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 25, 2020
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.)**

College Business & Technology Park, Cruiserath,
Blanchardstown, Dublin 15, Ireland
(Address of principal executive offices) (Zip Code)
Telephone: +353 1 696 0000
(Registrant's telephone number, including area code)

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

Title of each class
Ordinary shares, par value $0.20 per share

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☒ No ☐

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 26, 2020, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $232.4 million (based upon the closing price of $2.77 per share as reported by the New York Stock Exchange ("NYSE") on that date).

The number of shares of the registrant's common stock outstanding as of March 5, 2021 was 84,505,217.

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 25, 2020, 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)").

We continue to pursue 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.

Our principal executive offices are located at College Business & Technology Park, Cruiserath, Blanchardstown, Dublin 15, Ireland, 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 Hampton, New Jersey, and our Specialty Generics headquarters and technical development center in Webster Groves, Missouri.

Voluntary Filing Under Chapter 11 and Going Concern

On October 12, 2020, Mallinckrodt plc and certain of its subsidiaries voluntarily initiated proceedings (the "Chapter 11 Cases") under chapter 11 of title 11 ("Chapter 11") of the United States Code (the "Bankruptcy Code") to modify our capital structure, including restructuring portions of our debt, and to resolve potential legal liabilities, including but not limited to a proposed resolution of all opioid-related claims against us (the "Amended Proposed Opioid-Related Litigation Settlement") and a proposed resolution of various Acthar® Gel (repository corticotropin injection) ("Acthar Gel")-related matters (the "Proposed Acthar Gel-Related Settlement"), including the Medicaid lawsuit with the Centers for Medicare and Medicaid Services ("CMS"), an associated False Claims Act ("FCA") lawsuit in Boston and an Eastern District of Pennsylvania ("EDPA") FCA lawsuit relating to Acthar Gel's previous owner's interactions with an independent charitable foundation. The entities that filed the Chapter 11 Cases include Mallinckrodt plc, substantially all of our U.S. subsidiaries, including certain subsidiaries of Mallinckrodt plc operating the Specialty Generics business (the "Specialty Generics Subsidiaries") and the Specialty Brands business (the "Specialty Brands Subsidiaries"), and certain of our international subsidiaries (together with Mallinckrodt plc, Specialty Generics Subsidiaries and Specialty Brands Subsidiaries, the "Debtors"). In connection with the filing of the Chapter 11 Cases, we entered into a restructuring support agreement (as amended, supplemented or otherwise modified, "Restructuring Support Agreement" or "RSA") as part of a prearranged plan of reorganization. Refer to Note 2 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 on the voluntary petitions for reorganization, the RSA and subsequent joinders and an amendment thereto.

On October 27, 2020, the U.S. Trustee for the District of Delaware appointed an official committee of unsecured creditors and an official committee of opioid-related claimants pursuant to section 1102 of the Bankruptcy Code. Generally, these statutory committees and their legal representatives have a right to be heard on all matters that come before the Bankruptcy Court with respect to the Chapter 11 Cases.

Substantial doubt about our ability to continue as a going concern exists in light of our Chapter 11 Cases. Our ability to continue as a going concern is contingent upon, among other things, our ability to, subject to the approval by the U.S. Bankruptcy Court for the District of Delaware (the "Bankruptcy Court"), implement a plan of reorganization, emerge from the Chapter 11 proceedings and generate sufficient liquidity following the reorganization to meet our obligations, most notably our opioid and Acthar Gel-related settlements and restructured debt obligations, and operating needs.

Although management believes that our reorganization through the Chapter 11 proceedings will appropriately position us upon emergence, the commencement of these proceedings constituted an event of default under certain of our debt agreements, enforcement of any remedies in respect of which is automatically stayed as a result of the Chapter 11 proceedings. There are a number of risks and uncertainties associated with our bankruptcy, including, among others that: (a) our prearranged plan of reorganization may never be confirmed or become effective, (b) the RSA may be terminated by one or more of the parties thereto, (c) the Bankruptcy Court may

grant or deny motions in a manner that is adverse to Mallinckrodt plc and its subsidiaries, and (d) the Chapter 11 Cases may be converted into cases under Chapter 7 of the Bankruptcy Code.

The transactions contemplated by the RSA are subject to approval by the Bankruptcy Court, among other conditions. Accordingly, no assurance can be given that the transactions described therein will be consummated. As a result, we have concluded that management's plans at this stage do not alleviate substantial doubt about our ability to continue as a going concern.

Information about the Chapter 11 Cases, including the case docket, may be found free of charge at https://restructuring.primeclerk.com/Mallinckrodt/.

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 almost 400 sales representatives as of December 25, 2020. 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* 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 nine 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 two 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. 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.

  There is significant clinical evidence to support the effectiveness of Acthar Gel. This evidence is the result of company-sponsored controlled clinical trials, as well as previously completed and largely independent clinical case series and smaller trials that have expanded the product's evidence base and strengthened its clinical profile. We continue our efforts to extend the value of the product through product enhancements including the ongoing development of the Acthar Gel self-injection device, which will create an easier and more patient-friendly application for single unit dosage indications, as well as through additional 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 is also approved 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 was completed early due to achievement of the pre-specified primary outcome measure, non-inferiority. The decision was made following the second planned interim analysis at 75% enrollment. The interim analysis assessed 54 premature and 84 term and near-term neonates and demonstrated that the trial achieved the significance level for non-inferiority. Evaluation of significant improvement for each neonate is based on at least a 25% decrease in oxygenation index or surrogate oxygenation index during the INOmax treatment period.

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.

- *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® (lubiprostone) (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 type-two 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 and right to market a competing 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. Par will pay a double-digit royalty to us based on a percentage of the gross profits of the licensed products sold during the term of the agreement, which continues until each of our related patents has expired; provided that the percentage of gross profits shall be reduced to zero if two or more generics or authorized generics are commercially marketing a generic product in addition to Par. Refer to Note 20 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K 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 three new products in fiscal 2021, 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 2020, we estimated that we received approximately 34.0% 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.

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.

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 pipeline, 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 (collectively "HRS-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 (i.e. CONFIRM) to evaluate the efficacy and safety of terlipressin, together with albumin, in adult patients with HRS-1, and announced positive top line results. The study met its prespecified primary endpoint of verified HRS reversal. It also met three of the four prespecified secondary endpoints with the fourth endpoint trending more positive for terlipressin but not achieving statistical significance. This Phase 3 clinical study was conducted under an FDA Special Protocol Assessment ("SPA"). In March 2020, we initiated and completed a rolling submission of a new drug application ("NDA") filing to the U.S. FDA for terlipressin, and in April 2020 the FDA accepted the NDA for review. In July 2020, the Cardiovascular and Renal Drugs Advisory Committee of the FDA voted to recommend approval of the investigational agent terlipressin to treat adults with HRS-1. During September 2020, the FDA issued a Complete Response Letter ("CRL") regarding the Company's NDA seeking approval for terlipressin. The CRL stated that, based on the available data, the agency cannot approve the terlipressin NDA in its current form and requires more information to support a positive risk-benefit profile for terlipressin for patients with HRS-1. In response to receipt of the CRL, the Company had an End of Review Meeting on October 26, 2020 and a Type A Meeting on January 29, 2021 with the FDA where both parties engaged in constructive dialogue in an effort to clarify a viable path to U.S. approval and we expect to have clarity on this path in fiscal 2021.
- *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. In April 2020, we initiated a rolling submission of a biologics license application ("BLA") filing to the FDA for StrataGraft, and we completed the submission in June 2020. The FDA accepted the BLA for review in August 2020, and granted the application priority review and assigned a Prescription Drug User Fee Act ("PDUFA") target date in early 2021. Subsequently, the FDA deferred action on the BLA due to the novel coronavirus ("COVID-19")-related travel restrictions,

which are delaying a required manufacturing site inspection. We plan to work closely with the FDA to complete the review and schedule the site inspection. We remain committed to the burn care community, with a goal of ultimately providing this patient population with a new treatment option that could reduce the need for autografting of healthy skin.

- *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. MNK-6105's intravenous ("IV") formulation, 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, and plan to initiate the Phase 3 trial for the IV formulation of this development product in the first half of 2022. The Phase 2 trial for the oral formulation was completed in 2020.
- *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 ("Silence") to develop and commercialize Silence's C3 complement asset, and in September 2020, we exercised an option for two additional complement protein targets under the collaboration.

Specialty Generics. The R&D efforts in this segment are 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 advance 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 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 from this facility was approved and launched in 2020.

Competition

Specialty Brands. Certain 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. However, certain of our Specialty Brands products now have direct competition in the U.S. market. For example, there is now direct competition in the U.S. market for INOmax. However, we believe INOmax's highly differentiated service offering and next generation delivery system 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.

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 channel type-two 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.

Specialty Generics. 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.

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 currently 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 a bioequivalent product. Certain 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, as well as generic drugs subject to 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 ("HHS"), 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 or BLAs, 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, BLAs or ANDAs, and the imposition of monetary fines, civil penalties or criminal prosecution.

In order to market and sell a new prescription non-biologic 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. A BLA is filed with the FDA so that the agency can assess, among other things, whether the biological product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency.

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").

In addition, 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 2021, the user fee rate has been set at $2,875,840 for a 505(b)(1) NDA and $1,437,920 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.

BLA Process. In many ways, the process undertaken to get a new biologic product approved by the FDA is very similar to the approval process for an NDA. However, biological products are typically derived from living systems, meaning that their large, complex structures are often difficult to characterize, as opposed to traditional drug molecules that are chemically synthesized and structurally both simpler and smaller in size. This underlying distinction drives key differences in the regulatory process, particularly with regard to how competitive versions of a biological product, known as biosimilars, can be brought to market.

Like an NDA, a BLA is submitted to the FDA in order to market a new drug in the US, and as such, both must contain enough information to demonstrate the efficacy and safety of the drug, as well as demonstrate a proper risk-to-benefit ratio, in order to be successful. Additionally, many of the same regulations apply to NDAs and BLAs, including clinical trial requirements, labeling and advertising rules, pre-marketing regulations, accelerated approval pathways, pediatric study requirements, and PDUFA fees. However, because biological products are processed from living material, BLA content must also demonstrate purity. In addition, the manufacturing process for biological products is more complicated, due to genetic variability in the source material. Therefore, it is critical that BLAs contain a thorough description of product development and relevant manufacturing procedures, as well as all steps taken to ensure that the final biological product performs consistently across batches.

Further, in March 2020 the Biologics Price Competition and Innovation (“BPCI”) Act went into effect, which created an abbreviated approval pathway (codified in Section 351(k) of the Public Health Service Act) to encourage the development of biosimilars, which are defined as a biologic that is "highly similar" to the reference product, notwithstanding minor differences in clinically inactive components and has no clinically meaningful differences from the reference product in terms of safety, purity and potency. Under Section 351(k), the FDA must wait four years after approval of a biological product under a BLA before accepting a filing for a biosimilar version of the reference product, and the FDA cannot approve a biosimilar version of the reference product until 12 years after the reference product was approved under a BLA. The BPCI Act also provides for limited regulatory exclusivity for the first FDA-approved interchangeable biologic with respect to each reference product. This means that the FDA will defer approval of additional interchangeable biologics to the same reference product for defined periods of one year or more.

Upon filing a biosimilar application, an applicant may trigger the patent negotiation and clearance process. Under the BCPI Act provisions, an applicant and the reference product company are required to share information to seek to resolve any patent disputes prior to regulatory approval and launch. A failure to share information or participate in the process has defined consequences that include the loss of the right to seek patent clearance on the applicant's part and the loss of the right to seek lost profits or injunctive relief for infringement on the reference product patent right holder's part. The process, if initiated by the applicant, has several stages, including defining which patents to include in a pre-approval litigation proceeding, initiating litigation, notice 180 days prior to launch of a biosimilar, the initiation of a second round of litigation relating to patents the parties did not include in the first round litigation, and, following approval, litigation on patents brought by the reference product company or other patent holders not involved in the prior patent process.

ANDA Process. The path leading to FDA approval of an ANDA is quite different from that of a NDA, a BLA or even a biosimilar. 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, 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 2021 user fee rate is set at $196,870 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 2021.

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 information related to getting 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 2020, manufacturing and procurement quotas granted by the DEA were sufficient to meet our sales and inventory requirements on most products. In November 2020, the DEA continued to further reduce, as it has done over the past several years, the manufacturing

quota for the top misused Schedule II opioids that may be manufactured in the U.S. in calendar year 2021. This includes oxycodone, hydrocodone, oxymorphone, hydromorphone 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.

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. One of our Specialty Generics subsidiaries utilizes all available transaction information to identify suspicious orders of any Mallinckrodt product and reports 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.

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 $665.3 million, $75.9 million and $98.9 million in fiscal 2020, 2019 and 2018, respectively. The fiscal 2020 provision is inclusive of the $536.0 million retrospective one-time charge related to the Medicaid lawsuit that is further discussed within Note 20 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K. The remaining $53.4 million increase in provision for Medicaid payments is due to a $47.8 million increase due to Specialty Brands, which includes the $40.4 million prospective impact of the Medicaid lawsuit on Acthar Gel, coupled with a $5.6 million decrease associated with Specialty Generics. The fiscal 2019 decrease in provision for Medicaid payments was due to a $12.6 million decrease in Specialty Generics coupled with a $10.4 million decrease associated with Acthar Gel. Our business was also impacted by the annual fee on branded prescription pharmaceutical manufacturers and recorded expense of $11.6 million, $20.1 million and $18.4 million in fiscal 2020, 2019 and 2018, 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 FCA 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 United Kingdom ("U.K.") Bribery Act of 2010, which generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside of the U.S. are with governmental entities and are therefore subject to such anti-bribery laws. Our policies mandate compliance with these anti-bribery laws; however, we operate in many parts of the world that have experienced governmental corruption to some degree and, in certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not protect us from reckless or criminal acts committed by our employees or agents.

Compliance Programs

In order to systematically and comprehensively mitigate the risks of non-compliance with regulatory requirements described within this Item 1. Business, we have developed what we believe to be 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 ("CEO") 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 SOM and 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.

Additionally, we implemented an Opioid Product Operating Injunction compliance program in 2020 as a result of certain Mallinckrodt entities agreeing to be bound by an Operating Injunction enjoining those entities from engaging in certain conduct related to the manner in which they operate their opioid business. The Operating Injunction prohibits certain promotional activities related to opioid products and pain treatment, financial and in-kind support for third parties involved with opioids or pain treatment, and certain lobbying activities and communications related to opioids and pain treatment. The Operating Injunction also contains requirements for controlled substances suspicious order monitoring and reporting. The Operating Injunction provides that Mallinckrodt must retain a monitor to evaluate and monitor compliance with the Operating Injunction for a term of five to seven years. On January 21, 2021, Mallinckrodt jointly filed a motion with the ad hoc committee of governmental claimants (consisting of the plaintiffs' executive committee appointed in the opioid multi-district litigation and seven states) (collectively, the "Governmental Plaintiff Ad Hoc Committee"), requesting that the bankruptcy court appoint R. Gil Kerlikowske to serve as monitor, a candidate unanimously selected by the Governmental Plaintiff Ad Hoc Committee and the additional states and territories who are signatories to the RSA. Under the terms of the Operating Injunction, the monitor is required to file regular updates with the Bankruptcy Court, including a work plan and compliance reports. An order approving the appointment was entered on February 8, 2021.

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 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 EMA 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 Note 20 to the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

We continue to be dedicated to environmental sustainability programs to minimize the use of natural resources and reduce the utilization and generation of hazardous materials from our manufacturing process and to remediate identified environmental concerns. Environmental laws are complex and generally have become more stringent over time. We believe that our operations currently comply in all material respects with applicable environmental laws and regulations, and have planned for future capital and operating

expenditures to comply with these laws and to address liabilities arising from past or future releases of, or exposures to, hazardous substances.

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 through manufacturing and procurement quotas that we must apply for annually in order to obtain and produce these substances.

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 2020, 2019 and 2018 were as follows:

	Fiscal Year		
	2020	**2019**	**2018**
CuraScript, Inc.	27.4 %	29.7 %	35.2 %
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 25, 2020, 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 93.1%, 4.2% and 2.7% of our manufacturing production (as measured by cost of production) was performed within the U.S., Ireland and Japan, respectively, in fiscal 2020.

As of December 25, 2020, 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 certain of our Specialty Brands products, including Acthar Gel (for finish and filling of the product) 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 25, 2020. As of December 25, 2020, our backlog was 9.9% of net sales, more than half of which is expected to be recognized as revenue in fiscal 2021.

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. DEA quotas for raw materials and final dosage products are allocated in each calendar year to companies and may impact our sales until the DEA grants additional quotas, if any. Impacts from quota limitations are most commonly experienced during the third and fourth calendar quarters, and we have typically experienced lower net sales in DEA controlled products during the fourth calendar quarter. While we have experienced these fluctuations in the past, they may not be indicative of what we will experience in the future.

Human Capital

Our objective regarding our human capital management priorities is to identify, attract and retain the highest quality of talent that demonstrate and exemplify our corporate vision to improve the lives of underserved patients with severe and critical conditions. To support this initiative, our human resources programs are designed to attract, develop and promote talent in support of our critical business priorities by: recognizing and rewarding through competitive pay and benefit programs; empowering and enhancing our workforce by advancing our culture of diversity, equity and inclusion, and investing in our employees' growth and development. Further, we encourage and support our employees to be active members of the communities within which they live and work.

We employ approximately 3,100 people as of December 25, 2020. Our multi-national workforce is 99.1% full time. Of the total population, 51.2% of employees work within the manufacturing and distribution operation locations across sites in the U.S., Ireland and Japan; 28.3% of our employees work within our corporate services locations of Hampton, New Jersey; Hazelwood, Missouri; Webster Groves, Missouri; Staines, U.K. and Dublin, Ireland. The remaining 20.5% of employees are field-based and work across multiple countries supporting the company's product sales and services.

Some examples of key programs and initiatives that are focused to identify, retain and develop our diverse workforce are listed below.

Health, Well-being and Family Resources.

We believe in providing comprehensive and competitive benefits to honor the important contributions our employees make. These benefits are designed to meet the varied and evolving needs of our employees and their families across our business. This year, we enhanced the ways we helped our employees care for themselves and their families, especially in response to the COVID-19 pandemic. These include:

- Child care referral, dependent care assistance and a variety of parental resources provided by an Enhanced Family Support Services Program;
- Free mental and behavioral health resources, including on-demand access to the Employee Assistance Program (EAP) for employees and their dependents to assist in a wide range of work/life concerns; and
- Interactive well-being activities inclusive of physical, emotional, social and financial well-being offered to employees and their families throughout the year to enable them to live their best lives, while lowering their out-of-pocket premium contributions.

New resources and benefits temporarily implemented during the course of the pandemic include:

- Provided financial relief to employees by deferring loan repayments and allowing hardship withdrawals from participants' 401(k); and
- Field and corporate employees working from home and essential workers have been provided quarantine pay aimed at continued financial stability for families.

Talent Development.

We are committed to providing a continuous learning environment aimed at advancing our workforce through personal and professional development. We invest in programs that provide our employees the ability to build and advance their career potential. The Company offers a wide range of leadership and individual development offerings for our employees inclusive of but not limited to, tuition reimbursement, mentoring programs, individual development planning, networking and professional coaching that is in-

person and/or remote. We have made technology investments to ensure we are flexible in meeting the needs and interests of employees. Additionally, we encourage Board of Director engagement with key talent.

Inclusion and Diversity ("I&D") Council.

I&D fosters a culture where every employee plays an important role in making our company a more rewarding place to work. Our workforce is built on the foundation of equal opportunity and fair treatment. As a multi-national company, we celebrate the diversity of our workforce. We believe the unique and diverse perspectives of our employees enable us to better understand and respond to our patients' needs. Our executive and senior leaders actively sponsor and mentor diverse employees.

We sponsor eight employee-led, volunteer Business Resource Groups ("BRGs") that support diversity and inclusion within the organization and in the community where employees work and live. These groups are open to anyone and are typically centered on shared interests, identities and affiliations. These groups provide resources for professional development, personal growth, community engagement, well-being and networking, all while fostering connectivity and enhancing our unique culture.

Our I&D Council has been named one of the top 10 councils in the nation for three consecutive years by Prism International, which recognized the outstanding achievements of our BRGs in creating a more diverse and inclusive organization.

We have advanced policies, practices and benefits to support every employee in a safe and welcoming environment that promotes individual respect. For five consecutive years, we have been awarded one of the "Best Places to Work for LGBTQ Equality" from the Human Rights Campaign Foundation's Corporate Equity Index.

Social and Community Responsibility.

We believe that our employees are the cornerstone of our corporate citizenship efforts, which we call "Giving Back." We also believe that supporting employees in this way enriches their individual needs and their overall engagement with the Company. Our culture of giving back supports building stronger communities and empowering our employees to dedicate their time and resources to the causes they care about most. Corporate-sponsored and employee activities include:

- Economic contributions for increasing access to quality, affordable health care;
- Supporting STEM (science, technology, engineering and mathematics) in K-12 schools, community colleges, and universities to create a diverse pipeline of professionals with scientific careers;
- Support for local and national non-profit organizations in the communities where we operate;
- Donations and support to organizations dedicated to innovative research and development projects that stimulate economic growth in areas where we operate; and
- Matching Gift program for employees, our Global Month of Service and policy that supports employee volunteerism with eight hours pay per employee.

Due to the unprecedented global health emergency of the COVID-19 pandemic, we are doing our part to help and support the needs and safety of our employees, patients and communities. We have:

- Produced and donated approximately 12,000 gallons of hand sanitizer to emergency operations centers;
- Donated approximately 54,000 plus pieces of Personal Protective Equipment ("PPE");
- Loaned ventilators from our Dublin-based operations to hospitals in Ireland;
- Instituted a volunteer leave program to give medically trained employees paid time off to treat and care for COVID-19 patients;
- Supported two investigator initiated research activities to evaluate the role of inhaled nitric oxide as a treatment for patients infected with COVID-19;
- Ensured there were no interruptions to manufacturing operations and supply continuity of critical therapies for our patients; and
- Operated our Patient Services and Reimbursement teams and Regional Service Centers in the U.S. non-stop (24/7) to ensure our patients have access to their therapies.

Information About Our Executive Officers

Set forth below are the names, ages as of February 1, 2021, and current positions of our executive officers.

Name	Age	Title
Mark Trudeau	59	President, Chief Executive Officer and Director
Bryan Reasons	52	Executive Vice President and Chief Financial Officer
Mark Casey	57	Executive Vice President and Chief Legal Officer
Hugh O'Neill	57	Executive Vice President and Chief Commercial Officer
Steven Romano, MD	61	Executive Vice President and Chief Scientific Officer
Ian Watkins	58	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 ("Covidien") in February 2012 as a Senior Vice President and President of its Pharmaceuticals business. He joined Covidien from Bayer HealthCare Pharmaceuticals LLC USA, the U.S. healthcare business of Bayer AG, where he served as Chief Executive Officer. He simultaneously served as President of Bayer HealthCare Pharmaceuticals, the U.S. organization of Bayer's global pharmaceuticals business. In addition, he served as Interim President of the global specialty medicine business unit from January to August 2010. Prior to joining Bayer in 2009, Mr. Trudeau headed the Immunoscience Division at Bristol-Myers Squibb ("BMS"). During his 10-plus years at BMS, he served in multiple senior roles, including President of the Asia/Pacific region, President and General Manager of Canada and General Manager/Managing Director in the United Kingdom. Mr. Trudeau was also with Abbott Laboratories, serving in a variety of executive positions, from 1988 to 1998. Mr. Trudeau has served as a director of TE Connectivity Ltd. since March 2016.

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 and Operations Officer. He has executive responsibility for the Company's Specialty Brands products, directly managing all commercialization and manufacturing 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, U.S. 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 25 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.

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 ("Exchange Act") 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.

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.

Summary of Risk Factors

Risks Related to Our Chapter 11 Cases

- We are subject to risks and uncertainties associated with our Chapter 11 Cases.
- Delays in the Chapter 11 Cases may increase the risks of our being unable to consummate a plan of reorganization and increase our costs associated with the Chapter 11 Cases.
- The RSA is subject to significant conditions and milestones that may be difficult for us to satisfy.
- If the RSA is terminated, our ability to confirm and consummate the plan of reorganization to be proposed by the Debtors (the “Plan”) could be materially and adversely affected.
- The Amended Proposed Opioid-Related Litigation Settlement and the Proposed Acthar Gel-Related Settlement (together the "Proposed Settlements") are subject to certain contingencies and may not go into effect in their current form or at all, which may have an adverse impact on our ability to consummate the Plan and our business, financial condition, results of operations and cash flows.
- Even if the Plan is consummated, we may not be able to achieve our stated goals or continue as a going concern.
- In certain instances, a Chapter 11 case may be converted to a case under Chapter 7 of the Bankruptcy Code.

- Termination of our exclusive right to file a Chapter 11 plan and the exclusive right to solicit acceptances could result in competing plans of reorganization, which could have less favorable terms or result in significant litigation and expenses.
- As a result of the Chapter 11 Cases, our historical financial information may not be indicative of our future performance, which may be volatile.
- We may be subject to claims that will not be discharged in the Chapter 11 Cases, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.
- The pursuit of the Chapter 11 Cases has consumed, and will continue to consume, a substantial portion of the time and attention of our management, which may have an adverse effect on our business, financial condition, results of operations and cash flows, and we may experience increased levels of employee attrition.
- Aspects of the Chapter 11 Cases limit the flexibility of our management team in running our business.

Risks Related to Our Business

- 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.
- Our business may be adversely affected by public health crises and epidemics/pandemics, including the recent coronavirus outbreak.
- 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.
- 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.
- 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.
- 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.
- Cost-containment efforts of our customers, purchasing groups, third-party payers and governmental organizations could materially adversely affect our business.
- 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.
- 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.
- We may not achieve the anticipated benefits of price increases enacted on our pharmaceutical products, which may adversely affect our business.
- We face significant competition and may not be able to compete effectively.
- 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.
- Clinical trials demonstrating the efficacy of 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.
- 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 may incur product liability losses and other litigation liability.
- Our operations expose us to the risk of violations of applicable health, safety and environmental laws and regulations and related liabilities and litigation.

- Potential indemnification liabilities to Covidien pursuant to the separation and distribution agreement could materially adversely affect us.
- If our business development activities are unsuccessful, it may adversely affect us.
- If we are unable to retain our key scientific, technical, regulatory and commercial personnel, we may be unable to maintain or expand 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.
- Our customer concentration may materially adversely affect our business.
- Our product concentration may materially adversely affect our business.
- 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 manufacture of our products is highly exacting and complex, and our business could suffer if we, or our suppliers, encounter manufacturing or supply problems.
- Our global operations expose us to risks and challenges associated with conducting business internationally.
- 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.
- 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.
- We are subject to labor and employment laws and regulations, which could increase our costs and restrict our operations in the future.
- Our operations may be interrupted by the occurrence of a natural disaster or other catastrophic event at our facilities.

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 Proposed Settlements.
- Even if our existing indebtedness is restructured, 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.
- 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.
- Even if our existing indebtedness is restructured, our 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 variable-rate indebtedness exposes us to interest rate risk, which could cause our debt service obligations to increase significantly.
- 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 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.
- The phase out of London Inter-Bank Offered Rate ("LIBOR"), or the replacement of LIBOR with a different reference rate, may adversely affect interest rates.

Risks Related to Tax Matters

- The Company’s tax attributes and future tax deductions may be reduced or significantly limited as a result of the Chapter 11 filing.

- 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, results of operations and cash flow.
- Our status as a foreign corporation for U.S. federal tax purposes could be affected by a change in law.
- Future changes to U.S. and foreign tax laws could adversely affect us.
- We may not be able to maintain a competitive worldwide effective corporate tax rate.
- A change in our tax residency could have a negative effect on our future profitability and taxes on dividends.

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.
- Irish law imposes restrictions on certain aspects of capital management.

Risks Related to Our Ordinary Shares

- Our ordinary shares are quoted on the Pink Open Market, and thus may have a limited market and lack of liquidity.
- The Plan contemplates the cancellation of our ordinary shares without any value being delivered to shareholders. Any trading in our ordinary shares during the pendency of our Chapter 11 Cases is highly speculative and poses substantial risks to purchasers of our ordinary shares.

Risks Related to Our Chapter 11 Cases

We are subject to risks and uncertainties associated with our Chapter 11 Cases.

The Chapter 11 Cases could have a material adverse effect on our business, financial condition, results of operations and cash flows. So long as the Chapter 11 Cases continue, our senior management may be required to spend a significant amount of time and effort dealing with the reorganization instead of focusing on our business operations. Bankruptcy Court protection also may make it more difficult to retain management and the key personnel necessary to the success and growth of our business. In addition, during the period of time we are involved in the Chapter 11 Cases, our customers and suppliers may lose confidence in our ability to reorganize our business successfully and may seek to establish alternative commercial relationships.

Other significant risks associated with the Chapter 11 Cases that could result in material adverse effects on our business, financial condition, results of operations, and cash flows include or relate to the following:

- Bankruptcy Court rulings in the Chapter 11 Cases, including our ability to obtain the Bankruptcy Court's approval of the Plan under Chapter 11 of the Bankruptcy Code notwithstanding any objections that may be lodged to, or votes cast against, such Plan and the outcome of any motions or other requests made to the Bankruptcy Court in the Chapter 11 Cases;
- our ability to obtain approvals from certain governmental bodies in foreign jurisdictions, including Ireland and Canada, that are required to consummate the Plan;
- our ability to consummate the Plan;
- the effects of the filing of the Chapter 11 Cases on our business and the interests of various constituents, including our shareholders;
- the high costs of the Chapter 11 Cases;
- our ability to maintain relationships with suppliers, customers, employees and other third parties as a result of the Chapter 11 Cases;
- the outcome of pending litigation;
- the possibility that we will not be able to maintain control of our assets as debtors-in-possession;
- the length of time that we will operate with Chapter 11 protection and any resulting risk that we will not satisfy the milestones specified in the RSA and in our agreement with our secured lenders with respect to our use of their cash collateral;
- the availability of operating capital during the pendency of the Chapter 11 Cases, including any event that could terminate our right to continued access to the cash collateral of our lenders to use as operating capital;

- third-party motions in the Chapter 11 Cases, including motions which may be filed by creditors or the creditors' committees that have been appointed in the Chapter 11 Cases, which may interfere with our ability to consummate the Plan;
- the potential adverse effects of the Chapter 11 Cases on our liquidity and results of operations;
- the feasibility of the Plan, including in light of possible changes in our business and its prospects;
- the possibility that creditor claims could be asserted against debtors other than those we believe are liable on those claims;
- the adequacy of our cash balances at the time of our projected exit from the Chapter 11 Cases; and
- our ability to continue as a going concern.

Because of the risks and uncertainties associated with the Chapter 11 Cases, we may not be able to accurately predict or quantify the ultimate impact the Chapter 11 Cases may have on our business, financial condition, results of operations and cash flows, nor can we accurately predict the ultimate impact the Chapter 11 Cases may have on our corporate or capital structure.

Delays in the Chapter 11 Cases may increase the risks of our being unable to consummate a plan of reorganization and increase our costs associated with the Chapter 11 Cases.

The RSA contemplates the consummation of the Plan, but there can be no assurance that we will be able to consummate the Plan. A prolonged Chapter 11 proceeding could adversely affect our relationships with customers, suppliers and employees, among other parties, which in turn could adversely affect our business, financial condition, results of operations and cash flows and our ability to continue as a going concern. A weakening of our financial condition, cash flows and results of operations could adversely affect our ability to implement the Plan (or any other plan of reorganization). If we are unable to consummate the Plan, we may be forced to liquidate our assets.

The RSA is subject to significant conditions and milestones that may be difficult for us to satisfy.

There are certain material conditions we must satisfy under the RSA, including the timely satisfaction of milestones in the Chapter 11 Cases, which include the consummation of the Plan. Our ability to timely complete such milestones is subject to risks and uncertainties, many of which are beyond our control.

If the RSA is terminated, our ability to confirm and consummate the Plan could be materially and adversely affected.

The RSA contains a number of termination events, upon the occurrence of which certain parties to the RSA may terminate the agreement. If the RSA is terminated as to all parties thereto, each of the parties thereto will be released from its obligations in accordance with the terms of the RSA. Such termination may result in the loss of support for the Plan by the parties to the RSA, which could adversely affect our ability to confirm and consummate the Plan. If the Plan is not consummated, there can be no assurance that the Chapter 11 Cases would not be converted to Chapter 7 liquidation cases or that any new plan would be as favorable to holders of claims against the Debtors as contemplated by the RSA.

The Amended Proposed Opioid-Related Litigation Settlement and the Proposed Acthar Gel-Related Settlement are subject to certain contingencies and may not go into effect in their current form or at all, which may have an adverse impact on our ability to consummate the Plan and our business, financial condition, results of operations and cash flows.

The Proposed Settlements are 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 Proposed Settlements. In particular, each of the Proposed Settlements is subject to a number of conditions, many of which may not be satisfied. Among other things, the Proposed Settlements are intended to be implemented through the Plan, the timing and consummation of which is subject to various risks and uncertainties as described elsewhere in this Annual Report on Form 10-K.

Furthermore, subject to the satisfaction of the conditions to the Proposed Settlements, the consummation of the Proposed Settlements would become effective upon our emergence from the Chapter 11 bankruptcy process, 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, one or both of the Proposed Settlements may not be implemented or consummated in its or their current form, or at all, as a result of which we would be subject to continued litigation, which, in turn, could adversely impact our ability to consummate the Plan and result in us and/or our subsidiaries becoming subject to some or all of the liabilities that would have otherwise been settled. In such circumstances, our business, financial condition, results of operations and cash flows could be materially and adversely affected.

Even if the Plan is consummated, we may not be able to achieve our stated goals or continue as a going concern.

Even if the Plan or any other Chapter 11 plan of reorganization is consummated, we may continue to face a number of risks, such as changes in economic conditions, changes in our industry, changes in demand for our services and increasing expenses. Some of these risks become more acute when a case under the Bankruptcy Code continues for a protracted period without indication of how or when the case may be completed. As a result of these risks and others, we cannot guarantee that the Plan will achieve our stated goals or that we will be able to continue as a going concern.

Furthermore, even if our debts and other liabilities are reduced or discharged through the Plan, we may need to raise additional funds through public or private debt or equity financing or other various means to fund our business after the completion of the Chapter 11 Cases. Among other things, our revolving credit facility is set to expire on February 28, 2022, shortly after when we anticipate completing the Chapter 11 restructuring process, and will need to be paid off or refinanced on or before that time. Our access to additional financing may be limited, if it is available at all. Therefore, adequate funds may not be available when needed or may not be available on favorable terms, or at all.

In certain instances, a Chapter 11 case may be converted to a case under Chapter 7 of the Bankruptcy Code.

Upon a showing of cause, the Bankruptcy Court may convert our Chapter 11 Cases to a case under Chapter 7 of the Bankruptcy Code. In such event, a Chapter 7 trustee would be appointed or elected to liquidate our assets for distribution in accordance with the priorities established by the Bankruptcy Code. We believe that liquidation under Chapter 7 would result in significantly smaller distributions being made to our creditors than those provided for in the Plan because of (i) the likelihood that the assets would have to be sold or otherwise disposed of in a distressed fashion over a short period of time rather than in a controlled manner and as a going concern, (ii) additional administrative expenses involved in the appointment of a Chapter 7 trustee, and (iii) additional expenses and claims, some of which would be entitled to priority, that would be generated during the liquidation and from the rejection of leases and other executory contracts in connection with a cessation of operations.

Termination of our exclusive right to file a Chapter 11 plan and the exclusive right to solicit acceptances could result in competing plans of reorganization, which could have less favorable terms or result in significant litigation and expenses.

We currently have the exclusive right to file a Chapter 11 plan through and including August 9, 2021, and the exclusive right to solicit acceptances of any such plan through October 11, 2021. Such deadlines may be extended from time to time by the Bankruptcy Court "for cause" (as permitted by §1121(d) of the Bankruptcy Code) until the dates 18 months and 20 months after the date we filed the Chapter 11 Cases, respectively. However, it is also possible that (a) parties in interest could seek to shorten or terminate such exclusive plan filing and solicitation periods "for cause" (as permitted by section 1121(d) of the Bankruptcy Code)) or (b) that such periods could expire without extension.

If our exclusive plan filing and solicitation periods expire or are terminated, other parties in interest will be permitted to file alternative plans of reorganization. There can be no assurances that recoveries under any such alternative plan would be as favorable to creditors as the Plan. In addition, the proposal of competing plans of reorganization may entail significant litigation and significantly increase the expenses of administration of the Debtors' cases, which could deplete creditor recoveries under any plan.

As a result of the Chapter 11 Cases, our historical financial information may not be indicative of our future performance, which may be volatile.

During the Chapter 11 Cases, we expect our financial results to continue to be volatile as restructuring activities and expenses, contract terminations and rejections, and claims assessments significantly impact our consolidated financial statements. As a result, our historical financial performance is likely not indicative of our financial performance after the date of the filing of the Chapter 11 Cases. In addition, if we emerge from Chapter 11, the amounts reported in subsequent consolidated financial statements may materially change relative to our historical consolidated financial statements, including as a result of revisions to our operating plans pursuant to the Plan. We also may be required to adopt fresh start accounting, in which case our assets and liabilities will be recorded at fair value as of the fresh start reporting date, which may differ materially from the recorded values of assets and liabilities on our consolidated balance sheets. Our financial results after the application of fresh start accounting may be different from historical trends.

We may be subject to claims that will not be discharged in the Chapter 11 Cases, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The Bankruptcy Code provides that the confirmation of a plan of reorganization discharges a debtor from substantially all debts arising prior to consummation of a plan of reorganization. With few exceptions, all claims that arose prior to confirmation of a plan of

reorganization (i) would be subject to compromise and/or treatment under the plan of reorganization and/or (ii) would be discharged in accordance with the Bankruptcy Code and the terms of the plan of reorganization. Any claims not ultimately discharged pursuant to the plan of reorganization could be asserted against the reorganized entities and may have an adverse effect on our business, financial condition, results of operations and cash flows on a post-reorganization basis.

The pursuit of the Chapter 11 Cases has consumed, and will continue to consume, a substantial portion of the time and attention of our management, which may have an adverse effect on our business, financial condition, results of operations and cash flows, and we may experience increased levels of employee attrition.

While the Chapter 11 Cases continue, our management will be required to spend a significant amount of time and effort focusing on the Chapter 11 Cases instead of focusing exclusively on our business operations. This diversion of attention may materially adversely affect the conduct of our business, and, as a result, our financial condition, results of operations and cash flows, particularly if the Chapter 11 Cases are protracted.

Furthermore, during the pendency of the Chapter 11 Cases, we may experience increased levels of employee attrition, and our employees may face considerable distraction and uncertainty. A loss of key personnel or material erosion of employee morale could adversely affect our business and results of operations. Our ability to engage, motivate and retain key employees or take other measures intended to motivate and incentivize key employees to remain with us through the pendency of the Chapter 11 Cases is limited by restrictions on implementation of incentive programs under the Bankruptcy Code. The loss of services of members of our senior management team could impair our ability to execute our strategy and implement operational initiatives, which would be likely to have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, the longer the Chapter 11 Cases continue, the more likely it is that vendors and employees will lose confidence in our ability to reorganize our business successfully.

Aspects of the Chapter 11 Cases limit the flexibility of our management team in running our business.

While we operate our business under supervision by the Bankruptcy Court, we are required to obtain approval of the Bankruptcy Court, and in some cases certain other parties, prior to engaging in activities or transactions outside the ordinary course of business. Bankruptcy Court approval of non-ordinary course activities entails preparation and filing of appropriate motions with the Bankruptcy Court, negotiation with various parties-in-interest, and one or more hearings. Parties-in-interest may be heard at any Bankruptcy Court hearing and may raise objections with respect to these motions. This process may delay major transactions and limit our ability to respond quickly to opportunities and events in the marketplace. Furthermore, in the event the Bankruptcy Court does not approve a proposed activity or transaction, we would be prevented from engaging in activities, transactions and internal restructurings that we believe are beneficial to us, which may have an adverse effect on our business, financial condition, results of operations and cash flows.

Risks Related to Our Business

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. 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. However, 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 March 10, 2021, the cases we are aware of include, but are not limited to, approximately 2,614 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 270 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers; approximately 124 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 March 10, 2021, 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 FCA, product liability, consumer fraud, unfair or deceptive trade practices, false advertising, insurance fraud, unjust enrichment negligence and 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. Other parties may file similar lawsuits against us in the future.

Certain Mallinckrodt entities have agreed to be bound by an Operating Injunction enjoining those entities from engaging in certain conduct related to the manner in which they operate their opioid business. The Operating Injunction is part of a global settlement of opioid-related litigation, supported by 50 Attorneys General of U.S. States and Territories. On January 8, 2021, the Bankruptcy Court entered an order subjecting Mallinckrodt to the Operating Injunction, *Mallinckrodt plc v. State of Conn. (In re Mallinckrodt plc)*, Adv. Proc. No. 20-50850 (Bankr. D. Del. 2020) (Dkt. No. 196, Annex 1). The Operating Injunction applies to the business operations of Mallinckrodt Enterprises LLC, Mallinckrodt LLC, and SpecGx LLC relating to the manufacture and sale of certain opioid products in the U.S. and its territories. The Operating Injunction prohibits certain promotional activities related to opioid products and pain treatment, financial and in-kind support for third parties involved with opioids or pain treatment, and certain lobbying activities and communications related to opioids and pain treatment. The Operating Injunction also contains requirements for controlled substances suspicious order monitoring and reporting. The Operating Injunction provides that Mallinckrodt must retain a monitor to evaluate and monitor compliance with the Operating Injunction for a term of five to seven years. On January 21, 2021, Mallinckrodt jointly filed a motion with the Governmental Plaintiff Ad Hoc Committee requesting that the Bankruptcy Court appoint R. Gil Kerlikowske to serve as monitor. The Operating Injunction also requires Mallinckrodt make available certain clinical data through a third-party data archive and publicly disclose certain produced documents related to the opioid litigation. An order approving the appointment of the monitor was entered on February 8, 2021.

While we are vigorously defending ourselves in these matters, and intend to use the Chapter 11 process to provide a fair, orderly, efficient and legally binding mechanism to implement a RSA pursuant to which, among other things, the parties thereto have agreed to support the Amended Proposed Opioid-Related Litigation Settlement, 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 Amended Proposed Opioid-Related Litigation Settlement 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 Amended Proposed Opioid-Related Litigation Settlement 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.

