in the 2022 Notes and the applicable indenture, and eliminate certain events of default, modify covenants regarding mergers and the transfer of assets, and modify and eliminate certain other provisions, including covenants regarding future guarantors and certain provisions relating to defeasance (such solicitation of consents, the "2022 Consent Solicitation"). The closing of the 2022 Exchange Offer will be conditioned on, among other things, the absence of events materially and adversely affecting the ability to implement the Litigation Settlement, and the funding of the new term loans and the effectiveness of the Amendment (as defined below). The noteholders have agreed to tender in the 2022 Exchange Offer all of their 2022 Notes, deliver their consents in the 2022 Consent Solicitation and if the aggregate principal amount of Exchange Offer Notes issued pursuant to the 2022 Exchange Offer is less than approximately $610.3 million (the "Exchange Cap"), exchange the outstanding October 2023 Notes held by the noteholders party to the Exchange Agreement for an amount of Exchange Offer Notes equal to the excess, if any, by which the Exchange Cap exceeds the aggregate principal amount of Exchange Offer Notes to be issued pursuant to the 2022 Exchange Offer, at a rate of $900 of Exchange Offer Notes for

every $1,000 of October 2023 Notes exchanged by each noteholder. The noteholders collectively hold approximately $271.0 million aggregate principal amount of the 2022 Notes and approximately $255.0 million aggregate principal amount of the October 2023 Notes. Additionally, pursuant to the Exchange Agreement, the noteholders have consented, in their capacity as holders of the 2020 Notes, to the adoption of an amendment to the 2020 Notes and the indenture governing the 2020 Notes to provide for the reduction of the optional redemption notice period from 30 days to three business days. The 2022 Exchange Offer will be subject to the satisfaction or waiver of certain conditions, and the failure to consummate the 2022 Exchange Offer could adversely affect the implementation and consummation of the Litigation Settlement.

Support Agreement

On February 25, 2020, the Company and the Issuers entered into a support agreement (the "Support Agreement") with the Noteholder Parties, as well as certain existing term lenders under the Credit Agreement (collectively, the "Lender Parties") dated as of March 19, 2014 (as amended, supplemented or otherwise modified from time to time, the “Credit Agreement”).

The descriptions below of an amendment (the "Amendment") to our existing credit agreement on terms consistent with an agreed term sheet and the New Term Loans (as defined below) are subject to the effectiveness of the Amendment, which is subject to the satisfaction or waiver of the conditions set forth in the term sheet and the Amendment. Conditions to the effectiveness of the Amendment, include, among other things, (i) the consent by certain thresholds of the existing term lenders and revolving lenders (which condition has not yet been satisfied as of this date) and (ii) the commencement of an exchange offer with respect to the 2022 Notes, pursuant to the Exchange Agreement.

The Amendment, if effected, on the terms contemplated by the term sheet, will provide for a commitment from the Noteholder Parties and certain of the Lender Parties (collectively, the "Backstop Lenders") to provide a new $800.0 million senior secured term loan facility (the “New Term Loans”) upon the satisfaction of certain conditions set forth in the term sheet. The New Term Loans will bear interest at an interest rate per annum equal to adjusted LIBOR plus a spread equal to 6.50%.

The New Term Loans will be guaranteed by the Company and the same subsidiaries of the Company that guarantee the Existing Term Loans (as defined below) and secured by liens on the same assets as secure the Existing Term Loans (as amended by the Amendment and, in each case, subject to certain exceptions set forth in the Amendment). The proceeds from the New Term Loans will be used to fund the redemption or repayment of all of the outstanding approximately $614.8 million of the 2020 Notes and additionally to partially repay loans and terminate corresponding commitments under the Company's revolving credit facility in respect of revolving lenders who agree to extend their loans and commitments to March 2024.

The New Term Loans will amortize at an annual rate equal to 5.00% of the initial principal amount of the New Term Loans, payable in equal quarterly payments. The remaining principal amount of the New Term Loans will mature on the fourth anniversary of the borrowing date of the New Term Loans. Amounts outstanding under the New Term Loans may be voluntarily prepaid at any time, subject to a prepayment premium.

Other than with respect to the maturity date, amortization, the applicable interest rate and prepayment premiums, the New Term Loans will have similar terms to the 2017 Term Loan and the 2018 Term Loan (collectively, the “Existing Term Loans”), in each case as amended by the Amendment.