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 $100.0 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. On September 14, 2020, a panel of the U.S. Court of Appeals for the Second Circuit reversed in part the lower court’s judgment, finding that the lower court should have dismissed our (and other parties’) challenges to the OSA for lack of subject matter jurisdiction. Together with the other plaintiffs, we filed a petition for rehearing en banc to challenge the panel's decision, which was denied on December 18, 2020. On February 12, 2021, the Second Circuit granted the parties' request to stay the mandate. The parties plan to file a petition for certiorari with the Supreme Court. 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, leading to parties being unwilling to engage with us from a business perspective, and could have a material impact on the results of litigation.

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

Our business may be adversely affected by public health crises and epidemics/pandemics, including the recent coronavirus outbreak.

A pandemic, epidemic or outbreak of an infectious disease occurring in the U.S., or elsewhere, could result in our business being adversely affected. Since December 2019, COVID-19, has spread to countries throughout the world and has resulted in the World Health Organization declaring the outbreak as a pandemic. Our business performance was significantly impacted by COVID-19, and we continue to expect to see challenges while the pandemic persists and potentially thereafter.

We may experience significant and unpredictable increases or decreases in demand for certain of our products as the needs of health care providers and patients evolve during this pandemic. For example, as 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 could experience an increase in demand which we may not be able to meet in accordance with the needs of the market. Additionally, our INOmax product is a potential treatment for acute respiratory distress syndrome (ARDS), which is a known clinical manifestation of infection with many respiratory viruses including coronaviruses, which could be subject to similar dynamics including with respect to the demands on our upstream supply chain. Alternatively, due to diverse factors ranging from the deprioritization of non-critical medical treatment, to directives that immunosuppressed patients stay-at-home, to the impact of home schooling on the market for attention-deficit/hyperactivity disorder (ADHD) treatments, demand for our products have been and may continue to be negatively impacted.

Furthermore, emergency powers could be invoked under the Defense Production Act, which allows the U.S. government to direct private companies to meet the needs of the nation in the time of an emergency. Given the critical nature of some of the products we manufacture, as well as our pharmaceutical and medical device manufacturing capabilities, we may be impacted by governmental action taken under this or similar legislation.

Many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus. Such disruptions could materially delay potential FDA approval with respect to our clinical trials and product candidates, including the FDA’s decision on the BLA for StrataGraft. Other factors caused by the COVID-19 virus have already impacted and could materially delay or otherwise impact clinical trials we are conducting related to our products, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to the COVID-19 virus. Furthermore, business pressures driven by the ongoing COVID-19 pandemic have led us to prioritize certain investments over others, resulting in the termination of two of our Phase 4 studies related to Acthar Gel, and such pressures could result in similar decisions across our product portfolio. Any delays in our clinical trials or regulatory review resulting from such disruptions could materially affect the development or approval of our product candidates or our lifecycle management efforts.

In addition, the economic impact of the spread of the COVID-19 virus, which has caused a broad impact globally, has adversely impacted our business and may continue to adversely affect us. In particular, the COVID-19 virus has negatively affected demand for our products due to limitations on the ability of our sales representatives to meet with physicians, and a reduction in patient visits to their doctors and pharmacists in order to receive prescriptions for our products, all of which may continue so long as the pandemic does not abate. There is also an increased risk of supply interruption at our third-party suppliers, impacting their ability to deliver components, which would then impede the ability of our manufacturing facilities to produce finished products on a timely basis, all of which could result in business or operational disruption. Additionally, while the potential long-term economic impact of the COVID-19 virus may be difficult to assess or predict, COVID-19 pandemic has resulted in significant disruption of global financial markets, which could reduce our ability to access capital, thereby negatively affecting our liquidity. The extent to which the COVID-19 pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted.

Given the rapid and evolving nature of the COVID-19 virus, the full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be predicted.

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 FCA, 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. In addition, over the past few years, there has been enhanced government scrutiny of industry-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide patients with 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/or 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/or burdensome remediation measures.

Many of these government investigations originate as "qui tam" actions under the FCA. Under the FCA, 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 often 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 EDPA, requesting documents pertaining to an investigation of its promotional practices for Acthar Gel. The USAO later expanded the scope of its investigation to include Questcor's donations to third-party independent charitable foundations that provide co-pay assistance to patients. In March 2019, the U.S. District Court for EDPA unsealed two qui tam actions involving the allegations under investigation by the USAO for the EDPA. The DOJ intervened in both actions, which were later consolidated. In September 2019, we executed a settlement agreement to resolve the portion of the investigation and the litigation involving Questcor's promotional practices for $15.4 million. As referenced above, on October 12, 2020, we announced the Proposed Acthar Gel-Related Settlement, which would resolve the second EDPA qui tam case relating to Questcor's donations to an independent third-party charitable foundation.

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 have cooperated 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 increases in the price of Acthar Gel over time, including related to the period prior to the acquisition of the product. Acthar Gel represented 27.9% of our net sales for fiscal 2020. In addition, U.S. federal prosecutors have issued subpoenas to certain pharmaceutical companies seeking information about their drug pricing practices, among other issues, and in October 2020, the U.S. House of Representatives Committee on Oversight and Reform held hearings relating to drug pricing at which our CEO testified along with executives from other major pharmaceutical companies. 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, including 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. 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.

For any marketed drug products which are covered in the U.S. by the federal or state healthcare programs, such as the Medicare and Medicaid programs, we have various obligations, including government price reporting and rebate requirements, which generally require medicines be offered at substantial rebates and/or discounts to the government and certain private purchasers including “covered entities” purchasing under the 340B Drug Discount Program. Some of these programs require submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations, and the guidance governing such calculations is not always clear or precise. Compliance with such requirements can require significant investment in personnel, systems and resources, but failure to properly calculate our prices, or offer required discounts or rebates could subject us to substantial penalties. One component of the rebate and discount calculations under the Medicaid and 340B programs, respectively, is the “additional rebate,” a complex calculation which is based, in part, on the extent that a branded drug’s price increases over time more than the rate of inflation (based on the Consumer Price Index for All Urban Consumers). This “additional rebate” calculation can result in Medicaid rebates up to 100% of a drug’s “average manufacturer price” and 340B prices of one penny. With respect to Acthar Gel, the “additional rebate” scheme of the 340B pricing rules, as applied to the historical pricing of Acthar Gel both before and after we acquired the medicine, have resulted in a 340B ceiling price of one penny, which has negatively impacted and is expected to continue to negatively impact our net sales of Acthar Gel.

With regard to private payers, 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 insurance carriers, there are a large number of guideline updates issued each year.

In addition, a number of markets outside the U.S. 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.

Specific to our business, in May 2019, CMS issued a final decision directing the Company to revert to the original base date average manufacturer price ("AMP") used to calculate Medicaid drug rebates for Acthar Gel despite CMS having given the previous owner of the product, Questcor, written authorization in 2012 to reset the base date AMP. Upon receipt of CMS's final decision, we filed suit in U.S. District Court for the District of Columbia ("D.C. District Court") against HHS and CMS seeking to have the decision declared unlawful and set aside. In March 2020, we received an adverse decision from the D.C. District Court. We immediately sought reconsideration by the D.C. District Court, which was denied. We then appealed to the U.S. Court of Appeals for the District of Columbia ("D.C. Circuit"). In June 2020, while our appeal remained pending, we were required to revert to the original base date AMP for Acthar Gel in the government's price reporting system.

As a result of this contingency, we incurred a retrospective one-time charge of $641.1 million (the "Acthar Gel Medicaid Retrospective Rebate"), of which $535.1 million and $105.1 million have been reflected as a component of net sales and operating expense, respectively, in the consolidated statement of operations for fiscal 2020. The $105.1 million reflected as a component of operating expenses represents a pre-acquisition contingency related to the portion of the Acthar Gel Medicaid Retrospective Rebate that arose from sales of Acthar Gel prior to our acquisition of Questcor in August 2014.

The D.C. Circuit heard argument on the merits of our appeal in September 2020, prior to our filing of the Chapter 11 Cases on October 12, 2020. At the joint request of the parties, the D.C. Circuit has agreed to hold the case in abeyance pending completion of the Proposed Acthar Gel-Related Settlement discussed above which was conditioned upon the Company entering the Chapter 11 restructuring process. Pursuant to the Proposed Acthar Gel-Related Settlement, we have agreed to pay $260.0 million over seven years and to reset Acthar Gel’s Medicaid rebate calculation as of July 1, 2020, such that state Medicaid programs will receive 100% rebates on Acthar Gel Medicaid sales, based on current Acthar Gel pricing. Additionally, upon execution of the Proposed Acthar Gel-Related Settlement, we will dismiss our D.C. Circuit appeal. We expect that the Proposed Acthar Gel-Related Settlement will be completed over the next several months, subject to Bankruptcy Court approval. The failure of the settlement in principle may subject us to additional risk and uncertainties that could adversely affect our business prospects, as further described in the risk factor captioned "*The Amended Proposed Opioid-Related Litigation Settlement and the Proposed Acthar Gel-Related Settlement are subject to certain contingencies and may not go into effect in their current form or at all, which may have an adverse impact on our ability to consummate the Plan and our business, financial condition, results of operations and cash flows.*"

Our reporting and payment obligations under the Medicare and Medicaid rebate programs, and other governmental purchasing and rebate programs, are complex. Any determination of failure to comply with these obligations or those relating to healthcare fraud and abuse laws could have a material adverse effect on our business.

The regulations regarding reporting and payment obligations with respect to Medicare and Medicaid reimbursement programs, and rebates and other governmental programs, are complex. Because our processes for these calculations and the judgments used in making these calculations involve subjective decisions and complex methodologies, these accruals may have a higher inherent risk for material changes in estimates. In addition, they are subject to review and challenge by the applicable governmental agencies, and in the case of the 340B program, certain private beneficiaries, and it is possible that such reviews could result in material adjustments to amounts previously paid. See the risk factor captioned “*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, as noted elsewhere in this Annual Report on Form 10-K, in May 2019, CMS issued a final decision directing the Company to revert to the original base date AMP used to calculate Medicaid drug rebates for Acthar Gel despite having granted Questcor written authorizations to reset the base date AMP in 2012. In addition, 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. are 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. Prior to approval of any product, the FDA inspects both our facilities and procedures to ensure compliance with regulatory standards, and those inspections are also conducted periodically once a product is approved. The FDA has been impeded in conducting such inspections due to the challenges of the COVID-19 pandemic, which could lead to delays to approval of our products. The FDA may also 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, particularly in light of the scrutiny being paid to drug pricing in the U.S. 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 technologies that are similar to our devices but may operate either more effectively or less expensively. 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. 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.

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.

Specifically, we believe that the following risks could impact our existing product portfolio:

- Acthar Gel – 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.
- INOmax – 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 in September 2017 that ruled five patents invalid and six patents not infringed. We appealed the decision all the way up to the U.S. Supreme Court but were unsuccessful in those efforts. As a result, we have begun to see a broader-scale launch of competitive nitric oxide products in the market 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.
- Therakos – Our Therakos products provide 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”). 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. Recently granted patents relating to improvements to the CELLEX system, processing of blood, disposable kit and overall photopheresis method may offer additional patent protection through approximately 2036.

Clinical trials demonstrating the efficacy of 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 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 conducted several Phase 4 clinical trials to supplement the non-clinical evidence supporting the use of Acthar Gel, but 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, or otherwise may not achieve approval. 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 or varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of product candidate or a new indication for a product candidate. For example, in September 2020 the FDA issued a CRL regarding our application seeking approval for the investigational agent terlipressin to treat adults with HRS-1. The CRL stated that, based on the available data, the agency cannot approve the terlipressin NDA in its current form and requires more information to support a positive risk-benefit profile for terlipressin for patients with HRS-1. We are currently in active discussions with the FDA in order to seek a viable path towards approval, but there is no assurance that such an outcome will result from this engagement.

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.

As noted elsewhere in this Item 1A, we are or may be involved in various legal proceedings and certain government inquiries and investigations, including with respect to, but not limited to, patent infringement, product liability, personal injury, antitrust matters, securities class action lawsuits, breach of contract, Medicare and Medicaid reimbursement claims, opioid related matters, promotional practices and compliance with laws relating to the manufacture and sale of controlled substances. Such proceedings, inquiries and investigations may involve claims for, or the possibility of, fines and penalties involving substantial amounts of money or other relief, including but not limited to civil or criminal fines and penalties, changes in business practices and exclusion from participation in various government healthcare-related programs. Such litigation and related matters are described in Note 20 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K. If any of these legal proceedings, inquiries or investigations were to result in an adverse outcome, the impact could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

With respect to product liability and clinical trial risks, in the ordinary course of business we are subject to liability claims and lawsuits, including potential class actions, alleging that our marketed products or products in development have caused, or could cause, serious adverse events or other injury. Any such claim brought against us, with or without merit, could be costly to defend and could result in an increase in our insurance premiums. We retain liability for $10.0 million per claim of the first $50.0 million of a loss in our primary liability policies and purchase an additional $60.0 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 25, 2020, it was probable that we would incur remediation costs in the range of $37.3 million to $85.8 million. We also concluded that, as of December 25, 2020, the best estimate within this range was $60.8 million. For further

information on our environmental obligations, 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. 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 and such liabilities are not discharged pursuant to the Plan or otherwise, we may be subject to substantial liabilities. These potential indemnification obligations, if not discharged pursuant to the Plan or otherwise, could have a material adverse effect on our financial condition, results of operations and cash flows. While the Amended Proposed Opioid-Related Litigation Settlement requires as a condition precedent that any of our indemnification liabilities to Covidien will be channeled to the establishment of a trust for the benefit of plaintiffs holding opioid-related claims against the Company (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 Amended Proposed Opioid-Related 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 scientific, technical, regulatory and commercial 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 one of our distributors that supplies our products to many end user customers, CuraScript Inc., accounted for 10.0% or more of our total net sales in each of the past three fiscal years. If we were to lose the business of this distributor, if this distributor failed to fulfill their obligations, if this distributor was to experience difficulty in paying us on a timely basis, or if this distributor negotiates 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, INOmax 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 continue to procure raw materials or finished goods, as applicable, for Acthar Gel, 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 2020, manufacturing and procurement quotas granted by the DEA were sufficient to meet our sales and inventory requirements on most products. Over the past several years and into 2021, the DEA has steadily reduced the amount of opioid medication that may be manufactured in the U.S. by approximately 10% to 20%, annually, as a response to the opioid crisis. These quota reductions have included oxycodone, hydrocodone, oxymorphone, hydromorphone, and fentanyl. 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. In addition, the DEA conducts periodic inspections of registered establishments that handle controlled substances and has stringent regulations on those establishments to prevent loss and diversion. Failure to maintain compliance with these regulations, 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.

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.

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 $6,184.5 million as of December 25, 2020. 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 3,100 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, results of operations and cash flows.

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 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 Hampton, New Jersey and our Specialty Generics headquarters and technical development center in Webster Groves, Missouri. As of December 25, 2020, 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, results of operations and cash flows.

Risks Related to Our Indebtedness

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

We have substantial indebtedness. As of December 25, 2020, total debt principal was $5,283.3 million, of which $3,622.6 million was classified as current, and the remainder classified as liabilities subject to compromise. Even if our existing indebtedness is reduced or discharged in part through the Plan, we expect to have substantial remaining indebtedness upon emergence from bankruptcy, which could adversely affect our ability to fulfill our financial obligations and have a negative impact on our financing options and liquidity positions.

Our degree of debt leverage, even if our existing indebtedness is reduced or discharged in part through the Plan, 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 "Significant Events: Voluntary Filing Under Chapter 11 and Going Concern" within Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report on Form 10-K, Mallinckrodt plc and certain of its subsidiaries initiated the Chapter 11 Cases to, among other things, restructure its existing indebtedness. As discussed in greater detail above in "Risks Related to Our Chapter 11 Cases," our ability to consummate the contemplated restructuring is subject to many risks and a number of conditions. We cannot guarantee that we will satisfy all such conditions and otherwise consummate the contemplated restructuring.

Even if our existing indebtedness is restructured, 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.

Even if our existing indebtedness is reduced or discharged in part through the Plan, 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 following emergence from bankruptcy 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 existing indebtedness restrict (and we expect that any agreement governing our remaining indebtedness upon emergence from bankruptcy will 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 following emergence from bankruptcy 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 following emergence from bankruptcy, we will be in default and, as a result, lenders under any of our then-outstanding indebtedness could declare essentially all outstanding principal and interest to be due and payable, our secured lenders could foreclose against the assets securing such borrowings and we could be forced to return to bankruptcy or into 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, permitting our creditors to exercise various remedies. Although the commencement of the Chapter 11 Cases itself constituted an event of default under substantially all of our existing indebtedness and any efforts to exercise remedies in respect of our indebtedness are automatically stayed as a result of the Chapter 11 Cases, the RSA contemplates the reinstatement of certain of our existing indebtedness through the Plan. As it is a condition to reinstatement of indebtedness that most defaults under the applicable indebtedness must be cured, we continue to adhere to the covenants in respect of such indebtedness.

Moreover, we expect that any indebtedness that remains outstanding following our emergence from bankruptcy will be subject to similar covenants.

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.

Even if our existing indebtedness is restructured, our 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 the Chapter 11 Cases, our debt levels (even if our existing indebtedness is reduced or discharged in part through the Plan) 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.

Our variable-rate indebtedness exposes us to interest rate risk, which could cause our debt service obligations to increase significantly.

During the pendency of the Chapter 11 Cases, we expect to pay interest on certain of our secured indebtedness as it accrues. Certain of our secured indebtedness, including borrowings under our senior secured credit facilities, 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 loss would increase, even though the amount borrowed under the facilities remained the same. As of December 25, 2020, we had $1,904.7 million outstanding variable-rate debt on our senior secured term loans and $900.0 million outstanding on our senior secured revolving credit facility. An unfavorable movement in interest rates, primarily 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. Applicable Bankruptcy Court orders in the Chapter 11 Cases may also permit the incurrence of additional indebtedness. 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.

In July 2017, the Financial Conduct Authority (the authority that regulates LIBOR) announced that it would phase out LIBOR by the end of 2021. In the U.S., the Alternative Reference Rates Committee has proposed the Secured Overnight Financing Rate ("SOFR") as an alternative to LIBOR. It is not presently known whether SOFR or any other alternative reference rates that have been proposed will attain market acceptance as replacements of LIBOR. 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

The Company's tax attributes and future tax deductions may be reduced or significantly limited as a result of the Chapter 11 filing.

Generally, any discharge of our external or internal debt obligations as a result of the Chapter 11 filing for an amount less than the adjusted issue price may give rise to cancellation of indebtedness income, which must either be included in our taxable income or result in a reduction to our tax attributes.

Certain tax attributes otherwise available and of value to the Company may be reduced, in most cases by the principal amount of the indebtedness forgiven. U.S. and non U.S. tax attributes subject to reduction include: (i) net operating losses ("NOL(s)") and NOL carryforwards; (ii) credit carryforwards (iii) capital losses and capital loss carryforwards; and (iv) the tax basis of the Company's depreciable, amortizable and other assets. Loss of these tax attributes may have an adverse effect on the Company's prospective cash flow.

To the extent, if any, that U.S. NOL carryforwards, other losses and credits generated by the Company prior to emergence from bankruptcy are available as deductions after emergence, the ability of the Company to utilize such deductions may be limited by Section 382 of the Internal Revenue Code (the "IRC"). Section 382 provides rules limiting the utilization of a corporation's NOLs and other losses, deductions and credits following a more than 50% change in ownership of a corporation's equity (an "ownership change"). An ownership change may occur with respect to the Company in connection with bankruptcy, unless the IRC Section 382(l)(5) exception applies. This exception is not easily met as it requires a majority of the holders of the Company's stock after bankruptcy to meet certain specific and narrow conditions. Therefore, the Company's U.S. NOLs may be significantly limited by Section 382 of the IRC. The amount of the Company's post ownership change annual U.S. taxable income that can be offset by the pre-ownership change U.S. NOLs generally cannot exceed an amount equal to the product of (a) the applicable federal long-term tax exempt rate in effect on the date of the ownership change and (b) the value of the Company's U.S. affiliate stock immediately prior to implementation of the Plan (the "Annual Limitation"). However, if the value of the Company's U.S. affiliate stock is zero, if the Company does not continue its historic business or use a significant portion of its assets in a new business for two years after the ownership change, the Annual Limitation resulting from the ownership change is zero and the Company may be significantly limited in its ability to use any of its pre-emergence U.S. NOLs. In addition, if the Company has a net unrealized built in loss at the time of an ownership change, future deductions for items such as amortization, depreciation, and settlement liabilities may also be significantly limited. Limitations on our ability to prospectively use these tax attributes may have an adverse effect on the Company's prospective cash flow.

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.

As a result of our Chapter 11 filing, taxing authorities have been notified of our bankruptcy status and their opportunity to make a tax claim against the Company for pre-bankruptcy periods. This notification process may lead to an increased level of tax claims and audits being made against the Company resulting in an adverse effect on our financial condition.

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 rules under IRC Section 7874 or the U.S. Treasury Regulations promulgated thereunder or other Internal Revenue Service ("IRS") guidance, could adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any such changes could have prospective or retroactive application to us and our shareholders and affiliates. In addition, legislative proposals issued by the U.S. Department of the Treasury and Congress have aimed to expand the scope of U.S. corporate tax residence, and such proposals, if passed, could have an adverse effect on us. Although the proposals would generally apply to prospective transactions, no assurance can be given that such proposals will not be changed to apply retroactively.

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, Japan, 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), the Biden administration's informal proposals to increase U.S. corporate income taxes, and changes in other E.U. jurisdiction tax laws to implement the recommendations of the OECD. 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 Ireland 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. From May 21, 2015 until July 15, 2020, 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 be treated as a resident only in the U.K. for tax purposes during this period. As of July 15, 2020 the activities of the Company’s principal executive offices were relocated from the U.K. to Ireland, which resulted in a change in the Company’s tax residence to Ireland. 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 Ireland. If Mallinckrodt plc were considered to be a tax resident of a jurisdiction other than Ireland, in addition to any Irish consequences, it could become liable for corporate tax in that jurisdiction and any dividends paid by it could be subject to dividend withholding tax in that jurisdiction.

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 2014, 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 2020 Annual General Meeting is due to expire on the earlier of our 2021 Annual General Meeting or August 15, 2021 unless renewed by shareholders for a further period. While the proposals for our 2021 Annual General Meeting remain subject to review, we anticipate seeking the renewal of this authority either at our 2021 Annual General Meeting or subsequently, but we cannot guarantee that such renewal will always be sought or 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 2020 Annual General Meeting and is due to expire on the earlier of our 2021 Annual General Meeting or August 15, 2021, unless renewed for a further period. While the proposals for our 2021 Annual General Meeting remain subject to review, we anticipate seeking the renewal of this opt-out at our 2021 Annual General Meeting or subsequently, but we cannot guarantee that such renewal of the opt-out from pre-emptive rights will always be sought or approved. We cannot provide assurance that these Irish legal restrictions will not interfere with our capital management.

Risks Related to Our Ordinary Shares

Our ordinary shares are quoted on the Pink Open Market, and thus may have a limited market and lack of liquidity.

The delisting of our ordinary shares on the New York Stock Exchange ("NYSE") could result in significantly lower trading volumes and reduced liquidity for investors seeking to buy or sell ordinary shares. Our ordinary shares are currently quoted on the Pink Open Market, which may have an unfavorable impact on our share price and liquidity. The Pink Open Market is a significantly more limited market than the NYSE. The quotation of our shares on the Pink Open Market may result in a less liquid market available for existing and potential shareholders to trade our ordinary shares, could further depress the trading price of our ordinary shares, and could have a long-term adverse impact on our ability to raise capital in the future. There can be no assurance that there will be an active market for our ordinary shares, either now or in the future, or that shareholders will be able to liquidate their investment or the price at which it may be liquidated. Accordingly, we urge extreme caution with respect to existing and future investments in our equity and other securities.

The Plan contemplates the cancellation of our ordinary shares without any value being delivered to shareholders. Any trading in our ordinary shares during the pendency of our Chapter 11 Cases is highly speculative and poses substantial risks to purchasers of our ordinary shares.

The Plan contemplates the cancellation of our ordinary shares. We have a significant amount of indebtedness and other liabilities that are senior to our current ordinary shares in our capital structure, and the Plan contemplates value being distributed in respect of such indebtedness and liabilities and not our shares. In addition, our existing ordinary shares have substantially decreased in value leading up to and during the Chapter 11 Cases. Accordingly, any trading in our ordinary shares during the pendency of our Chapter 11 Cases is highly speculative and poses substantial risks to purchasers of our ordinary shares.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal executive offices and 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 Hampton, New Jersey and our Specialty Generics headquarters and technical development center in Webster Groves, Missouri. As of December 25, 2020, 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 0.7 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. 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 will not have a material adverse effect on our financial condition, results of operations and cash flows.

Notwithstanding the foregoing, any litigation pending against us and any claims that could be asserted against us that arose prior to October 12, 2020 (the "Petition Date") (subject to certain exceptions) are automatically stayed as a result of the commencement of the Chapter 11 Cases pursuant to the Bankruptcy Code, subject to certain statutory exceptions.

For further 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, which is incorporated by reference into this Part I, Item 3.

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

Prior to our filing for Chapter 11, our ordinary shares were traded on the NYSE under the ticker symbol "MNK." On October 13, 2020, the NYSE filed a Form 25 with the SEC to delist the ordinary shares, $0.20 par value, of the registrant from the NYSE. The delisting became effective October 26, 2020. The deregistration of the ordinary shares under Section 12(b) of the Exchange Act became effective on January 11, 2021, at which point the ordinary shares were deemed registered under Section 12(g) of the Exchange Act. The registrant's ordinary shares began trading on the OTC Pink Marketplace on October 13, 2020 under the symbol "MNKKQ."

There were approximately 2,282 shareholders of record of our ordinary shares as of March 5, 2021.

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 25, 2020, we repurchased 125 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 26, 2020 to October 23, 2020	—	$ —	—	$ 564.2
October 24, 2020 to November 27, 2020	38	0.14	—	564.2
November 28, 2020 to December 25, 2020	87	0.19	—	564.2
September 26, 2020 to December 25, 2020	**125**	**0.18**		

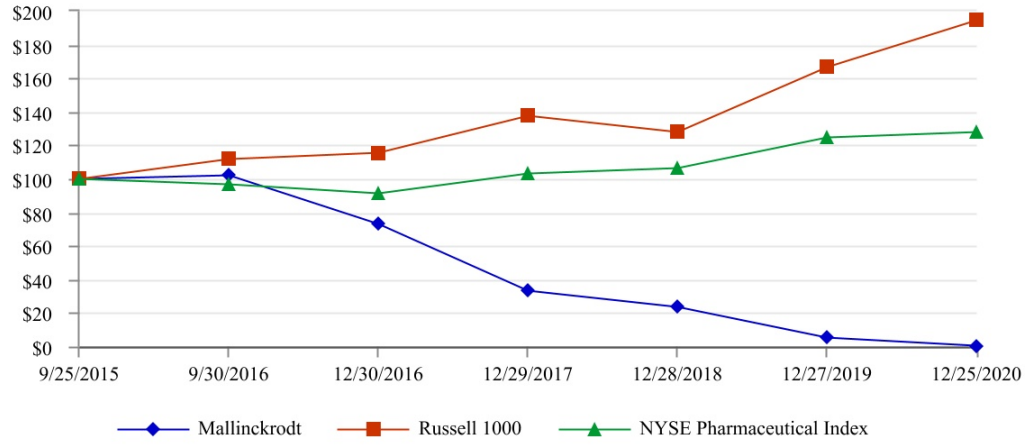
Performance Graph

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 25, 2020. 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 2020, 2019 and 2018, and the consolidated balance sheet data as of December 25, 2020 and December 27, 2019 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 2017 and 2016 and the three months ended December 30, 2016, and the consolidated balance sheet data as of December 28, 2018, December 29, 2017, December 30, 2016 and September 30, 2016 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 25, 2020	December 27, 2019	December 28, 2018	December 29, 2017	September 30, 2016	December 30, 2016
Consolidated Statement of Operations Data:						
Net sales [3]	$ 2,213.4	$ 3,162.5	$ 3,215.6	$ 3,221.6	$ 3,380.8	$ 829.9
Gross profit	669.4	1,421.4	1,471.2	1,657.5	1,857.6	446.7
Research and development expenses	290.8	349.4	361.1	276.9	261.2	66.1
Operating (loss) income [4]	(651.6)	(1,822.2)	(3,720.9)	492.9	633.1	(158.6)
(Loss) income from continuing operations before income taxes	(960.8)	(1,591.5)	(4,052.0)	61.6	233.4	(298.5)
(Loss) income from continuing operations	(969.7)	(1,007.2)	(3,621.9)	1,771.2	489.0	(176.8)
Share Data:						
Basic (loss) income from continuing operations per share	$ (11.48)	$ (12.00)	$ (43.12)	$ 18.13	$ 4.42	$ (1.67)
Diluted (loss) income from continuing operations per share	(11.48)	(12.00)	(43.12)	18.09	4.39	(1.67)
Cash dividends per ordinary share	—	—	—	—	—	—
Consolidated Balance Sheet Data:						
Total assets	$ 9,715.4	$ 10,338.9	$ 10,877.3	$ 15,280.9	$ 15,498.7	$ 15,206.3
Total debt [5]	5,248.6	5,374.8	6,091.6	6,734.6	6,045.0	6,152.0
Shareholders' equity	1,019.2	1,940.7	2,887.3	6,522.0	5,270.7	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.

(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 covers the period from September 26, 2015 through September 30, 2016.

(3) Fiscal 2020 includes a retrospective one-time charge of $536.0 million related to the Medicaid lawsuit. For further information, refer to Note 20 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

(4) Fiscal 2020 includes a charge of $641.1 million related to the Medicaid lawsuit. 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 in-process research and development ("IPR&D") asset. For further information, refer to Notes 14 and 20 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

(5) As of December 25, 2020. $1,660.7 million of the Company's debt is recorded within liabilities subject to compromise on the consolidated balance sheet.

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).

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

Significant Events

Voluntary Filing Under Chapter 11 and Going Concern

Chapter 11 Proceedings

On the Petition Date, we voluntarily initiated the Chapter 11 Cases under Chapter 11 of the Bankruptcy Code in the Bankruptcy Court to modify our capital structure, including restructuring portions of our debt, and resolve otherwise unmanageable potential legal liabilities. We are continuing to operate our business as debtors-in-possession and supply customers and patients with products as normal.

To assure ordinary course operations, we received Bankruptcy Court approval of our customary motions filed on the Petition Date ("First Day Motions") on an interim basis seeking court authorization to continue to support our business operations during the Chapter 11 Cases, including the continued payment of employee wages and benefits without interruption, payment of critical and foreign vendors, continuation of customer programs, continuation of use of existing cash management programs and allowance of certain financing payments under a cash collateral order. The First Day Motions were subsequently approved by the Bankruptcy Court on a final basis at hearings.

We intend to use the Chapter 11 process to provide a fair, orderly, efficient and legally binding mechanism to implement a RSA pursuant to which, among other things, the parties thereto have agreed to support:

- a financial restructuring that would, among other things, reduce our total debt by approximately $1,300.0 million, improving our financial position and better positioning us for long-term growth;
- the Amended Proposed Opioid-Related Litigation Settlement; and
- the Proposed Acthar Gel-Related Settlement.

Taken together, these actions are intended to enable us to move forward with our vision to become an innovation-driven biopharmaceutical company meeting the needs of underserved patients with severe and critical conditions.

For further information on the Chapter 11 Cases, refer to Notes 2 and 20 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Reorganization items, net

Reorganization items, net, represent amounts incurred after the Petition Date as a direct result of the Chapter 11 Cases and are comprised of professional fees and adjustments to reflect the carrying value of liabilities subject to compromise at their estimated allowed claim amounts, as such adjustments are approved by the Bankruptcy Court. During fiscal 2020, reorganization items, net from the Petition Date through December 25, 2020 were $61.4 million.

Chapter 11 Financing

In accordance with the terms of the RSA, we obtained the entry in the Chapter 11 Cases of an order of the Bankruptcy Court (in a form agreed with, among others, the agent under the senior secured credit facilities, lenders under the senior secured revolving credit facility and the senior secured term loans and holders of the first lien senior notes and the second lien senior notes) permitting the use of cash collateral to finance the Chapter 11 Cases.

Such order requires that we make cash adequate protection payments on the senior secured revolving credit facility and the senior secured term loans for, among other things, unpaid pre-petition and post-petition fees, unpaid pre-petition interest (at the specified contract rate), and post-petition interest (at a rate equal to (1) the adjusted LIBOR, plus (2) the contract-specified applicable margin and plus (3) an incremental 200 basis points), quarterly amortization payments on the senior secured term loans and reimbursement of certain costs. Such order further requires that we make cash adequate protection payments on the first lien senior notes and the second lien senior notes for, among other things, unpaid pre-petition and post-petition interest (at the specified non-default interest rate) and reimbursement of certain costs.

With respect to the incremental 200 basis points paid on the senior secured revolving credit facility and the senior secured term loans, noted above, we incurred $11.7 million of expense, of which $7.8 million was paid, during the three months ended December 25, 2020, which has provisionally been classified as interest expense in the consolidated statement of operations. The cash collateral order, however reserves all parties rights to seek recharacterization or reallocation to principal of such payments and we expect the incremental expense affiliated with these debt instruments to be reclassified as a reduction in principal in connection with the confirmation of a plan of reorganization by the Bankruptcy Court.

Going Concern

The accompanying consolidated financial statements have been prepared assuming we will continue as a going concern. The transactions contemplated by the RSA are subject to approval by the Bankruptcy Court, among other conditions. Accordingly, no assurance can be given that the transactions described therein will be consummated. As a result, we have concluded that management’s plans at this stage do not alleviate substantial doubt about our ability to continue as a going concern.

Medicaid Lawsuit

In May 2019, CMS issued a final decision directing the Company to revert to the original base date AMP used to calculate Medicaid drug rebates for Acthar Gel despite CMS having given the previous owner of the product, Questcor, written authorization in 2012 to reset the base date AMP. Upon receipt of CMS’s final decision, we filed suit in D.C. District Court against HHS and CMS under the Administrative Procedure Act seeking to have the decision declared unlawful and set aside. In March 2020, we received an adverse decision from the D.C. District Court. We immediately sought reconsideration by the D.C. District Court, which was denied. We then appealed to the D.C. Circuit. In June 2020, while our appeal remained pending, we were required to revert to the original base date AMP for Acthar in the government’s price reporting system.

During fiscal 2020, we incurred a retrospective one-time charge of $641.1 million related to the Acthar Gel Medicaid Retrospective Rebate, of which $536.0 million and $105.1 million have been reflected as a component of net sales and operating expenses, respectively, in the consolidated statement of operations. The $105.1 million reflected as a component of operating expenses represents a pre-acquisition contingency related to the portion of the Acthar Gel Medicaid Retrospective Rebate that arose from sales of Acthar Gel prior to our acquisition of Questcor in August 2014. Fiscal 2020 includes the prospective change to the Medicaid rebate calculation beginning in June 2020, which impacted Acthar Gel net sales by $40.4 million.

The D.C. Circuit heard argument on the merits of our appeal in September 2020, prior to our filing of the Chapter 11 Cases on October 12, 2020. At the joint request of the parties, the D.C. Circuit has agreed to hold the case in abeyance pending completion of the Proposed Acthar Gel-Related Settlement discussed above, which was conditioned upon the Company entering the Chapter 11 restructuring process. Pursuant to the Proposed Acthar Gel-Related Settlement, we have agreed to pay $260.0 million over seven years and to reset Acthar Gel’s Medicaid rebate calculation as of July 1, 2020, such that state Medicaid programs will receive 100% rebates on Acthar Gel Medicaid sales, based on current Acthar Gel pricing. Additionally, upon execution of the Proposed Acthar Gel-Related Settlement, we will dismiss our D.C. Circuit appeal. We expect that the Proposed Acthar Gel-Related Settlement will be completed over the next several months, subject to Bankruptcy Court approval.

This report contains certain financial measures, including net sales, gross profit, gross profit margin, SG&A expenses as a percentage of net sales and R&D expenses as a percentage of net sales, which exclude the one-time charge related to the Medicaid lawsuit that is included as a component of net sales.

We have provided these measures because they are used by management to evaluate our operating performance. In addition, we believe that they will be used by certain investors to measure Mallinckrodt's operating results. Management believes that presenting these measures provides useful information about our performance across reporting periods on a consistent basis by excluding items that we do not believe are indicative of our core operating performance. These measures should be considered supplemental to and not a substitute for financial information prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP").

Because these measures exclude the effect of items that will increase or decrease our reported results of operations, management strongly encourages investors to review our consolidated financial statements and this report in its entirety. A reconciliation of certain of these financial measures to the most directly comparable GAAP financial measures is included herein.

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 2020, 2019 and 2018, we incurred $55.7 million, $56.2 million and $38.8 million in opioid defense costs, respectively, which are included in SG&A expenses. As of the Petition Date, opioid defense costs directly related to the Chapter 11 proceedings are being classified on a go-forward basis as reorganization items, net. As a result, we expect a significant reduction in opioid defense costs classified within SG&A expenses during the pendency of the Chapter 11 proceedings.

Opioid-Related Litigation Settlement

On February 25, 2020, the Company announced that it had reached an agreement in principle with a court-appointed plaintiffs' executive committee representing the interest of thousands of plaintiffs in the multi-district litigation ("MDL") and supported by a broad-based group of 48 state and U.S. Territory Attorneys General on the terms of a global settlement that would resolve all opioid-related claims against the Company and its subsidiaries (the "Opioid-Related Litigation Settlement"). The Opioid-Related Litigation Settlement contemplated the filing of voluntary petitions under Chapter 11 by the Specialty Generics Subsidiaries and the establishment of the Opioid Claimant Trust. Furthermore, under the terms of the Opioid-Related Litigation Settlement, subject to court approval and other conditions, it was contemplated that, the Company would (i) 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 would be expected to be contributed to the Opioid Claimant Trust and (ii) issue warrants with an eight year term to the Opioid Claimant Trust exercisable at a strike price of $3.15 per share to purchase the Company's ordinary shares that would represent approximately 19.99% of the Company's fully diluted outstanding shares, including after giving effect to the exercise of the warrants (the "Settlement Warrants").

Amended Proposed Opioid-Related Litigation Settlement

In conjunction with our Chapter 11 filing on October 12, 2020, the Company entered into a RSA which includes the Amended Proposed Opioid-Related Litigation Settlement that supersedes the Opioid-Related Litigation Settlement. The RSA provides that upon the Company's emergence from Chapter 11 process, subject to court approval and other conditions:

- Opioid claims would be channeled to one or more trusts, which would receive $1,600.0 million in structured payments consisting of (i) a $450.0 million payment upon the Company's emergence from Chapter 11; (ii) a $200.0 million payment upon each of the first and second anniversaries of emergence; and (iii) a $150.0 million payment upon each of the third through seventh anniversaries of emergence with a one-year prepayment option at a discount for all but the first payment.
- Opioid claimants would also receive warrants for approximately 19.99% of the reorganized Company's new outstanding shares, after giving effect to the exercise of the warrants, but subject to dilution from equity reserved under the management incentive plan, exercisable at any time on or prior to the seventh anniversary of the Company's emergence, at a strike price reflecting an aggregate equity value for the reorganized Debtors of $1,551.0 million (the "New Opioid Warrants").
- Upon commencing the Chapter 11 filing, the Company will comply with an agreed-upon operating injunction with respect to the operation of its opioid business.

During fiscal 2019, we recorded a charge of $1,643.4 million attributed to the anticipated structured cash payments and Settlement Warrants that were previously intended to be issued upon effectiveness of the superseded Opioid-Related Litigation Settlement. At this time, we cannot reasonably estimate the equity value at emergence. As such, no value has been ascribed to the warrants as of December 25, 2020, resulting in a non-cash gain recorded of $43.4 million during fiscal 2020. For further information on the terms of this proposed resolution and valuation of the warrants as of December 25, 2020, refer to Notes 20 and 21, respectively, 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, in December 2018, we announced our plans to spin off to our shareholders a new independent public company that would hold the Specialty Generics business. In August 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. On October 12, 2020, we voluntarily initiated Chapter 11 proceedings. Separating the Specialty Generics and Specialty Brands businesses remains one of our goals. We will continue to evaluate strategic options for the Specialty Generics business at an appropriate time and when market conditions are favorable.

During fiscal 2020, 2019 and 2018, we incurred $93.4 million, $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, costs incurred in preparation for the Chapter 11 proceedings as we work to resolve opioid and other legal uncertainties, incremental costs incurred to build out the corporate infrastructure of the previously planned spin-off of the Specialty Generics business as well as rebranding initiatives associated with the Specialty Brands ongoing transformation. As of the Petition Date, professional fees directly related to the Chapter 11 proceedings that were previously reflected as separation costs are being classified on a go-forward basis as reorganization items, net. As a result, we expect a significant reduction in separation costs classified within SG&A expenses during the pendency of the Chapter 11 proceedings.

Tax Matters

In August 2020, a settlement was reached with the IRS related to the audit of Mallinckrodt Hospital Products Inc.'s ("MHP") (formerly known as Cadence Pharmaceuticals, Inc. ("Cadence")) tax year ended September 26, 2014. Cadence was acquired as a U.S. subsidiary in March 2014. Following the acquisition of Cadence, we transferred certain rights and risks in the Ofirmev intellectual property ("Transferred IP") to one of our wholly owned non-U.S. subsidiaries. The transfer occurred at a price determined in conjunction with 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 asserted the transfer price of the Transferred IP was understated. The settlement increased the transfer price of the Transferred IP, resulting in an increase to taxable income of $356.5 million and underpayment interest of $11.8 million. The increase to taxable income was satisfied through a noncash offset against our U.S. Federal NOLs and interest expense for the tax year ended September 25, 2020, while the underpayment interest was satisfied through a cash payment of $11.8 million. We were adequately reserved for this item; therefore there were no impacts to the consolidated statement of operations for fiscal 2020.

On July 15, 2020, the activities of our principal executive offices were relocated from the U.K. to Ireland, which resulted in a change in our tax residence to Ireland. Mallinckrodt plc has always been and remains incorporated in Ireland. Relocation of Mallinckrodt plc's tax residence to Ireland allows us to mitigate the potential impacts of the U.K.'s departure from the European Union and align with our commercial activity in Ireland. We continue to be subject to taxation in various tax jurisdictions worldwide. Accordingly, in fiscal 2020 we will report the Irish tax jurisdiction as our Domestic jurisdiction using an Irish statutory tax rate of 12.5% versus the U.K. statutory rate of 19.0%, and the International jurisdiction will represent areas outside the Irish tax jurisdiction. There is no material financial impact to this change.

Ofirmev

During the three months ended June 26, 2020, due to decreased demand as a result of the deprioritization of non-critical medical treatment in the face of the COVID-19 pandemic, along with increased generic competition anticipated in the marketplace after the product's loss of exclusivity in December 2020, we identified a triggering event with respect to the Ofirmev intangible asset within the Specialty Brands segment and assessed the recoverability of the definite-lived asset. Additionally, we evaluated whether these events warranted a revision to the remaining period of amortization that previously extended to March 2022. As a result of this analysis, we revised the useful life to end December 25, 2020, commensurate with the final period of market exclusivity. After this change in estimate of the asset's useful life, we determined that the undiscounted cash flows related to the Ofirmev intangible asset were less than its net book value, which required us to record an impairment charge of $63.5 million for the difference between the fair value of the Ofirmev intangible asset and its net book value. The intangible asset was fully amortized as of December 25, 2020. We anticipate that the product sales for Ofirmev will decrease significantly from current levels following the loss of exclusivity and the entrance of generic competition.

Terlipressin

During September 2020, the FDA issued a CRL regarding our NDA seeking approval for the investigational agent terlipressin to treat adults with HRS-1. The CRL stated that, based on the available data, the agency cannot approve the terlipressin NDA in its current form and requires more information to support a positive risk-benefit profile for terlipressin for patients with HRS-1.

In response to receipt of the CRL, we had an End of Review Meeting on October 26, 2020 and a Type A Meeting on January 29, 2021 with the FDA where both parties engaged in constructive dialogue in an effort to clarify a viable path to approval and we expect to have clarity on this path in fiscal 2021. As we continue to engage with the FDA over the coming months, we will continue to assess the impact of any changes to planned revenue or earnings on the fair value of the associated IPR&D asset of $81.0 million included within intangible assets, net on the consolidated balance sheets as of December 25, 2020 and December 27, 2019.

Amitiza

Prior to our acquisition of this product in February 2018, the prior owner had entered into an agreement with 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 and right to market a competing 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. While a competitive entrant has entered the market, we do not anticipate a material impact to Amitiza net sales in fiscal 2021 as Par will pay a double-digit royalty to us based on a percentage of the gross profits of the licensed products sold during the term of the agreement. The agreement continues until each of our related patents has expired; provided that the percentage of gross profits shall be reduced to zero if two or more generics or authorized generics are commercially marketing a generic product in addition to Par.

Business Factors Influencing the Results of Operations

COVID-19 Business Update

The COVID-19 pandemic has presented a substantial public health and economic challenge around the world. As we navigate the unprecedented challenges created by the COVID-19 pandemic, we remain committed to supporting our employees, customers, patients and the broader communities in which we operate.

Since the onset of the COVID-19 pandemic, we have continued to manufacture, supply and deliver our products largely without interruption. At present, we do not anticipate significant COVID-19-related manufacturing or supply chain disruptions, and we continue to evaluate our end-to-end supply chain and assess opportunities to refine our processes going forward.

We are supporting the fight against COVID-19 in a number of ways, including by partnering with Novoteris, LLC and Massachusetts General Hospital to study inhaled nitric oxide for use as a therapeutic option for COVID-19 patients; giving medically trained employees paid time off to volunteer to treat or care for COVID-19 patients; providing funding and therapies to hospitals to conduct treatment-related research; adapting certain of our manufacturing facilities to produce hand sanitizers for designated counties, state health departments and emergency operation distribution centers located in states where we have operations; donating excess PPE and other resources to healthcare providers, first responders, and medical facilities; and partnering with advocacy groups to help mitigate the impact of the pandemic on patients.

We expect the coming months to continue to be challenging due to the impact of COVID-19, as some of our products are sensitive to reduced numbers of surgical procedures and doctor visits. Our business performance was significantly impacted by COVID-19 during fiscal 2020. The ultimate business impact going forward will largely be determined by the ongoing return to work guidance issued by international, national, and local governments and health officials and organizations. We are monitoring the demand for our products, including the duration and degree to which we may see declines in customer orders or delays in starting new patients on a product, such as Acthar Gel, due to the limited ability of our sales representatives to meet with physicians and patients to visit their doctors and pharmacists to receive prescriptions for certain of our products. In regards to Acthar Gel, we continue to see a reduction in new patients, which may impact results in fiscal 2021. We also experienced and may continue to experience reduced demand for Therakos due to immunosuppressed patients who have been instructed to stay-at-home during the COVID-19 pandemic. Furthermore, while we are supporting the continuation of ongoing patients in our clinical trials, as much as possible, we expect that COVID-19 precautions may directly or indirectly impact the timeline for some of our clinical trials.

Given the rapid and evolving nature of the COVID-19 virus, the full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be predicted. For additional information on the various risks posed by the COVID-19 pandemic, refer to Part I, Item 1A. Risk Factors included within this report.

Specialty Brands

Net sales of Acthar Gel for fiscal 2020 decreased $184.8 million, or 19.4%, to $767.9 million driven primarily by the marketplace impact of the COVID-19 pandemic and continued payer scrutiny on overall specialty pharmaceutical spending. The prospective change to the Medicaid rebate calculation also served to reduce Acthar Gel net sales by $40.4 million during fiscal 2020. In addition, net sales of Ofirmev decreased $107.5 million or 28.0%, to $276.5 million primarily driven by the overall reduction in elective surgeries due to public health orders implemented as part of the COVID-19 pandemic, as well as the product's loss of exclusivity in December 2020.

Research and Development

We devote significant resources to R&D of products and proprietary drug technologies. During fiscal 2020, we incurred R&D expenses of $290.8 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 business, 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-1 and StrataGraft for the treatment of deep partial-thickness burns, both of which had positive top line results.

- *Terlipressin.* In March 2020, we submitted the NDA filing to the FDA for terlipressin and in April 2020 the FDA accepted the NDA for review. In June 2020, the Company paid $5.0 million to acquire product rights for terlipressin in Japan. Upon FDA approval, we would be responsible for a one-time milestone payment related to terlipressin of $12.5 million in relation to product rights in the U.S., in addition to a $5.0 million one-time milestone payment in relation to product rights in Japan. For further information on the development of this asset and receipt of the CRL during September 2020, refer to "Significant Events" within this Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.
- *StrataGraft.* In April 2020, we initiated a rolling submission of a BLA filing to the FDA for StrataGraft, a regenerative skin tissue therapy for the treatment of adult patients with deep partial-thickness thermal burns, and we completed the submission in June 2020. In July 2020, the FDA accepted our submission which triggered a $20.0 million payment to the prior shareholders of Stratatech. We are responsible for another $20.0 million payment upon approval by the FDA. The FDA accepted the BLA for review in August 2020, and granted the application priority review and assigned a PDUFA target date in early 2021. Subsequently, the FDA deferred action on the BLA due to COVID-19-related travel restrictions, which are delaying a required manufacturing site inspection. We plan to work closely with the FDA to complete the review and schedule the site inspection.

Specialty Generics

Net sales from the Specialty Generics segment were $689.8 million for fiscal 2020 compared to $738.7 million for fiscal 2019. This decrease in net sales was driven primarily by a change in product mix due to market shifts as a result of COVID-19.

Results of Operations

Fiscal Year Ended December 25, 2020 Compared with Fiscal Year Ended December 27, 2019

Net Sales

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

	Fiscal Year		
	2020	2019	Percentage Change
U.S.	$ 2,465.5	$ 2,765.6	(10.9)%
Europe, Middle East and Africa	227.5	281.8	(19.3)
Other	56.4	115.1	(51.0)
Geographic area net sales	2,749.4	3,162.5	(13.1)
Medicaid lawsuit (Note 20)	(536.0)	—	*
Net sales	$ 2,213.4	$ 3,162.5	(30.0)%

*Not meaningful

Net sales in fiscal 2020 decreased $949.1 million, or 30.0%, to $2,213.4 million, compared with $3,162.5 million in fiscal 2019. This decrease was primarily driven by the retrospective one-time charge of $536.0 million reflected as a component of net sales related to the Medicaid lawsuit.

Net sales (excluding the one-time charge related to the Medicaid lawsuit) in fiscal 2020 decreased $413.1 million, or 13.1%, to $2,749.4 million, compared with $3,162.5 million in fiscal 2019. This decrease was primarily driven by a decrease in our Specialty Brands segment including a significant decrease in net sales of Acthar Gel and Ofirmev, as previously discussed. In addition, Other Specialty Brands products included an additional $40.1 million of net sales in fiscal 2019 related to BioVectra, Inc. ("BioVectra") prior to the completion of the sale of this business in November 2019. For further information on changes in our net sales, refer to "Business Segment Results" within this Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Operating Loss

Gross profit. Gross profit for fiscal 2020 decreased $752.0 million, or 52.9%, to $669.4 million, compared with $1,421.4 million in fiscal 2019. This decrease was primarily driven by the retrospective one-time charge of $536.0 million reflected as a component of net sales related to the Medicaid lawsuit.

Gross profit (excluding the one-time charge related to the Medicaid lawsuit) in fiscal 2020 decreased $216.0 million, or 15.2%, to $1,205.4 million, compared with $1,421.4 million in fiscal 2019. Gross profit margin was 43.8% for fiscal 2020, compared with 44.9% in fiscal 2019. The decrease in gross profit and gross profit margin was primarily attributable to the $413.1 million decrease in net sales, as discussed above, as well as the change in product mix driven by the decrease in Acthar Gel net sales. This decrease was partially offset by decreases in amortization in fiscal 2020 as compared to fiscal 2019. Fiscal 2019 had additional amortization related to the Ofirmev intangible asset resulting from a change in amortization method on day 1 of fiscal 2019, and 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 2020 were $884.1 million, compared with $831.0 million for fiscal 2019, an increase of $53.1 million, or 6.4%. This increase is attributable to a $9.9 million increase in the fair value of our contingent consideration liabilities in fiscal 2020, compared to a $60.2 million decrease in fiscal 2019, a $29.4 million increase in separation costs, as well as an increase in employee compensation and benefits driven by certain changes made to the design of our long-term incentive compensation program in an effort to manage share usage and dilution and the approval of a key employee incentive program during fiscal 2020, both of which reflect the shorter-term nature of our new target opportunities. These increases were partially offset by decreases in legal expenses driven by a $28.2 million charge associated with the settlement of the MDL Track 1 Cases during fiscal 2019, decreased professional fees, and a decrease in travel expense due to temporary travel restrictions as a result of COVID-19. As a percentage of net sales, SG&A expenses were 39.9% for fiscal 2020. As a percentage of net sales, (excluding the one-time charge related to the Medicaid lawsuit, as previously discussed above), SG&A expenses were 32.2% and 26.3% in fiscal 2020 and 2019, respectively.

Research and development expenses. R&D expenses decreased $58.6 million, or 16.8%, to $290.8 million in fiscal 2020, compared with $349.4 million in fiscal 2019. This decrease was driven by the completion of certain development programs as well as a $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 13.1% for fiscal 2020. As a percentage of net sales, (excluding the one-time charge related to the Medicaid lawsuit, as previously discussed above), R&D expenses were 10.6% and 11.0% in fiscal 2020 and 2019, respectively.

Restructuring and related charges, net. During fiscal 2020, we recognized $49.8 million of restructuring and related charges, net, of which $12.3 million related to accelerated depreciation and was included in SG&A. The accelerated depreciation and remaining $37.5 million primarily related to the exiting of our Bedminster, New Jersey facility as we move our Specialty Brands commercial headquarters from Bedminster to Hampton, New Jersey, as well as employee severance and benefits. During fiscal 2019, we recognized a benefit of $1.7 million, of restructuring and related charges, net, primarily related to 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.

Non-restructuring impairment charges. Non-restructuring impairment charges were $63.5 million for fiscal 2020 resulting from the partial impairment related to our Ofirmev product intangible asset, as previously discussed. Non-restructuring impairment charges were $388.0 million for fiscal 2019 primarily related to a $274.5 million full impairment related to our VTS-270 intangible asset and a $113.5 million full impairment related to our stannsoporfin intangible asset.

(Gains) losses on divestiture. During fiscal 2020 we recorded gains on divestiture of $16.6 million, related to the achievement of milestones affiliated with the sale of a portion of our Hemostasis business in fiscal 2018 to Baxter International, Inc. ("Baxter"). During fiscal 2019, we completed the sale of BioVectra for a loss of $33.5 million.

Opioid-related litigation settlement (gain) loss. During fiscal 2020, we recorded a gain of $43.4 million due to the decrease in the fair value of the New Opioid Warrants, which were determined to have no value as of December 25, 2020 given we cannot reasonably

estimate the equity value at emergence. During fiscal 2019, we recorded a charge of $1,643.4 million attributed to the anticipated structured cash payments and the Settlement Warrants that were to be issued upon effectiveness of the superseded Opioid-Related Litigation Settlement.

Medicaid lawsuit. During fiscal 2020, we incurred a retrospective one-time charge of $105.1 million, which represents a pre-acquisition contingency related to the portion of the Acthar Gel Medicaid Retrospective Rebate that arose from sales of Acthar Gel prior to our acquisition of Questcor in August 2014.

Non-Operating Items

Interest expense and interest income. During fiscal 2020 and fiscal 2019, net interest expense was $255.2 million and $299.5 million, respectively. This $44.3 million decrease was attributable to a lower average outstanding debt balance during fiscal 2020, partially offset by $11.7 million of expense related to adequate protection payments which have provisionally been classified as interest expense. This yielded a decrease in interest expense of $39.2 million. Additionally, fiscal 2020 and fiscal 2019 included the recognition of a $19.2 million and $8.6 million benefit to interest expense, respectively, due to a lapse of certain statute of limitations. For further information, refer to Note 20 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K. Interest income decreased to $5.9 million during fiscal 2020, compared to $9.5 million during fiscal 2019, primarily driven by lower interest rates during fiscal 2020, partially offset by interest earned on our preferred equity certificates that were received as contingent consideration related to the sale of the Nuclear Imaging business.

Gains on debt extinguishment, net. During fiscal 2019, we recorded gains on debt extinguishment, net, of $466.6 million, primarily related to 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 15 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.

Other income, net. During fiscal 2020 and 2019, we recorded other income, net, of $7.4 million and $63.6 million, respectively. This decrease was primarily driven by a $39.0 million decrease in royalty income, as well as a $16.4 million decrease in the unrealized gain on investment related to our equity investment in Silence. The remaining income in both periods represented non-service pension expense and other items, including gains and losses on intercompany financing, foreign currency transactions and related hedging instruments.

Reorganization items, net. During fiscal 2020, we recorded $61.4 million of reorganization items, net in conjunction with our Chapter 11 proceedings. These charges included $51.1 million of advisor and legal fees directly related to the Chapter 11 Cases and $10.2 million of deferred financing fee write-offs related to the unsecured notes in order to reflect the carrying value of the unsecured notes within liabilities subject to compromise on the consolidated balance sheet as of December 25, 2020 at their estimated allowed claim amounts.

Expense (benefit) from income taxes. During fiscal 2020, we recognized an income tax expense of $8.9 million on a loss from continuing operations before income taxes of $960.8 million. The fiscal 2020 income tax expense was comprised of $375.3 million of current tax benefit and $384.2 million of deferred tax expense. The current tax benefit was primarily the result of the Coronavirus Aid, Relief, and Economic Security ("CARES") Act and unrecognized tax benefits, partially offset by the fiscal 2020 reorganization of our intercompany financing and associated asset and legal entity ownership. The deferred tax expense was predominantly related to the valuation allowance recorded against our net deferred tax assets, and the fiscal 2020 reorganization of our intercompany financing and associated asset and legal entity ownership. 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.

Our effective tax rate was negative 0.9% and 36.7% for fiscal 2020 and 2019, respectively. Our effective tax rate for fiscal 2020 was most significantly impacted by the recognition of a $618.2 million tax expense associated with valuation allowances and an $82.0 million tax expense associated with the reorganization of our intercompany financing and associated asset and legal entity ownership, offset with a $281.5 million tax benefit associated with the CARES Act and $11.9 million of tax benefit associated with accrued income tax liabilities and uncertain tax positions. Additional impacts to the effective tax rate include receiving $11.8 million of tax benefit associated with $93.4 million of separation costs, $5.4 million of tax benefit associated with $61.4 million of reorganization items, $0.5 million of tax benefit associated with $25.3 million of share-based compensation, and no tax expense associated with $43.4 million of gain due to the decrease in the fair value of the New Opioid Warrants. All of these additional impacts are offset with the above referenced valuation allowance thus resulting in no net impact on tax expense or benefit. 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 $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 the $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.

Income from discontinued operations, net of income taxes. We recorded income of $25.1 million and $10.7 million on discontinued operations, net of income taxes, during fiscal 2020 and 2019, respectively. Fiscal 2020 included the recognition of a tax benefit related to a release of tax and interest on unrecognized tax benefits due to a lapse of certain statute of limitations related to the Nuclear Imaging business. The remaining income during fiscal 2020 and fiscal 2019 primarily related to the receipt of contingent consideration associated with the sale of the Nuclear Imaging business, partially offset by various post-sale adjustments associated with our previous divestitures.

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		
	2019	2018	Percentage Change
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 continued 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 continued 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. 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. R&D activities focused on performing clinical studies and publishing clinical and non-clinical experiences and generating 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 associated with 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. 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 (gain) loss. During fiscal 2019, we recorded a charge of $1,643.4 million attributed to the anticipated structured cash payments and the Settlement Warrants that were to be issued upon effectiveness of the superseded Opioid-Related Litigation Settlement.

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. 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. 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. The increase was primarily driven by a $23.5 million increase in royalty income. 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.

Expense (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 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.

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 net sales and operating income because management and the chief operating decision maker evaluate the operating results of the segments excluding such items. These items include, but are not limited to, depreciation and amortization, share-based compensation, net restructuring charges, non-restructuring impairment charges, separation costs, R&D upfront payments, changes related to the Opioid-Related Litigation Settlement and the Acthar Gel Medicaid Retrospective Rebate incurred as a result of the Medicaid lawsuit. During fiscal 2020, management began excluding depreciation and share-based compensation from its evaluation of the operating results of its segments. As a result, prior period segment operating income has been recast to reflect this change on a comparable basis. Although these amounts are excluded from segment net sales and segment operating income, as applicable, they are included in reported consolidated net sales and operating (loss) income and in the reconciliations presented below. Selected information by business segment is as follows:

Fiscal Year Ended December 25, 2020 Compared with Fiscal Year Ended December 27, 2019

Net Sales

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

	Fiscal Year		Percentage Change
	2020	2019	
Specialty Brands	$ 2,059.6	$ 2,423.8	(15.0)%
Specialty Generics	689.8	738.7	(6.6)
Net sales	2,749.4	3,162.5	(13.1)
Medicaid lawsuit (Note 20)	(536.0)	—	*
Net sales	$ 2,213.4	$ 3,162.5	(30.0)

*Not meaningful

Specialty Brands. Net sales for fiscal 2020 decreased $364.2 million, or 15.0%, to $2,059.6 million, compared with $2,423.8 million for fiscal 2019. This decrease was primarily driven by a $184.8 million, or 19.4%, decrease in Acthar Gel net sales driven primarily by the marketplace impact of the COVID-19 pandemic and continued payer scrutiny on overall specialty pharmaceutical spending. The prospective change to the Medicaid rebate calculation also served to reduce Acthar Gel net sales by $40.4 million during fiscal 2020. The decrease was also driven by a $107.5 million, or 28.0%, decrease in Ofirmev net sales primarily due to overall reduction in elective surgeries due to public health orders implemented as part of the COVID-19 pandemic, as well as the product's loss of exclusivity in December 2020. In addition, Other Specialty Brands product sales included an additional $40.1 million of net sales in fiscal 2019 related to BioVectra, which was sold in November 2019, and net sales for Amitiza decreased $19.7 million, or 9.4% due to decreased volumes driven by increased competition. The remaining decrease relates to Therakos net sales due to stay-at-home directives issued as part of COVID-19 public health orders.

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

	Fiscal Year		
	2020	2019	Percentage Change
U.S.	$ 1,901.0	$ 2,164.3	(12.2)%
Europe, Middle East and Africa	116.7	161.4	(27.7)
Other	41.9	98.1	(57.3)
Net sales	$ 2,059.6	$ 2,423.8	(15.0)

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

	Fiscal Year		
	2020	2019	Percentage Change
Acthar Gel	$ 767.9	$ 952.7	(19.4)%
INOmax	574.1	571.4	0.5
Ofirmev	276.5	384.0	(28.0)
Therakos	238.6	246.9	(3.4)
Amitiza	188.8	208.5	(9.4)
Other	13.7	60.3	(77.3)
Specialty Brands	$ 2,059.6	$ 2,423.8	(15.0)

Specialty Generics. Net sales for fiscal 2020 decreased $48.9 million, or 6.6%, to $689.8 million, compared to $738.7 million for fiscal 2019. The decrease in net sales was driven by decreased net sales of $62.6 million, or 17.8%, and $24.6 million, or 54.5%, for Other controlled substance and Other products, respectively. These decreases were partially offset by a $23.1 million, or 12.2%, increase in acetaminophen net sales, and a $21.7 million, or 28.4%, increase in hydrocodone-related products net sales.

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

	Fiscal Year		
	2020	2019	Percentage Change
U.S.	$ 564.5	$ 601.3	(6.1)%
Europe, Middle East and Africa	110.8	120.4	(8.0)
Other	14.5	17.0	(14.7)
Net sales	$ 689.8	$ 738.7	(6.6)

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

	Fiscal Year		
	2020	2019	Percentage Change
Hydrocodone (API) and hydrocodone-containing tablets	$ 98.0	$ 76.3	28.4 %
Oxycodone (API) and oxycodone-containing tablets	68.4	74.9	(8.7)
Acetaminophen (API)	213.0	189.9	12.2
Other controlled substances	289.9	352.5	(17.8)
Other	20.5	45.1	(54.5)
Specialty Generics	$ 689.8	$ 738.7	(6.6)

Operating Loss

Operating income by segment and as a percentage of segment net sales for fiscal 2020 and 2019 is shown in the following table (dollars in millions):

	Fiscal Year			
	2020		2019	
Specialty Brands [1]	$ 1,015.7	49.3 %	$ 1,210.1	49.9 %
Specialty Generics	206.4	29.9	168.5	22.8
Segment operating income	1,222.1	44.4	1,378.6	43.6
Unallocated amounts:				
Corporate and unallocated expenses [2]	(166.1)		(102.3)	
Depreciation and amortization	(885.2)		(951.1)	
Share-based compensation	(25.3)		(33.8)	
Restructuring charges, net	(37.5)		1.7	
Non-restructuring impairment charges	(63.5)		(388.0)	
Separation costs	(93.4)		(63.9)	
R&D upfront payment [3]	(5.0)		(20.0)	
Opioid-related litigation settlement	43.4		(1,643.4)	
Medicaid lawsuit (Note 20)	(641.1)		—	
Total operating loss	$ (651.6)		$ (1,822.2)	

(1) Includes $10.0 million of inventory fair-value step up expense related to Amitiza during fiscal 2019.

(2) Includes administration expenses and certain compensation, legal, environmental and other costs not charged to our reportable segments.

(3) Represents R&D expense incurred related to an upfront payment made to acquire product rights in Japan for terlipressin in fiscal 2020 and an upfront payment made to Silence in connection with the license and collaboration agreement entered into in fiscal 2019.

Specialty Brands. Operating income for fiscal 2020 decreased $194.4 million to $1,015.7 million, compared with $1,210.1 million for fiscal 2019. Operating margin decreased to 49.3% for fiscal 2020, compared with 49.9% for fiscal 2019. The decrease in operating income is primarily driven by the $364.2 million, or 15.0%, decrease in net sales over the same period, which resulted in a $278.9 million decrease in gross profit. This was partially offset by a $47.9 million or 9.1% decrease in SG&A expenses primarily driven by lower travel costs due to temporary travel restrictions for COVID-19, lower consulting and professional fees, and a $36.5 million or 13.2% decrease in R&D expenses.

Specialty Generics. Operating income for fiscal 2020 increased $37.9 million to $206.4 million, compared with $168.5 million for fiscal 2019. Operating margin increased to 29.9% for fiscal 2020, compared with 22.8% for fiscal 2019. As a result of the Opioid-Related Litigation Settlement announced during the three months ended March 27, 2020, the corresponding opioid defense costs are considered to be non-recurring; therefore, such costs are excluded from segment operating income and presented as a corporate and unallocated expense on a go-forward basis. In comparison, there were $56.2 million of opioid defense costs reflected in operating income during fiscal 2019. This was partially offset by a decrease in gross profit primarily driven by the decrease in net sales.

Corporate and unallocated expenses. Corporate and unallocated expenses were $166.1 million and $102.3 million for fiscal 2020 and 2019, respectively. This increase is attributable to a $9.9 million increase in the fair value of our contingent consideration liabilities in fiscal 2020, compared to a $60.2 million decrease in fiscal 2019, as well as opioid defense costs of $55.7 million being presented as a corporate and unallocated expense beginning during the three months ended March 27, 2020, as a result of the Opioid-Related Litigation Settlement, as previously discussed. The remaining increase is primarily related to employee compensation and benefits driven by certain changes made to the design of our long-term incentive compensation program in an effort to manage share usage and dilution and the approval of a key employee incentive program during fiscal 2020. This is partially offset by gains on divestiture in fiscal 2020 of $16.6 million primarily related to the achievement of milestones related to the sale of a portion of our Hemostasis business in fiscal 2018 to Baxter, compared with a $33.5 million loss on the divestiture of BioVectra during fiscal 2019, and lower consulting and professional fees. In addition, fiscal 2019 included a $28.2 million charge associated with the settlement of the MDL Track 1 Cases.

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
Other	60.3	87.0	(30.7)
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 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

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]	$ 1,210.1	49.9 %	$ 1,136.1	45.5 %
Specialty Generics	168.5	22.8	153.5	21.4
Segment operating income	1,378.6	43.6	1,289.6	40.1
Unallocated amounts:				
Corporate and unallocated expenses	(102.3)		(121.7)	
Depreciation and amortization	(951.1)		(852.1)	
Share-based compensation	(33.8)		(34.6)	
Restructuring charges, net	1.7		(103.0)	
Non-restructuring impairment charges	(388.0)		(3,893.1)	
Separation costs	(63.9)		(6.0)	
R&D upfront payment [2]	(20.0)		—	
Opioid-related litigation settlement	(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) 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.

Specialty Brands. Operating income for fiscal 2019 increased $74.0 million to $1,210.1 million, compared with $1,136.1 million for fiscal 2018. Operating margin increased to 49.9% for fiscal 2019, compared with 45.5% for fiscal 2018. The increase in operating income and margin includes a $31.0 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 $20.7 million decrease in R&D spending and a $22.8 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 $15.0 million to $168.5 million, compared with $153.5 million for fiscal 2018. Operating margin increased to 22.8% for fiscal 2019, compared with 21.4% for fiscal 2018. The increase in operating

income and margin was impacted by a $21.6 million increase in gross profit primarily due to product mix as well as a $9.8 million decrease in R&D spending, partially offset by a $16.5 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 unallocated expenses. Corporate and unallocated expenses were $102.3 million and $121.7 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.

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.

On October 12, 2020, Mallinckrodt plc and certain of its subsidiaries voluntarily initiated the Chapter 11 Cases in the Bankruptcy Court, to modify its capital structure, including restructuring portions of its debt, and resolve potential legal liabilities, including but not limited to those in connection with the Amended Proposed Opioid-Related Litigation Settlement and the Proposed Acthar Gel-Related Settlement. We intend to use the Chapter 11 process to provide a fair, orderly, efficient and legally binding mechanism to implement a RSA, entered into in connection with the filing of the Chapter 11 Cases, that provides for a financial restructuring designed to strengthen our balance sheet and reduce our total debt by approximately $1,300.0 million, improving our financial position and allowing us to continue driving our strategic priorities and investing in the business to develop and commercialize therapies to improve health outcomes.

The accompanying consolidated financial statements have been prepared assuming we will continue as a going concern. The transactions contemplated by the RSA are subject to approval by the Bankruptcy Court, among other conditions. Accordingly, no assurance can be given that the transactions described therein will be consummated. As a result, we have concluded that management's plans at this stage do not alleviate substantial doubt about our ability to continue as a going concern. Consequently, our future cash from operations and access to capital markets may not provide adequate resources to fund our working capital needs, capital expenditures and strategic investments for the foreseeable future.

In general, we intend to fund capital expenditures with cash generated from operations. As of December 25, 2020, we had no capital expenditure commitments.

Under our credit agreement, we are required to prepay our term loans in an amount equal to a specified percentage of excess cash flow. We have sought Bankruptcy Court approval to make such mandatory prepayment in an amount equal to approximately $114.0 million with respect to fiscal 2020.

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

	Fiscal Year		
	2020	2019	2018
Net cash from:			
Operating activities	$ 498.9	$ 742.9	$ 665.5
Investing activities	(11.2)	(8.3)	(480.3)
Financing activities	(185.6)	(280.1)	(1,095.0)
Effect of currency exchange rate changes on cash, cash equivalents and restricted cash	2.3	0.6	(1.8)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 304.4	$ 455.1	$ (911.6)

Operating Activities

Net cash provided by operating activities of $498.9 million for fiscal 2020 included a loss of $944.6 million, adjusted for non-cash items of $1,331.2 million driven by depreciation and amortization of $885.2 million, a $385.3 million reduction in our deferred income tax assets, and a $63.5 million non-cash impairment charge related to the Ofirmev product intangible asset. The net loss was also offset by cash provided from net investment in working capital of $112.3 million, primarily driven by the $638.9 million Medicaid lawsuit liability. Also included within this change in working capital was a $37.9 million decrease in accounts receivable,

and a $15.7 million increase in accounts payable, net of transfers to liabilities subject to compromise. These items were offset by a $433.8 million increase in net receivables related to income taxes that was driven by tax benefits from the CARES Act and changes in uncertain tax positions, a $95.3 million net cash outflow related to other assets and liabilities primarily driven by decreases in accrued payroll and accrued restructuring, net of transfers to liabilities subject to compromise, and a $51.1 million increase in inventory.

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. 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 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.

Investing Activities

Net cash used in investing activities of $11.2 million for fiscal 2020 was primarily attributable to capital expenditures of $47.7 million, partially offset by cash proceeds of $29.8 million for the redemption of 100% of the outstanding preferred equity certificates received as part of contingent earn-out payments related to the sale of the Nuclear Imaging business, as previously discussed. The remaining activity primarily relates to post-sale adjustments from various divestitures.

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 acquisition of Sucampo Pharmaceuticals, Inc. ("Sucampo") in fiscal 2018 of $698.0 million and capital expenditures of $127.0 million. These outflows were 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.

Under our credit agreement and our notes, 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 prepayments on our term loans and offer to repurchase certain of our notes.

Financing Activities

Net cash used in financing activities was $185.6 million for fiscal 2020, compared with $280.1 million for fiscal 2019. This decrease was primarily attributable to a $110.6 million decrease in debt repayments, net of issuances. Our current year debt repayments included a $119.8 million payment on the remaining principal amount of the 4.875% senior unsecured notes that had a maturity date of April 15, 2020 (the "2020 Notes"), and $19.7 million in aggregate payments on our variable-rate term loans. The significant components of our debt repayments during fiscal 2019 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 $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 debt repayments during fiscal 2018 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

As of December 25, 2020, total debt principal was $5,283.3 million, of which $1,660.7 million was classified within liabilities subject to compromise on the consolidated balance sheet, compared with $5,422.8 million as of December 27, 2019, with total debt reduction of $139.5 million during fiscal 2020. Total debt principal at December 25, 2020 is comprised of the following:

	December 25, 2020
Variable-rate instruments:	
Term loan due September 2024	$ 1,505.2
Term loan due February 2025	399.5
Revolving credit facility	900.0
Fixed-rate instruments	2,478.6
Debt principal	$ 5,283.3

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 25, 2020, our fixed-rate instruments had a weighted-average interest rate of 7.05% and pay interest at various dates throughout the fiscal year. As of December 25, 2020, we were fully drawn on our $900.0 million revolving credit facility.

In November 2015, our Board of Directors authorized us to reduce our outstanding debt at our discretion. As conditions warrant, and subject to limitations under Chapter 11, we may repurchase debt securities issued by us, in the open market, in privately negotiated transactions, by tender offer or otherwise.

2020 Notes

On April 7, 2020, we and Mallinckrodt International Finance S.A. and Mallinckrodt CB LLC, two of our wholly owned subsidiaries (“Issuers”), entered into an exchange agreement (the “Exchange Agreement”) with certain third parties (collectively, the “Exchanging Holders”). Pursuant to the Exchange Agreement, the Exchanging Holders agreed to exchange with the Issuers, on April 7, 2020, their holdings of the 2020 Notes issued by the Issuers (the “Existing Notes”) (consisting of approximately $495.0 million aggregate principal amount of the Existing Notes) for new 10.00% First Lien Senior Secured Notes due 2025 issued by the Issuers (the “First Lien 2025 Notes”), at a rate of $1,000 of First Lien 2025 Notes for every $1,000 of Existing Notes exchanged (such exchange, the “Exchange”). The Issuers and Exchanging Holders consummated the Exchange on April 7, 2020.

Interest on the First Lien 2025 Notes is contractually payable semi-annually in cash on April 15th and October 15th of each year, commencing on October 15, 2020. The Bankruptcy Court order permitting the use of cash collateral to finance the Chapter 11 Cases requires that we make cash adequate protection payments quarterly during the pendency of the proceedings on the first lien senior notes and the second lien senior notes for, among other things, unpaid pre-petition and post-petition interest (at the specified non-default interest rate) and reimbursement of certain costs.

The Issuers may redeem some or all of the First Lien 2025 Notes prior to April 15, 2022 by paying a “make-whole” premium. The Issuers may redeem some or all of the First Lien 2025 Notes on or after April 15, 2022 at specified redemption prices. In addition, prior to April 15, 2022, the Issuers may redeem up to 40% of the aggregate principal amount of the First Lien 2025 Notes with the net proceeds of certain equity offerings. The Issuers may also redeem all, but not less than all, of the First Lien 2025 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 First Lien 2025 Notes.

The Issuers are obligated to offer to repurchase (a) all of the First Lien 2025 Notes at a price of 101% of their principal amount plus accrued and unpaid interest, if any, as a result of certain change of control events and (b) First Lien 2025 Notes using asset sale proceeds at a price of 100% of their principal amount plus accrued and unpaid interest, if any, in the event of certain asset sales. These obligations are subject to certain qualifications and exceptions.

The First Lien 2025 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 First Lien 2025 Notes and could cause a cross-default that could result in the acceleration of our other indebtedness. The commencement of the Chapter 11 Cases on October 12, 2020 constituted an event of default and accordingly, the principal balance of this debt instrument was classified as current on the consolidated balance sheet as of December 25, 2020. However, any efforts to enforce payment obligations under the debt instruments are automatically stayed as a result of the Chapter 11 Cases.

The First Lien 2025 Notes are jointly and severally guaranteed, on a secured, unsubordinated basis by us and each of our subsidiaries (other than the Issuers) (the “Note Guarantors”) that guarantees the obligations under the Issuers’ existing senior secured credit facilities, subject to certain exceptions.

The First Lien 2025 Notes and the guarantees thereof are secured by liens on the same assets of the Issuers and the Note Guarantors that are subject to liens securing the existing senior secured credit facilities, subject to certain exceptions.

On April 15, 2020, we paid in full the remaining approximately $119.8 million in principal amount of outstanding 2020 Notes at the maturity thereof with cash on hand.

The risks associated with the failure to consummate the Proposed Settlement are further described in the risk factor “*The Amended Proposed Opioid-Related Litigation Settlement and Proposed Acthar Gel-Related Settlement are subject to certain contingencies and may not go into effect in their current form or at all, which may have an adverse impact on our ability to consummate the Plan and our business, financial condition, results of operations and cash flows*.” in Part I, Item 1A. "Risk Factors."

The commencement of the Chapter 11 Cases on October 12, 2020 constituted an event of default under certain of our debt agreements. As of December 25, 2020, other than any defaults relating to the Chapter 11 Cases, we were in full compliance with the provisions and covenants associated with our debt agreements. Accordingly, all long-term debt was classified as current on the consolidated balance sheet as of December 25, 2020. However, any efforts to enforce payment obligations under the debt instruments are automatically stayed as a result of the Chapter 11 Cases.

For additional information regarding the Chapter 11 Cases and our debt agreements, refer to Note 2 and Note 15 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K, respectively.

Capitalization

Shareholders' equity was $1,019.2 million at December 25, 2020 compared with $1,940.7 million at December 27, 2019. The decrease in shareholders' equity is primarily attributed to the fiscal 2020 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 2020 or fiscal 2019, due to our shift to debt reduction as one of our primary focuses of our capital allocation strategy in fiscal 2019. For further information, refer to Note 17 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

Historically, we have not made any cash dividend payments, as we have retained earnings to finance acquisitions, R&D and the operation and expansion of our business, while executing disciplined capital allocation. Currently, the declaration and payment of dividends is subject to the approval of the Bankruptcy Court until such proceedings are complete upon emergence.

Commitments and Contingencies

Contractual Obligations

The following table summarizes our contractual obligations as of December 25, 2020 (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 [1]	$ 5,283.3	$ 24.6	$ 2,212.9	$ 3,045.8	$ —
Interest on long-term debt obligations [2]	1,089.0	324.9	526.0	238.1	—
Operating lease obligations [3]	92.7	20.9	30.3	18.7	22.8
Purchase obligations [4]	14.9	4.7	4.3	4.3	1.6
Total contractual obligations	$ 6,479.9	$ 375.1	$ 2,773.5	$ 3,306.9	$ 24.4

(1) The commencement of the Chapter 11 Cases on October 12, 2020 constituted an event of default under certain of our debt agreements. Accordingly, all long-term debt was classified as current on the consolidated balance sheet as of December 25, 2020. Certain of our long-term debt instruments are classified as liabilities subject to compromise, for which no principal payments will be made during the pendency of the proceedings

(2) Interest on long-term debt obligations are projected for future periods using interest rates in effect as of December 25, 2020. Contractual obligations under the long-term debt agreements have been shown in the table above. Certain of our long-term debt instruments are classified as liabilities subject to compromise, for which no interest payments will be made during the pendency of the proceedings. Certain of these projected interest payments may differ in the future based on changes in market interest rates.

As previously discussed in 'Significant Events', we are contractually obligated under the cash collateral order approved by the Bankruptcy Court to make cash adequate protection payments on the senior secured revolving credit facility and the senior secured term loans at a rate that is 200 basis points greater than the otherwise applicable non-default rate based on LIBOR. Under the cash collateral order, we will make approximately $43.3 million of incremental interest payments as a result thereof within twelve months of the December 25, 2020 balance sheet date, which is subject to change based on timing of emergence from bankruptcy. This incremental expense, which has provisionally been classified as interest expense in the consolidated statement of operations, is not included within this table as we expect such incremental expense to be reclassified as a reduction in principal in connection with the confirmation of a plan of reorganization by the Bankruptcy Court.

(3) Refer to Note 13 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K for further information.

(4) Purchase obligations consist of commitments for purchases of goods and services made in the normal course of business to meet operational requirements.

The preceding table does not include other liabilities of $2,836.2 million, primarily consisting of the opioid-related litigation settlement liability of $1,600.0 million, the Medicaid lawsuit liability of $638.9 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, asset retirement obligations and liabilities subject to compromise, because the timing of their future cash outflow is uncertain. The most significant of these liabilities, other than the opioid-related settlement liability and Medicaid lawsuit liability which are discussed in Note 20 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K, 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 25, 2020, we have accrued $34.7 million for these potential payments, which have been classified as liabilities subject to compromise. For further information on our contingent consideration arrangements, refer to Note 21 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

As part of our divestitures and licensing agreements, we have the potential to earn in excess of $50.0 million in milestone payments in the future. During fiscal 2020, we received preferred equity certificates of $9.0 million and royalty income of $0.8 million. 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 6 and 7 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

We are obligated to pay royalties under certain agreements with third parties. During fiscal 2020, 2019 and 2018, we made payments under these arrangements of $81.9 million, $95.7 million and $106.4 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 25, 2020, was $100.1 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 taxing authorities related to tax positions we take. For further information on income tax related matters, refer to Note 9 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

As of December 25, 2020, we had net unfunded pension and postretirement benefit obligations of $29.4 million and $40.1 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 2021, but may elect to make voluntary contributions to our defined pension plans or our postretirement benefit plans during fiscal 2021. As a result of our Chapter 11 filing on October 12, 2020, $32.4 million of defined benefit obligations have been reclassified as liabilities subject to compromise on our consolidated balance sheet as of December 25, 2020, which included the U.S. pension benefit plans and a portion of the postretirement benefit plans.

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 25, 2020, we believe that it is probable that we will incur investigation and remediation costs of approximately $60.8 million, of which $1.0 million is included in accrued and other current liabilities on our consolidated balance sheet at December 25, 2020. Note 20 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K provides additional information regarding environmental matters.

Legal Proceedings

We are subject to various legal proceedings and claims, including present and former operations, including those described in Note 20 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K, which are incorporated by reference into this Part II, Item 7. 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 their ultimate resolutions will not have a material adverse effect on our financial condition, results of operations and cash flows. These representations, warranties and indemnities are discussed in Note 19 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

As of December 25, 2020, we had various other letters of credit, guarantee and surety bonds totaling $31.7 million and restricted cash of $37.4 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.

Liabilities Subject to Compromise

As a result of the commencement of the Chapter 11 Cases, the payment of pre-petition liabilities is subject to compromise or other treatment pursuant to a plan of reorganization. The determination of how liabilities will ultimately be settled or treated cannot be made until the Bankruptcy Court confirms a Chapter 11 plan of reorganization and such plan becomes effective. Accordingly, the ultimate amount of such liabilities is not determinable at this time. Pre-petition liabilities that are subject to compromise are to be reported at the amounts expected to be allowed by the Bankruptcy Court, even if they may be settled for different amounts. The amounts currently classified as liabilities subject to compromise are preliminary and may be subject to future adjustments depending on Bankruptcy

Court actions, further developments with respect to disputed claims, determinations of the secured status of certain claims, the values of any collateral securing such claims, rejection of executory contracts, continued reconciliation or other events.