The Amendment would also implement certain amendments to the terms of the Credit Agreement. The interest rate margins applicable to the Existing Term Loans will be increased by 100 basis points. The Existing Term Loans will also amortize at an annual rate increased to 2.00% of the outstanding principal amount of the Existing Term Loans on the effective date of the Amendment, payable in equal quarterly payments. Certain other covenants (including the financial covenant), mandatory prepayments and events of default set forth in the existing Credit Agreement will also be modified pursuant to the Amendment, including to facilitate the implementation of the Litigation Settlement.

The consummation of the aforementioned financing activities may have a material impact on the Company's financial condition, results of operations and cash flows.

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 27, 2019. Based on that evaluation, our CEO and CFO concluded that, as of that date, our disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined under Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with 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 27, 2019. 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.

Our internal control over financial reporting as of December 27, 2019 has been audited by Deloitte & Touche LLP, the independent registered public accounting firm that audited and reported on the consolidated financial statements included in this Annual Report on Form 10-K. This report is included below.

Remediation of Prior 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.

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.

During fiscal 2019, management, under the oversight of the executive leadership team and those charged with governance, completed the remedial actions below to improve the Company's internal control over financial reporting and remediated the design of the material weakness:

- Continued to emphasize the importance of, and monitor the sustained compliance with, the execution of our internal controls over financial reporting through, among other activities, numerous meetings and trainings.

- Enhanced, and will continue to enhance, the design of internal controls governing oversight and evaluation of future cash flow forecasts used to develop certain management estimates, including those related to goodwill and other intangible assets.
- Tested the design effectiveness of the enhanced internal controls by performing them to re-evaluate the appropriateness, and test the accuracy, of information used to develop future cash flow forecasts in fiscal 2018.
- Concluded the enhanced controls were designed effectively and developed a plan to implement them to support future cash flow forecasts.

During fiscal 2019, we successfully completed the actions above of testing the design of the enhanced internal controls to the extent necessary to conclude that the deficiencies in the design of the internal controls over future cash flows have been remediated. Based on the activities and evaluation described above, our CEO and CFO concluded that, as of December 27, 2019, our disclosure controls and procedures were effective.

The remediation efforts were 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 three months ended December 27, 2019 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 (the "Company") as of December 27, 2019, based on the criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 27, 2019, 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 27, 2019 and December 28, 2018, the related consolidated statements of operations, comprehensive operations, changes in shareholders' equity, and cash flows, for the fiscal years ended December 27, 2019, December 28, 2018 and December 29, 2017, 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 25, 2020, 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.

/s/ DELOITTE & TOUCHE LLP
St. Louis, Missouri
February 25, 2020

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 27, 2019.

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 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 27, 2019.

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

Information regarding individuals or groups which own more than 5.0% 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 27, 2019.

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 27, 2019.

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 27, 2019.

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 Operations for the fiscal year ended December 27, 2019, December 28, 2018 and December 29, 2017
- Consolidated Statements of Comprehensive Operations for the fiscal year ended December 27, 2019, December 28, 2018 and December 29, 2017
- Consolidated Balance Sheets as of December 27, 2019 and December 28, 2018
- Consolidated Statements of Cash Flows for the fiscal year ended December 27, 2019, December 28, 2018 and December 29, 2017
- Consolidated Statements of Changes in Shareholders' Equity for the period from December 30, 2016 to December 27, 2019
- 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 Operations	Additions and Other	Deductions	Balance at End of Period
Allowance for doubtful accounts:					
Fiscal year ended December 27, 2019	$ 5.0	$ 1.5	$ —	$ (2.5)	$ 4.0
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
Sales reserve accounts:					
Fiscal year ended December 27, 2019	$ 405.4	$ 2,437.7	$ —	$ (2,505.7)	$ 337.4
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
Tax valuation allowance:					
Fiscal year ended December 27, 2019	$ 2,604.9	$ 526.6	$ —	$ —	$ 3,131.5
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

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

Item 16. Form 10-K Summary.

None.