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 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	2,065.9	28.9	59.5	2,154.3
Provision for Medicaid lawsuit [(1)]	536.0	—	—	536.0
Payments or credits	(2,701.2)	(30.7)	(60.4)	(2,792.3)
Balance as of December 25, 2020	$ 196.5	$ 26.6	$ 12.3	$ 235.4

(1) Excludes the $105.1 million that is reflected as a component of operating expenses as it represents a pre-acquisition contingency related to the portion of the liability that arose from sales of Acthar Gel prior to the Company's acquisition of Questcor Pharmaceuticals Inc. in August 2014. For further 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.

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

Total provisions for fiscal 2020 increased $252.6 million compared with fiscal 2019, which is inclusive of the $536.0 million provision for the Medicaid lawsuit incurred in fiscal 2020. Excluding the impact of the Medicaid lawsuit, the decrease in rebates and chargebacks of $281.4 million primarily related to a decrease of $315.2 million in the Specialty Generics segment driven by decreased pricing resulting in lower chargeback amounts, offset by a $33.8 million increase in Specialty Brands. Provisions for returns increased $6.7 million driven by the Specialty Generics segment, and other sales deductions increased by $8.7 million from fiscal 2019 to fiscal 2020.

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 by 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.

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 5 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Goodwill and Other Intangible Assets

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 2020 or 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 3 and 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.

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 21 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Contingencies

We are involved, either as a plaintiff or a defendant, in various legal proceedings that arise in the ordinary course of business, including, without limitation, patent infringement claims, product liability matters, government investigations, environmental matters, employment disputes, contractual disputes and other commercial disputes, and other legal proceedings as further discussed in Note 20 of Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K. Accruals recorded for various contingencies, including legal proceedings, self-insurance and other claims, are based on judgment, the probability of losses and, where applicable, the consideration of opinions of internal and/or external legal counsel, internal and/or external technical consultants and actuarially determined estimates. When a range is established but a best estimate cannot be made, we record the minimum loss contingency amount. These estimates are often initially developed substantially earlier than the ultimate loss is known, and the estimates are reevaluated each accounting period as additional information becomes available. When we are initially unable to develop a best estimate of loss, we record the minimum amount of loss, which could be zero. As information becomes known, additional loss provisions are recorded when either a best estimate can be made or the minimum loss amount is increased. When events result in an expectation of a more favorable outcome than previously expected, our best estimate is changed to a lower amount. We record receivables from third-party insurers up to the amount of the related liability when we have determined that existing insurance policies will provide reimbursement. In making this determination, we consider applicable deductibles, policy limits and the historical payment experience of the insurance carriers. Receivables are not netted against the related liabilities for financial statement presentation.

Income Taxes

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

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

As previously discussed, we concluded that there is substantial doubt about our ability to continue as a going concern within one year from the date of issuance of the consolidated financial statements. We considered this in determining that certain net deferred tax assets were no longer more likely than not realizable. As a result, we recorded an increase in a valuation allowance against our net deferred tax assets. Our income tax benefit or expense recorded in the future may be impacted to the extent of changes 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, or a reduction to a deferred tax asset (“contra-DTA”), is established. We adjust these liabilities and contra-DTAs 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 4 of Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K for a discussion regarding recently issued accounting standards and their estimated impact on our financial condition, results of operations and cash flows.

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

Our operations include activities in the U.S. and countries outside of the U.S. These operations expose us to a variety of market risks, including the effects of changes in interest rates and currency exchange rates. We monitor and manage these financial exposures as an integral part of our overall risk management program. We do not utilize derivative instruments for trading or speculative purposes.

Interest Rate Risk

Our exposure to interest rate risk relates primarily to our variable-rate debt instruments, which bear interest based on LIBOR plus margin. As of December 25, 2020, our outstanding debt included $1,904.7 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 2020 would increase by approximately $28.0 million.

The remaining outstanding debt as of December 25, 2020 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 $0.5 million as of December 25, 2020, 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 ("Debtor-in-Possession") (the "Company") as of December 25, 2020 and December 27, 2019, the related consolidated statements of operations, comprehensive operations, changes in shareholders' equity, and cash flows for the fiscal years ended December 25, 2020, December 27, 2019 and December 28, 2018 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 25, 2020 and December 27, 2019, and the results of its operations and its cash flows for the fiscal years ended December 25, 2020, December 27, 2019 and December 28, 2018, 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 25, 2020, 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 March 10, 2021, expressed an unqualified opinion on the Company’s internal control over financial reporting.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company initiated proceedings under chapter 11 of title 11 ("Chapter 11") of the United States Code (the "Bankruptcy Code") that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Bankruptcy Proceedings

As discussed in Note 1 to the financial statements, the Company has filed for reorganization under Chapter 11 of the U.S. Bankruptcy Code. The accompanying financial statements do not purport to reflect or provide for the consequences of the bankruptcy proceedings. In particular, such financial statements do not purport to show (1) as to assets, their realizable value on a liquidation basis or their availability to satisfy liabilities; (2) as to prepetition liabilities, the settlement amounts for allowed claims, or the status and priority thereof; (3) as to shareholder accounts, the effect of any changes that may be made in the capitalization of the Company; or (4) as to operations, the effect of any changes that may be made in its business.

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 Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Commitments and Contingencies - Medicaid Lawsuit - Refer to Note 20 to the financial statements

Critical Audit Matter Description

In March 2020, the Company received an adverse decision from the U.S. District Court of Columbia ("D.C. District Court") in its lawsuit against the U.S. Department of Health and Human Services and the Centers for Medicare & Medicaid Services. The dispute involves the base date average manufacturer price ("AMP") under the Medicaid Drug Rebate Program for Acthar Gel. In June 2020, while appealing the ruling by the D.C. District Court, the Company reverted the base date AMP in the government's price reporting system. As a result, the Company incurred a retrospective one-time charge of $641.1 million related to the Acthar Gel Medicaid retrospective rebate. The Company recorded $536.0 million as a component of net sales and $105.1 million as a component of operating expenses in the consolidated statement of operations.

In connection with the filing of Chapter 11 of the Bankruptcy Code, the Company entered into a Restructuring Support Agreement (as amended, supplemented or otherwise modified, the "RSA"). As part of the RSA, the Company reached an agreement in principle with the U.S. Department of Justice ("DOJ") and other governmental parties to settle a range of litigation matters and disputes relating to Acthar Gel for $260.0 million, including the Medicaid lawsuit. The agreement in principle is subject to the approval by the U.S. Bankruptcy Court for the District of Delaware.

We identified the Medicaid lawsuit and disclosure as a critical audit matter because of the significant judgment exercised by management in the interpretation and application of the Accounting Standard Codification ("ASC") 606 – Revenue From Contracts With Customers and ASC 805 – Business Combinations when determining how to appropriately record and classify the Acthar Gel Medicaid retrospective rebates in the statement of operations. 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 Medicaid lawsuit and disclosure included the following, among others:

- We tested the effectiveness of controls over the Medicaid lawsuit, which included management’s review of the legal background and facts, applicable accounting guidance, and related disclosure.
- We inspected D.C. District Court documents related to the Medicaid lawsuit.
- We inspected the terms of the Restructuring Support Agreement.
- We corroborated key facts about the Medicaid lawsuit through our inquiries with internal legal counsel and executive members of management.
- We requested and received written responses from internal legal counsel regarding the Medicaid lawsuit.
- We requested and received written responses from the Company’s external legal counsel regarding the Medicaid lawsuit. We also inquired directly with the Company's external legal counsel regarding the Medicaid lawsuit.
- With the assistance of professionals in our firm having expertise in complex accounting and reporting matters, we evaluated the Company's conclusions regarding the Medicaid lawsuit classification within the statement of operations by obtaining and evaluating management's documented accounting treatment based on the applicable accounting principles generally accepted in the United States of America.
- We recalculated the Company's Acthar Gel Medicaid retrospective rebate.
- We evaluated the Company's disclosures for consistency with our knowledge of the Medicaid lawsuit.

/s/ DELOITTE & TOUCHE LLP
St. Louis, Missouri
March 10, 2021

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

MALLINCKRODT PLC
(DEBTOR-IN-POSSESSION)
CONSOLIDATED STATEMENTS OF OPERATIONS
(in millions, except per share data)

	Fiscal Year		
	2020	**2019**	**2018**
Net sales (includes refined estimate of the retrospective one-time charge of $536.0 related to the Medicaid lawsuit for fiscal 2020)	$ 2,213.4	$ 3,162.5	$ 3,215.6
Cost of sales	1,544.0	1,741.1	1,744.4
Gross profit	669.4	1,421.4	1,471.2
Selling, general and administrative expenses	884.1	831.0	834.1
Research and development expenses	290.8	349.4	361.1
Restructuring charges, net	37.5	(1.7)	103.0
Non-restructuring impairment charges	63.5	388.0	3,893.1
(Gains) losses on divestiture	(16.6)	33.5	0.8
Opioid-related litigation settlement (gain) loss (Note 20)	(43.4)	1,643.4	—
Medicaid lawsuit (Note 20)	105.1	—	—
Operating loss	(651.6)	(1,822.2)	(3,720.9)
Interest expense	(261.1)	(309.0)	(370.2)
Interest income	5.9	9.5	8.2
Gains on debt extinguishment, net	—	466.6	8.5
Other income, net	7.4	63.6	22.4
Reorganization items, net	(61.4)	—	—
Loss from continuing operations before income taxes	(960.8)	(1,591.5)	(4,052.0)
Expense (benefit) from income taxes	8.9	(584.3)	(430.1)
Loss from continuing operations	(969.7)	(1,007.2)	(3,621.9)
Income from discontinued operations, net of tax (benefit) expense of ($16.2), $1.7 and $1.4	25.1	10.7	14.9
Net loss	$ (944.6)	$ (996.5)	$ (3,607.0)
Basic loss per share (Note 10):			
Loss from continuing operations	$ (11.48)	$ (12.00)	$ (43.12)
Income from discontinued operations	0.30	0.13	0.18
Net loss	$ (11.18)	$ (11.88)	$ (42.94)
Basic weighted-average shares outstanding	84.5	83.9	84.0
Diluted loss per share (Note 10):			
Loss from continuing operations	$ (11.48)	$ (12.00)	$ (43.12)
Income from discontinued operations	0.30	0.13	0.18
Net loss	$ (11.18)	$ (11.88)	$ (42.94)
Diluted weighted-average shares outstanding	84.5	83.9	84.0

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
(DEBTOR-IN-POSSESSION)
CONSOLIDATED STATEMENTS OF COMPREHENSIVE OPERATIONS
(in millions)

	Fiscal Year		
	2020	**2019**	**2018**
Net loss	$ (944.6)	$ (996.5)	$ (3,607.0)
Other comprehensive (loss) income, net of tax			
Currency translation adjustments	2.1	18.3	(12.2)
Unrecognized gain on derivatives	0.4	1.8	0.7
Unrecognized (loss) gain on benefit plans, net of tax (benefit) expense	(4.2)	(4.2)	1.6
Total other comprehensive (loss) income, net of tax	(1.7)	15.9	(9.9)
Comprehensive loss	$ (946.3)	$ (980.6)	$ (3,616.9)

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
(DEBTOR-IN-POSSESSION)
CONSOLIDATED BALANCE SHEETS
(in millions, except share data)

	December 25, 2020	December 27, 2019
Assets		
Current Assets:		
Cash and cash equivalents	$ 1,070.6	$ 790.9
Accounts receivable, less allowance for doubtful accounts of $4.5 and $4.0	538.8	577.5
Inventories	344.9	312.1
Prepaid expenses and other current assets	350.0	150.2
Total current assets	2,304.3	1,830.7
Property, plant and equipment, net	833.1	896.5
Intangible assets, net	6,184.5	7,018.0
Other assets	393.5	593.7
Total Assets	$ 9,715.4	$ 10,338.9
Liabilities and Shareholders' Equity		
Current Liabilities:		
Current maturities of long-term debt	$ 3,587.9	$ 633.6
Accounts payable	93.3	139.8
Accrued payroll and payroll-related costs	79.4	105.2
Accrued interest	26.9	62.9
Accrued and other current liabilities	331.2	485.4
Total current liabilities	4,118.7	1,426.9
Long-term debt	—	4,741.2
Opioid-related litigation settlement liability (Note 20)	—	1,643.4
Pension and postretirement benefits	34.6	62.4
Environmental liabilities	59.8	60.0
Deferred income taxes	80.6	11.0
Other income tax liabilities	100.1	227.1
Other liabilities	109.8	226.2
Liabilities subject to compromise (Note 2)	4,192.6	—
Total Liabilities	8,696.2	8,398.2
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; 94,111,303 and 93,459,206 issued; 84,605,156 and 84,105,786 outstanding	18.8	18.7
Ordinary shares held in treasury at cost, 9,506,147 and 9,353,420	(1,616.1)	(1,615.7)
Additional paid-in capital	5,587.6	5,562.5
Retained deficit	(2,961.5)	(2,016.9)
Accumulated other comprehensive loss	(9.6)	(7.9)
Total Shareholders' Equity	1,019.2	1,940.7
Total Liabilities and Shareholders' Equity	$ 9,715.4	$ 10,338.9

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
(DEBTOR-IN-POSSESSION)
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in millions)

	Fiscal Year		
	2020	**2019**	**2018**
Cash Flows From Operating Activities:			
Net loss	$ (944.6)	$ (996.5)	$ (3,607.0)
Adjustments to reconcile net cash provided by operating activities:			
Depreciation and amortization	885.2	951.1	852.1
Share-based compensation	25.3	33.8	34.6
Deferred income taxes	385.3	(604.3)	(541.5)
Non-cash impairment charges	63.5	388.0	3,893.1
Inventory provisions	18.5	18.0	37.9
(Gains) losses on divestiture	(16.6)	33.5	0.8
Gain on debt extinguishment, net	—	(466.6)	(8.5)
Other non-cash items	(40.2)	(65.7)	(42.4)
Reorganization items, net	10.2	—	—
Changes in assets and liabilities, net of the effects of acquisitions:			
Accounts receivable, net	37.9	31.6	(145.8)
Inventories	(51.1)	(23.1)	63.1
Accounts payable	15.7	6.7	24.6
Income taxes	(433.8)	(2.1)	99.0
Opioid-related litigation settlement liability	—	1,600.0	—
Medicaid lawsuit	638.9	—	—
Other	(95.3)	(161.5)	5.5
Net cash from operating activities	498.9	742.9	665.5
Cash Flows From Investing Activities:			
Capital expenditures	(47.7)	(133.0)	(127.0)
Acquisitions, net of cash acquired	—	—	(699.9)
Proceeds from divestiture, net of cash	(0.7)	95.1	313.0
Other	37.2	29.6	33.6
Net cash from investing activities	(11.2)	(8.3)	(480.3)
Cash Flows From Financing Activities:			
Issuance of external debt	—	695.0	690.3
Repayment of external debt	(139.5)	(945.1)	(1,693.6)
Debt financing costs	(9.4)	(10.1)	(12.1)
Proceeds from exercise of share options	—	0.6	1.0
Repurchase of shares	(0.4)	(2.6)	(57.5)
Other	(36.3)	(17.9)	(23.1)
Net cash from financing activities	(185.6)	(280.1)	(1,095.0)
Effect of currency rate changes on cash	2.3	0.6	(1.8)
Net change in cash, cash equivalents and restricted cash	304.4	455.1	(911.6)
Cash, cash equivalents and restricted cash at beginning of period	822.6	367.5	1,279.1
Cash, cash equivalents and restricted cash at end of period	$ 1,127.0	$ 822.6	$ 367.5
Cash and cash equivalents at end of period	$ 1,070.6	$ 790.9	$ 348.9
Restricted cash included in prepaid expenses and other assets at end of period	20.2	—	—
Restricted cash included in other long-term assets at end of period	36.2	31.7	18.6
Cash, cash equivalents and restricted cash at end of period	$ 1,127.0	$ 822.6	$ 367.5
Supplemental Disclosures of Cash Flow Information:			
Cash paid for interest	$ 256.1	$ 314.2	$ 309.7
Cash paid for income taxes, net	39.9	30.7	12.4

See Notes to Consolidated Financial Statements.

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

	Ordinary Shares		Treasury Shares					
	Number	Par Value	Number	Amount	Additional Paid-In Capital	Retained Earnings (Deficit)	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
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)
Other comprehensive loss	—	—	—	—	—	—	(9.9)	(9.9)
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)
Other comprehensive income	—	—	—	—	—	—	15.9	15.9
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 as of December 27, 2019	93.5	$ 18.7	9.4	$ (1,615.7)	$ 5,562.5	$ (2,016.9)	$ (7.9)	$ 1,940.7
Net loss	—	—	—	—	—	(944.6)	—	(944.6)
Other comprehensive loss	—	—	—	—	—	—	(1.7)	(1.7)
Vesting of restricted shares	0.6	0.1	0.1	(0.4)	(0.2)	—	—	(0.5)
Share-based compensation	—	—	—	—	25.3	—	—	25.3
Balance at December 25, 2020	94.1	$ 18.8	9.5	$ (1,616.1)	$ 5,587.6	$ (2,961.5)	$ (9.6)	$ 1,019.2

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 and maintains its principal executive offices in Ireland. The Company continues to be subject to United States ("U.S.") Securities and Exchange Commission ("SEC") reporting requirements.

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.

Going Concern

The accompanying consolidated financial statements are prepared in accordance with GAAP applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

On October 12, 2020, Mallinckrodt plc and certain of its subsidiaries voluntarily initiated proceedings (the "Chapter 11 Cases") under chapter 11 of title 11 ("Chapter 11") of the United States Code (the "Bankruptcy Code"), to modify its capital structure, including restructuring portions of its debt, and resolve potential legal liabilities, including but not limited to those described in Note 20 as *Opioid-Related Matters* and *Acthar Gel-Related Matters*. In connection with the filing of the Chapter 11 Cases, the Company entered into a Restructuring Support Agreement (as amended, supplemented or otherwise modified, the "RSA") (further detail for which is provided in Note 2) as part of a prearranged plan of reorganization. See Note 2 for further information on the voluntary petitions for reorganization and the RSA.

Substantial doubt about the Company's ability to continue as a going concern exists in light of its Chapter 11 Cases. The Company's ability to continue as a going concern is contingent upon, among other things, its ability to, subject to the approval by the U.S. Bankruptcy Court for the District of Delaware (the "Bankruptcy Court"), implement a plan of reorganization, emerge from the Chapter 11 proceedings and generate sufficient liquidity following the reorganization to meet its obligations, most notably its opioid and Acthar® Gel (repository corticotropin injection) ("Acthar Gel")-related settlements, restructured debt obligations, and operating needs.

Although management believes that the reorganization of the Company through the Chapter 11 proceedings will appropriately position the Company upon emergence, the commencement of these proceedings constituted an event of default under certain of the Company’s debt agreements, enforcement of any remedies in respect of which is automatically stayed as a result of the Chapter 11 proceedings. There are a number of risks and uncertainties associated with the Company’s bankruptcy, including, among others that: (a) the Company’s prearranged plan of reorganization may never be confirmed or become effective, (b) the RSA may be terminated by

one or more of the parties thereto, (c) the Bankruptcy Court may grant or deny motions in a manner that is adverse to the Company and its subsidiaries, and (d) the Chapter 11 Cases may be converted into cases under chapter 7 of the Bankruptcy Code.

The transactions contemplated by the RSA are subject to approval by the Bankruptcy Court, among other conditions. Accordingly, no assurance can be given that the transactions described therein will be consummated. As a result, the Company has concluded that management’s plans at this stage do not alleviate substantial doubt about the Company’s ability to continue as a going concern.

The consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts and classification of liabilities that might result from the outcome of this uncertainty.

Pursuant to sections 1107(a) and 1108 of the Bankruptcy Code, the Debtors (as defined in Note 2) retain control of their assets and are authorized to operate their business as debtors-in-possession while being subject to the jurisdiction of the Bankruptcy Court. While operating as debtors-in-possession under Chapter 11, the Debtors may sell or otherwise dispose of or liquidate assets or settle liabilities, subject to the approval of the Bankruptcy Court or as otherwise permitted in the ordinary course of business and subject to applicable orders of the Bankruptcy Court, for amounts other than those reflected in the accompanying consolidated financial statements. Any such actions occurring during the Chapter 11 Cases authorized by the Bankruptcy Court could materially impact the amounts and classifications of assets and liabilities reported in the Company's consolidated financial statements. For more information regarding the Chapter 11 Cases, see Note 2.

Fiscal Year

The Company reports its results based on a "52-53 week" year ending on the last Friday of December. Fiscal 2020, 2019 and 2018 each consisted of 52 weeks. Unless otherwise indicated, fiscal 2020, 2019 and 2018 refer to the Company's fiscal years ended December 25, 2020, December 27, 2019 and December 28, 2018, respectively.

2. Bankruptcy Proceedings

Voluntary Filing Under Chapter 11

On October 12, 2020 (the "Petition Date"), Mallinckrodt plc and certain of its subsidiaries voluntarily initiated the Chapter 11 Cases under the Bankruptcy Code in the Bankruptcy Court to effectuate settlements contemplated in the RSA. The entities that filed the Chapter 11 Cases include the Company, substantially all of the Company’s U.S. subsidiaries, including certain subsidiaries of Mallinckrodt plc operating the Specialty Generics business (the "Specialty Generics Subsidiaries") and the Specialty Brands business (the "Specialty Brands Subsidiaries"), and certain of the Company’s international subsidiaries (together with the Company, Specialty Generics Subsidiaries and Specialty Brands Subsidiaries, the "Debtors"). The Chapter 11 Cases are being jointly administered under the caption In re Mallinckrodt plc, Case No. 20-12522 (JTD). Information about the Chapter 11 Cases, including the case docket, may be found free of charge at https://restructuring.primeclerk.com/Mallinckrodt/.

The Debtors continue to operate their businesses as debtors-in-possession under the jurisdiction of the Bankruptcy Court and in accordance with the applicable provisions of the Bankruptcy Code and orders of the Bankruptcy Court. As debtors in possession, the Debtors are authorized to continue to operate as ongoing businesses, and may pay all debts and honor all obligations arising in the ordinary course of their businesses after the Petition Date. However, the Debtors may not pay third-party claims or creditors on account of obligations arising before the Petition Date or engage in transactions outside the ordinary course of business without approval of the Bankruptcy Court.

Under the Bankruptcy Code, third-party actions to collect pre-petition indebtedness owed by the Debtors, as well as most litigation pending against the Company as of the Petition Date, are subject to an automatic stay. However, under the Bankruptcy Code, certain regulatory or criminal proceedings generally are not subject to the automatic stay and may continue unless otherwise ordered by the Bankruptcy Court. Absent an order of the Bankruptcy Court providing otherwise, substantially all pre-petition liabilities will be resolved under a Chapter 11 plan of reorganization.

Among other requirements, a Chapter 11 plan of reorganization must comply with the priority scheme established by the Bankruptcy Code, under which certain post-petition and secured or “priority” pre-petition liabilities need to be satisfied before general unsecured creditors and holders of the Company's equity are entitled to receive any distribution. Upon solicitation of the plan of reorganization to creditors, with an accompanying court-approved disclosure statement, certain impaired creditors and interest holders will vote by ballot to approve or reject the plan. No assurance can be given as to what values, if any, will be ascribed in the Chapter 11 Cases to the claims and interests of each of these constituencies. See *Restructuring Support Agreement* section below for contemplated distributions to creditors and interest holders.

Under the Bankruptcy Code, the Debtors may assume, modify, assign or reject certain executory contracts and unexpired leases, including, without limitation, leases of real property and equipment, subject to the approval of the Bankruptcy Court and to certain other conditions. Generally, the rejection of an executory contract or unexpired lease is treated as a pre-petition breach of such

executory contract or unexpired lease and, subject to certain exceptions, relieves the Debtors from performing their future obligations under such executory contract or unexpired lease but entitles the contract counterparty or lessor to a pre-petition general unsecured claim for damages caused by such deemed breach. Generally, the assumption of an executory contract or unexpired lease requires the Debtors to cure existing monetary defaults under such executory contract or unexpired lease and provide adequate assurance of future performance. Accordingly, any description of an executory contract or unexpired lease in this Annual Report on Form 10-K, including, where applicable, the express termination rights thereunder or a quantification of their obligations, must be read in conjunction with, and is qualified by, any overriding rejection rights the Debtors have under the Bankruptcy Code.

As discussed further below, the Debtors obtained approval from the Bankruptcy Court for certain "first day" motions, including motions to obtain customary relief intended to continue ordinary course operations after the Petition Date.

Significant Bankruptcy Court Actions

First Day Motions

On October 14, 2020, the Debtors received Bankruptcy Court approval of their customary motions filed on the Petition Date ("First Day Motions") on an interim basis seeking court authorization to continue to support its business operations during the Chapter 11 Cases, including the continued payment of employee wages and benefits without interruption, payment of critical and foreign vendors, continuation of customer programs, continuation of use of existing cash management programs and allowance of certain financing payments under a cash collateral order. The First Day Motions were subsequently approved by the Bankruptcy Court on a final basis at hearings.

Chapter 11 Financing

In accordance with the terms of the RSA, the Company obtained the entry in the Chapter 11 Cases of an order of the Bankruptcy Court (in a form agreed with, among others, the agent under the senior secured credit facilities, lenders under the senior secured revolving credit facility and the senior secured term loans and holders of the first lien senior notes and the second lien senior notes) permitting the use of cash collateral to finance the Chapter 11 Cases. Such use is subject to an approved budget, updated and submitted every four weeks, consisting of rolling thirteen-week periods subject to the consent of the lenders under the senior secured revolving credit facility and the senior secured term loans.

Such order requires that the Company make cash adequate protection payments on the senior secured revolving credit facility and the senior secured term loans for, among other things, unpaid pre-petition and post-petition fees, unpaid pre-petition interest (at the specified contract rate) and post-petition interest (at a rate equal to (1) the adjusted London Inter-Bank Offered Rate ("LIBOR"), plus (2) the contract-specified applicable margin, and plus (3) an incremental 200 basis points), quarterly amortization payments on the senior secured term loans and reimbursement of certain costs. Such order further requires that we make cash adequate protection payments on the first lien senior notes and the second lien senior notes for, among other thing, unpaid pre-petition and post-petition interest (at the specified non-default interest rate) and reimbursement of certain costs.

However, all cash adequate protection payments are provisional in nature and are subject to recharacterization, or reallocation as payments of principal if such relief is granted by the Bankruptcy Court. The cash collateral order provides that it is without prejudice to (i) the rights of certain parties to request additional or alternative adequate protection from the Bankruptcy Court, (ii) the rights of lenders under the senior secured revolving credit facility and the senior secured term loans to seek a higher rate of interest and (iii) the rights of the holders of the first lien senior notes and the second lien senior notes to seek payment of a make-whole premium.

With respect to the incremental 200 basis points paid on the senior secured revolving credit facility and the senior secured term loans, noted above, the Company incurred $11.7 million of expense, of which $7.8 million was paid, during the three months ended December 25, 2020, which has provisionally been classified as interest expense in the consolidated statement of operations. The Company may pursue recharacterization of these interest payments to principal through Bankruptcy Court filings or through a plan of reorganization. There can be no assurance that the treatment of this or other cash adequate protection payments will not change during the pendency of the proceedings or in connection with the confirmation of a plan of reorganization by the Bankruptcy Court.

As of December 25, 2020, the outstanding borrowings under the senior secured revolving credit facility, the senior secured term loans, the first lien senior notes and the second lien senior notes were classified outside of liabilities subject to compromise ("LSTC") as the related debt instruments were expected to be reinstated upon emergence from bankruptcy in accordance with the RSA.

Bar Date

On December 31, 2020, the Bankruptcy Court entered an order approving a deadline of February 16, 2021 at 5:00 pm (Eastern Time) (the "General Bar Date") and April 12, 2021, at 5:00 p.m. (Eastern Time) (the “Governmental Bar Date”) (collectively, together the "Bar Dates") for filing claims against the Debtors relating to the period prior to the Petition Date for general claims and government claims, respectively. The preceding Bar Dates do not cover opioid claims (inclusive of voluntary injunction opioid claims). The Company's review of asserted claims is discussed further below in *Chapter 11 Claims Process*.

Injunctive Litigation Relief

The Bankruptcy Court entered orders approving a 270-day injunction against certain opioid and Acthar Gel-related litigation matters proceeding against the Debtors and also against certain covered non-Debtors on November 25, 2020 and December 4, 2020. Refer to Note 20 for further discussion.

Restructuring Support Agreement

On October 11, 2020, the Company and the other Debtors entered into a RSA with creditors holding approximately 84%, by aggregate principal amount, of the Company's outstanding guaranteed unsecured senior notes and with a group of governmental plaintiffs in the opioid litigation pending against the Company and certain of its subsidiaries, including 50 state and territory attorneys general and the court-appointed plaintiffs' executive committee in the opioid multidistrict litigation (collectively, the "Supporting Parties"). After the bankruptcy filing, the Multi-State Governmental Entities Group entered into a joinder to the RSA that gained the support of approximately 1,300 cities, municipalities, hospital and school districts, amongst others.

The RSA incorporates the terms agreed to by the parties reflected in the term sheets attached to the RSA, including an agreement by the Supporting Parties to support the following:

- *A proposed resolution of all opioid-related claims against the Company and its subsidiaries*. Under the terms of the amended proposed settlement (the "Amended Proposed Opioid-Related Litigation Settlement"), which would become effective upon Mallinckrodt's emergence from the Chapter 11 process, subject to court approval and other conditions:
    - Opioid claims would be channeled to one or more trusts, which would receive $1,600.0 million in structured payments consisting of (i) a $450.0 million payment upon the Company's emergence from Chapter 11; (ii) a $200.0 million payment upon each of the first and second anniversaries of emergence; and (iii) a $150.0 million payment upon each of the third through seventh anniversaries of emergence with a one-year prepayment option at a discount for all but the first payment.
    - Opioid claimants would also receive warrants for approximately 19.99% of the reorganized Company's new outstanding shares, after giving effect to the exercise of the warrants, but subject to dilution from equity reserved under the management incentive plan, exercisable at any time on or prior to the seventh anniversary of the Company's emergence, at a strike price reflecting an aggregate equity value for the reorganized Debtors of $1,551.0 million (the "New Opioid Warrants").
    - Upon commencing the Chapter 11 filing, the Company will comply with an agreed-upon operating injunction with respect to the operation of its opioid business.
- *A proposed resolution with the U.S. Department of Justice and other governmental parties to settle a range of litigation matters and disputes relating to Acthar Gel*.
    - The Company has reached an agreement in principle with the U.S. Department of Justice ("DOJ") and other governmental parties to settle a range of litigation matters and disputes relating to Acthar Gel (the "Proposed Acthar Gel-Related Settlement") including the Medicaid lawsuit with the Centers for Medicare and Medicaid Services ("CMS"), a related False Claims Act ("FCA") lawsuit in Boston, and an Eastern District of Pennsylvania ("EDPA") FCA lawsuit relating to Acthar Gel's previous owner's (Questcor Pharmaceuticals Inc. ("Questcor")) interactions with an independent charitable foundation. Under the Proposed Acthar Gel-Related Settlement, which was conditioned upon the Company entering the Chapter 11 restructuring process, the Company has agreed to pay $260.0 million to the DOJ and other parties over seven years and reset Acthar Gel's Medicaid rebate calculation as of July 1, 2020, such that state Medicaid programs will receive 100% rebates on Acthar Gel Medicaid sales, based on current Acthar Gel pricing. Additionally, upon execution of the settlement, the Company will dismiss its appeal of the U.S. District Court of Columbia's ("D.C. District Court") adverse decision in the Medicaid lawsuit, which appeal was filed in the U.S. Court of Appeals for the District of Columbia ("D.C. Circuit"). In turn, the U.S. Government will drop its demand for approximately $640 million in retrospective Medicaid rebates for Acthar Gel and agree to dismiss the FCA lawsuit in Boston and the EDPA FCA lawsuit.

      Mallinckrodt has entered into the Proposed Acthar Gel-Related Settlement to settle with the DOJ and other governmental parties solely to move past these litigation matters and disputes and will make no admission of liability. The Company is working to complete the settlement with the DOJ, as well as various states that are party to the Boston FCA litigation, over the next several months, subject to court approval.
- *The reinstatement of the agreements associated with the Company's senior secured term loans, senior secured revolving credit facility, 10.00% first and second lien senior notes*. At the end of the court-supervised process, all allowed claims under these agreements would be reinstated at existing rates and maturities.

- *A restructuring of the Company's unsecured notes under the Guaranteed Unsecured Notes Indentures.* At the end of the court-supervised process, holders of allowed claims under indentures governing the Guaranteed Unsecured Notes (the 5.75% Senior Notes due 2022, the 5.625% Senior Notes due 2023 and the 5.50% Senior Notes due 2025,) and the Guaranteed Unsecured Notes are expected to receive their pro rata share of $375.0 million of new 10.00% second lien senior secured notes due seven years after emergence and 100% of the new Mallinckrodt ordinary shares, subject to dilution by the warrants described above and certain other equity.
- *A proposed resolution of other remaining claims and treatment of equity holders.* At the end of the court-supervised process, trade creditors and holders of allowed general unsecured claims are expected to share in $150.0 million in cash, and equity holders and holders of the 9.50% debentures due May 2022, the 8.00% debentures due March 2023 and the 4.75% senior notes due April 2023 would receive no recovery.

The restructuring transactions contemplated by the RSA will be effectuated through a plan of reorganization to be proposed by the Debtors (the "Plan"), which among other things as outlined above, provides for a financial restructuring that would reduce the Company's total debt by approximately $1,300.0 million. Pursuant to the RSA, each of the Debtors and the Supporting Parties has made certain customary commitments to each other in connection with the pursuit of the transactions contemplated by the term sheets attached thereto. The Debtors have agreed, among other things, to use commercially reasonable efforts to make all requisite filings with the Bankruptcy Court; continue to involve and update the Supporting Parties' representatives in the bankruptcy process; and satisfy certain other covenants. The Supporting Parties have committed to support and vote for the Plan and have agreed to use commercially reasonable efforts to take, or refrain from taking, certain actions in furtherance of such support.

The RSA contains milestones for the progress of the Chapter 11 Cases (the "Milestones"), which include the dates by which the Debtors are required to, among other things, obtain certain orders of the Bankruptcy Court and consummate the Debtors' emergence from bankruptcy. Among other milestones, the RSA (as expected to be amended by the Joinder and Amendment (as defined in Note 24)) will require the Debtors to file a Plan by no later than March 31, 2021, the Bankruptcy Court to have entered an order confirming the Plan by no later than August 15, 2021 and the Debtors to have emerged from bankruptcy by no later than November 15, 2021.

Each of the parties to the RSA may terminate the agreement (and thereby their support for the Plan) under certain limited circumstances. Any Debtor may terminate the RSA upon, among other circumstances: (i) its board of directors, after consultation with legal counsel, reasonably determining in good faith that performance under the RSA would be inconsistent with its fiduciary duties; and (ii) certain actions by the Bankruptcy Court, including dismissing the Chapter 11 Cases or converting the Chapter 11 Cases into cases under Chapter 7 of the Bankruptcy Code.

The Supporting Parties also have specified termination rights, including, among other circumstances, termination rights that arise if certain of the Milestones have not been achieved, extended, or waived. Termination by one of these creditor groups will result in the termination of the RSA as to the terminating group only, with the RSA remaining in effect with respect to the Debtors and the non-terminating group.

The transactions contemplated by the RSA are subject to approval by the Bankruptcy Court, among other conditions. Accordingly, no assurance can be given that the transactions described therein will be consummated.

On March 10, 2021, the Company announced that the Debtors have agreed to a joinder and amendment to the RSA whereby an ad hoc group of lenders holding approximately $1,300.0 million by aggregate principal amount, of the Company's outstanding 2017 Term Loan (as defined in Note 15) and the Company's outstanding 2018 Term Loan (as defined in Note 15) have agreed to join the RSA as supporting parties and certain of the existing supporting parties have agreed to certain amendments thereto. See further discussion in Note 24.

Event of default

The commencement of the Chapter 11 Cases above constituted an event of default under certain of the Company's debt agreements. Subject to any applicable provisions of the Bankruptcy Code, the Company's debt instruments and agreements described in Note 15 provide that, as a result of the commencement of the Chapter 11 Cases, the principal amount, together with accrued and unpaid interest thereon, and in the case of the indebtedness outstanding under the senior notes, premium, if any, thereon, shall be immediately due and payable. Accordingly, all long-term debt was classified as current on the consolidated balance sheet as of December 25, 2020. However, any efforts to enforce payment obligations under the debt instruments are automatically stayed as a result of the Chapter 11 Cases and the creditors' rights in respect of the debt instruments are subject to the applicable provisions of the Bankruptcy Code.

Financial Reporting in Reorganization

Effective on the Petition Date, the Company began to apply Financial Accounting Standards Board Accounting Standards Codification ("ASC") Topic 852 - Reorganizations, which specifies the accounting and financial reporting requirements for entities

reorganizing through Chapter 11 bankruptcy proceedings. These requirements include distinguishing transactions directly associated with the reorganization from activities related to the ongoing operations of the business within the financial statements for periods subsequent to the Petition Date. Expenses, realized gains and losses, and provisions for losses that are directly associated with reorganization proceedings must be reported separately as reorganization items, net in the consolidated statements of operations. In addition, the consolidated balance sheet must distinguish pre-petition LSTC of the Debtors from pre-petition liabilities that are not subject to compromise, post-petition liabilities, and liabilities of the subsidiaries of the Company that are not debtors in the Chapter 11 Cases. LSTC are pre-petition obligations that are not fully secured and have at least a possibility of not being repaid at the full claim amount. Where there is uncertainty about whether a secured claim will be paid or impaired pursuant to the Chapter 11 Cases, the Debtors have classified the entire amount of the claim as LSTC.

Furthermore, the realization of assets and the satisfaction of liabilities are subject to uncertainty. While operating as debtors-in-possession, actions to enforce or otherwise effect the payment of certain claims against the Debtors in existence before the Petition Date are stayed while the Debtors continue business operations as debtors-in-possession. These claims are reflected as LSTC in the consolidated balance sheet at December 25, 2020. Additional claims (which could be LSTC) may arise after the Petition Date resulting from the rejection of executory contracts, including leases, and from the determination by the Bankruptcy Court (or agreement by parties-in-interest) of allowed claims for contingencies and other disputed amounts.

Certain subsidiary entities are not debtors under the Chapter 11 Cases. However, condensed combined financial statements of the Debtors are not presented in the notes to the consolidated financial statements as the assets and liabilities, operating results and cash flows of the non-debtor entities included in the consolidated financial statements are insignificant and, therefore, the consolidated financial statements presented herein materially represent the condensed combined financial statements of the debtor entities for all periods presented. As of December 25, 2020, the non-debtor entities have intercompany receivables and intercompany payables from/to the debtor entities of $282.3 million and $120.3 million, respectively, which are primarily attributable to the Company's centralized approach to cash management and financing of its operations. The permission to continue the use of existing cash management systems during the pendency of the Chapter 11 Cases was approved by the Bankruptcy Court on a final basis as part of the First Day motions as described further above.

The Company is currently assessing whether or not it qualifies for fresh start accounting upon emergence from Chapter 11. If the Company were to meet the requirements to adopt the fresh start accounting rules, its assets and liabilities would be recorded at fair value as of the fresh start reporting date, which may differ materially from the recorded values of assets and liabilities on its consolidated balance sheet as of December 25, 2020.

Notice of Delisting

On October 13, 2020, New York Stock Exchange ("NYSE") Regulation Inc. filed a Form 25 with the SEC to remove the Company's ordinary shares from listing and registration on the NYSE. The delisting became effective October 26, 2020. The deregistration of the ordinary shares under Section 12(b) of the Securities Exchange Act of 1934 ("Exchange Act") became effective on January 11, 2021, at which point the ordinary shares were deemed registered under Section 12(g) of the Exchange Act. The Company's ordinary shares began trading on the OTC Pink Marketplace on October 13, 2020 under the symbol “MNKKQ.”

Liabilities Subject to Compromise

As a result of the commencement of the Chapter 11 Cases, the payment of pre-petition liabilities is subject to compromise or other treatment pursuant to a plan of reorganization. Generally, actions to enforce or otherwise effect payment of pre-petition liabilities are stayed. Although payment of pre-petition claims generally is not permitted, the Bankruptcy Court granted the Debtors the authority to pay certain pre-petition claims in designated categories and subject to certain terms and conditions. This relief generally was designed to preserve the value of the Debtors' business and assets. As described above, among other things, the Bankruptcy Court authorized, but did not require, the Debtors to pay certain pre-petition claims relating to employee wages and benefits, critical and foreign vendors and customer programs.

The determination of how liabilities will ultimately be settled or treated cannot be made until the Bankruptcy Court confirms a Chapter 11 plan of reorganization and such plan becomes effective. Accordingly, the ultimate amount of such liabilities is not determinable at this time. GAAP requires pre-petition liabilities that are subject to compromise to be reported at the amounts expected to be allowed by the Bankruptcy Court, even if they may be settled for different amounts. The amounts currently classified as LSTC are preliminary and may be subject to future adjustments depending on Bankruptcy Court actions, further developments with respect to disputed claims, determinations of the secured status of certain claims, the values of any collateral securing such claims, rejection of executory contracts, continued reconciliation or other events.

Liabilities subject to compromise as of December 25, 2020 consisted of the following:

	December 25, 2020
Accounts payable	$ 61.9
Accrued interest	35.2
Debt	1,660.7
Medicaid lawsuit	638.9
Opioid-related litigation settlement liability	1,600.0
Other current and non-current liabilities	163.5
Pension and postretirement benefits	32.4
Total liabilities subject to compromise	$ 4,192.6

Contractual interest

While the Chapter 11 Cases are pending, the Company is not accruing interest on its unsecured debt instruments as of the Petition Date on a go-forward basis, as the Debtors do not anticipate making interest payments due under their respective unsecured debt instruments; however, the Debtors expect to pay all interest payments in full as they come due under their respective senior secured debt instruments. The total aggregate amount of interest paid pursuant to the Company's unsecured debt instruments was $64.2 million and $147.3 million during fiscal 2020 and 2019, respectively. The total aggregate amount of interest payments due under the Company's unsecured debt instruments from the Petition Date through December 25, 2020, which it did not pay is $28.8 million.

Chapter 11 Claims Process

The Debtors have received over 30,000 proofs of claim since the Petition Date. The Debtors continue their review and analysis of certain claims including litigation claims, trade creditor claims, non-qualified benefit plan claims, customer deposits and advances, along with other tax and regulatory claims, and therefore, the ultimate liability of the Debtors for such claims may differ from the amount recorded in LSTC. To the extent that the Debtors believe that such claims will be allowed by the Bankruptcy Court, the Debtors will continue to record the expected allowed amounts of such claims as LSTC. The determination of the expected allowed amount of a claim is based on many factors, including whether the Debtors are party to a settlement agreement with applicable claimholders or their representatives, and is not necessarily limited to information available to the Debtors. Claims covered by a settlement agreement include the Proposed Acthar Gel-Related Settlement and Amended Opioid-Related Litigation Settlement (collectively, the "Proposed Settlements"). See *Restructuring Support Agreement* section within this note for more information on settlement of these claims. As the Debtors continue to resolve claims, differences between those final allowed claims and the liabilities recorded in the consolidated balance sheet will be recognized as reorganization items, net in the Company's consolidated statements of operations as they are resolved. The determination of how liabilities will ultimately be resolved cannot be made until the Bankruptcy Court approves a plan of reorganization or approves orders related to settlement of specific liabilities. Accordingly, the ultimate amount or resolution of such liabilities is not determinable at this time. The resolution of such claims could result in substantial adjustments to the Company's financial statements.

Reorganization items, net

Reorganization items, net, represent amounts incurred after the Petition Date as a direct result of the Chapter 11 Cases and are comprised of bankruptcy-related professional fees and adjustments to reflect the carrying value of LSTC at their estimated allowed claim amounts, as such adjustments are approved by the Bankruptcy Court. Cash paid for reorganization items, net for fiscal 2020 was $8.7 million. Reorganization items, net from the Petition Date through December 25, 2020 include the following:

	December 25, 2020
Professional fees	$ 51.1
Debt valuation adjustments	10.2
Adjustments of other claims	0.1
Total reorganization items, net	$ 61.4

3. Summary of Significant Accounting Policies

Liabilities Subject to Compromise

As a result of the commencement of the Chapter 11 Cases, the payment of pre-petition liabilities is subject to compromise or other treatment pursuant to a plan of reorganization. The determination of how liabilities will ultimately be settled or treated cannot be made until the Bankruptcy Court confirms a Chapter 11 plan of reorganization and such plan becomes effective. Accordingly, the ultimate amount of such liabilities is not determinable at this time. Pre-petition liabilities that are subject to compromise are to be reported at the amounts expected to be allowed by the Bankruptcy Court, even if they may be settled for different amounts. The amounts currently classified as LSTC are preliminary and may be subject to future adjustments depending on Bankruptcy Court actions, further developments with respect to disputed claims, determinations of the secured status of certain claims, the values of any collateral securing such claims, rejection of executory contracts, continued reconciliation or other events.

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® (lubiprostone) ("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		
	2020	2019	2018
Shipping costs	$ 20.1	$ 17.6	$ 12.8

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 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 ("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.

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, current facts and circumstances, reasonable and supportable forecasts 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 less accumulated depreciation. 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 loss.

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 4 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 2020 and 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 25, 2020 were the following:

Completed technology	9	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 20. The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. The Company discounts environmental liabilities using a risk-free rate of return when the obligation is fixed or reasonably determinable. The impact of the discount in the consolidated balance sheets was not material in any period presented. Legal fees, other than those pertaining to environmental and asbestos matters, are expensed as incurred. Insurance recoveries related to potential claims are recognized up to the amount of the recorded liability when coverage is confirmed and the estimated recoveries are probable of payment. Assets and liabilities are not netted for financial statement presentation.

Share-Based Compensation

The Company recognizes the cost of employee services received in exchange for awards of equity instruments based on the grant-date fair value of those awards. That cost is recognized over the period during which an employee is required to provide service in exchange for the award, the requisite service period (generally the vesting period).

Restructuring

The Company recognizes charges associated with 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.

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, or a reduction to a deferred tax asset 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 9 for further information regarding the classification of such amounts in the consolidated balance sheets.

4. 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 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 13 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.

5. Revenue from Contracts with Customers

Product Sales Revenue

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

Reserves for variable consideration

On November 16, 2020, the Debtors received final approval from the Bankruptcy Court to continue customer programs during the pendency of the Chapter 11 Cases. 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
Provisions	2,065.9	28.9	59.5	2,154.3
Provision for Medicaid lawsuit (Note 20) [1]	536.0	—	—	536.0
Payments or credits	(2,701.2)	(30.7)	(60.4)	(2,792.3)
Balance as of December 25, 2020 [1]	$ 196.5	$ 26.6	$ 12.3	$ 235.4

(1) Excludes the $105.1 million that is reflected as a component of operating expenses as it represents a pre-acquisition contingency related to the portion of the liability that arose from sales of Acthar Gel prior to the Company’s acquisition of Questcor in August 2014. See Note 20 for further detail on the status of the Medicaid lawsuit.

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

	Fiscal Year		
	2020	2019	2018
Product sales transferred at a point in time	78.9 %	81.8 %	82.9 %
Product sales transferred over time	21.1	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 25, 2020:

Fiscal 2021	$ 125.2
Fiscal 2022	62.3
Fiscal 2023	28.0
Thereafter	0.6

Costs to fulfill a contract

As of December 25, 2020 and December 27, 2019, 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 $25.8 million and $26.5 million, respectively, and was classified in property, plant and equipment, net, on the consolidated balance sheets. The associated depreciation expense recognized during fiscal 2020 and 2019 was $5.5 million and $6.7 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 7, it acquired an arrangement under which the Company licenses certain rights to Amitiza to a third party in exchange for royalties on net sales of the product. The Company recognizes such royalty revenue as the related sales occur. The 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 fiscal 2020, 2019 and 2018 was $70.3 million, $81.3 million and $81.3 million, respectively.

Contract Liabilities

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

	December 25, 2020	December 27, 2019
Accrued and other current liabilities	$ 2.7	$ 5.6
Other liabilities	0.4	0.6
Contract liabilities	$ 3.1	$ 6.2

Revenue recognized during fiscal 2020 and 2019 from amounts included in contract liabilities at the beginning of the period was approximately $5.1 million and $13.7 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.

6. Discontinued Operations and Divestitures

Discontinued Operations

Nuclear Imaging: The Company received a total of $9.0 million, $9.0 million and $15.0 million in contingent consideration in fiscal 2020, 2019 and 2018, respectively, related to the 2017 sale of the Nuclear Imaging business, consisting primarily of the issuance of $9.0 million par value non-voting preferred equity certificates in fiscal 2020, 2019 and 2018, with an additional $6.0 million cash payment in fiscal 2018. The preferred equity certificates accrued interest at a rate of 10.0% per annum and were 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. Interest was able to be paid on an annual basis in additional preferred equity certificates. The receipt of the preferred equity certificates are presented as a non-cash investing activity on the consolidated statements of cash flows for fiscal 2020, 2019 and 2018. On December 4, 2020, the issuer elected to redeem 100% of the outstanding preferred equity certificates, and the Company received a

cash payment of $32.5 million, which included $29.8 million for the outstanding preferred equity certificates and $2.7 million for accrued interest receivable through the redemption date. In addition, during fiscal 2020, a tax benefit of $18.1 million, comprised of tax and interest on unrecognized tax benefits related to the Nuclear Imaging business, was recognized due to a lapse of statute of limitations.

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. During fiscal 2020, the Company recorded a $16.5 million gain on divestiture related to certain commercial milestones for the Recothrom product.

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.

7. Acquisitions and License Agreements

Business Acquisitions

Sucampo Pharmaceuticals, Inc.

In February 2018, the Company acquired Sucampo through the acquisition of all the outstanding common stock of Sucampo. Consideration for the transaction consisted of approximately $1.2 billion, including the assumption of Sucampo's third-party debt ("the Sucampo Acquisition"). The acquisition was funded through the issuance of a $600.0 million aggregate principal amount of senior secured term loan, a $900.0 million borrowing under the Company's revolving credit facility, as discussed further in Note 15, 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.

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.

Fair Value Allocation

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

Cash	$ 149.6
Accounts receivable	35.7
Inventory	153.2
Intangible assets [1]	919.5
Goodwill (non-tax deductible) [2]	248.6
Other assets, current and non-current	25.8
Total assets acquired	1,532.4
Current liabilities	109.4
Other liabilities (non-current)	33.3
Deferred tax liabilities, net (non-current)	175.8
Debt	366.3
Total liabilities assumed	684.8
Net assets acquired	$ 847.6

(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 14 for further information.

(2) Refer to Note 14 for further information relating to the full goodwill impairment recorded in fiscal 2018.

The following reconciles the total consideration to net assets acquired:

Total consideration, net of cash	$ 698.0
Plus: cash assumed in acquisition	149.6
Net assets acquired	$ 847.6

Intangible assets acquired consist of the following:

Intangible Asset Acquired	Amount	Amortization Period	Discount Rate	Segment
Completed technology - Amitiza	$ 634.0	9 years	14.0 %	Specialty Brands
Completed technology - Other [1]	11.0	8 years	14.0	Specialty Brands
In-process research and development - VTS-270 [2]	274.5	Non-Amortizable	15.0	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.

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 in the Company's consolidated statements of operations related to the Sucampo were $192.9 million, $217.2 million and $190.5 million for fiscal 2020, 2019 and 2018, respectively. The amount of operating income for fiscal 2020 and operating losses for fiscal 2019 and 2018 included in the Company's consolidated statement of operations were $65.3 million, $210.6 million and $369.1 million, 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 2020, 2019 and 2018 results was $70.4 million, $70.9 million and $62.9 million of amortization associated with intangibles recognized from this acquisition, respectively, and zero, $10.0 million and $118.8 million of expense associated with fair value adjustments of acquired inventory, respectively. During fiscal 2020, 2019 and 2018, the Company in total recognized zero, $10.0 million and $120.8 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	**2019**	**2018**
Sucampo	$ 5.2	$ 4.2
Other	0.6	2.2
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 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. The Company has since exercised its option on the two additional target assets.

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. In fiscal 2020, Silence also received $2.0 million for each exercise of the second and third options to expand the total C3 target assets to three. Silence is also eligible to receive up to $10.0 million in research milestones for each target asset, in addition to funding for Phase 1 clinical development including good manufacturing practice (GMP) manufacturing. Silence will be responsible for preclinical activities, and for executing the development program 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 per target asset in commercial milestone payments and tiered low double-digit to high-teen royalties on net sales for approved products.

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® (acetaminophen) injection ("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., 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 2020, 2019 and 2018, the Company paid royalties of $66.1 million, $69.8 million and $76.9 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, net in the consolidated statements of operations.

8. Restructuring and Related Charges

During fiscal 2018 and 2016, 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 commenced 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		
	2020	2019	2018
Specialty Brands	$ 0.1	$ (13.7)	$ 54.6
Specialty Generics	0.1	10.0	5.3
Corporate	49.6	2.0	48.3
Restructuring and related charges, net	49.8	(1.7)	108.2
Less: accelerated depreciation	(12.3)	—	(5.2)
Restructuring charges, net	$ 37.5	$ (1.7)	$ 103.0

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

	Fiscal Year		
	2020	2019	2018
2018 Program	$ 52.0	$ 9.8	$ 5.2
2016 Program	(0.3)	(10.6)	71.6
Acquisition programs	(1.9)	(0.9)	31.4
Total programs	49.8	(1.7)	108.2
Less: non-cash charges, including accelerated depreciation	(23.8)	—	(5.2)
Total charges expected to be settled in cash	$ 26.0	$ (1.7)	$ 103.0

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	Acquisition Programs	Total
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 and other	—	(1.0)	—	(1.0)
Balance as of December 27, 2019	2.7	31.3	0.2	34.2
Charges from continuing operations	28.6	0.1	—	28.7
Changes in estimate from continuing operations	(0.4)	(0.4)	(1.9)	(2.7)
Cash payments	(20.1)	(30.7)	(0.2)	(51.0)
Reclassifications [2]	(10.0)	—	—	(10.0)
Currency translation and other	0.2	(0.3)	1.9	1.8
Balance as of December 25, 2020	$ 1.0	$ —	$ —	$ 1.0

(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.

(2) Represents the reclassification of certain restructuring reserve balances to LSTC as a result of the Company rejecting certain of its executory contracts.

As of December 25, 2020, net restructuring and related charges incurred cumulative to date were as follows:

	2018 Program [1]	2016 Program [2]
Specialty Brands	$ 3.0	$ 68.1
Specialty Generics	10.1	14.6
Corporate	53.9	28.6
	$ 67.0	$ 111.3

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

(2) The 2016 Program was completed in fiscal 2020.

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.

9. Income Taxes

On March 27, 2020, the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security ("CARES") Act. The CARES Act was a response to the market volatility and instability resulting from the novel coronavirus ("COVID-19") pandemic. It includes provisions to support individuals and businesses in the form of loans, grants, and tax changes among other types of relief. Estimates of the effects of the changes to the U.S. tax code have been incorporated into the Company’s fiscal 2020 provision for income taxes, as applicable.

The CARES Act income tax provisions applicable to the Company include, but are not limited to (1) carrybacks of certain net operating losses ("NOL(s)") generated in tax years beginning after December 31, 2017 and before January 1, 2021 to the preceding five taxable years, (2) suspension of the 80.0% taxable income limitation for NOLs generated in tax years beginning after December 31, 2017 and before January 1, 2021, (3) increase in the limitation of the interest expense deduction under Internal Revenue Code ("IRC") §163(j) from 30.0% to 50.0% of adjusted taxable income for any taxable year beginning in 2019 or 2020, (4) expansion of the charitable contribution deduction limit to 25.0% of taxable income versus the previous 10.0% limitation for contributions made during 2020, and (5) acceleration of alternative minimum tax credits being refunded incrementally in tax years 2018, 2019, 2020 and 2021 to recover the entire remaining balance in either the 2018 or 2019 tax year.

As a result of the CARES Act, the Company is able to carryback a portion of its prior year and estimated current year U.S. Federal NOLs resulting in anticipated cash tax refunds recorded as $177.8 million of current receivable and $136.6 million of non-current receivable. These refunds are subject to review and audit by the Internal Revenue Service ("IRS"), and the timing of the receipt of the refunds by the Company is dependent upon the actions of the IRS. A tax benefit of $281.5 million has been recognized in fiscal 2020. The carryback of the U.S. Federal NOLs has an ancillary effect on the Company’s unrecognized tax benefits, as disclosed below.

On July 15, 2020, the activities of the Company's principal executive offices were relocated from the United Kingdom ("U.K.") to Ireland, which resulted in a change in the Company's tax residence to Ireland. Mallinckrodt plc has always been and remains incorporated in Ireland. Relocation of Mallinckrodt plc’s tax residence to Ireland allows the Company to mitigate the potential impacts of the U.K.’s departure from the European Union and aligns with the Company's commercial activity in Ireland. The Company continues to be subject to taxation in various tax jurisdictions worldwide. Accordingly, in fiscal 2020 the Company will report the Irish tax jurisdiction as the Company's domestic jurisdiction using an Irish statutory tax rate of 12.5% versus the U.K. statutory rate of 19.0%, and the international jurisdiction for fiscal 2020 will represent areas outside the Irish tax jurisdiction. There is no material financial impact to this change.

The domestic and international components[1] of loss from continuing operations before income taxes were as follows:

	Fiscal Year		
	2020	2019	2018
Domestic	$ (656.9)	$ (75.3)	$ (233.7)
International	(303.9)	(1,516.2)	(3,818.3)
Total	$ (960.8)	$ (1,591.5)	$ (4,052.0)

(1) Domestic reflects Ireland in fiscal 2020, and U.K. in fiscal 2019 and 2018.

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

	Fiscal Year		
	2020	2019	2018
Current:			
Domestic	$ 0.1	$ 0.1	$ (0.2)
International	(375.4)	21.7	113.0
Current income tax (benefit) provision	(375.3)	21.8	112.8
Deferred:			
Domestic	102.2	(1.1)	1.4
International	282.0	(605.0)	(544.3)
Deferred income tax provision (benefit)	384.2	(606.1)	(542.9)
Total	$ 8.9	$ (584.3)	$ (430.1)

(1) Domestic reflects Ireland in fiscal 2020, and U.K. in fiscal 2019 and 2018.

The domestic current income tax provision reflects a tax benefit of $0.2 million, $1.2 million and $8.5 million from using NOL carryforwards for fiscal 2020, 2019 and 2018, respectively. For fiscal 2020, domestic reflects Ireland; and for fiscal 2019 and 2018, domestic reflects the U.K. The international current income tax provision reflects a tax benefit of $33.4 million, $0.9 million and $13.7 million from using NOL carryforwards for fiscal 2020, 2019 and 2018, respectively. The fiscal 2020 international current income tax provision also includes a tax benefit of $1.0 million related to refundable credits and a tax benefit of $281.5 million related to carryback claims. The international credit utilization is comprised of credit carryforwards.

As further discussed in Note 1, the Company concluded that there is substantial doubt about its ability to continue as a going concern within one year from the date of issuance of the consolidated financial statements. The Company considered this in determining that certain net deferred tax assets were no longer more likely than not realizable. As a result, the Company recorded an increase in a valuation allowance of $204.9 million against its beginning net deferred tax assets.

During fiscal years 2020, 2019 and 2018, net cash payments for income taxes were $39.9 million, $30.7 million and $12.4 million, respectively.

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

	Fiscal Year		
	2020	2019	2018
Benefit for income taxes at domestic statutory income tax rate [1]	$ (120.1)	$ (302.4)	$ (770.1)
Adjustments to reconcile to income tax provision:			
Rate difference between domestic and international jurisdictions [2]	(315.3)	(206.3)	(235.7)
Adjustments to accrued income tax liabilities and uncertain tax positions	14.7	(12.4)	60.1
Interest and penalties on accrued income tax liabilities and uncertain tax positions	2.0	(6.3)	13.1
Credits, principally research and orphan drug [3]	(11.2)	(13.5)	(25.9)
Impairments non deductible	—	—	788.7
Permanently nondeductible and nontaxable items [4]	2.8	98.1	7.2
Divestitures [5]	—	9.6	(2.7)
U.S. Tax Reform [6]	(281.5)	—	(8.5)
Legal entity reorganization [7]	82.0	(212.8)	(256.0)
Separation costs	8.4	—	—
Reorganization items, net	8.8	—	—
Other	0.1	—	(0.3)
Valuation allowances [4]	618.2	61.7	—
Provision (benefit) for income taxes	$ 8.9	$ (584.3)	$ (430.1)

(1) The statutory tax rate reflects the Irish statutory tax rate of 12.5% for fiscal 2020, and the U.K. statutory tax rate of 19.0% for fiscal 2019 and 2018.

(2) For fiscal 2019 and fiscal 2018, includes the impact of certain recurring valuation allowances for domestic and international jurisdictions.

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

(4) For fiscal 2020, an expense of $204.9 million was included as a discrete valuation allowance on certain net deferred tax assets that were no longer more likely than not realizable, as explained further above. For fiscal 2019, the valuation allowances and permanently nondeductible and nontaxable item were primarily driven by the impact from the opioid-related litigation settlement charge. Refer to Note 20 for further discussion. Additional valuation allowance impacts are netted within other line items, as referenced in the associated footnotes.

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

(6) For fiscal 2020, the Company has recognized a tax benefit as a result of the CARES Act. Associated unrecognized tax benefit and valuation allowance are netted within this line. For fiscal 2018, the Company completed its analysis of the TCJA and recognized an additional tax benefit to the original estimate recorded in fiscal 2017.

(7) Associated unrecognized tax benefit and valuation allowance are netted within this line.

The rate difference between domestic and international jurisdictions changed from $206.3 million of tax benefit to $315.3 million of tax benefit for fiscal 2019 to fiscal 2020, respectively. Of the $109.0 million increase in the tax benefit, $92.7 million of the increase results from presenting the impact of recurring valuation allowances within the rate difference between domestic and international jurisdictions in fiscal 2019 and within valuation allowances in fiscal 2020 and an increase of $48.9 million is attributable to the Medicaid lawsuit; partially offset by a $79.0 million decrease attributable to the fiscal 2019 gain on debt extinguishment, a $60.9 million decrease attributable to the fiscal 2019 opioid-related settlement charge and a $30.0 million decrease attributable to changes in operating income. The remaining $137.3 million increase is predominately attributable to the change in the referenced rate from the U.K. statutory rate of 19.0% to the Irish statutory rate of 12.5%.

The rate difference between domestic and international 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.

During fiscal 2020, the Company commenced the reorganization of its intercompany financing and associated asset and legal entity ownership in preparation for and in response to the Chapter 11 bankruptcy filing, described in Note 2. As a result, the Company recognized current income tax expense of $17.9 million and deferred income tax expense of $64.1 million with a corresponding net increase to deferred tax liabilities.

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

	Fiscal Year		
	2020	2019	2018
Balance at beginning of period	$ 398.6	$ 287.7	$ 182.5
Additions related to current year tax positions	71.1	123.5	19.6
Additions related to prior period tax positions	9.8	19.2	125.1
Reductions related to prior period tax positions	(14.2)	(5.7)	(32.7)
Settlements	(80.3)	(1.0)	(2.0)
Lapse of statute of limitations	(36.0)	(25.1)	(4.8)
Balance at end of period	$ 349.0	$ 398.6	$ 287.7

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

	December 25, 2020	December 27, 2019
Other assets [1]	$ 256.4	$ 204.7
Other income tax liabilities	83.2	193.9
Deferred income taxes	9.4	—
	$ 349.0	$ 398.6

(1) Included as a reduction to deferred tax assets.

Included within total unrecognized tax benefits as of December 25, 2020, December 27, 2019 and December 28, 2018 were $85.9 million, $395.9 million and $275.8 million, respectively, of unrecognized tax benefits, which if favorably settled would benefit the effective tax rate, of which approximately $20.0 million would be reported in discontinued operations in fiscal 2019 and 2018. The remaining unrecognized tax benefits are reflected as the write-off of related other tax assets. If these unrecognized tax benefits were recognized, they would be offset by a valuation allowance in fiscal 2020. During fiscal 2020, due to a lapse of the statute of limitations, $18.1 million of tax and interest on unrecognized tax benefits related to the Nuclear Imaging business were eliminated, and a benefit of $18.1 million was recorded in discontinued operations within the consolidated statement of operations. During fiscal 2020, the Company recorded $23.7 million of additional interest and penalties through tax provision and decreased accrued interest and penalties by $39.9 million related to prior period reductions, settlements and lapse of statute of limitations. During fiscal 2019 and 2018, the Company had a net decrease of interest and penalties activity of $4.2 million and a net increase of interest and penalties activity of $30.0 million, respectively. The total amount of accrued interest and penalties related to uncertain tax positions was $16.7 million, $32.9 million and $37.1 million, respectively.

It is reasonably possible that within the next twelve months the unrecognized tax benefits could decrease by up to $25.7 million and the amount of related interest and penalties could decrease by up to $6.9 million as a result of payments or releases due to the resolution of examinations, appeals and litigation, and the expiration of various statutes of limitation.

In August 2020, a settlement was reached with the IRS related to the audit of Mallinckrodt Hospital Products Inc.'s ("MHP") (formerly known as Cadence Pharmaceuticals, Inc. ("Cadence")) tax year ended September 26, 2014. Cadence was acquired as a U.S. subsidiary in March 2014. Following the acquisition of Cadence, the Company transferred certain rights and risks in the Ofirmev intellectual property ("Transferred IP") to one of its wholly owned non-U.S. subsidiaries. The transfer occurred at a price determined in conjunction with external advisors, in accordance with applicable Treasury Regulations and with reference to the $1,329.0 million taxable consideration the Company paid to the shareholders of Cadence. The IRS asserted the transfer price of the Transferred IP was understated. The settlement increased the transfer price of the Transferred IP, resulting in an increase to taxable income of $356.5 million and underpayment interest of $11.8 million. The increase to taxable income was satisfied through a noncash offset against the Company’s U.S. Federal NOLs and interest expense for the tax year ended September 25, 2020, while the underpayment interest was satisfied through a cash payment of $11.8 million. The Company was adequately reserved for this item; therefore there were no impacts to the consolidated statement of operations for fiscal 2020.

Certain of the Company's subsidiaries continue to be subject to examination by taxing authorities. The earliest open years subject to examination for various jurisdictions, including Ireland, the U.S., Japan, Luxembourg, Switzerland and the U.K. are from 2013 to present and the earliest open year for the U.S. state tax jurisdictions is 2009.

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

	December 25, 2020	December 27, 2019
Accrued and other current liabilities	$ 26.5	$ 15.0
Other income tax liabilities	100.1	227.1
	$ 126.6	$ 242.1

Tax receivables were included in the following consolidated balance sheet captions in the amounts shown:

	December 25, 2020	December 27, 2019
Other assets	$ 139.4	$ 3.1
Prepaid expenses and other current assets	188.7	8.0
	$ 328.1	$ 11.1

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 25, 2020	December 27, 2019
Deferred tax assets:		
Tax loss and credit carryforward	$ 4,026.0	$ 2,263.4
Capital tax loss carryforward and related assets	1,600.1	—
Intangible assets	—	981.2
Opioid-related litigation settlement liability	269.3	273.7
Excess interest	150.7	81.5
Other	294.9	200.4
	6,341.0	3,800.2
Deferred tax liabilities:		
Intangible assets	(191.2)	(139.4)
Investment in partnership	(74.8)	(178.9)
Other	(44.8)	(46.3)
	(310.8)	(364.6)
Net deferred tax asset before valuation allowances	6,030.2	3,435.6
Valuation allowances	(6,110.8)	(3,131.5)
Net deferred tax (liability) assets	$ (80.6)	$ 304.1

The net deferred tax asset before valuation allowances increased from $3,435.6 million as of December 27, 2019 to $6,030.2 million as of December 25, 2020 due to a $1,157.0 million increase to tax loss and credit carryforwards predominately related to current and prior years' operational activity, a $1,048.4 million increase associated with the reorganization of the Company's intercompany financing and associated asset and legal entity ownership, a $282.6 million increase associated with the amortization of

intangible assets, and a $165.8 million decrease associated with the CARES Act. The $1,048.4 million increase associated with the reorganization of the Company's intercompany financing and associated asset and legal entity ownership includes an increase in capital tax loss carryforwards and related assets of $1,600.1 million, an increase in tax loss and credit carryforwards of $605.6 million, an increase related to a reduction to the investment in partnership deferred tax liability of $103.6 million, an increase to other deferred tax assets of $15.5 million, and a decrease to intangible assets of $1,276.4 million.

The deferred tax asset valuation allowances of $6,110.8 million and $3,131.5 million as of December 25, 2020 and December 27, 2019, respectively, relate both to the Company's substantial doubt about its ability to continue as a going concern, as well as the uncertainty of the utilization of certain deferred tax assets, driven by domestic and international net operating and capital losses, credits, intangible assets and the opioid-related settlement liability.

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

	December 25, 2020	December 27, 2019
Other assets	$ —	$ 315.1
Deferred income taxes	(80.6)	(11.0)
Net deferred tax (liability) asset	$ (80.6)	$ 304.1

As of December 25, 2020, the Company had approximately $3,908.8 million of NOL carryforwards in certain international jurisdictions measured at the applicable statutory rates, of which $1,832.2 million have no expiration and the remaining $2,076.6 million will expire in future years through 2041. The Company had $32.9 million of domestic NOL carryforwards measured at the applicable statutory rates at December 25, 2020, which have no expiration date.

As of December 25, 2020, the Company had $179.8 million of capital loss carryforwards in certain international jurisdictions measured at the applicable statutory rates, which will expire in future years through 2025. As of December 25, 2020, the Company had approximately $1,194.9 million of domestic capital loss carryforwards measured at the applicable statutory rates, which have no expiration date.

As of December 25, 2020, the Company also had $84.3 million of tax credits available to reduce future income taxes payable, in international jurisdictions, of which $2.3 million have no expiration and the remainder will expire in future years through 2041.

As of December 25, 2020, the Company's financial reporting basis in subsidiaries that may be subject to tax was in excess of its corresponding tax basis by $15.1 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.

10. Loss per Share

Loss per share is computed by dividing net loss by the number of weighted-average shares outstanding during the period. Dilutive securities, including participating securities, have not been included in the computation of loss per share as the Company reported a net loss from continuing operations during all periods presented below and therefore, the impact would be anti-dilutive.

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

	Fiscal Year		
	2020	2019	2018
Basic	84.5	83.9	84.0

The computation of diluted weighted-average shares outstanding for fiscal 2020, 2019 and 2018 excluded approximately 5.6 million, 6.3 million and 3.3 million, respectively, shares of equity award because the effect would have been anti-dilutive.

11. Inventories

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

	December 25, 2020	December 27, 2019
Raw materials	$ 58.1	$ 62.7
Work in process	200.7	166.5
Finished goods	86.1	82.9
Inventories	$ 344.9	$ 312.1

12. 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 25, 2020	December 27, 2019
Land	$ 43.6	$ 43.4
Buildings	416.9	363.6
Capitalized software	134.0	142.2
Machinery and equipment	1,260.4	1,157.0
Construction in process	56.0	193.9
	1,910.9	1,900.1
Less: accumulated depreciation	(1,077.8)	(1,003.6)
Property, plant and equipment, net	$ 833.1	$ 896.5

Depreciation expense was as follows:

	Fiscal Year		
	2020	2019	2018
Depreciation expense	$ 114.0	$ 97.7	$ 111.9

13. Leases

As a result of the Chapter 11 Cases, certain of the Company's lease liabilities were classified as LSTC as of December 25, 2020 due to rejection of executory contracts. Refer to Note 2 for further information on LSTC.

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

	December 25, 2020	December 27, 2019
Other assets	$ 58.6	$ 83.5
Accrued and other current liabilities	$ 13.0	$ 19.2
Other liabilities	28.0	70.2
Other current and non-current liabilities subject to compromise	31.9	—
Total lease liabilities	$ 72.9	$ 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	
	2020	2019
Lease cost:		
Operating lease cost	$ 21.2	$ 21.3
Short-term lease cost	1.1	3.5
Variable lease cost	3.1	—
Total lease cost	$ 25.4	$ 24.8

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

Lease terms and discount rates were as follows:

	December 25, 2020	December 27, 2019
Weighted-average remaining lease term (in years) - operating lease	6.1	6.6
Weighted-average discount rate - operating leases	3.9 %	3.8 %

Contractual maturities of operating lease liabilities as of December 25, 2020 were as follows:

Fiscal 2021	$ 20.3
Fiscal 2022	16.7
Fiscal 2023	13.6
Fiscal 2024	10.8
Fiscal 2025	7.9
Thereafter	22.8
Total lease payments	92.1
Less: Interest	(19.2)
Present value of lease liabilities	72.9
Less: Amounts reclassified to liabilities subject to compromise	(31.9)
Present value of lease liabilities not subject to compromise	$ 41.0

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

	Fiscal Year	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 23.1	$ 23.2
Lease assets obtained in exchange for lease obligations:		
Operating leases	6.9	7.3

14. 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, ongoing INOmax® (nitric oxide) gas, for inhalation ("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 25, 2020		December 27, 2019	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortizable:				
Completed technology	$ 10,394.6	$ 4,586.6	$ 10,456.9	$ 3,822.8
License agreements	120.1	78.1	120.1	74.1
Trademarks	77.7	23.5	77.7	20.1
Total	$ 10,592.4	$ 4,688.2	$ 10,654.7	$ 3,917.0
Non-Amortizable:				
Trademarks	$ 35.0		$ 35.0	
In-process research and development	245.3		245.3	
Total	$ 280.3		$ 280.3	

The Company recorded impairment charges totaling $63.5 million, $388.0 million and $220.3 million during fiscal 2020, 2019 and 2018, 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. The fiscal 2020 impairment charge relates to the Ofirmev product, discussed further below. The fiscal 2019 impairment charges included $274.5 million related to VTS-270, primarily driven by continued regulatory challenges, and $113.5 million related to stannsoporfin as a result of the Company ending the development program. The 2018 impairment charges primarily related to the MNK-1411 intangible asset a result of lower than previously anticipated pricing assumptions.

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 drew nearer to loss of exclusivity, the Company was better positioned to reliably determine the pattern in which the remaining economic benefits of the intangible asset were 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.

During the three months ended June 26, 2020, due to decreased demand as a result of the deprioritization of non-critical medical treatment in the face of the COVID-19 pandemic, along with increased generic competition anticipated in the marketplace post the product's loss of exclusivity in December 2020, the Company identified a triggering event with respect to the Ofirmev intangible asset within the Specialty Brands segment and assessed the recoverability of the definite-lived asset. Additionally, the Company evaluated whether these events warranted a revision to the remaining period of amortization that previously extended to March 2022. As a result of this analysis, the Company revised the useful life to end December 25, 2020, commensurate with the final period of market exclusivity. After this change in estimate of the asset's useful life, the Company determined that the undiscounted cash flows related to the Ofirmev intangible asset were less than its net book value, which required the Company to record an impairment charge for the difference between the fair value of the Ofirmev intangible asset and its net book value.

The Company determined the fair value of the Ofirmev intangible asset using the income approach, a level three measurement technique. For purposes of determining fair value, the Company made various assumptions regarding estimated future cash flows, the discount rate and other factors in determining the fair value of the intangible asset. The Company's projections in relation to the

Ofirmev intangible asset included long-term net sales and operating income at lower than historical levels. These changes in assumptions resulted in a fair value of the Ofirmev intangible asset that was less than its net book value. Therefore, the Company recorded an impairment charge of $63.5 million. The intangible asset is fully amortized as of December 25, 2020.

Terlipressin

During September 2020, the FDA issued a Complete Response Letter ("CRL") regarding the Company's New Drug Application ("NDA") seeking approval for the investigational agent terlipressin to treat adults with hepatorenal syndrome type 1 ("HRS-1"). The CRL stated that, based on the available data, the agency cannot approve the terlipressin NDA in its current form and requires more information to support a positive risk-benefit profile for terlipressin for patients with HRS-1.

In response to receipt of the CRL, the Company had an End of Review Meeting on October 26, 2020 and a Type A Meeting on January 29, 2021 with the FDA where both parties engaged in constructive dialogue in an effort to clarify a viable path to approval and the Company expects to have clarity on this path in 2021. As the Company continues to engage with the FDA over the coming months, it will continue to assess the impact of any changes to planned revenue or earnings on the fair value of the associated in-process research and development asset of $81.0 million included within intangible assets, net on the consolidated balance sheets as of December 25, 2020 and December 27, 2019.

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. Management relies on a number of qualitative factors when considering a potential impairment such as changes to planned revenue or earnings that could affect significant inputs used to determine the fair value of the indefinite-lived intangible asset.

Intangible asset amortization expense was as follows:

	Fiscal Year		
	2020	2019	2018
Amortization expense	$ 771.2	$ 853.4	$ 740.2

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

Fiscal 2021	$ 581.1
Fiscal 2022	581.1
Fiscal 2023	581.1
Fiscal 2024	581.1
Fiscal 2025	579.6

15. Debt

The commencement of the Chapter 11 Cases above constituted an event of default under certain of the Company's debt agreements. Accordingly, all debt not reclassified as LSTC with original long-term stated maturities was classified as current on the consolidated balance sheet as of December 25, 2020. However, any efforts to enforce payment obligations under the debt instruments are automatically stayed as a result of the Chapter 11 Cases and the creditors' rights in respect of the debt instruments are subject to the applicable provisions of the Bankruptcy Code. See Note 2 for further information.

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

	December 25, 2020		December 27, 2019	
	Principal	Unamortized Discount and Debt Issuance Costs [1]	Principal	Unamortized Discount and Debt Issuance Costs
Secured debt:				
Term loan due September 2024	$ 1,505.2	$ 12.3	$ 1,520.8	$ 15.7
Term loan due February 2025	399.5	5.0	403.6	6.2
10.00% first lien senior notes due April 2025	495.0	7.7	—	—
10.00% second lien senior notes due April 2025	322.9	8.0	322.9	9.9
Revolving credit facility	900.0	1.7	900.0	3.1
Total secured debt	3,622.6	34.7	3,147.3	34.9
Unsecured debt:				
4.875% senior notes due April 2020	—	—	614.8	0.6
9.50% debentures due May 2022	10.4	—	10.4	—
5.75% senior notes due August 2022	610.3	—	610.3	3.7
8.00% debentures due March 2023	4.4	—	4.4	—
4.75% senior notes due April 2023	133.7	—	133.7	0.8
5.625% senior notes due October 2023	514.7	—	514.7	4.4
5.50% senior notes due April 2025	387.2	—	387.2	3.6
Total unsecured debt:	1,660.7	—	2,275.5	13.1
Total debt, prior to reclassification to liabilities subject to compromise	5,283.3	34.7	5,422.8	48.0
Less: Current portion	(3,622.6)	(34.7)	(634.5)	(0.9)
Less: Amounts reclassified to liabilities subject to compromise [2]	(1,660.7)	—	—	—
Total long-term debt, net of current portion	$ —	$ —	$ 4,788.3	$ 47.1

(1) As a result of the Company's Chapter 11 Cases, the Company expensed $10.2 million of unamortized discount and debt issuance costs, net, recorded in reorganization items, net in the consolidated statement of operations for fiscal 2020.

(2) In connection with the Company's Chapter 11 Cases, $1,660.7 million outstanding unsecured debt instruments have been reclassified to LSTC in the Company's consolidated balance sheet as of December 25, 2020. Up to the Petition Date, the Company continued to accrue interest expense in relation to these debt instruments reclassified to LSTC.

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 Senior Secured Credit 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 Senior Secured Credit 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 Senior Secured Credit 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 certain then-outstanding outstanding term loans. The refinanced term loan had an initial aggregate principal amount of $1,865.0 million, is due September 2024 and, pursuant to its terms, bears interest at a per annum rate equal to LIBOR plus 2.75%, subject to certain adjustments (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, which 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 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"), replacing, and increasing the commitments under, an existing revolving credit facility. The Revolving Credit Facility bears interest at a per annum rate equal to LIBOR plus 2.25% and contains a $50.0 million letter of credit provision, of which none had been issued as of December 25, 2020. Unused commitments on the Revolving Credit Facility are subject to an annual commitment fee, which was 0.275% as of December 25, 2020, 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.

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 all $200.0 million of then-outstanding obligations under the Receivables Securitization. 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"). Pursuant to its terms, the 2018 Term Loan bears interest at a per annum rate equal to LIBOR plus 3.00%, subject to certain potential adjustments. The 2018 Term Loan requires quarterly principal amortization payments in an amount equal to 0.25% of the original principal balance of the 2018 Term Loan, which 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.

The 2017 Term Loan, 2018 Term Loan and Revolving Credit Facility (collectively "the Senior Secured Credit Facilities") are fully and unconditionally guaranteed by Mallinckrodt plc, certain of its direct or indirect wholly owned U.S. subsidiaries and each of its direct or indirect wholly owned subsidiaries that owns directly or indirectly any such wholly owned U.S. subsidiaries and certain of its other subsidiaries (collectively, "the Guarantors"). The Senior Secured Credit Facilities are secured by a security interest in certain assets of MIFSA, MCB and the Guarantors. The Senior Secured Credit 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 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 "Second Lien 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 Second Lien Notes. The Second Lien 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 Second Lien Notes are secured by a second lien security interest in all collateral that currently secures the Senior Secured Credit Facilities, subject to certain exceptions. The Second Lien 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 Second Lien Notes at any time at specified redemption prices. The Issuers are obligated to (a) offer to repurchase all of the Second Lien 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 Second Lien 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 Second Lien Notes. The exchanges also resulted in the capitalization of $10.1 million of deferred financing fees related to the Second Lien 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.

On April 7, 2020, the Company, Mallinckrodt International Finance S.A. and Mallinckrodt CB LLC (the "Exchange Issuers") entered into an exchange agreement (the “Exchange Agreement”) with certain third parties (collectively, the “Exchanging Holders”). Pursuant to the Exchange Agreement, the Exchanging Holders agreed to exchange with the Exchange Issuers, on April 7, 2020, their holdings of 2020 Notes (consisting of approximately $495.0 million aggregate principal amount of the 2020 Notes) for new 10.00% First Lien Senior Secured Notes due 2025 issued by the Exchange Issuers (the “First Lien Notes”), at a rate of $1,000 of First Lien Notes for every $1,000 of 2020 Notes exchanged (such exchange, the “Exchange”). The Exchange Issuers and Exchanging Holders consummated the Exchange on April 7, 2020.

The First Lien 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 First Lien Notes are secured by a first lien security interest in all collateral that currently secures the Senior Secured Credit Facilities, subject to certain exceptions. The First Lien Notes are guaranteed by each entity that currently guarantees the Senior Secured Credit Facilities, subject to certain exceptions. The Issuers may redeem any or all of the First Lien Notes at any time at specified redemption prices. The Issuers are obligated to (a) offer to repurchase all of the First Lien 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 First Lien 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.

On April 15, 2020, the Company paid in full the remaining approximately $119.8 million in principal amount of outstanding 2020 Notes at the maturity thereof with cash on hand.

As of December 25, 2020, the applicable interest rate and outstanding borrowings on the Company's variable-rate debt instruments were as follows:

	Applicable interest rate[1]	Outstanding borrowings
Term loan due September 2024	5.50 %	$ 1,505.2
Term loan due February 2025	5.75	399.5
Revolving credit facility	4.47	900.0

(1) Includes the incremental 200 basis points related to the cash adequate protection payments. Refer Note 2 for further information.

The commencement of the Chapter 11 Cases on October 12, 2020 constituted an event of default under certain of the Company's debt agreements. Accordingly, all long-term debt not subject to compromise was classified as current on the consolidated balance sheet as of December 25, 2020. The Company's stated long-term debt principal maturity amounts as of December 25, 2020 are as follows:

Fiscal 2021	$ 24.6
Fiscal 2022	1,540.4
Fiscal 2023	672.5
Fiscal 2024	1,457.6
Fiscal 2025	1,588.2

16. Retirement Plans

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 25, 2020, U.S. plans represented 32.8% 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.

On November 16, 2020, the Debtors received approval from the Bankruptcy Court to maintain foreign pension benefit plans and certain postretirement benefit plans during the pendency of the Chapter 11 Cases. As such, these obligations are not classified as LSTC on the consolidated balance sheet as of December 25, 2020. For further information refer to Note 2.