SIGNATURES

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

MALLINCKRODT PLC

February 25, 2020

By: /s/ Bryan M. Reasons

Bryan M. Reasons
Executive Vice President and Chief Financial Officer
(principal financial officer)

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

Signature	Title	Date
/s/ Mark C. Trudeau Mark C. Trudeau	President, Chief Executive Officer and Director *(principal executive officer)*	February 25, 2020
/s/ Bryan M. Reasons Bryan M. Reasons	Executive Vice President and Chief Financial Officer *(principal financial officer)*	February 25, 2020
/s/ Kathleen A. Schaefer Kathleen A. Schaefer	Senior Vice President, Finance and Corporate Controller *(principal accounting officer)*	February 25, 2020
/s/ Angus C. Russell Angus C. Russell	Chairman of the Board of Directors	February 25, 2020
/s/ David R. Carlucci David R. Carlucci	Director	February 25, 2020
/s/ J. Martin Carroll J. Martin Carroll	Director	February 25, 2020
/s/ Paul R. Carter Paul R. Carter	Director	February 25, 2020
/s/ David Y. Norton David Y. Norton	Director	February 25, 2020
/s/ Carlos V. Paya Carlos V. Paya	Director	February 25, 2020
/s/ JoAnn A. Reed JoAnn A. Reed	Director	February 25, 2020
/s/ Anne C. Whitaker Anne C. Whitaker	Director	February 25, 2020
/s/ Kneeland C. Youngblood, M.D. Kneeland C. Youngblood, M.D.	Director	February 25, 2020

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).
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).
4.6	Indenture, dated as of December 6, 2019, among Mallinckrodt International Finance S.A., Mallinckrodt CB LLC, the Note Guarantors party thereto from time to time and Wilmington Savings Fund Society, FSB, as second lien trustee and second lien collateral agent (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed December 9, 2019).
4.7	Description of Mallinckrodt plc's Registered Securities.
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	Form of Deed of Indemnification by and between Mallinckrodt plc and Directors and Secretary (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 24, 2019).
10.11	Form of Deed of Indemnification by and between Mallinckrodt plc and Officers (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed September 24, 2019).
10.12	Form of Indemnification Agreement by and between Sucampo Pharmaceuticals, Inc. and Directors and Secretary (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed September 24, 2019).
10.13*	Mallinckrodt Pharmaceuticals Severance Plan for U.S. Officers and Executives (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed September 24, 2019).
10.14*	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).
10.15*	Mallinckrodt Pharmaceuticals Stock and Incentive Plan (incorporated by reference to Appendix A to the Company's Proxy Statement filed April 4, 2018.)
10.16*	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).
10.17*	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).
10.18*	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).
10.19*	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).
10.20*	Form of Mallinckrodt plc Stock and Incentive Plan Terms and Conditions of Performance Unit Award (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the fiscal year ended December 28, 2018).
10.21*	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).
10.22*	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).
10.23*	Form of 2019 ERPB Award Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 5, 2019 - Film No. 191191616).
10.24	Exchange Agreement, dated as November 5, 2019 by and among Mallinckrodt International Finance S.A., Mallinckrodt CB LLC and the Exchanging Holders (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 5, 2019 - Film No. 191191640).
10.25	Amendment to the Exchange Agreement, dated as November 27, 2019, by and among Mallinckrodt International Finance S.A., Mallinckrodt CB LLC and the Exchanging Holders (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed November 27, 2019).
10.26	Intercreditor Agreement, dated as of December 6, 2019, among Deutsche Bank AG New York Branch, as first lien collateral agent and first lien credit agreement representative, Wilmington Savings Fund Society, FSB, as second lien collateral agent and initial second lien document representative, each other first lien representative party thereto from time to time and each other second lien representative party thereto from time to time and acknowledged and agreed to by Mallinckrodt plc, Mallinckrodt International Finance S.A, Mallinckrodt CB LLC and each other obligor party thereto from time to time (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed December 9, 2019).
10.27	Support and Exchange Agreement, dated as February 25, 2020, by and among Mallinckrodt plc, Mallinckrodt International Finance S.A., Mallinckrodt CB LLC and the Exchanging Holders (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 25, 2020).

10.28	Support Agreement, dated as of February 25, 2020, by and among Mallinckrodt plc, Mallinckrodt International Finance, S.A., Mallinckrodt CB LLC, the Noteholder Parties and the Lender Parties (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed February 25, 2020).
21.1	Subsidiaries of Mallinckrodt plc.
23.1	Consent of Deloitte & Touche LLP.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certifications of the Chief Executive Officer and 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 27, 2019 formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Statements of Operations, (ii) the Consolidated Statements of Comprehensive Operations, (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.
104	Cover Page Interactive Data File (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.