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		
	2020	2019	2018	2020	2019	2018
Service cost	$ 0.2	$ 0.1	$ 0.2	$ —	$ —	$ —
Interest cost	0.5	0.7	0.6	1.2	1.6	1.5
Amortization of net actuarial loss	0.7	0.5	0.5	—	—	0.1
Amortization of prior service cost (credit)	0.1	0.2	0.1	(2.1)	(2.1)	(2.1)
Loss (gain) on plan settlements	—	—	0.1	—	—	(0.7)
Net periodic benefit cost (credit)	$ 1.5	$ 1.5	$ 1.5	$ (0.9)	$ (0.5)	$ (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 25, 2020	December 27, 2019	December 25, 2020	December 27, 2019
Change in benefit obligations:				
Projected benefit obligations at beginning of year	$ 27.0	$ 26.1	$ 40.5	$ 39.8
Service cost	0.2	0.1	—	—
Interest cost	0.5	0.7	1.2	1.6
Actuarial loss	1.8	2.3	1.2	1.7
Benefits and administrative expenses paid	(1.5)	(1.7)	(2.8)	(2.6)
Plan settlements	(0.1)	(0.2)	—	—
Currency translation	1.5	(0.3)	—	—
Projected benefit obligations at end of year	$ 29.4	$ 27.0	$ 40.1	$ 40.5

	Pension Benefits		Postretirement Benefits	
	December 25, 2020	December 27, 2019	December 25, 2020	December 27, 2019
Amounts recognized on the consolidated balance sheet:				
Current liabilities	$ 0.8	$ 1.8	$ 1.9	$ 3.3
Non-current liabilities	18.9	25.2	15.5	37.2
Liabilities subject to compromise	9.7	—	22.7	—
Net amount recognized on the consolidated balance sheet	$ 29.4	$ 27.0	$ 40.1	$ 40.5
Amounts recognized in accumulated other comprehensive loss consist of:				
Net actuarial loss	$ (11.8)	$ (10.1)	$ (2.0)	$ (0.8)
Prior service (cost) credit	(0.1)	(0.2)	3.8	5.9
Net amount recognized in accumulated other comprehensive loss	$ (11.9)	$ (10.3)	$ 1.8	$ 5.1

The estimated amounts that will be amortized from accumulated other comprehensive loss into net periodic benefit cost (credit) in fiscal 2021 are as follows:

	Pension Benefits	Postretirement Benefits
Amortization of net actuarial loss	$ 0.9	$ 0.2
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		
	2020	2019	2018	2020	2019	2018
Discount rate	2.8 %	4.0 %	3.3 %	1.3 %	2.0 %	1.9 %
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		
	2020	2019	2018	2020	2019	2018
Discount rate	1.8 %	2.8 %	4.0 %	1.0 %	1.3 %	2.0 %
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 Investor Services, Inc. or Standard & Poor's Corporation) 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		
	2020	2019	2018
Net periodic benefit credit	3.0 %	4.1 %	3.4 %
Benefit obligations	2.0 %	3.0 %	4.1 %

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

	December 25, 2020	December 27, 2019
Healthcare cost trend rate assumed for next fiscal year	5.8 %	5.8 %
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 2020 and 2019, the Company made $1.6 million and $1.9 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 2021	$ 2.0	$ 3.4
Fiscal 2022	1.7	3.0
Fiscal 2023	1.7	2.9
Fiscal 2024	1.7	2.8
Fiscal 2025	1.6	2.7
Fiscal 2026 - 2030	7.3	11.8

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 3% 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 8% 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 $26.0 million, $21.9 million and $25.3 million for fiscal 2020, 2019 and 2018, respectively.

Rabbi Trusts and Other Investments

The Company maintains several rabbi trusts, the assets of which are used to pay retirement benefits. The rabbi trust assets are subject to the claims of the Company's creditors in the event of the Company's insolvency. Plan participants are general creditors of the Company with respect to these benefits. The trusts primarily hold life insurance policies and debt and equity securities, the value of which is included in other assets on the consolidated balance sheets. Note 21 provides additional information regarding the debt and equity securities. During fiscal 2019, a portion of these policies were liquidated. The carrying value of the 61 and 62 life insurance contracts held by these trusts was $45.0 million and $43.8 million as of December 25, 2020 and December 27, 2019, respectively. These contracts had a total death benefit of $92.7 million and $94.0 million as of December 25, 2020 and December 27, 2019, respectively. However, there are outstanding loans against the policies amounting to $23.2 million and $23.6 million as of December 25, 2020 and December 27, 2019, 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 as of both December 25, 2020 and December 27, 2019, respectively. These amounts were included in other assets on the consolidated balance sheets.

17. 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 25, 2020. Rights as to dividends, return of capital, redemption, conversion, voting and otherwise with respect to these shares may be determined by Mallinckrodt's Board of Directors on or before the time of issuance. In the event of the liquidation of the Company, the holders of any preferred shares then outstanding would, if issued on such terms that they carry a preferential distribution entitlement on liquidation, be entitled to payment to them of the amount for which the preferred shares were subscribed and any unpaid dividends prior to any payment to the ordinary shareholders.

Share Repurchases

From time to time, the Company's Board of Directors have authorized share repurchase programs. The details of the March 2017 Repurchase Program, which has no time limit or expiration date is as follows:

	Number of Shares	Amount
Authorized repurchase amount		$ 1,000.0
Repurchases:		
Fiscal 2017	13,490,448	380.6
Fiscal 2018	3,610,968	55.2
Fiscal 2019	—	—
Fiscal 2020	—	—
Remaining amount available		$ 564.2

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 $0.4 million, $2.6 million and zero to acquire shares in connection with equity-based awards in fiscal 2020, 2019 and 2018, respectively.

18. Share Plans

Total share-based compensation cost was $25.3 million, $33.8 million and $34.6 million for fiscal 2020, 2019 and 2018, 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 zero, $1.2 million and zero in fiscal 2020, 2019 and 2018, respectively.

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 25, 2020, all equity awards held by the Company's employees were converted from equity awards issued by 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 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		
Expired/Forfeited	(820,988)	39.65		
Outstanding as of December 25, 2020	6,069,712	35.95	2.7	$ —
Vested and non-vested expected to vest as of December 25, 2020	5,660,657	36.11	6.3	$ —
Exercisable as of December 25, 2020	3,923,668	43.22	3.1	—

As of December 25, 2020, there was $8.3 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 1.8 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 and 2018, along with the weighted-average grant-date fair value, were as follows:

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

In fiscal 2019 and 2018, the total intrinsic value of options exercised was $0.3 million and $0.2 million, respectively, and the related tax benefit was $0.1 million for both periods, 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 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
Exercised	(647,167)	24.23
Expired/Forfeited	(281,182)	22.11
Non-vested as of December 25, 2020	490,671	20.96

The total vest date fair value of Mallinckrodt RSUs vested during fiscal 2020 was $15.7 million. As of December 25, 2020, there was $6.4 million of total unrecognized compensation cost related to non-vested RSUs granted, which is expected to be recognized over a weighted-average period of 1.9 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.

During December 2020, all outstanding PSUs were cancelled by the Human Resources and Compensation Committee of the Company's Board of Directors.

PSU activity was as follows [1]:

	Shares	Weighted-Average Grant-Date Fair Value
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
Forfeited	(1,195,505)	23.85
Non-vested as of December 25, 2020	—	—

(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
Expected stock price volatility	55.2 %	56.9 %
Peer group stock price volatility	41.3 %	39.1 %
Correlation of returns	47.8 %	2.1 %

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 IRC 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 25, 2020.

19. Guarantees

In disposing of assets or businesses, the Company has from time to time provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to 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 LSTC and other liabilities on the Company's consolidated balance sheets as of December 25, 2020 and December 27, 2019, respectively, was $15.4 million and $15.0 million, respectively, of which $12.7 million and $12.3 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 as of December 25, 2020 and December 27, 2019. As of December 25, 2020, 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 $19.0 million

and $18.9 million remained in restricted cash, included in other long-term assets on the consolidated balance sheets as of December 25, 2020 and December 27, 2019, respectively.

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

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 25, 2020, the Company had various other letters of credit, guarantees and surety bonds totaling $31.7 million and restricted cash of $37.4 million held in segregated accounts primarily to collateralize surety bonds for the Company's environmental liabilities.

20. Commitments and Contingencies

The Company has purchase obligations related to commitments to purchase certain goods and services. As of December 25, 2020, such obligations were as follows:

Fiscal 2021	$ 4.7
Fiscal 2022	2.1
Fiscal 2023	2.1
Fiscal 2024	2.1
Fiscal 2025	2.1

The Company is subject to various legal proceedings and claims, including government investigations, environmental matters, product liability matters, patent infringement claims, personal injury, employment disputes, contractual disputes and other commercial disputes, including those described below. Although it is not feasible to predict the outcome of these matters, the Company believes, unless otherwise 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.

On October 12, the Company announced that Mallinckrodt plc and certain of its subsidiaries voluntarily initiated the Chapter 11 Cases under the Bankruptcy Code in the Bankruptcy Court. As a result of initiating the Chapter 11 Cases, all litigation and proceedings against the Company have been automatically stayed, subject to certain limited exceptions. In addition, the Bankruptcy Court issued orders enjoining certain litigation against the Company and various individuals named in certain of the litigation described below that might otherwise be subject to such an exception. For further information about the Chapter 11 Cases, refer to Note 2.

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 March 10, 2021, the cases the Company is aware of include, but are not limited to, approximately 2,614 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 270 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers; approximately 124 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 March 10, 2021, 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 October 8, 2020, the State of Rhode Island filed a lawsuit against the Company's President and Chief Executive Officer ("CEO"), Mark C. Trudeau, asserting similar claims relating to the marketing and distribution of prescription opioid medications. Rhode Island has voluntarily agreed to a stay of the lawsuit against Mr. Trudeau.

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.

Other lawsuits remain pending in various state courts. In some jurisdictions, certain of the state lawsuits have been consolidated or coordinated for pre-trial proceedings before a single court within their respective state court systems.

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.

Opioid-Related Litigation Settlement. On February 25, 2020, the Company announced that it had reached an agreement in principle with a court-appointed plaintiffs' executive committee representing the interest of thousands of plaintiffs in the MDL and supported by a broad-based group of 48 state and U.S. Territory Attorneys General on the terms of a global settlement that would resolve all opioid-related claims against the Company and its subsidiaries (the "Opioid-Related Litigation Settlement"). The Opioid-Related Litigation Settlement contemplated the filing of voluntary petitions under Chapter 11 by 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"). Furthermore, under the terms of the Opioid-Related Litigation Settlement, subject to court approval and other conditions, it was contemplated that, the Company 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 would be 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 the Company’s ordinary shares that would represent approximately 19.99% of the Company's fully diluted outstanding shares, including after giving effect to the exercise of the warrants (the “Settlement Warrants”).

As a result of the Opioid-Related 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.

Amended Opioid-Related Litigation Settlement. In conjunction with the Company's Chapter 11 filing on October 12, 2020, the Company entered into a RSA which includes a proposed resolution of all opioid-related claims against the Company and its subsidiaries that supersedes the Opioid-Related Litigation Settlement, The RSA provides that, upon the Company’s emergence from the Chapter 11 process, subject to court approval and other conditions:

- Opioid claims would be channeled to one or more trusts, which would receive $1,600.0 million in structured payments consisting of (i) a $450.0 million payment upon the Company’s emergence from Chapter 11; (ii) a $200.0 million payment upon each of the first and second anniversaries of emergence; and (iii) a $150.0 million payment upon each of the third through seventh anniversaries of emergence with a one-year prepayment option at a discount for all but the first payment.
- Opioid claimants would also receive warrants for approximately 19.99% of the reorganized Company’s new outstanding shares, after giving effect to the exercise of the warrants, but subject to dilution from equity reserved under the management incentive plan, exercisable at any time on or prior to the seventh anniversary of the Company's emergence, at a strike price reflecting an aggregate equity value for the reorganized Debtors of $1,551.0 million (the "New Opioid Warrants").
- Upon commencing the Chapter 11 filing, the Company will comply with an agreed-upon operating injunction with respect to the operation of its opioid business.

As of December 25, 2020, the Company maintained an accrual for this contingency of $1,600.0 million and the New Opioid Warrants were ascribed no value. Refer to Note 21 for further information regarding the valuation of the New Opioid Warrants. For further information on the terms of this proposed resolution, refer to Note 2.

Other Opioid-Related Matters. 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 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. On December 15, 2020, the Company received a subpoena from the Western District of Virginia for documents related to services provided by an outside consulting firm. 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. The Company intends to vigorously defend itself in these matters. At this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with these investigations and/or lawsuits.

On April 21, 2020, New York Governor Andrew Cuomo announced that the New York State Department of Financial Services had filed a Statement of Charges against Mallinckrodt, including allegations that it misrepresented the safety and efficacy of its branded and unbranded opioid products and downplayed the risks of negative outcomes to patients, resulting in claims for payment of medically unnecessary opioid prescriptions to commercial insurance companies. The Statement of Charges claims that Mallinckrodt violated Section 403 of the New York Insurance Law, which prohibits fraudulent insurance acts and includes penalties of up to $5,000 plus the amount of the fraudulent claim for each violation. It further alleges that Mallinckrodt violated Section 408 of the Financial Services Law, which prohibits intentional fraud or intentional misrepresentation of a material fact with respect to a financial product or service and includes penalties of up to $5,000 per violation. The Department claims that each fraudulent prescription constitutes a separate violation of these laws. A hearing on the Statement of Charges was scheduled for January 25, 2021, but the Department of Financial Services agreed to a voluntary stay on October 15, 2020. 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.

On June 1, 2020, a putative class action lawsuit was filed against Mallinckrodt plc, Mallinckrodt Canada ULC, the Canadian Ministry of Health ("Province") and the College of Pharmacists of British Columbia ("College") in the Supreme Court of British Columbia, captioned Laura Shaver v. Mallinckrodt Canada ULC, et al., No. VLC-S-S-205793. The action purports to be brought on behalf of any persons (1) prescribed Methadose for opioid agonist treatment in British Columbia after March 1, 2014, (2) covered by Pharmacare Plan C within British Columbia who were prescribed Methadose for opioid agonist treatment after February 1, 2014, (3) who transitioned from compounded methadone to Methadose for opioid agonist treatment in British Columbia after March 1, 2014, or (4) covered by Pharmacare Plan C within British Columbia who were transitioned from compounded methadone to Methadose for opioid agonist treatment after February 1, 2014. The suit generally alleges that the Province’s decision to grant Methadose coverage under Pharmacare Plan C and remove compounded methadone from coverage under Pharmacare Plan C had adversely affected those being treated for opioid use disorder. The suit asserts that the Province, the College and the Mallinckrodt defendants failed to warn patients about, and made false representations concerning, the efficacy of Methadose and the risks of switching from compounded methadone to Methadose. The suit seeks general, special, aggravated, punitive and exemplary damages in an unspecified amount, costs and interest and injunctive relief against the Province, the College and the Mallinckrodt defendants. Pursuant to two orders granted by the Ontario Superior Court of Justice (Commercial List) on October 15, 2020, the Chapter 11 proceedings commenced by Mallinckrodt plc and Mallinckrodt Canada ULC pursuant to the U.S. Bankruptcy Code were recognized and given effect in Canada. Among other things, the Canadian Court has stayed all proceedings against the Mallinckrodt defendants, including the British Columbia class action proceedings. 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.

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. On September 14, 2020, a panel of the U.S. Court of Appeals for the Second Circuit reversed in part the lower court’s judgment, finding that the lower court should have dismissed the Company’s (and other parties’) challenges to the OSA for lack of subject matter jurisdiction. Together with the other plaintiffs, we filed a petition for rehearing en banc to challenge the panel's decision, which was denied on December 18, 2020. On February 12, 2021, the Second Circuit granted the parties' request to stay the mandate. The parties plan to file a petition for certiorari with the Supreme Court. 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.

Acthar Gel-Related Matters

SEC Subpoena. In August 2019, the Company received a subpoena from the SEC for documents related to the Company's disclosure of its dispute with the U.S. Department of Health and Human Services ("HHS") and CMS (together with HHS, the "Agency") concerning the base date average manufacturer price ("AMP") for Acthar Gel under the Medicaid Drug Rebate Program for Mallinckrodt's Acthar Gel, which is also the subject of litigation that the Company filed against the Agency (see *Medicaid Lawsuit* below). The Company is cooperating with the SEC's investigation, which is ongoing.

Medicaid Lawsuit. In May 2019, CMS issued a final decision directing the Company to revert to the original base date AMP used to calculate Medicaid drug rebates for Acthar Gel despite CMS having given the previous owner of the product, Questcor, written authorization in 2012 to reset the base date AMP. Upon receipt of CMS’s final decision, the Company filed suit in the D.C. District Court against the Agency under the Administrative Procedure Act seeking to have the decision declared unlawful and set aside. In March 2020, the Company received an adverse decision from the D.C. District Court. The Company immediately sought reconsideration by the D.C. District Court, which was denied. The Company then appealed the D.C. District Court’s decision to the D.C. Circuit. In June 2020, while its appeal remained pending, the Company was required to revert to the original base date AMP for Acthar in the government’s price reporting system.

As a result of this contingency, the Company incurred a retrospective one-time charge of $641.1 million (the "Acthar Gel Medicaid Retrospective Rebate"), of which $536.0 million and $105.1 million have been reflected as a component of net sales and operating expenses, respectively, in the consolidated statement of operations for fiscal 2020. The $105.1 million reflected as a component of operating expenses represents a pre-acquisition contingency related to the portion of the Acthar Gel Medicaid Retrospective Rebate that arose from sales of Acthar Gel prior to the Company’s acquisition of Questcor in August 2014. As of December 25, 2020, $638.9 million related to the Medicaid lawsuit was recorded within LSTC.

The D.C. Circuit heard argument on the merits of the Company's appeal in September 2020, prior to the Company's filing of the Chapter 11 Cases on October 12, 2020. At the joint request of the parties, the D.C. Circuit has agreed to hold the case in abeyance pending completion of the Proposed Acthar Gel-Related Settlement, which was conditioned upon the Company entering the Chapter 11 restructuring process. Pursuant to the Proposed Acthar Gel-Related Settlement, the Company has agreed to pay $260.0 million over seven years and to reset Acthar Gel’s Medicaid rebate calculation as of July 1, 2020, such that state Medicaid programs will receive 100% rebates on Acthar Gel Medicaid sales, based on current Acthar Gel pricing. Additionally, upon execution of the Proposed Acthar Gel-Related Settlement, the Company will dismiss its D.C. Circuit appeal. The Company expects that the Proposed Acthar Gel-Related Settlement will be completed over the next several months, subject to Bankruptcy Court approval.

Florida Civil Investigative Demand. In February 2019, the Company received a CID from the USAO 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 has cooperated 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 cooperated with the Committee's investigation. The Company's President and CEO Mark C. Trudeau accepted an invitation from the Committee to discuss the Company's pricing policies and modernization strategy for Acthar Gel at a hearing before the Committee, which took place on October 1, 2020.

Boston Civil Investigative Demand. In January 2019, the Company received a CID from the USAO for the District of Massachusetts for documents related to the Company's participation in the Medicaid Drug Rebate Program. The Company responded to the government's requests and cooperated with the investigation.

In March 2020, the U.S. District Court for the District of Massachusetts unsealed a *qui tam* complaint under the federal FCA ("Boston FCA") against the Company in which the DOJ and 32 states and territories have intervened alleging that the Company had failed to pay the correct amount of rebates for Acthar Gel. Other related legal proceedings involving the Company, including the litigation described as the *Medicaid Lawsuit*, are discussed above. The Company disagrees with the government's characterization of

the facts and applicable law. The Company moved to dismiss the DOJ's Complaint in Intervention in July 2020 and moved to dismiss the complaint of the intervening states in September 2020. As previously disclosed, in the event that the Company does not prevail in its Medicaid lawsuit the potential for damages in this matter could be up to approximately $1,280.0 million, after subtracting out potential restitution, related to the Acthar Gel Medicaid Retrospective Rebate. The Company has not recognized an accrual for this contingency in its financial results for fiscal 2020.

As discussed above, on October 12, 2020, the Company announced the Proposed Acthar Gel-Related Settlement to resolve various Acthar Gel-related matters, which includes this associated Boston FCA lawsuit. The court administratively closed the case on November 4, 2020, upon the parties' joint request for a stay of the litigation due to the Proposed Acthar Gel-Related Settlement and Chapter 11 Cases.

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 has responded to these requests and cooperated in the investigation.

Questcor EDPA Qui Tam Litigation. In September 2012, Questcor received a subpoena from the USAO for the EDPA for information relating to its promotional practices related to Acthar Gel. The investigation eventually expanded to include Questcor's provision of financial and other support to patients, including through charitable foundations and related matters. The Company cooperated with the investigation. In March 2019, the U.S. District Court for the EDPA unsealed two *qui tam* actions involving the allegations under investigation by the USAO for the EDPA. 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.

In June 2019, the DOJ filed its Complaint in Intervention in the litigation, alleging claims under the FCA 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. In January 2020, the court denied the Company's motion to dismiss the Complaint in Intervention.

As discussed above, on October 12, 2020, the Company announced the Proposed Acthar Gel-Related Settlement to resolve various Acthar Gel-related matters, which includes this *Questcor EDPA Qui Tam Litigation*. On October 15, 2020, the court agreed to stay the proceedings, at the request of the parties, as they work towards completion of the Proposed Acthar Gel-Related Settlement.

Other Related Matters

Generic Pricing Subpoena. In March 2018, the Company received a grand jury subpoena issued by the U.S. District Court for the EDPA 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.

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 U.S. (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 EDPA requested the production of documents related to an investigation of the U.S. promotion of Therakos® photopheresis ("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 EDPA sent Therakos a subsequent request for documents related to the investigation and has since made certain related requests. The Company responded to these requests.

Patent Litigation

Branded Products: The Company will continue to vigorously enforce its intellectual property rights relating to its Branded products to prevent the marketing of infringing generic or competing products prior to the expiration of patents covering those products, which, if unsuccessful, could adversely affect the Company's ability to successfully maximize the value of individual Branded products and have an adverse effect on its financial condition, results of operations and cash flows. In the case of litigation filed against potential generic or competing products to Company's Branded products, those litigation matters can either be settled or the litigation pursued through a trial and any potential appeals of the lower court decision.

Amitiza Patent Litigation: 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) initiated litigation against six parties that submitted ANDAs with Paragraph IV certifications seeking to launch a generic version of Company's Amitiza product. Each of those litigation matters were subsequently settled by entering into non-exclusive license agreements that granted the right to market a competing generic version of Amitiza in the U.S. on or after a specified entry date, or earlier under certain circumstances. One party (Par Pharmaceutical) entered into a settlement agreement that granted an entry date on or after January 1, 2021, or earlier under certain circumstances. Par has announced the launch of an authorized generic version of Company's Amitiza product. The other five parties (Dr. Reddy's Laboratories, Amneal Pharmaceuticals, Teva Pharmaceuticals, Sun Pharmaceutical and Zydus Pharmaceuticals) entered into settlement agreements that granted each party an entry date on or after January 1, 2023, or earlier under certain circumstances. The Company intends to vigorously enforce its intellectual property rights relating to Amitiza against any additional parties that may seek to market a generic version of Company's Amitiza product.

Ofirmev Patent Litigation: The Company initiated litigation against eleven parties that submitted ANDA or 505(b)(2) NDA applications with Paragraph IV certifications seeking to launch a generic or competing version of Company's Ofirmev product. One party (Exela) was prohibited from launching a generic of Ofirmev as the Company obtained a decision from the District Court that Exela infringed certain patents covering Ofirmev. That decision was affirmed on appeal to the Federal Circuit Court of Appeals ("Federal Circuit"). If Exela were to pursue their ANDA after expiration of the infringed patent expiring December 6, 2021 (including PED exclusivity) they would still be subject to potential litigation regarding the other Ofirmev patents listed in the Orange Book. Each of the other ten litigation matters were settled by entering into non-exclusive license agreements that granted each party the right to market a competing version of Ofirmev in the U.S. on or after December 6, 2020, or earlier under certain circumstances. The parties that entered settlement agreements are Paddock Laboratories (now Custopharm), Sandoz, Wockhardt, Fresenius Kabi, Mylan, InnoPharma/West-Ward Pharmaceuticals, Aurobindo, B. Braun Medical, Altan Pharma and Baxter Healthcare. Paddock, Sandoz, Fresenius Kabi, Mylan, Aurobindo and B. Braun Medical have obtained FDA approval and Custopharm, Sandoz, Fresenius Kabi, Mylan, Aurobindo and B. Braun Medical have publicly announced that they have launched (or have plans to launch) their competing products.

INOmax Patent Litigation: The Company initiated litigation against Praxair Distribution, Inc. and Praxair, Inc. (collectively "Praxair") following receipt of a notice from Praxair concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a nitric oxide drug product. Praxair also made a 510(k) regulatory submission for a nitric oxide delivery system. The District Court issued a decision ruling that five of the Company's patents were invalid and six were not infringed by Praxair. The Company appealed that decision to the Federal Circuit but the District Court decision was substantively affirmed with respect to invalidity and non-infringement. The Company's pursuit of en banc review at the Federal Circuit and review by the U.S. Supreme Court were unsuccessful. 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 adverse final outcome in the appeal of the Praxair litigation resulted in Praxair's 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. The Company continues to develop and pursue patent protection of next generation nitric oxide delivery systems and additional uses of nitric oxide. The Company further intends to vigorously enforce its intellectual property rights relating to its nitric oxide products against any additional parties that may seek to market a generic version of Company's INOmax product and/or next generation delivery systems.

Generic Products: The Company continues to pursue development of a portfolio of generic products, some of which require submission of a Paragraph IV certification against patents listed in the FDA Orange Book for the Branded product asserting that the Company's proposed generic product does not infringe and/or the Orange Book patent(s) are invalid and/or unenforceable. In the case of litigation filed against Company for such potential generic products, those litigation matters can either be settled or the litigation pursued through a trial and any potential appeals of the lower court decision in order to successfully launch those generic products in the future.

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") initiated litigation 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 litigation is currently stayed with respect to the Company as a result of the Company's Chapter 11 filing. If the stay is lifted, the Company intends to vigorously defend its position.

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") initiated litigation 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.

Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland v. Mallinckrodt PLC, Mallinckrodt Inc. and Mallinckrodt LLC. In January 2018, Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland (collectively, "Jazz") initiated litigation against the Company alleging that the Company infringed U.S. Patent Nos. 7,668,730, 7,765,106, 7,765,107, 7,895,059, 8,457,988, 8,589,182, 8,731,963, 8,772,306, 9,050,302, and 9,486,426 following receipt of a November 2017 notice from the Company concerning its submission of an ANDA, containing a Paragraph IV patent certification with the FDA for a competing version of Xyrem. On June 4, 2018, the parties entered into a settlement agreement under which Company was granted the non-exclusive right to market a competing sodium oxybate product in the U.S. under its ANDA on or after December 31, 2025, or earlier under certain circumstances.

Commercial and Securities Litigation

Shareholder Litigation (HealthCor). In October 2020, four purported shareholders of the Company's stock filed a complaint in the D.C. District Court against the Company, its CEO Mark C. Trudeau and its former Chief Financial Officer ("CFO") Matthew K. Harbaugh. The lawsuit, captioned *HealthCor Offshore Master Fund, L.P., et al. v. Mallinckrodt plc, et al.*, asserts claims for false and misleading statements in violation of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, common law fraud, and negligent misrepresentation arising from substantially similar allegations as those contained in the *Shenk* class action lawsuit. The complaint seeks damages in an unspecified amount. The defendants intend to vigorously defend themselves in this matter. As this stage, the Company is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit. As to the Company, this litigation is subject to the automatic stay under §362 of the Bankruptcy Code and the Company has requested an order from the Bankruptcy Court enjoining proceedings against the individual named defendants.

Health Care Service Corporation Litigation. In February 2020, Health Care Service Corp. ("HCSC") filed a non-class complaint against the Company in California state court alleging improper pricing, marketing and distribution of Acthar Gel, and challenging the acquisition of rights to Synacthen® Depot ("Synacthen") by the Company's predecessor-in-interest. The complaint included claims for violation of the New Jersey RICO statute and various states' antitrust laws. It also included claims for conspiracy to violate the New Jersey RICO statute, fraud, unlawful restraint of trade, unfair and deceptive trade practices, insurance fraud, tortious interference with contract and unjust enrichment. The case, which is proceeding as *Health Care Service Corp. v. Mallinckrodt ARD LLC, et al.*, alleges similar facts as those alleged in the *Humana* matter below. The Company intends to vigorously defend itself in this matter and the Company moved to dismiss the complaint in June 2020. In August 2020, the court dismissed the antitrust and tortious interference claims without prejudice, but held that HCSC could proceed to discovery on its remaining counts. The Company disagrees with the court's decision and contests liability. The Company was preparing to move to dismiss an amended complaint when the Company filed the Chapter 11 Cases. In January 2021, the Company removed this case to federal court and moved for transfer to the District of Delaware where the Company's Chapter 11 Cases are pending. HCSC has moved to remand the case back to state court. 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.

City of Marietta Litigation. In February 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 as well as people without insurance in the U.S. and its Territories who paid for Acthar Gel from four years prior to the filing of the Complaint until the date of trial. The case is proceeding as *City of Marietta v. Mallinckrodt ARD 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, and has moved to dismiss the complaint. The Company's motion to dismiss was pending when the Company filed the Chapter 11 Cases. On October 16, 2020, the court ordered the case administratively closed in light of the Chapter 11 Cases.

Local 322. In November 2019, the United Association of Plumbers & Pipefitters Local 322 of Southern New Jersey ("Local 322") filed a putative class action complaint against the Company and other defendants in New Jersey state court on behalf of New Jersey and third party payers for alleged deceptive marketing and anti-competitive conduct related to the sale and distribution of Acthar Gel. The complaint asserts claims under the New Jersey Consumer Fraud Act, the New Jersey Antitrust Act, the New Jersey RICO statute, negligent misrepresentation, conspiracy/aiding and abetting and unjust enrichment. The proposed class is defined as "All third-party payers and their beneficiaries (1) who are current citizens and residents of the State of New Jersey, and (2) who, for purposes other

than resale, purchased or paid for Acthar Gel from August 27, 2007 through the present." In January 2020, after removing the complaint to federal court in New Jersey, the Company moved to dismiss or stay the case. On August 18, 2020 the court dismissed all claims against the Company other than Local 322's antitrust claim relating to the Company's predecessor-in-interest's acquisition of Synacthen. The Company disagrees with the court's decision and contests liability. 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. In October 2020, the court ordered the case administratively closed in light of the Company's Chapter 11 Cases. In January 2021, the Company moved to transfer this case to the District of Delaware where the Company's Chapter 11 Cases are pending.

Shareholder Derivative Litigation (Brandhorst). In September 2019, a purported shareholder of the Company's stock filed a shareholder derivative complaint in the D.C. District Court against the Company, as nominal defendant, as well as its CEO, its former CFO, its Executive Vice President Hugh O'Neill, and the following members of the 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 "Brandhorst 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 Brandhorst Defendants caused the Company to make the allegedly false or misleading statements at issue in the *Shenk* class action 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 Brandhorst Defendants intend to vigorously defend themselves in this matter. As to the Company, this litigation is subject to the automatic stay under §362 of the Bankruptcy Code, and on December 4, 2020, the Bankruptcy Court also enjoined the proceedings against the Brandhorst Defendants.

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; 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 and marketing of Acthar Gel and the acquisition of Synacthen by the Company's predecessor-in-interest. 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 EDPA (see *Questcor EDPA Qui Tam Litigation* above). The case is proceeding as *Humana Inc. v. Mallinckrodt ARD LLC*. In March 2020, the court granted-in-part and denied-in-part the Company's motion to dismiss Humana's claims. The court dismissed Humana's antitrust and tortious interference claims with leave to amend. The court denied the Company's motion to dismiss Humana's RICO and other fraud-based claims. Humana filed an amended complaint in May 2020, which the Company moved to dismiss. In August 2020, the court granted-in-part and denied-in-part the Company's motion to dismiss the amended complaint. The court dismissed with prejudice Humana's claims under most state antitrust laws to the extent predicated on conduct before 2014 and Humana's tortious interference claims. The court ruled that Humana's federal antitrust, federal RICO, state insurance fraud and unjust enrichment claims may proceed. The Company disagrees with the court's decision and contest liability. 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. In September 2020, the Company answered the remaining allegations and claims of the operative complaint. In October 2020, the court entered an order acknowledging the automatic stay of this litigation pursuant to §362 of the Bankruptcy Code. In January 2021, the Company moved to transfer this case to the District of Delaware where the Company's Chapter 11 Cases are pending. Humana opposes transfer.

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 EDPA, 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 New Jersey, Illinois, Pennsylvania, Tennessee and Maryland (now dismissed; see *WCBE* below), and includes references to allegations at issue in a qui tam action that was filed against the Company in the U.S. District Court for the EDPA (see *Questcor EDPA Quit Tam Litigation* above). 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. In December 2019, the court denied the Company's motion to dismiss the complaint. The Company disagrees with the court's decision and contests liability. 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. In January 2021, the Company moved to transfer this case to the District of Delaware where the Company's Chapter 11 Cases are pending. Steamfitters Local Union No. 420 opposes transfer.

Putative Class Action Securities Litigation (Strougo). In July 2019, a putative class action lawsuit was filed against the Company, its CEO Mark C. 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. A lead plaintiff was designated by the court on June 25, 2020, and on July 30, 2020, the court approved the transfer of the case to the U.S. District Court for the District of New Jersey. On August 10, 2020, an amended complaint was filed by the lead plaintiff alleging an expended putative class period of May 3, 2016 through March 18, 2020 against the Company and Mark C. Trudeau, Bryan M. Reasons, George A. Kegler and Matthew K. Harbaugh, as well as newly named defendants Kathleen A. Schaefer, Angus C. Russell, Melvin D. Booth, JoAnn A. Reed, Paul R. Carter, and Mark J. Casey (collectively with Trudeau, Reasons, Kegler and Harbaugh, the "Strougo Defendants"). The amended complaint claims that the defendants made false and/or misleading statements and/or failed disclose that: (i) the CMS had informed the Company that it was using the wrong base date AMP for calculating the Medicaid rebate the Company owed CMS for Acthar Gel each quarter since 2014; (ii) the Company's reported net income was improperly inflated in violation of GAAP; (iii) the Company's contingent liabilities associated with the rebates owed to CMS for Acthar Gel were misrepresented; (iv) the Company's fiscal year 2019 guidance for Acthar Gel net sales was false; (v) the Company failed to disclose material information regarding the cases captioned Landolt v. Mallinckrodt ARD LLC, No. 1:18-cv-11931-PBS (D. Mass.) (Landolt) and U.S. ex rel. Strunck v. Mallinckrodt ARD LLC, No. 2:12-cv-0175-BMS (E.D. Pa.) (Strunck), or the related investigation by the DOJ and (vi) the Company failed to disclose that the clinical trials for Acthar Gel were purportedly initiated in order to make it appear that alternative revenue opportunities for Acthar Gel existed and thus offset the expected 10% decline in net sales as a result of the rebates the Company now had to pay. On October 1, 2020, the defendants filed a motion to dismiss the amended complaint. The defendants intend to vigorously defend themselves 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. As to the Company, this litigation is subject to the automatic stay under §362 of the Bankruptcy Code, and on December 4, 2020, the Bankruptcy Court also enjoined proceedings against the Strougo Defendants. The plaintiffs subsequently appealed the Bankruptcy Court action to the U.S. District Court in Delaware through a motion for leave to appeal. The Company filed its opposition to this motion on December 28, 2020.

Acument Global. In May 2019, Acument Global Technologies, Inc. ("Acument"), 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 discussed below, and is captioned *Acument Global Technologies, Inc., v. Mallinckrodt ARD Inc., et al.* In February 2020, the court granted-in-part and denied-in-part the Company's motion to dismiss. While the court dismissed Acument's fraud-based claims and its claim under the Tennessee Consumer Protection Act, the court ruled that the antitrust and unjust enrichment claims may proceed. The Company disagrees with the court's decision and contests liability. 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. In January 2021, the Company removed this case to federal court and moved for transfer to the District of Delaware where the Company's Chapter 11 Cases are pending. Acument has moved to remand the case back to state court.

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 in June 2019, alleges similar facts as those alleged in the *MSP* and *Rockford* matters discussed below, and was captioned *Washington County Board of Education v. Mallinckrodt ARD Inc., et al.* On January 4, 2020, the District Court of Maryland dismissed the complaint. Thereafter, the plaintiff filed a notice of voluntary dismissal in the District Court of Maryland, which the Company moved to strike. The District Court of Maryland granted the Company's motion to strike, and the plaintiff appealed that order to the U.S. Court of Appeals for the Fourth Circuit in June 2020. The Fourth Circuit dismissed plaintiff's appeal in September 2020.

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 discussed below, and is captioned *Int'l Union of Operating Engineers Local 542 v. Mallinckrodt ARD Inc., et al.* Plaintiff filed an amended complaint in August 2018, the Company's objections to which were denied by the court. The Company disagrees with the court's decision and contest liability. 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. In January 2021, the Company removed this case to federal court and moved for transfer to the District of Delaware where the Company's Chapter 11 Cases are pending. Local 542 has moved to remand the case back to the state court. On March 10, 2021, the federal court in Pennsylvania granted the Company's motion to transfer the case to the District of Delaware and denied without prejudice Local 542's motion to remand the case to state court.

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 in

February 2018, which was granted in January 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 alleged that the Company unlawfully maintained a monopoly in a purported ACTH product market by its predecessor in interest's acquisition of the U.S. rights to Synacthen and reaching anti-competitive agreements with the other defendants by selling Acthar Gel through an exclusive distribution network. The complaint purported 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. In March 2020, the court granted the Company's motion to dismiss the complaint with leave to amend. MSP filed an amended complaint on July 3, 2020. The Company intends to vigorously defend itself in this matter and moved to dismiss the second amended complaint in August 2020. 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. On October 13, 2020, the court entered an order acknowledging the automatic stay of this litigation as to the Company pursuant to §362 of the Bankruptcy Code. In January 2021, the Company moved for transfer to the District of Delaware where the Company's Chapter 11 Cases are pending. MSP opposes transfer.

Employee Stock Purchase Plan (ESPP) Securities Litigation. In July 2017, a purported purchaser of Mallinckrodt stock through Mallinckrodt's ESPPs filed a derivative and class action lawsuit in the Federal District Court in the Eastern District of Missouri, captioned *Solomon v. Mallinckrodt plc, et al.*, against the Company, its CEO, its former CFO, its Controller Kathleen A. Schaefer, and current and former directors of the Company (collectively, the "Solomon Defendants"). 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 D.C. District Court. 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 *Shenk* class action lawsuit. 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. The complaint seeks damages in an unspecified amount. On July 6, 2018, this matter was stayed by agreement of the parties pending resolution of the *Shenk* class action lawsuit. The defendants intends to vigorously defend themselves in this matter. On October 13, 2020, the trial court entered an order acknowledging the automatic stay of this litigation as to the Company pursuant to §362 of the Bankruptcy Code, and the Company has requested an order from the Bankruptcy Court enjoining proceedings against the individual named defendants.

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. In January 2018, the Company filed a motion to dismiss the Second Amended Complaint, which was granted in part in January 2019. The court dismissed 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 its predecessor-in-interest's acquisition of 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 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. On October 13, 2020, the court entered an order acknowledging the automatic stay of this litigation as to the Company pursuant to §362 of the Bankruptcy Code. In January 2021, the Company moved for transfer to the District of Delaware where the Company's Chapter 11 Cases are pending. Rockford opposes transfer.

Putative Class Action Securities Litigation (Shenk). In January 2017, a putative class action lawsuit was filed against the Company and its CEO in the D.C. District Court, 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 D.C. District Court. 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 D.C. District Court. 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 its former CFO in the D.C. District Court. 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. 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, against the Company, its CEO, its former CFO, and Executive Vice President, Hugh O'Neill, as defendants (collectively, the "Shenk Defendants"), and containing similar claims, but further alleging misstatements regarding payer reimbursement restrictions for Acthar Gel. The consolidated complaint seeks damages in an unspecified amount. 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. On September 1, 2020, the case deadlines were suspended to allow the parties to pursue mediation. On October 13, 2020, the trial court entered an order acknowledging the automatic stay of this litigation as to the Company pursuant to §362 of the Bankruptcy Code, and on December 4, 2020, the Bankruptcy Court also enjoined the proceedings against the individual named defendants. On December 4, 2020, the Bankruptcy Court granted the Company's motion pursuant to 11 U.S.C. §105 seeking to enjoin lawsuits or administrative proceedings brought by various parties, with an exception for the *Shenk* lawsuit solely to the extent necessary to allow the previously scheduled mediation to proceed to its conclusion and to potentially settle the *Shenk* lawsuit, subject to Bankruptcy Court approval. On December 7, 2020 and January 12, 2021, the parties participated in mediation sessions, which resulted in an agreement in principle to settle the *Shenk* lawsuit. The settlement will be funded solely from the proceeds of the remaining Shenk Defendant's applicable directors and officers liability insurance policies and is subject to approval of the D.C. District Court and the Bankruptcy Court, among other terms and conditions.

Generic Price Fixing Litigation

Generic Pharmaceutical Antitrust MDL. In August 2016, a multidistrict litigation was established in the EDPA 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 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.

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 EDPA, 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 May 2009 to the present. The lawsuit generally alleges that defendants conspired to allocate customers and fix prices for generic pharmaceutical drugs beginning in May 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. This lawsuit has been consolidated with the Generic Pricing MDL. An amended complaint was filed on January 7, 2021.

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 EDPA, 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. This lawsuit has been consolidated with the Generic Pricing MDL.

The Kroger Co. Litigation. In February 2020, a proposed amended complaint filed in the U.S. District Court for the EDPA 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. This lawsuit has been consolidated with the Generic Pricing MDL. A revised motion for leave to file a proposed amended complaint was filed in September 2020 and remains pending.

State Attorneys General Litigation. In June 2020, the Company, along with more than 20 other pharmaceutical manufacturers, was named as a defendant in a lawsuit brought by Attorneys General for 51 States, Territories, and the District of Columbia. The lawsuit, filed in the U.S. District Court for the District of Connecticut, alleges that manufacturers of generic drugs conspired to fix prices for certain generic drugs by communicating in advance of price increases and agreeing to certain market share allocations amongst competitors to thwart competition. The lawsuit alleges that prices for the generic drugs at issue were inflated as a result of the

alleged conspiracies, causing harm to the U.S. healthcare system. The complaint seeks monetary damages and injunctive relief for violations of Section 1 of the Sherman Antitrust Act and various state antitrust, consumer protection, and unjust enrichment claims. This lawsuit has been consolidated with the Generic Pricing MDL. The Company disagrees with the Attorneys Generals' characterization of the facts and applicable law.

Rite Aid Litigation. In July 2020, a direct action complaint filed in the U.S. District Court for the EDPA named the Company and several other pharmaceutical manufacturers as new defendants in an action captioned *Rite Aid Corp. et al. v. Actavis Holdco U.S., Inc. et al.* The lawsuit purports to be brought by entities that directly purchased generic drugs from defendants or a co-conspirator. The 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 *State Attorneys General Litigation*. This lawsuit has been consolidated with the Generic Pricing MDL.

Suffolk County, N.Y. Litigation. In August 2020, a direct action complaint filed in the U.S. District Court for the Eastern District of New York named the Company and several other pharmaceutical manufacturers as new defendants in an action captioned *County of Suffolk v. Actavis Holdco U.S., Inc. et al.* The lawsuit purports to be brought by Suffolk County, New York, which directly and indirectly purchased generic drugs from defendants or a co-conspirator. The complaint seeks monetary damages and injunctive relief for violations of Sections 1 and 3 of the Sherman Antitrust Act, the Donnelly Act, New York General Business Law § 340, and New York Social Services Law § 145-b, and is premised on facts similar to those alleged in the *State Attorneys General Litigation*. This lawsuit has been transferred to the U.S. District Court for the EDPA and consolidated with the Generic Pricing MDL.

J M Smith Litigation. In September 2020, a direct action complaint filed in the U.S. District Court for the EDPA named the Company and several other pharmaceutical manufacturers as new defendants in an action captioned *J M Smith Corporation v. Actavis Holdco U.S., Inc. et al.* The lawsuit purports to be brought by entities that directly purchased generic drugs from defendants or a co-conspirator. The 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 *State Attorneys General Litigation*. This lawsuit has been consolidated with the Generic Pricing MDL.

Walgreen Litigation. In December 2020, a direct action complaint filed in the U.S. District Court for the EDPA named the Company and other pharmaceutical manufacturers as defendants in an action captioned *Walgreen Company v. Actavis Holdco U.S., Inc., et al.* The plaintiff purports to have directly purchased generic drugs from defendants or a co-conspirator. The 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 *State Attorneys General Litigation*. This lawsuit has been consolidated with the Generic Pricing MDL.

Winn-Dixie Litigation. In December 2020, a direct action complaint filed in the U.S. District Court for the EDPA named the Company and other pharmaceutical manufacturers as defendants in an action captioned *Winn-Dixie Stores, Inc., et al v. Actavis Holdco US, Inc., et al.* The lawsuit purports to be brought by entities that directly purchased generic drugs from defendants or a co-conspirator. The 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 *State Attorneys General Litigation*. This lawsuit has been consolidated with the Generic Pricing MDL.

Canadian (Eaton) Litigation. In December 2020, the Company received a statement of claim filed in federal court in Toronto, Ontario, Canada, naming the Company, Mallinckrodt ULC, and certain other of the Company's subsidiaries, as well as other pharmaceutical manufacturers, as defendants in an action captioned *Kathryn Eaton v Teva Canada Limited et al*. The claim purports to be brought on behalf of all persons or entities in Canada who, from January 1, 2012 to the present, purchased generic drugs in the private sector. The allegations and requests for relief in the statement of claim, in substance, are similar to those in the *1199SEIU National Benefit Fund* litigation, and include the claim that the Company breached the Competition Act in Canada.

Xyrem Litigation

Self-Insured Schools Litigation. In August 2020, a complaint filed in the U.S. District Court for the Southern District of New York named the Company and several other pharmaceutical manufacturers as new defendants in an action captioned *Self-Insured Schools of California v. Jazz Pharmaceuticals Plc et al.* The lawsuit is brought on behalf of a purported class of individuals and entities that indirectly purchased Xyrem (sodium oxybate). The complaint alleges that Jazz Pharmaceuticals delayed generic competition by the Company and others by providing substantial consideration to the Company and others to delay market entry for sodium oxybate, causing consumers to pay supracompetitive prices for Xyrem and its generic bioequivalent products. The complaint seeks monetary damages and declaratory and injunctive relief for violations of Sections 1 and 3 of the Sherman Antitrust Act, Section 16 of the Clayton Antitrust Act, and various state antitrust laws and, state consumer protection statutes, and state laws prohibiting unfair and deceptive practices. 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.

Hollman Litigation. In September 2020, a complaint filed in the U.S. District Court for the Northern District of California named the Company and several other pharmaceutical manufacturers as new defendants in an action captioned *Ruth Hollman v. Jazz Pharmaceuticals Plc et al.* The lawsuit is brought on behalf of a purported class of individuals and entities that indirectly purchased

Xyrem (sodium oxybate). The complaint alleges that Jazz Pharmaceuticals delayed generic competition by the Company and others by providing substantial consideration to the Company and others to delay market entry for sodium oxybate, causing consumers to pay supracompetitive prices for Xyrem and its generic bioequivalent products. The complaint seeks monetary damages and declaratory and injunctive relief for violations of Sections 1 and 3 of the Sherman Antitrust Act, Section 16 of the Clayton Antitrust Act, and various state antitrust laws, state consumer protection statutes, and state laws prohibiting unfair and deceptive practices. On November 3, 2020, the plaintiff dismissed the case against the Company and certain other defendants without prejudice. The lawsuit remains pending against several other defendants.

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 25, 2020, it was probable that it would incur remediation costs in the range of $37.3 million to $85.8 million. The Company also concluded that, as of December 25, 2020, the best estimate within this range was $60.8 million, of which $1.0 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 25, 2020. 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.

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 DOJ, 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 25, 2020, 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.

Internal Revenue Code Section 453A Interest

As a result of historical internal installment sales, the Company has reported IRC §453A interest on its tax returns on the basis of its interpretation of the IRC. Alternative interpretations of these provisions could result in additional interest payable. 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 $28.2 million and $47.4 million as of December 25, 2020 and December 27, 2019, respectively. The decrease of $19.2 million was recognized as a benefit to interest expense during fiscal 2020 due to lapses 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

In August 2020, a settlement was reached with the IRS related to the audit of MHP. Refer to Note 9 for further information.

Other Matters

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

21. Financial Instruments and Fair Value Measurements

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

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

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

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

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

	December 25, 2020	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	$ 33.0	$ 23.5	$ 9.5	$ —
Equity securities	31.1	31.1	—	—
	$ 64.1	$ 54.6	$ 9.5	$ —
Liabilities:				
Deferred compensation liabilities [1]	$ 38.0	$ —	$ 38.0	$ —
Contingent consideration and acquired contingent liabilities [2]	34.7	—	—	34.7
Settlement Warrants [2]	—	—	—	—
	$ 72.7	$ —	$ 38.0	$ 34.7

(1) On November 16, 2020, the Debtors received approval from the Bankruptcy Court to maintain existing postretirement benefit plans during the pendency of the Chapter 11 Cases. For further information refer to Note 2.

(2) These liabilities are governed by executory contracts and recorded at their estimated allowed claim amount within liabilities subject to compromise on the consolidated balance sheet as of December 25, 2020. For further information on executory contracts and LSTC refer to Note 2.

	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
Settlement Warrants	43.4	$ —	$ —	43.4
	$ 151.9	$ —	$ 39.2	$ 112.7

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 2020 and 2019, the Company recognized an unrealized gain of

$3.8 million and $20.2 million, respectively, related to this investment within other income, 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 25, 2020, the Company maintains various contingent consideration liabilities associated with the acquisitions of Stratatech Corporation ("Stratatech") and Ocera Therapeutics, Inc. ("Ocera"). Additionally, the Company historically maintained acquired contingent liabilities associated with the acquisition of Questcor.

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 2020 and suspended its rights and obligations to Novartis under such agreement. As of December 25, 2020, there are no further contingent liabilities associated with Synacthen. 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 25, 2020 and December 27, 2019 was zero and $24.5 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®. For each indication, the Company is responsible for a payment upon acceptance of the Company's submission and another upon approval by the FDA. Accordingly, upon acceptance by the FDA of the Company's deep partial-thickness submission during fiscal 2020, the Company made a $20.0 million payment to the prior shareholders of Stratatech. 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 $19.1 million and $29.0 million at December 25, 2020 and December 27, 2019, respectively. As a result of the Chapter 11 Cases filed on October 12, 2020, this liability was reclassified to LSTC on the consolidated balance sheet as of December 25, 2020.

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 $15.6 million and $15.8 million as of December 25, 2020 and December 27, 2019, respectively. As a result of the Chapter 11 Cases filed on October 12, 2020, this liability was reclassified to LSTC on the consolidated balance sheet as of December 25, 2020.

All contingent consideration liabilities were classified as LSTC in the consolidated balance sheet as of December 25, 2020. The following table summarizes the fiscal 2020 activity for contingent consideration:

Balance as of December 27, 2019	$ 69.3
Payments	(45.0)
Accretion expense	0.5
Fair value adjustments	9.9
Less: Liabilities subject to compromise	(34.7)
Balance as of December 25, 2020	$ —

New Opioid Warrants. In conjunction with the Company’s Chapter 11 filing on October 12, 2020, the Company entered into a RSA which includes a proposed resolution of all opioid-related claims against the Company and its subsidiaries that supersedes the Opioid-Related Litigation Settlement, as described further below in relation to the corresponding estimate of fair value as of December 27, 2019. The proposed resolution contemplates that, upon the Company's emergence from the Chapter 11 process, opioid claimants would receive warrants for approximately 19.99% of the reorganized Company's new outstanding shares (giving effect to the exercise of the warrants, but subject to dilution from equity reserved under the management incentive plan), exercisable at a strike price reflecting an aggregate equity value of $1,551.0 million. For further information on the terms of this amended proposed settlement, refer to Note 20.

The equity value for the reorganized Company upon the emergence from bankruptcy, for which the New Opioid Warrants value is based, cannot be determined. This projected equity value upon emergence is determined by the Company and its investment bankers in consultation with parties-in-interest in the bankruptcy, and will be included in the disclosure statement which will be used for

solicitation of votes on the Company's Plan after the disclosure statement is approved by the Bankruptcy Court. Critical inputs to the valuation are currently being analyzed by the Company and its advisors including but not limited to the impact to the Company's business from the Chapter 11 process, the projected post-emergence cash flows of the reorganized Company, proofs of claim filed by creditors, the assumption/rejection of executory contracts, litigation claims and contingencies, claims to be reinstated upon emergence, and the completion of negotiations with creditor constituencies. Furthermore, the final terms of any resolution of opioid-related claims against the Company, including the terms upon which any New Opioid Warrants would be issued, are subject to Bankruptcy Court approval and other certain other conditions, which are outside of management control. Since these critical inputs to the valuation are unable to be assessed at the initial stages of bankruptcy, the Company cannot reasonably estimate the equity value upon emergence. As such, no value has been ascribed to the warrants as of December 25, 2020.

The estimated fair value for the New Opioid 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 New Opioid 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 fair value of the Settlement Warrants as of December 27, 2019 was estimated using the Black-Scholes pricing model and related terms as set forth in the now superseded Opioid-Related Litigation Settlement, which contemplated that the Company would issue to the Opioid Claimant Trust warrants, upon emergence from the Chapter 11 process contemplated by the Opioid-Related Litigation Settlement, 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. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. The expected volatility assumption was based on the historical and implied volatility of the Company's peer group with similar business models. The expected term assumption was based on the contractual term of the Settlement Warrants. The expected annual dividend per share was based on the Company's current intentions regarding payment of cash dividends. The risk-free interest rate was based on U.S. Treasury zero-coupon issues with a remaining term equal to the expected term assumed.

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

	December 27, 2019
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

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 25, 2020 and December 27, 2019:

- 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 $56.4 million and $31.7 million as of December 25, 2020 and December 27, 2019, (level 1), respectively. As of December 25, 2020, $20.2 million and $36.2 million of the restricted cash balance was included in prepaid and other current assets and other assets, respectively, on the consolidated balance sheet. As of December 27, 2019, substantially all of the restricted cash was included in other assets on the consolidated balance sheet.
- 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 2020, 2019 and 2018. On December 4, 2020, the Company received a $32.5 million cash payment from the issuer of these securities, which included $29.8 million for the redemption 100% of the outstanding preferred equity certificates and $2.7 million in accrued interest receivable. These securities were classified as held-to-maturity and carried at amortized cost, which approximated fair value (level 3), of zero and $18.9 million as of December 25, 2020 and December 27, 2019, respectively. These securities were 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 $52.3 million and $51.1 million at December 25, 2020 and December 27, 2019, 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% first and second lien senior 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 25, 2020		December 27, 2019	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Level 1:				
4.875% senior notes due April 2020	$ —	$ —	$ 614.8	$ 480.0
5.75% senior notes due August 2022	610.3	191.2	610.3	251.0
4.75% senior notes due April 2023	133.7	11.1	133.7	53.7
5.625% senior notes due October 2023	514.7	158.9	514.7	193.2
5.50% senior notes due April 2025	387.2	115.4	387.2	135.5
10.00% first lien senior notes due April 2025	495.0	528.4	—	—
10.00% second lien senior notes due April 2025	322.9	279.0	322.9	253.8
Revolving credit facility	900.0	900.0	900.0	900.0
Level 2:				
9.50% debentures due May 2022	10.4	4.2	10.4	5.4
8.00% debentures due March 2023	4.4	1.3	4.4	2.0
Term loan due September 2024	1,505.2	1,386.9	1,520.8	1,240.0
Term loan due February 2025	399.5	367.9	403.6	326.2
Total Debt	$ 5,283.3	$ 3,944.3	$ 5,422.8	$ 3,840.8

Concentration of Credit and Other Risks

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

The following table shows net sales attributable to distributors that accounted for 10.0% or more of the Company's total segment net sales, which excludes the one-time charge related to the Medicaid lawsuit:

	Fiscal Year		
	2020	2019	2018
CuraScript, Inc.	27.4 %	29.7 %	35.2 %
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 25, 2020	December 27, 2019
AmerisourceBergen Corporation	33.6%	31.3%
McKesson Corporation	18.2	15.3
CuraScript, Inc.	*	12.1

* Accounts receivable attributable to this distributor was less than 10.0% of total gross accounts receivable at the end of the respective period presented above.

The following table shows net sales attributable to products that accounted for 10.0% or more of the Company's total segment net sales, which excludes the one-time charge related to the Medicaid lawsuit:

	Fiscal Year		
	2020	2019	2018
Acthar Gel	27.9 %	30.1 %	34.5 %
INOmax	20.9	18.1	16.9
Ofirmev	10.1	12.1	10.6

22. 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).

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 net sales and operating income because management and the chief operating decision maker evaluate the operating results of the segments excluding such items. These items may include, but are not limited to, depreciation and amortization, share-based compensation, net restructuring, non-restructuring impairment charges, separation costs, R&D upfront payments, changes related to the Opioid-Related Litigation Settlement and the Acthar Gel Medicaid Retrospective Rebate incurred as a result of the Medicaid lawsuit. During the three months ended September 25, 2020, the Company began excluding depreciation and share-based compensation from its evaluation of the operating results of its segments. As a result, prior period segment operating income has been recast to reflect this change on a comparable basis. Although these amounts are excluded from segment net sales and operating income, as applicable, they are included in reported consolidated net sales and operating loss and are reflected in the 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 $9,715.4 million and $10,338.9 million as of December 25, 2020 and December 27, 2019, respectively.

Selected information by reportable segment was as follows:

	Fiscal Year		
	2020	2019	2018
Net sales:			
Specialty Brands [1]	$ 2,059.6	$ 2,423.8	$ 2,496.7
Specialty Generics	689.8	738.7	718.9
Segment net sales	2,749.4	3,162.5	3,215.6
Medicaid lawsuit (Note 20) [1]	(536.0)	—	—
Net sales	2,213.4	3,162.5	3,215.6
Operating (loss) income:			
Specialty Brands	$ 1,015.7	$ 1,210.1	$ 1,136.1
Specialty Generics	206.4	168.5	153.5
Segment operating income	1,222.1	1,378.6	1,289.6
Unallocated amounts:			
Corporate and unallocated expenses [2]	(166.1)	(102.3)	(121.7)
Depreciation and amortization	(885.2)	(951.1)	(852.1)
Share-based compensation	(25.3)	(33.8)	(34.6)
Restructuring charges, net	(37.5)	1.7	(103.0)
Non-restructuring impairment charges	(63.5)	(388.0)	(3,893.1)
Separation costs [3]	(93.4)	(63.9)	(6.0)
R&D upfront payment [4]	(5.0)	(20.0)	—
Opioid-related litigation settlement gain (loss) (Note 20)	43.4	(1,643.4)	—
Medicaid lawsuit (Note 20) [1]	(641.1)	—	—
Operating loss	$ (651.6)	$ (1,822.2)	$ (3,720.9)
Depreciation and amortization:			
Specialty Brands	$ 799.3	$ 862.4	$ 762.5
Specialty Generics	85.9	88.7	89.6
	$ 885.2	$ 951.1	$ 852.1

(1) Specialty Brands net sales for fiscal 2020 includes the prospective change to the Medicaid rebate calculation, which served to reduce Acthar Gel net sales by $40.4 million for the period from June 15, 2020 through December 25, 2020. See Note 20 for further detail on the status of the Medicaid lawsuit.

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

(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 acquire product rights in Japan for terlipressin during fiscal 2020 and an upfront payment made to Silence in connection with the license and collaboration agreement entered into in fiscal 2019. See Note 7 for further information.

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

	Fiscal Year		
	2020	2019	2018
Acthar Gel [1]	$ 767.9	$ 952.7	$ 1,110.1
INOmax	574.1	571.4	542.7
Ofirmev	276.5	384.0	341.9
Therakos	238.6	246.9	231.2
Amitiza [2]	188.8	208.5	183.8
Other [3]	13.7	60.3	87.0
Specialty Brands	2,059.6	2,423.8	2,496.7
Hydrocodone (API) and hydrocodone-containing tablets	98.0	76.3	65.9
Oxycodone (API) and oxycodone-containing tablets	68.4	74.9	66.1
Acetaminophen (API)	213.0	189.9	192.7
Other controlled substances	289.9	352.5	343.8
Other	20.5	45.1	50.4
Specialty Generics	689.8	738.7	718.9
Segment net sales	2,749.4	3,162.5	3,215.6
Medicaid lawsuit (Note 20)	536.0	—	—
Net Sales	$ 2,213.4	$ 3,162.5	$ 3,215.6

(1) Fiscal 2020 includes the prospective change to the Medicaid rebate calculation of $40.4 million for the period from June 15, 2020 through December 25, 2020. See Note 20 for further detail on the status of the Medicaid lawsuit.

(2) Amitiza net sales consist of both product and royalty net sales. Refer to Note 5 for further details on Amitiza's revenues.

(3) Fiscal 2019 and fiscal 2018 includes $40.1 million and $53.1 million of net sales, respectively, related to BioVectra prior to the completion of the sale of this business in November 2019. Refer to Note 6 for further details.

Selected information by geographic area was as follows:

	Fiscal Year		
	2020	2019	2018
Net sales [1]:			
U.S.	$ 2,465.5	$ 2,765.6	$ 2,834.5
Europe, Middle East and Africa	227.5	281.8	256.8
Other	56.4	115.1	124.3
Geographic area net sales	2,749.4	3,162.5	3,215.6
Medicaid lawsuit (Note 20)	(536.0)	—	—
Net Sales	$ 2,213.4	$ 3,162.5	$ 3,215.6

	December 25, 2020	December 27, 2019
Long-lived assets [2]:		
U.S.	$ 676.3	$ 734.3
Europe, Middle East and Africa [3]	165.5	169.9
Other	4.6	4.8
	$ 846.4	$ 909.0

(1) Net sales are attributed to regions based on the location of the entity that records the transaction, none of which relate to the country of Ireland.

(2) Long-lived assets are primarily composed of property, plant and equipment, net.

(3) Includes long-lived assets located in Ireland of $164.0 million and $168.4 million as of December 25, 2020 and December 27, 2019, respectively.

23. Selected Quarterly Financial Data (Unaudited)

A summary of quarterly financial information for fiscal 2020 and 2019 is as follows:

	For the Quarter Ended			
	March 27, 2020	June 26, 2020	September 25, 2020	December 25, 2020
Net sales [1]	$ 665.8	$ 166.5	$ 698.3	$ 682.8
Gross profit	283.8	(220.2)	295.3	310.5
(Loss) income from continuing operations [1]	(56.7)	(950.6)	191.8	(154.2)
Income (loss) from discontinued operations	6.5	17.5	(0.2)	1.3
Net (loss) income	(50.2)	(933.1)	191.6	(152.9)
Basic (loss) earnings per share from continuing operations [2]	$ (0.67)	$ (11.25)	$ 2.27	$ (1.82)
Diluted (loss) earnings per share from continuing operations [2]	(0.67)	(11.25)	2.27	(1.82)

	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) income from continuing operations [3]	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)

(1) For the quarter ended June 26, 2020, net sales includes retrospective one-time charge of $534.4 million and loss from continuing operations included an additional charge of $105.3 million related to the Medicaid lawsuit. See Note 20 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) 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 20 for further information.

24. Subsequent Events

Joinder and Amendment to the RSA

On March 10, 2021, the Company announced that the Debtors have agreed to a joinder and amendment to the RSA (the "Joinder and Amendment") whereby an ad hoc group of lenders holding approximately $1,300.0 million, by aggregate principal amount, of the Company's outstanding 2017 Term Loan and the Company's outstanding 2018 Term Loan (the "Supporting Term Lenders") have agreed to join the RSA as supporting parties and certain of the existing supporting parties have agreed to certain amendments thereto. Pursuant to the terms of the Joinder and Amendment, the RSA, as set forth in Note 2, will be amended as follows:

- The supporting parties under the RSA, including the Supporting Term Lenders, will support a plan of reorganization providing for distributions to lenders holding allowed claims in respect of the Company's senior secured term loans a mandatory prepayment in an amount equal to approximately $114.0 million arising from excess cash flow with respect to fiscal 2020 (if not previously paid following Bankruptcy Court approval thereof) (the "ECF Payment") and either (1) new senior secured term loans in an amount equal to the remaining principal amount of claims (as reduced by, inter alia, the ECF Payment) bearing interest at a rate per annum equal to LIBOR plus 5.25% (with respect to the 2017 Term Loan) or LIBOR plus 5.50% (with respect to the 2018 Term Loan) (the "Adjusted Interest Rate"), maturing on the earlier of September 30, 2027 and 5.75 years after emergence and without any financial maintenance covenant or (2) payment in full in cash.
- The Debtors will seek Bankruptcy Court approval to make ongoing adequate protection interest payments in respect of the senior secured term loans at the Adjusted Interest Rate.
- The Debtors will seek Bankruptcy Court approval to pay an exit fee equal to 0.5% of the principal amount of the senior secured term loans (after giving effect to the ECF Payment), which fee will increase to 1.0% of such principal amount if the senior secured term loans are not paid in full in cash through the plan.
- Certain milestones were adjusted with the consent of the supporting parties.

The Joinder and Amendment is not yet effective and shall become effective upon receipt of signatures thereto from (i) lenders holding 66.7% of each of the Company's outstanding 2017 Term Loan and the 2018 Term Loan, (ii) the required supporting unsecured noteholders, (iii) the governmental plaintiff ad hoc committee and (iv) the multi-state governmental entities group.

Commitments and Contingencies

Certain litigation matters occurred in fiscal 2020 or prior but had subsequent updates through the date of this report. See further discussion in Note 20.

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 25, 2020. 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 25, 2020. 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 25, 2020 has been audited by Deloitte & Touche LLP, the independent registered public accounting firm that audited and reported on the consolidated financial statements included in this Annual Report on Form 10-K. This report is included below.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended December 25, 2020 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 ("Debtor-in-Possession") (the "Company") as of December 25, 2020, 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 25, 2020, 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 25, 2020 and December 27, 2019, the related consolidated statements of operations, comprehensive operations, changes in shareholders' equity, and cash flows, for the fiscal years ended December 25, 2020, December 27, 2019 and December 28, 2018, 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 March 10, 2021, expressed an unqualified opinion on those financial statements and included an explanatory paragraph regarding certain conditions that give rise to substantial doubt about the Company’s ability to continue as a going concern and an emphasis of a matter paragraph concerning the bankruptcy proceedings.

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
March 10, 2021

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 filed with the SEC within 120 days after December 25, 2020 pursuant to General Instruction G(3) to Form 10-K.

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 CEO, CFO 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 filed with the SEC within 120 days after December 25, 2020 pursuant to General Instruction G(3) to Form 10-K.

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 filed with the SEC within 120 days after December 25, 2020 pursuant to General Instruction G(3) to Form 10-K.

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 filed with the SEC within 120 days after December 25, 2020 pursuant to General Instruction G(3) to Form 10-K.

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 filed with the SEC within 120 days after December 25, 2020 pursuant to General Instruction G(3) to Form 10-K.

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 25, 2020, December 27, 2019 and December 28, 2018
- Consolidated Statements of Comprehensive Operations for the fiscal year ended December 25, 2020, December 27, 2019 and December 28, 2018
- Consolidated Balance Sheets as of December 25, 2020 and December 27, 2019
- Consolidated Statements of Cash Flows for the fiscal year ended December 25, 2020, December 27, 2019 and December 28, 2018
- Consolidated Statements of Changes in Shareholders' Equity for the period from December 29, 2017 to December 25, 2020
- 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 25, 2020	$ 4.0	$ 1.2	$ —	$ (0.7)	$ 4.5
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
Sales reserve accounts:					
Fiscal year ended December 25, 2020 [(1)]	$ 337.4	$ 2,154.3	$ 536.0	$ (2,792.3)	$ 235.4
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
Tax valuation allowance:					
Fiscal year ended December 25, 2020	$ 3,131.5	$ 2,979.3	$ —	$ —	$ 6,110.8
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

(1) The $536.0 million charge to the sales reserve accounts during fiscal 2020 relates to the Medicaid lawsuit, which is further described within Note 20 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

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

March 10, 2021

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)*	March 10, 2021
/s/ Bryan M. Reasons Bryan M. Reasons	Executive Vice President and Chief Financial Officer *(principal financial officer)*	March 10, 2021
/s/ Kathleen A. Schaefer Kathleen A. Schaefer	Senior Vice President, Finance and Corporate Controller *(principal accounting officer)*	March 10, 2021
* Angus C. Russell	Chairman of the Board of Directors	March 10, 2021
* David R. Carlucci	Director	March 10, 2021
* J. Martin Carroll	Director	March 10, 2021
* Paul R. Carter	Director	March 10, 2021
* David Y. Norton	Director	March 10, 2021
* Carlos V. Paya	Director	March 10, 2021
* JoAnn A. Reed	Director	March 10, 2021
* Anne C. Whitaker	Director	March 10, 2021
* Kneeland C. Youngblood, M.D.	Director	March 10, 2021

*By: /s/ Bryan M. Reasons
Bryan M. Reasons
Attorney-In-Fact
March 10, 2021

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	Indenture, dated as of April 7, 2020, among the Issuers and the Note Guarantors party thereto from time to time and Wilmington Savings Fund Society, FSB, as first lien trustee and Deutsche Bank AG New York Branch, as first lien collateral agent (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed April 7, 2020).**
4.8	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*	Form of Employment Agreement by and between ST Shared Services LLC and Executive Officers (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 24, 2020).
10.14*	Mallinckrodt Pharmaceuticals Severance Plan for U.S. Officers and Executives (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 24, 2020).
10.15*	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).
10.16*	Mallinckrodt Pharmaceuticals Stock and Incentive Plan (incorporated by reference to Appendix A to the Company's Proxy Statement filed April 4, 2018.)
10.17*	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).
10.18*	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).
10.19*	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).
10.20*	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).
10.21*	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).
10.22*	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).
10.23*	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	Form of 2020/2021 ERBP Award Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 8, 2020).
10.25	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).
10.26	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).
10.27	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).

10.28	Restructuring Support Agreement, dated October 11, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 13, 2020).
10.29	Joinder Agreement and Amendment to Restructuring Support Agreement, dated March 10, 2021 (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed March 10, 2021.
10.30	Joinder Agreement to the Restructuring Support Agreement for the Multi-State Governmental Entities Group, dated November 13, 2020.
21.1	Subsidiaries of Mallinckrodt plc.
23.1	Consent of Deloitte & Touche LLP.
24.1	Powers of Attorney.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certifications of the Chief Executive Officer and 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 25, 2020 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.
**Portions of this exhibit have been omitted in accordance with Item 601(b)(10) of Regulations S-K.

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.

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of the share capital of Mallinckrodt plc ("Mallinckrodt") is a summary. This summary does not purport to be complete and is qualified in its entirety by reference to the Irish Companies Act 2014 (the "Companies Act") and the complete text of Mallinckrodt's memorandum and articles of association, each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this exhibit is a part. You should read those laws and documents carefully. As used in this exhibit, "we," and "our" refer to Mallinckrodt.

Description of Ordinary Shares

Legal Name; Formation; Fiscal Year; Registered Office

The legal name of the company is Mallinckrodt public limited company. Mallinckrodt was incorporated in Ireland as a public limited company on January 9, 2013 with company registration number 522227. Mallinckrodt's fiscal year ends on the last Friday in December and Mallinckrodt's registered address is College Business & Technology Park, Cruiserath, Blanchardstown, Dublin 15, Ireland.

Share Capital

The authorized share capital of Mallinckrodt is €40,000 and $200,000,000, divided into 40,000 ordinary A shares with a par value of €1.00 per share, 500,000,000 ordinary shares with a par value of $0.20 per share and 500,000,000 preferred shares with a par value of $0.20 per share.

Mallinckrodt may issue shares subject to the maximum prescribed by its authorized share capital contained in its memorandum of association.

As a matter of Irish company law, the directors of a company may cause the company to issue new ordinary or preferred shares without shareholder approval once authorized to do so by the articles of association of the company or by an ordinary resolution adopted by the shareholders at a general meeting. An ordinary resolution requires over 50% of the votes of a company's shareholders cast at a general meeting (in person or by proxy). The authority conferred can be granted for a maximum period of five years, at which point it must be renewed by the shareholders of the company by an ordinary resolution. The board of directors of Mallinckrodt was granted authority to issue up to approximately 33% of its issued ordinary share capital (excluding shares held in treasury) pursuant to a resolution of shareholders at its last annual general meeting, such authority to expire no later than 15 months from the date on which it was granted unless renewed at the next annual general meeting. While the proposals for the next annual general meeting remain subject to review, it is expected that Mallinckrodt will seek such renewed authority at subsequent annual general meetings but it is not guaranteed that such renewal will always be sought or approved.

The authorized share capital may be increased or reduced (but not below the number of issued ordinary shares, preferred shares or ordinary A shares, as applicable) by way of an ordinary resolution of Mallinckrodt's shareholders, but not below the number of shares then outstanding. The shares comprising the authorized share capital of Mallinckrodt may be divided into shares of such par value as the resolution prescribes.

The rights and restrictions to which the ordinary shares are subject are prescribed in Mallinckrodt's articles of association. Mallinckrodt's articles of association entitle the board of directors, without shareholder approval, to determine the terms of the preferred shares issued by Mallinckrodt. Preferred shares may be preferred as to dividends, rights on a winding up, voting or in such manner as the directors of Mallinckrodt may resolve. The preferred shares may also be redeemable at the option of the holder of the preferred shares or at the option of Mallinckrodt, and may be convertible into or exchangeable for shares of any other class or classes of Mallinckrodt, depending on the terms of such preferred shares. The issuance of preferred shares is subject to applicable law, including the Irish Takeover Rules.

Irish law does not recognize fractional shares held of record; accordingly, Mallinckrodt's articles of association do not provide for the issuance of fractional ordinary shares of Mallinckrodt, and the official Irish register of Mallinckrodt will not reflect any fractional ordinary shares.

Whenever an alteration or reorganization of the share capital of Mallinckrodt would result in any Mallinckrodt shareholder becoming entitled to fractions of a share, the Mallinckrodt board of directors may, on behalf of those shareholders that would become entitled to fractions of a share, arrange for the

sale of the shares representing fractions and the distribution of the net proceeds of sale in due proportion among the shareholders who would have been entitled to the fractions. For the purpose of any such sale the board may authorize some person to transfer the shares representing fractions to the purchaser, who shall not be bound to see to the application of the purchase money, nor shall his title to the shares be affected by any irregularity or invalidity in the proceedings relating to the sale.

Preemption Rights, Share Warrants and Share Options

Under Irish law, certain statutory preemption rights apply automatically in favor of Mallinckrodt's shareholders where shares in Mallinckrodt are to be issued for cash, unless Mallinckrodt is authorized to opt out of these preemption rights by a special resolution of the shareholders. A special resolution requires not less than 75% of the votes of Mallinckrodt's shareholders cast at a general meeting (in person or by proxy). Mallinckrodt was granted authority to opt out of these preemption rights in the event of the issuance of shares for cash, if the issuance is limited to up to approximately 5% of Mallinckrodt's issued ordinary share capital (excluding shares held in treasury), pursuant to a resolution of shareholders at its last annual general meeting, such authority to expire no later than 15 months from the date on which it was granted unless renewed at the next annual general meeting. While the proposals for the next annual general meeting remain subject to review, it is expected that Mallinckrodt will seek such renewed authority at subsequent annual general meetings, but it is not guaranteed that such renewal will always be sought or approved. If the opt-out is not renewed, shares issued for cash must be offered to pre-existing shareholders of Mallinckrodt pro-rata to their existing shareholding before the shares can be issued to any new shareholders. The statutory preemption rights do not apply where shares are issued for non-cash consideration (such as in a stock-for stock acquisition) and do not apply to the issue of not-equity shares (that is, shares that have the right to participate only up to a specified amount in any income or capital distribution) or when shares are issued pursuant to an employee option or similar equity plan.

The articles of association of Mallinckrodt provide that, subject to any shareholder approval requirement under any laws, regulations or the rules of any stock exchange to which Mallinckrodt is subject, the board is authorized, from time to time, in its discretion, to grant such persons, for such periods and upon such terms as the board deems advisable, options to purchase or subscribe for such number of shares of any class or classes or of any series of any class as the board may deem advisable, and to cause warrants or other appropriate instruments evidencing such options to be issued. The Companies Act provides that directors may issue share warrants or options without shareholder approval once authorized to do so by the articles of association or an ordinary resolution of shareholders. Under Irish law, the board may issue shares upon exercise of validly issued warrants or options without shareholder approval or authorization.

Dividends

Under Irish law, dividends and distributions may only be made from "distributable reserves." Distributable reserves, broadly, means the accumulated realized profits of Mallinckrodt less accumulated realized losses of Mallinckrodt and includes reserves created by way of capital reduction. In addition, no distribution or dividend may be made unless the net assets of Mallinckrodt are equal to, or in excess of, the aggregate of Mallinckrodt's called up share capital plus distributable reserves and the distribution does not reduce Mallinckrodt's net assets below such aggregate. Undistributable reserves include the share premium account, the capital redemption reserve fund and the amount by which Mallinckrodt's accumulated unrealized profits, so far as not previously utilized by any capitalization, exceed Mallinckrodt's accumulated unrealized losses, so far as not previously written off in a reduction or reorganization of capital.

The determination as to whether or not Mallinckrodt has sufficient distributable reserves to fund a dividend must be made by reference to the "relevant financial statements s" of Mallinckrodt. The "relevant financial statements" are either the last set of unconsolidated annual audited financial statements or unaudited financial statements prepared in accordance with the Companies Act, which give a "true and fair view" of Mallinckrodt's unconsolidated financial position and accord with accepted accounting practice.

The mechanism as to who declares a dividend and when a dividend becomes payable is governed by the articles of association of Mallinckrodt. Mallinckrodt's articles of association authorize the directors to declare such dividends as appear justified from the profits of Mallinckrodt without the approval of the shareholders at a general meeting. The board of directors may also recommend a dividend to be approved and declared by the shareholders at a general meeting. Any general meeting declaring a dividend and any resolution of the directors declaring a dividend may direct that the payment be made by

distribution of assets, shares or cash, no dividend issued may exceed the amount recommended by the directors. No dividend issued may exceed the amount recommended by the directors. The dividends can be declared and paid in the form of assets, shares or cash.

The directors of Mallinckrodt may deduct from any dividend payable to any shareholder all sums of money (if any) immediately payable by such shareholder to Mallinckrodt in relation to the shares of Mallinckrodt.

The directors of Mallinckrodt are also entitled to issue shares with preferred rights to participate in dividends declared by Mallinckrodt. The holders of such preferred shares may, depending on their terms, be entitled to claim arrears of a declared dividend out of subsequently declared dividends in priority to ordinary shareholders. The holders of ordinary A shares are not entitled to receive any dividend.

Share Repurchases and Redemptions

Overview

Mallinckrodt's articles of association provides that unless the board of directors specifically resolves to treat such acquisition as a purchase for the purposes of the Companies Act, any ordinary share or an interest in any ordinary share which Mallinckrodt has acquired or agreed to acquire from a third party is deemed to be a redeemable share. Accordingly, for Irish company law purposes, the repurchase of ordinary shares by Mallinckrodt may technically be effected as a redemption of those shares as described below under "—Share Repurchases and Redemptions—Repurchases and Redemptions by Mallinckrodt." If such shares were not to be deemed to be redeemable shares, their repurchase by Mallinckrodt would be subject to additional requirements imposed by Irish law. Neither Irish law nor any constituent document of Mallinckrodt places limitations on the right of non-resident or foreign owners to vote or hold Mallinckrodt ordinary shares. Except where otherwise noted, when we refer elsewhere in this exhibit to repurchasing or buying back ordinary shares of Mallinckrodt, we are referring to the redemption of ordinary shares by Mallinckrodt or the purchase of Mallinckrodt ordinary share by a subsidiary of Mallinckrodt, in each case in accordance with the Mallinckrodt articles of association and Irish company law as described below.

Repurchases and Redemptions by Mallinckrodt

Under Irish law, a company can issue redeemable shares and redeem them out of distributable reserves (which are described above under "—Dividends") or the proceeds of a new issue of shares for that purpose. The issue of redeemable shares may only be made by Mallinckrodt where the nominal value of the issued share capital that is not redeemable is not less than 10% of the nominal value of the total issued share capital of Mallinckrodt. All redeemable shares must also be fully paid and the terms of redemption of the shares must provide for payment on redemption. Based on the provision of Mallinckrodt's articles described above, shareholder approval is not required to redeem Mallinckrodt ordinary shares.

The board of directors of Mallinckrodt is also entitled to issue preferred shares which may be redeemed at the option of either Mallinckrodt or the shareholder, depending on the terms of such preferred shares. For additional information on redeemable shares, see "—Share Capital."

Mallinckrodt may also be given an additional general authority by its shareholders to purchase its own shares as overseas market purchases on a recognized stock exchange such as the New York Stock Exchange or the Nasdaq stock market, which would take effect on the same terms and be subject to the same conditions as applicable to purchases by Mallinckrodt's subsidiaries as described below. Mallinckrodt was granted this authority pursuant to a resolution of shareholders at its last annual general meeting, such authority to expire no later than 15 months from the date on which it was granted unless renewed at the next annual general meeting. While the proposals for the next annual general meeting remain subject to review, it is expected that Mallinckrodt will seek such renewed authority at subsequent annual general meetings but it is not guaranteed that such renewal will always be sought or approved.

Repurchased and redeemed shares may be cancelled or held as treasury shares. The nominal value of treasury shares held by Mallinckrodt at any time must not exceed 10% of the nominal value of the issued share capital of Mallinckrodt. While Mallinckrodt holds shares as treasury shares, it cannot exercise any voting rights in respect of those shares. Treasury shares may be cancelled by Mallinckrodt or re-issued subject to certain conditions.

Purchases by Subsidiaries of Mallinckrodt

Under Irish law, it may be permissible for an Irish or non-Irish subsidiary to purchase ordinary shares of Mallinckrodt either as overseas market purchases on a recognized stock exchange or off-market. A

general authority of the shareholders of Mallinckrodt is required to allow a subsidiary of Mallinckrodt to make on-market purchases of Mallinckrodt ordinary shares; however, as long as this general authority has been granted, no specific shareholder authority for a particular on-market purchase by a subsidiary of Mallinckrodt ordinary shares is required. The shareholders of Mallinckrodt granted such authority pursuant to a resolution approved at its last annual general meeting, which must expire no later than 15 months after the date on which it was granted unless it is renewed at the next annual general meeting of Mallinckrodt's shareholders. While the proposals for the next annual general meeting remain subject to review, it is expected that Mallinckrodt will seek such renewed authority at subsequent annual general meetings but it is not guaranteed that such renewal will always be sought or approved.

In order for a subsidiary of Mallinckrodt to make an on-market purchase of Mallinckrodt's ordinary shares, such shares must be purchased on a "recognized stock exchange." Each of the New York Stock Exchange and the Nasdaq stock market are specified as a recognized stock exchange for this purpose by Irish company law.

For an off-market purchase by a subsidiary of Mallinckrodt, the proposed purchase contract must be authorized by special resolution of the shareholders of Mallinckrodt before the contract is entered into. The person whose shares are to be bought back cannot vote in favor of the special resolution and, for at least 21 days prior to the special resolution, the purchase contract must be on display or must be available for inspection by shareholders at the registered office of Mallinckrodt.

The number of shares held by the subsidiaries of Mallinckrodt at any time will count as treasury shares and will be included in any calculation of the permitted treasury share threshold of 10% of the nominal value of the issued share capital of Mallinckrodt. While a subsidiary holds Mallinckrodt ordinary shares, it cannot exercise any voting rights in respect of those shares. The acquisition of the ordinary shares of Mallinckrodt by a subsidiary must be funded out of distributable reserves of the subsidiary.

Lien on Shares, Calls on Shares and Forfeiture of Shares

Mallinckrodt's articles of association provide that Mallinckrodt will have a first and paramount lien on every share for all moneys, whether presently due or not, payable in respect of such Mallinckrodt ordinary share. Subject to the terms of their allotment, directors may call for any unpaid amounts in respect of any shares to be paid, and if payment is not made, the shares may be forfeited. These provisions are standard inclusions in the articles of association of an Irish company limited by shares such as Mallinckrodt and will only be applicable to Mallinckrodt shares that have not been fully paid up.

Bonus Shares

Under Mallinckrodt's articles of association, the board may resolve to capitalize any amount for the time being standing to the credit of Mallinckrodt's reserves accounts or to the credit of the profit and loss account which is not available for distribution by applying such sum in paying up in full unissued shares to be allotted as fully paid-up bonus shares to shareholders of Mallinckrodt who would have been entitled to that sum if it were distributable and had been distributed by way of dividend (and in the same proportions).

Consolidation and Division; Subdivision

Under its articles of association, Mallinckrodt may, by ordinary resolution, consolidate and divide all or any of its share capital into shares of larger par value than its existing shares or subdivide its shares into smaller amounts than are fixed by its articles of association.

Reduction of Share Capital

Mallinckrodt may, by ordinary resolution, reduce its authorized but unissued share capital in any way. Mallinckrodt also may, by special resolution and subject to confirmation by the High Court of Ireland, reduce or cancel its issued share capital (which includes share premium) in any way permitted by the Companies Act.

Annual General Meetings of Shareholders

Mallinckrodt held its first annual general meeting on March 20, 2014, and is required to hold subsequent annual general meetings at intervals of no more than 15 months thereafter, provided that an annual general meeting is held in each calendar year following the first annual general meeting, no more than nine months after Mallinckrodt's fiscal year end. Any annual general meeting may be held outside Ireland if a resolution so authorizing has been passed at the preceding annual general meeting. Because of the 15-month requirement described in this paragraph, Mallinckrodt's articles of association include a

provision reflecting this requirement of Irish law. Under emergency legislation implemented in response to Covid-19, Irish companies may extend the date of their annual general meetings. The current legislation, the Companies (Miscellaneous Provisions) Covid-19 Act 2020 is due to expire on 9 June 2021, but there is the probability that it may be extended and that, if extended, Mallinckrodt may avail of its provisions.

Notice of an annual general meeting must be given to all Mallinckrodt shareholders and to the auditors of Mallinckrodt. The articles of association of Mallinckrodt provide for a minimum notice period of 21 days, which is the minimum permitted under Irish law.

The only matters which must, as a matter of Irish company law, be transacted at an annual general meeting are the review by the members of the company's affairs, presentation of the statutory financial statements and reports of the directors and auditors, the appointment of new auditors and the fixing of the auditor's remuneration (or delegation of same). If no resolution is made in respect of the reappointment of an existing auditor at an annual general meeting, the existing auditor will be deemed to have continued in office.

At any annual general meeting, only such business may be conducted as has been brought before the meeting (i) by or at the direction of the board of directors, (ii) in certain circumstances, at the direction of the Irish High Court, (iii) as required by law or (iv) such business that the chairman of the meeting determines is properly within the scope of the meeting. The business to be conducted at any extraordinary general meeting must be set forth in the notice of the meeting. In addition, shareholders entitled to vote at an annual general meeting may make nominations of candidates for election to the board of directors.

Extraordinary General Meetings of Shareholders

Extraordinary general meetings of Mallinckrodt may be convened by (i) the board of directors, (ii) on requisition of the shareholders holding not less than 10% of the paid-up share capital of Mallinckrodt carrying voting rights, (iii) on requisition of Mallinckrodt's auditors upon their resignation or (iv) in exceptional cases, by court order. Extraordinary general meetings are generally held for the purposes of approving shareholder resolutions of Mallinckrodt as may be required from time to time. At any extraordinary general meeting only such business shall be conducted as is set forth in the notice thereof.

Notice of an extraordinary general meeting must be given to all Mallinckrodt shareholders and to the auditors of Mallinckrodt. Under Irish law and Mallinckrodt' articles of association, the minimum notice periods are 21 days' notice in writing for an extraordinary general meeting to approve a special resolution and 14 days' notice in writing for any other extraordinary general meeting. General meetings may be called by shorter notice in accordance with the terms of the Companies Act.

In the case of an extraordinary general meeting convened by shareholders of Mallinckrodt, the proposed purpose of the meeting must be set out in the requisition notice. The requisition notice can contain any resolution. Upon receipt of this requisition notice, the board of directors has 21 days to convene a meeting of Mallinckrodt's shareholders to vote on the matters set out in the requisition notice. This meeting must be held within two months of the receipt of the requisition notice. If the board of directors does not convene the meeting within such 21-day period, the requisitioning shareholders, or any of them representing more than one half of the total voting rights of all of them, may themselves convene a meeting, which meeting must be held within three months of the receipt of the requisition notice.

If the directors become aware that the net assets of Mallinckrodt are half or less of the amount of Mallinckrodt's called-up share capital, the directors of Mallinckrodt must convene an extraordinary general meeting of Mallinckrodt's shareholders not later than 28 days from the date that they learn of this fact. This meeting must be convened for the purposes of considering whether any, and if so what, measures should be taken to address the situation.

Voting

Where a vote is to be taken at a general meeting, every shareholder has one vote for each ordinary share that he or she holds as of the record date for the meeting. Voting rights may be exercised by shareholders registered in Mallinckrodt's share register as of the record date for the meeting or by a duly appointed proxy of such a registered shareholder, which proxy need not be a shareholder. Where interests in shares are held by a nominee trust company, this company may exercise the rights of the beneficial holders on their behalf as their proxy. All proxies must be appointed in the manner prescribed by Mallinckrodt's articles of association. The articles of association of Mallinckrodt permit the appointment of proxies by the shareholders to be notified to Mallinckrodt electronically.

Except where a greater majority is required by the Companies Act, any question, business or resolution proposed at any general meeting shall be decided by a simple majority of the votes cast.

Mallinckrodt's articles provide that all resolutions are decided by a show of hands unless a poll (before or on the declaration of the result of the show of hands) is demanded by (i) the Chairman, (ii) at least three shareholders present in person or by proxy, (iii) any shareholder or shareholders present in person or by proxy, holding not less than one-tenth of the total voting rights of Mallinckrodt having the right to vote at such meeting, or (iv) any shareholder or shareholders holding shares in Mallinckrodt conferring the right to vote at the meeting being shares on which an aggregate sum has been paid equal to not less than one-tenth of the total sum paid up on all shares conferring that right. Each Mallinckrodt ordinary shareholder of record as of the record date for the meeting has one vote at a general meeting on a show of hands.

In accordance with Mallinckrodt's articles of association, the board of directors may from time to time cause Mallinckrodt to issue preferred or any other class or series of shares. These shares may have such voting rights, if any, as may be specified in the terms of such shares (i.e. they may carry more votes per share than ordinary shares or may entitle their holders to a class vote on such matters as may be specified in the terms of the shares). Treasury shares and shares held by subsidiaries will not be entitled to vote at general meetings of shareholders.

Irish company law requires "special resolutions" of the shareholders at a general meeting to approve certain matters. A special resolution requires not less than 75% of the votes cast of Mallinckrodt's shareholders present in person or by proxy at a general meeting. This may be contrasted with "ordinary resolutions," which require a simple majority of the votes of Mallinckrodt's shareholders cast in person or by proxy at a general meeting. Examples of matters requiring special resolutions include:

- amending the objects (i.e., main purposes) of Mallinckrodt;
- amending the articles of association of Mallinckrodt;
- approving a change of name of Mallinckrodt;
- authorizing the entering into of a guarantee or provision of security in connection with a loan, quasi-loan or credit transaction to a director or a person who is deemed to be "connected" to a director for the purposes of the Companies Act;
- opting-out of preemption rights on the issuance of new shares;
- re-registration of Mallinckrodt from a public limited company to a private company;
- variation of class rights attaching to classes of shares;
- purchasing Mallinckrodt's ordinary shares off-market;
- any reduction of Mallinckrodt's issued share capital;
- resolving that Mallinckrodt be wound up by the Irish courts;
- sanctioning a compromise/scheme of arrangement;
- resolving in favor of a shareholders' voluntary winding-up;
- re-designation of shares into different share classes; and
- setting the re-issue price of treasury shares.

Unanimous Shareholder Consent to Action Without Meeting

The Companies Act provides that shareholders may approve an ordinary or special resolution of shareholders without a meeting only if (a) all shareholders sign the written resolution and (b) the company's articles of association permit written resolutions of shareholders. Mallinckrodt's articles of association permit unanimous written resolutions of shareholders, as permitted under Irish law.

Variation of Class Rights Attaching to Shares

Variation of all or any special rights attached to any class of shares of Mallinckrodt is addressed in the articles of association of Mallinckrodt as well as the Companies Act. Any variation of class rights attaching to the issued shares of Mallinckrodt must be approved by a special resolution of the shareholders of the class affected. Mallinckrodt's articles of association expressly provide that any issue of preferred shares

(whatever the rights attaching to them) will be deemed not to be a variation of the rights of ordinary shareholders.

The provisions of the articles of association of Mallinckrodt relating to general meetings shall apply to every such general meeting of the holders of any class of shares with certain exceptions in relation to quorum and the right to demand a poll.

Quorum for General Meetings

The presence, in person or by proxy, of the holders of shares in Mallinckrodt entitling them to exercise a majority of the voting power of Mallinckrodt constitutes a quorum for the conduct of business. No business may take place at a general meeting of Mallinckrodt if a quorum is not present in person or by proxy. The board of directors has no authority to waive quorum requirements stipulated in the articles of association of Mallinckrodt. Abstentions and broker non-votes will be counted as present for purposes of determining whether there is a quorum in respect of the proposals.

Requirements for Advance Notification of Director Nominations and Proposals of Shareholders

Mallinckrodt's articles of association provide that with respect to an annual or extraordinary general meeting of shareholders, nominations of persons for election to its board of directors and the proposal of business to be considered by shareholders may be made only (i) pursuant to Mallinckrodt's notice of meeting; (ii) by the board of directors; (iii) by any shareholders pursuant to the valid exercise of power granted to them under the Companies Act; (iv) or by a shareholder who is entitled to vote at the meeting and who has complied with the advance notice procedures provided for in the articles of association.

In order to comply with the advance notice procedures of Mallinckrodt's articles of association, a shareholder must give written notice to Mallinckrodt's secretary on a timely basis. To be timely for an annual general meeting, notice must be delivered not earlier than the close of business on the 120th day and not later than the close of business on the 90th day prior to the first anniversary of the preceding year's annual general meeting, provided, however, that in the event that the date of the annual general meeting is more than 30 days before or more than 60 days after such anniversary date, notice by the member must be so delivered not earlier than the close of business on the 120th day prior to the date of such annual general meeting and not later than the close of business on the later of the 90th day prior to the date of such annual general meeting or, if the first public announcement of the date of such annual general meeting is less than 100 days prior to the date of such annual general meeting, the 10th day following the day on which public announcement is first made of the date of the annual general meeting. In no event shall the public announcement of an adjournment or postponement of an annual general meeting commence a new time period (or extend any time period) for the giving of a shareholder's notice.

To be timely for an extraordinary general meeting, notice must be delivered not earlier than the close of business on the 120th day prior to the date of such extraordinary general meeting and not later than the close of business on the 90th day prior to the date of such extraordinary general meeting or, if the first public announcement of the date of such extraordinary general meeting is less than 100 days prior to the date of such extraordinary general meeting, the 10th day following the day on which public announcement is first made of the date of the extraordinary general meeting and of the nominees proposed by the board of directors to be elected at such meeting. In no event shall the public announcement of an adjournment or postponement of an annual general meeting commence a new time period (or extend any time period) for the giving of a shareholder's notice.

In addition, whether relating to an annual or extraordinary general meeting, to be timely, a shareholder's notice must be updated and supplemented, if necessary, so the information provided or required to be provided is true and correct as of the record date for the meeting and as of the date that is 10 business days prior to the meeting or any adjournment or postponement thereof. Such update and supplement shall be delivered to Mallinckrodt's secretary (i) not later than five business days after the record date for the meeting in the case of the update and supplement required to be made as of the record date and (ii) not later than eight business days prior to the meeting or any adjournment or postponement thereof in the case of the update and supplement required to be made as of 10 business days prior to the meeting on any adjournment or postponement thereof.

For nominations to the board, the notice must include (i) all information about the director nominee that is required to be disclosed by SEC rules regarding the solicitation of proxies for the election of directors pursuant to Section 14 under the Securities Exchange Act of 1934, as amended (the "Exchange Act") (including such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected), (ii) a description of all direct and indirect compensation and other material

monetary agreements or arrangements during the past three years, any other material relationships between the nominating shareholder, and their affiliates and associates or others acting in concert, and the proposed nominee and his or her affiliates and associates and other concert parties (including, but not limited to, information that would be required to be disclosed pursuant to Rule 404 promulgated under Regulation S-K under the Exchange Act) and (iii) such other information as Mallinckrodt may reasonably require to determine the eligibility of the proposed nominee, as well as a completed questionnaire, representation and agreement signed by the proposed nominee regarding the background, qualification and certain existing relationships and arrangements of the proposed nominee.

For other business that a shareholder proposes to bring before the meeting, the notice must include a brief description of the business, the reasons for proposing the business at the meeting, the text of the proposal or wording (including the text of any proposed resolutions for consideration and if such business includes a proposal to amend the articles of association of Mallinckrodt, the text of the proposed amendment), a discussion of any material interest of the shareholder in the business and a description of all arrangements between the shareholder(s) any other person or persons in connection with the proposal.

Whether the notice relates to a nomination to the board of directors or to other business to be proposed at the meeting, the notice also must include information about (i) the shareholder, (ii) the shareholder's holdings of Mallinckrodt shares (as well as "derivative instruments" or "short interests" with respect to Mallinckrodt shares, as defined in the articles of association), (iii) any arrangements giving the shareholder the right to vote shares of Mallinckrodt, (iv) any rights to dividends on the Mallinckrodt shares that are separated or separable from the underlying Mallinckrodt shares, (v) any proportionate interest in Mallinckrodt's shares or "derivative instruments," held by a general or limited partnership in which the shareholder has an interest, (vi) any performance-related fees (other than an asset-based fee) that the shareholder is entitled to base on any increase or decrease in the value of the Mallinckrodt shares or "derivative instruments," (vii) any significant equity interests or any "derivative instruments" or "short interests" in any of Mallinckrodt's principal competitors held by the shareholder, (viii) any interest of the shareholder in any contract with Mallinckrodt or any of its affiliates or principal competitors and (ix) any other information that would be required to be disclosed by SEC rules regarding solicitation of proxies for the director nomination and/or other business to be proposed at the meeting.

The chairman of the meeting shall have the power and duty to determine whether any business proposed to be brought before the meeting was made or proposed in accordance with these procedures (as set out in Mallinckrodt's articles of association), and if any proposed business is not in compliance with these provisions, to declare that no action shall be taken in respect of such defective proposal and that it shall be disregarded.

In addition, the Companies Act provides that shareholders holding not less than 10% of the total voting rights may call an extraordinary general meeting for the purpose of considering director nominations or other proposals, as described above under "—Extraordinary General Meetings of Shareholders."

Inspection of Books and Records

Under Irish law, shareholders have the right to: (i) receive a copy of the memorandum and articles of association of Mallinckrodt and any act of the Irish legislature which alters the memorandum and articles of association of Mallinckrodt; (ii) inspect and obtain copies of the minutes and resolutions of general meetings of Mallinckrodt; (iii) inspect and receive a copy of the register of shareholders, register of directors and secretaries, register of directors' interests and other statutory registers maintained by Mallinckrodt; (iv) receive copies of statutory financial statements and directors' and auditors' reports which have previously been sent to shareholders prior to an annual general meeting; and (v) receive any statutory financial statement of a subsidiary company of Mallinckrodt which have previously been sent to shareholders prior to an annual general meeting for the preceding 10 years. The auditors of Mallinckrodt also have the right to inspect all books, records and vouchers of Mallinckrodt. The auditors' report must be circulated to the shareholders 21 days before the annual general meeting with Mallinckrodt's financial statements prepared in accordance with the Companies Act, and must be available to the shareholders at Mallinckrodt's annual general meeting.

Acquisitions

There are a number of mechanisms for acquiring an Irish public limited company, including:

(a) a court-approved scheme of arrangement under the Companies Act. A scheme of arrangement with shareholders requires a court order from the High Court of Ireland and the approval of a majority in number representing 75% in value of the shareholders present and voting in person or by proxy at a meeting called to approve the scheme;

(b) through a tender offer or takeover offer by a third party for all of the shares of Mallinckrodt. Where the holders of 80% or more of Mallinckrodt's shares have accepted an offer by a bidder for their shares in Mallinckrodt, the remaining shareholders may be statutorily required to also transfer their shares to such bidder. If the bidder does not exercise its "squeeze out" right, then the non-accepting shareholders also have a statutory right to require the bidder to acquire their shares on the same terms. If shares of Mallinckrodt were listed on the main market of the Irish Stock Exchange or another regulated stock exchange in the European Economic Area (the European Economic Area includes all member states of the E.U. and Norway, Iceland and Liechtenstein), this threshold would be increased to 90%; and

(c) it is also possible for Mallinckrodt to be acquired by way of a merger with an E.U.-incorporated public company under the E.U. Cross Border Merger Directive 2017/1132. Such a merger must be approved by a special resolution. If Mallinckrodt is being merged with another E.U. public company under the E.U. Cross Border Merger Directive 2017/1132 and the consideration payable to Mallinckrodt's shareholders is not all in the form of cash, Mallinckrodt's shareholders may be entitled to require their shares to be acquired at fair value.

Under Irish law, there is no requirement for a company's shareholders to approve a sale, lease or exchange of all or substantially all of a company's property and assets. However, Mallinckrodt's articles of association provide that the passing of an ordinary resolution is required to approve a sale, lease or exchange of all or substantially all of its property or assets.

Appraisal Rights

Generally, under Irish law, shareholders of an Irish company do not have dissenters' or appraisal rights. Under the European Communities (Cross-Border Mergers) Regulations 2008 (as amended) governing the merger of an Irish company limited by shares such as Mallinckrodt and a company incorporated in the European Economic Area, a shareholder (i) who voted against the special resolution approving the transaction or (ii) of a company in which 90% of the shares are held by the other party to the transaction has the right to request that the company acquire its shares for cash at a price determined in accordance with the share exchange ratio set out in the transaction.

In the event of a takeover of Mallinckrodt by a third party in accordance with the Irish Takeover Rules and the Companies Act where the holders of 80% or more in value of a class of Mallinckrodt' shares (excluding any shares already beneficially owned by the bidder) have accepted an offer for their shares, the remaining shareholders in that class may be statutorily required to transfer their shares, unless, within one month, the non-tendering shareholders can obtain an Irish court order otherwise providing. If the bidder does not exercise this "squeeze out" right, the non-accepting shareholders also have a statutory right to require the bidder to acquire their shares on the same terms as the original offer, or such other terms as the bidder and the non-tendering shareholders may agree or on such terms as an Irish court, on application of the bidder or non-tendering shareholder, may order.

Disclosure of Interests in Shares

Under the Companies Act, there is a notification requirement for shareholders who acquire or cease to be interested in 3% of the shares of an Irish public company. A shareholder of Mallinckrodt must notify Mallinckrodt (but not the public at large) if as a result of a transaction the shareholder will be interested in 3% or more of any class of shares of Mallinckrodt carrying voting rights; or if as a result of a transaction a shareholder who was interested in more than 3% of any class of shares of Mallinckrodt carrying voting rights ceases to be so interested. Where a shareholder is interested in more than 3% of any class of shares of Mallinckrodt carrying voting rights, any alteration of his or her interest that brings his or her total holding through the nearest whole percentage number, whether an increase or a reduction, must be notified to Mallinckrodt (but not the public at large). The relevant percentage figure is calculated by reference to the aggregate par value of the class of shares in which the shareholder is interested as a proportion of the entire par value of the issued shares of that class. Where the percentage level of the shareholder's interest does not amount to a whole percentage, this figure may be rounded down to the

next whole number. All such disclosures must be notified to Mallinckrodt within five business days of the transaction or alteration of the shareholder's interests that gave rise to the requirement to notify. Where a person fails to comply with the notification requirements described above, no right or interest of any kind whatsoever in respect of any shares in Mallinckrodt concerned, held by such person, will be enforceable by such person, whether directly or indirectly, by action or legal proceeding. However, such person may apply to the Irish High Court to have the rights attaching to the shares concerned reinstated.

In addition to the above disclosure requirement, Mallinckrodt, under the Companies Act, may by notice in writing require a person whom Mallinckrodt knows or has reasonable cause to believe to be or, at any time during the three years immediately preceding the date on which such notice is issued, to have been interested in shares comprised in Mallinckrodt's relevant share capital: (i) to indicate whether or not it is the case, and (ii) where such person holds or has during that time held an interest in any class of shares of Mallinckrodt carrying voting rights to give such further information as may be required by Mallinckrodt, including particulars of such person's own past or present interests in such class of shares of Mallinckrodt. Any information given in response to the notice is required to be given in writing within such reasonable time as may be specified in the notice.

Where such a notice is served by Mallinckrodt on a person who is or was interested in shares of Mallinckrodt carrying voting rights and that person fails to give Mallinckrodt any information required within the reasonable time specified, Mallinckrodt may apply to the court for an order directing that the affected shares be subject to certain restrictions.

Under the Companies Act, the restrictions that may be placed on the shares by the court are:

(a) any transfer of those shares, or in the case of unissued shares any transfer of the right to be issued with shares and any issue of shares, is void;

(b) no voting rights are exercisable in respect of those shares;

(c) no further shares may be issued in right of those shares or in pursuance of any offer made to the holder of those shares; and

(d) no payment may be made of any sums due from Mallinckrodt on those shares, whether in respect of capital or otherwise.

Where the shares in Mallinckrodt are subject to these restrictions, the court may order the shares to be sold and may also direct that the shares will cease to be subject to these restrictions.

In the event that Mallinckrodt is in an offer period pursuant to the Irish Takeover Rules, accelerated disclosure provisions apply for persons holding an interest in Mallinckrodt securities of 1% or more.

Anti-Takeover Provisions

Business Combinations with Interested Shareholders

Mallinckrodt's articles of association include a provision which generally prohibits Mallinckrodt 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, unless, in general:

- the Mallinckrodt board of directors approved the transaction which resulted in the shareholder becoming an "interested shareholder";
- upon consummation of the transaction which resulted in the shareholder becoming an "interested shareholder", the shareholder owned at least 85% of the voting shares outstanding at the time of commencement of such transaction, excluding for purposes of determining the number of voting shares outstanding (but not the outstanding voting shares owned by the "interested shareholder"), voting shares owned by persons who are directors and also officers and by certain employee share plans; or
- at or subsequent to such time the business combination is approved by the Mallinckrodt board of directors and authorized by a special resolution of Mallinckrodt's shareholders (excluding the "interested shareholder").

A "business combination" is generally defined as a merger, scheme of arrangement, asset or share sale or other transaction resulting in a financial benefit to the interested shareholder. An "interested shareholder" is generally defined as a person who, together with affiliates and associates, owns or, within three years prior to the date in question, owned 15% or more of the outstanding voting shares of Mallinckrodt.

Shareholder Rights Plans and Share Issuances

Irish law does not expressly prohibit companies from issuing share purchase rights or adopting a shareholder rights plan (commonly known as a "poison pill") as an anti-takeover measure. However, there is no directly relevant case law on the validity of such plans under Irish law. In addition, such a plan is subject to the Irish Takeover Rules described below.

Mallinckrodt's articles of association allow the board to adopt a shareholder rights plan upon such terms and conditions as the board deems expedient and in the best interests of Mallinckrodt, subject to applicable law.

Subject to the Irish Takeover Rules described below, the board also has power to cause Mallinckrodt to issue any of its authorized and unissued shares on such terms and conditions as the board may determine (as described under "—Share Capital") and any such action must be taken in the best interests of Mallinckrodt. It is possible, however, that the terms and conditions of any issue of preferred shares could discourage a takeover or other transaction that holders of some or a majority of the ordinary shares believe to be in their best interests or in which holders might receive a premium for their shares over the then market price of the shares.

Irish Takeover Rules

A transaction by virtue of which a third party is seeking to acquire 30% or more of the voting rights of Mallinckrodt will be governed by the Irish Takeover Panel Act 1997 and the Irish Takeover Rules made thereunder and will be regulated by the Irish Takeover Panel. The "General Principles" of the Irish Takeover Rules and certain important aspects of the Irish Takeover Rules are described below.

General Principles. The Irish Takeover Rules are built on the following General Principles which will apply to any transaction regulated by the Irish Takeover Panel:

- in the event of an offer, all classes of shareholders of the target company should be afforded equivalent treatment and, if a person acquires control of a company, the other holders of securities must be protected;
- the holders of securities in the target company must have sufficient time and information to allow them to make an informed decision regarding the offer. If the board of the target company advises the holders of securities as regards the offer, it must advise on the effects of the implementation of the offer on employment, employment conditions and the locations of the target company's place of business;
- the board of the target company must act in the interests of the company as a whole and must not deny the holders of securities the opportunity to decide on the merits of the offer;
- false markets (i.e., a market based on erroneous, imperfect or unequally disclosed information) must not be created in the securities of the target company, the bidder or any other company concerned by the offer in such a way that the rise or fall of the prices of the securities become artificial and the normal functioning of the markets is distorted;
- a bidder must announce an offer only after ensuring that he or she can pay in full the consideration offered and after taking all reasonable measures to secure the implementation of any other type of consideration;
- a target company may not be hindered in the conduct of its affairs longer than is reasonable by an offer for its securities, (this is a recognition that an offer will disrupt the day-to-day running of a target company, particularly if the offer is hostile, and the board of the target company must divert its attention to deal with the offer); and
- a substantial acquisition of securities (whether such acquisition is to be effected by one transaction or a series of transactions) shall take place only at an acceptable speed and shall be subject to adequate and timely disclosure.

Mandatory Bid. Under certain circumstances, a person who acquires shares or other voting rights in Mallinckrodt may be required under the Irish Takeover Rules to make a mandatory cash offer for the remaining outstanding shares in Mallinckrodt at a price not less than the highest price paid for the shares by the acquirer (or any parties acting in concert with the acquirer) during the previous 12 months. This mandatory bid requirement is triggered if an acquisition of shares would increase the aggregate holding of an acquirer (including the holdings of any parties acting in concert with the acquirer) to shares representing 30% or more of the voting rights in Mallinckrodt, unless the Irish Takeover Panel otherwise

consents. An acquisition of shares by a person holding (together with its concert parties) shares representing between 30% and 50% of the voting rights in Mallinckrodt would also trigger the mandatory bid requirement if, after giving effect to the acquisition, the percentage of the voting rights held by that person (together with its concert parties) would increase by 0.05% within a 12-month period. Any person (excluding any parties acting in concert with the holder) holding shares representing more than 50% of the voting rights of a company is not subject to these mandatory offer requirements in purchasing additional securities.

Voluntary Bid; Requirements to Make a Cash Offer and Minimum Price Requirements. If a person makes a voluntary offer to acquire outstanding Mallinckrodt ordinary shares, the offer price must be no less than the highest price paid for Mallinckrodt ordinary shares by the bidder or its concert parties during the three month period prior to the commencement of the offer period. The Irish Takeover Panel has the power to extend the "look back" period to 12 months if the Irish Takeover Panel, taking into account the General Principles, believes it is appropriate to do so.

If the bidder or any of its concert parties has acquired Mallinckrodt ordinary shares (i) during the period of 12 months prior to the commencement of the offer period which represent more than 10% of the total Mallinckrodt ordinary shares or (ii) at any time after the commencement of the offer period, the offer must be in cash (or accompanied by a full cash alternative) and the price per Mallinckrodt ordinary share must not be less than the highest price paid by the bidder or its concert parties during, in the case of (i), the 12-month period prior to the commencement of the offer period and, in the case of (ii), the offer period. The Irish Takeover Panel may apply this rule to a bidder who, together with its concert parties, has acquired less than 10% of the total Mallinckrodt ordinary shares in the 12-month period prior to the commencement of the offer period if the Irish Takeover Panel, taking into account the General Principles, considers it just and proper to do so.

A voluntary offer period will generally commence on the date of the first announcement of the offer or proposed offer.

Substantial Acquisition Rules. The Irish Takeover Rules also contain rules governing substantial acquisitions of shares that restrict the speed at which a person may increase his or her holding of voting shares and rights over voting shares to an aggregate of between 15% and 30% of the voting rights of Mallinckrodt. Except in certain circumstances, an acquisition or series of acquisitions of shares or rights over shares representing 10% or more of the voting rights is prohibited if such acquisition(s), when aggregated with shares or rights already held, would result in the acquirer holding 15% or more but less than 30% of the voting rights of Mallinckrodt and such acquisitions are made within a period of seven days. These rules also require accelerated disclosure of acquisitions of shares or rights over shares relating to such acquisitions.

Frustrating Action. Under the Irish Takeover Rules, the board of directors of Mallinckrodt is not permitted to take any action which might frustrate an offer for the shares of Mallinckrodt once the board of directors has received an approach which may lead to an offer, or has reason to believe an offer is imminent, except as noted below. Potentially frustrating actions such as (i) the issue of shares, options or convertible securities, (ii) material disposals, (iii) entering into contracts other than in the ordinary course of business or (iv) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any time during which the board has reason to believe an offer is imminent. Exceptions to this prohibition are available:

(a) where the action is approved by Mallinckrodt's shareholders at a general meeting; or

(b) with the consent of the Irish Takeover Panel where:

(i) the Irish Takeover Panel is satisfied the action would not constitute a frustrating action;

(ii) the Mallinckrodt shareholders that hold 50% of the voting rights state in writing that they approve the proposed action and would vote in favor of it at a general meeting;

(iii) such action is in accordance with a contract entered into prior to the announcement of the offer; or

(iv) the decision to take such action was made before the announcement of the offer and either has been at least partially implemented or is in the ordinary course of business.

For other provisions that could be considered to have an anti-takeover effect, see above at "—Share Capital" (regarding issuance of preferred shares) "—Preemption Rights, Share Warrants and Share Options," "—Disclosure of Interests in Shares," "—Requirements for Advance Notification of Director

Nominations and Proposals of Shareholders" and "—Unanimous Shareholder Consent to Action Without Meeting," in addition to "—Election of Directors," "—Vacancies on Board of Directors" and "—Amendment of Governing Documents" below.

Insider Dealing

The Irish Takeover Rules also provide that no person, other than the bidder, who is privy to confidential price-sensitive information concerning an offer made in respect of the acquisition of our company (or a class of its securities) or a contemplated offer shall deal in relevant securities of the target during the period from the time at which such person first has reason to suppose that such an offer, or an approach with a view to such an offer being made, is contemplated to the time of (i) the announcement of such offer or approach or (ii) the termination of discussions relating to such offer, whichever is earlier.

Corporate Governance

The articles of association of Mallinckrodt delegate the day-to-day management of Mallinckrodt to its board of directors. The board of directors may then delegate management of Mallinckrodt to committees, executives or to a management team, but regardless, the directors remain responsible, as a matter of Irish law, for the proper management of the affairs of Mallinckrodt. Committees may meet and adjourn as they determine proper. Unless otherwise determined by the board of directors, the quorum necessary for the transaction of business at any committee meeting shall be a majority of the members of such committee then in office unless the committee shall consist of one or two members, in which case one member shall constitute a quorum.

Election of Directors

The Companies Act provides for a minimum of two directors. Mallinckrodt's articles of association provide for a minimum of two directors and a maximum of 15 directors. The shareholders of Mallinckrodt may from time to time increase or reduce the maximum number, or increase the minimum number, of directors by a special resolution amending the articles of association.

At each annual general meeting of Mallinckrodt, all the directors shall retire from office and be eligible for re-election. Upon the resignation or termination of office of any director, if a new director shall be appointed to the board he will be designated to fill the vacancy arising. In the event that an election results in either only one or no directors receiving the required majority vote, either the nominee or each of the two nominees receiving the greatest number of votes in favor of his or her election, in accordance with Mallinckrodt's articles of association, hold office until his or her successor shall be elected.

No person shall be appointed director unless nominated in accordance with the articles of association of Mallinckrodt. Mallinckrodt's articles of association provide that with respect to an annual or extraordinary general meeting of shareholders, nominations of persons for election to the board of directors and the proposal of business to be considered by shareholders may be made only pursuant to Mallinckrodt's notice of meeting by (i) the board of directors, (ii) any shareholders pursuant to the valid exercise of power granted to them under the Companies Act; (iii) a shareholder who is entitled to vote at the meeting and who has complied with the advance notice procedures provided for in Mallinckrodt articles of association or (iv) by holders of any class of shares in Mallinckrodt then in issue having special rights to nominate or appoint directors in accordance with the terms of issue of such class or series, but only to the extent provided in such terms of issue. In addition, the Companies Act provides that shareholders holding not less than 10% of the total voting rights may call an extraordinary general meeting for the purpose of considering director nominations or other proposals.

Directors shall be appointed as follows:

(a) by shareholders by ordinary resolution at the annual general meeting in each year or at any extraordinary general meeting called for the purpose;

(b) by the board in accordance with the articles of association of Mallinckrodt; or

(c) so long as there is in office a sufficient number of directors to constitute a quorum of the board in accordance with the articles of association of Mallinckrodt, the directors shall have the power at any time and from time to time to appoint any person to be director, either to fill a vacancy in the board or as an addition to the existing directors but so that the total number of directors shall not any time exceed the maximum number provided for in the articles of association. A director so appointed shall hold office only until the next following annual general meeting.

Vacancies on the Board of Directors

Mallinckrodt's articles of association provide that the directors have the authority to appoint one or more directors to the Mallinckrodt board of directors, subject to the maximum number of directors allowed for in the articles of association. A vacancy caused by the removal of a director may be filled at the meeting at which the director is removed by ordinary resolution of Mallinckrodt's shareholders, subject to compliance with the applicable advance notice requirements for the election of directors, see above at "- Requirements for Advance Notification of Director Nominations and Proposals of Shareholders". If not, it may be filled by the board of directors.

Any director appointed by the other directors will hold office until the next annual general meeting of Mallinckrodt. During any vacancy on the board, the remaining directors will have full power to act as the board but, if and so long as, their number is reduced below the minimum number, the continuing directors may act for increasing the number of directors to that minimum number or of summoning a general meeting of Mallinckrodt but for no other purpose.

Removal of Directors

The Companies Act provides that, notwithstanding anything contained in the articles of association of a company or in any agreement between that company and a director, the shareholders may, by an ordinary resolution, remove a director from office before the expiration of his or her term at a meeting held on no less than 28 days' notice and at which the director is entitled to be heard. Accordingly, the shareholders of Mallinckrodt may by an ordinary resolution remove a director from office before the expiration of his or her term (notwithstanding any agreement between Mallinckrodt and the director). The power of removal is without prejudice to any claim for damages for breach of contract (e.g., employment contract) which the director may have against Mallinckrodt in respect of his or her removal.

Amendment of Governing Documents

Irish companies, including Mallinckrodt, may only alter their memorandum of association and articles of association with the approval of a special resolution of a general meeting of the company.

Duration; Dissolution; Rights upon Liquidation

Mallinckrodt's corporate existence has unlimited duration. Mallinckrodt may be dissolved at any time by way of either a shareholders' voluntary winding up or a creditors' voluntary winding up. In the case of a shareholders' voluntary winding up, a special resolution of the shareholders of Mallinckrodt is required. Mallinckrodt may also be dissolved by way of court order on the application of a creditor, or by the Companies Registration Office as an enforcement measure where Mallinckrodt has failed to file certain returns. Mallinckrodt may also be dissolved by the Director of Corporate Enforcement in Ireland where the affairs of Mallinckrodt have been investigated by an inspector and it appears from the report or any information obtained by the Director of Corporate Enforcement that Mallinckrodt should be wound up.

The rights of the shareholders to a return of Mallinckrodt's assets on dissolution or winding up, following the settlement of all claims of creditors, may be prescribed in Mallinckrodt's articles of association or the terms of any preferred shares issued by the directors of Mallinckrodt from time to time. The holders of preferred shares in particular may have the right to priority in a dissolution or winding up of Mallinckrodt. If the articles of association contain no specific provisions in respect of a dissolution or winding up, then, subject to the priorities of any creditors, the assets will be distributed to shareholders in proportion to the paid-up par value of the shares held. Mallinckrodt's articles provide that the ordinary shareholders of Mallinckrodt are entitled to participate pro rata in a winding up, but their right to do so may be subject to the rights of any preferred shareholder to participate under the terms of any series or class of preferred shares.

Uncertificated Shares

Holders of ordinary shares of Mallinckrodt do not have the right to require Mallinckrodt to issue certificates for their shares. Mallinckrodt only issues uncertificated ordinary shares.

Bankruptcy Proceedings

On October 12, 2020, Mallinckrodt and certain of its subsidiaries voluntarily initiated proceedings (the "Chapter 11 Cases") under chapter 11 of title 11 ("Chapter 11") of the United States Code in the U.S. Bankruptcy Court for the District of Delaware (the "Bankruptcy Court"). In connection with the Chapter 11 Cases, Mallinckrodt anticipates that all its currently outstanding equity interests, including Mallinckrodt's outstanding ordinary shares will be cancelled and entitled to no recovery.

Stock Exchange Listing

In connection with the Chapter 11 Cases, Mallinckrodt ordinary shares were delisted from the New York Stock Exchange. Mallinckrodt ordinary shares are traded on the OTC Pink Marketplace under the symbol “MNKKQ.” Mallinckrodt ordinary shares are not listed on any Irish Stock Exchange (including Euronext Dublin) or any other exchange.

No Sinking Fund

The Mallinckrodt ordinary shares have no sinking fund provisions.

Transfer and Registration of Shares

Mallinckrodt’s official share register is maintained by its transfer agent and the transfer agent’s affiliates. Registration in this share register is determinative of membership in Mallinckrodt. A shareholder of Mallinckrodt who holds shares beneficially is not the holder of record of such shares. Instead, the depository (e.g., Cede & Co., as nominee for DTC) or other nominee is the holder of record of such shares. Accordingly, a transfer of shares from a person who holds such shares beneficially to a person who also holds such shares beneficially through the same depository or other nominee is not registered in Mallinckrodt’s official share register, as the depository or other nominee remains the record holder of such shares. Under Irish law, rights attaching to Mallinckrodt’s shares, including those outlined in this Exhibit 4.8 are generally only exercisable by the legal owner of the relevant shares on Mallinckrodt’s official Irish share register. A shareholder holding through a depository (including Cede & Co. as nominee for DTC) may only exercise such rights by either procuring the transfer of the shares from the depository into their direct legal ownership or by procuring the exercise by the depository nominee of those rights on their behalf in accordance with the applicable terms, procedures and rules of the depository.

A written instrument of transfer is required under Irish law in order to register on Mallinckrodt’s official share register any transfer of shares (i) from a person who holds such shares directly to any other person, (ii) from a person who holds such shares beneficially to a person who holds such shares directly, or (iii) from a person who holds such shares beneficially to another person who holds such shares beneficially where the transfer involves a change in the depository or other nominee that is the record owner of the transferred shares. An instrument of transfer also is required for a shareholder who directly holds shares to transfer those shares into his or her own broker account (or vice versa). Such instruments of transfer may give rise to Irish stamp duty which must be paid prior to registration of the transfer on Mallinckrodt’s official Irish share register. However, a shareholder who directly holds shares may transfer those shares into his or her own broker account (or vice versa) without giving rise to Irish stamp duty, provided there is no change in the ultimate beneficial ownership of the shares as a result of the transfer and the transfer is not made in contemplation of a sale of the shares by a beneficial owner to a third party.

Mallinckrodt has to date paid (or caused one of its affiliates to pay) stamp duty, if any, in connection with share transfers made in the ordinary course of trading by a seller who holds shares directly to a buyer who will hold the acquired shares beneficially. In other cases Mallinckrodt may, in its absolute discretion, pay (or cause one of its affiliates to pay) any stamp duty. Mallinckrodt’s articles of association provide that, in the event of any such payment, Mallinckrodt (i) may seek reimbursement from the buyer, (ii) will have a lien against the Mallinckrodt ordinary shares acquired by such buyer and any dividends paid on such shares and (iii) may set-off the amount of the stamp duty against future dividends on such shares. Parties to a share transfer may assume that any stamp duty arising in respect of a transaction in Mallinckrodt ordinary shares has been paid unless one or both of such parties is otherwise notified by Mallinckrodt. In light of the Chapter 11 Cases, Mallinckrodt may review its practice of paying stamp duty (or causing stamp duty to be paid) and there is no guarantee this practice will be continued.

Mallinckrodt’s articles of association delegate to Mallinckrodt’s secretary and certain other persons and delegates the authority to execute an instrument of transfer on behalf of a transferring party.

In order to help ensure that the official share register is regularly updated to reflect trading of Mallinckrodt ordinary shares occurring through normal electronic systems, Mallinckrodt intends to regularly produce any required instruments of transfer in connection with any transactions for which it pays stamp duty (subject to the reimbursement and set-off rights described above). In the event that Mallinckrodt notifies one or both of the parties to a share transfer that it believes stamp duty is required to be paid in connection with such transfer and that Mallinckrodt will not pay such stamp duty, such parties may either themselves arrange for the execution of the required instrument of transfer (and may request a form of instrument of transfer from Mallinckrodt for this purpose) or request that Mallinckrodt execute an instrument of transfer on behalf of the transferring party in a form determined by Mallinckrodt. In either

event, if the parties to the share transfer have the instrument of transfer duly stamped (to the extent required) and then provide it to Mallinckrodt's transfer agent, the transferee will be registered as the legal owner of the relevant shares on Mallinckrodt's official Irish share register (subject to the matters described below).

The directors of Mallinckrodt, in their absolute discretion, may decline to recognize any instrument of transfer unless (i) it is accompanied by such evidence as the directors may reasonably require to show the right of the transferor to make the transfer; (ii) it is in respect of one class of share only; (iii) it is in favor of not more than four transferees; and (iv) it is lodged at the registered office of Mallinckrodt or at such other place as the directors may appoint. In the case of a transfer of shares by means other than a sale through a stock exchange on which the shares are listed, the directors have absolute discretion and without assigning any reason therefor to decline to register such transfer of a share that is not fully paid or that is transferred to or by a minor or person of unsound mind.

The registration of transfers may be suspended by the directors at such times and for such period, not exceeding in the whole 30 days in each year, as the directors may from time to time determine.

Transfer Agent and Registrar

The transfer agent and registrar for Mallinckrodt ordinary shares is Computershare Trust Company, N.A.

Joinder Agreement

The undersigned counsel ("**Counsel**") to the Multi-State Governmental Entities Group (the "**MSGE Group**") representing the interests of the entities listed on the *Verified Statement of the Multi-State Governmental Entities Group Pursuant to Rule 2019 of the Federal Rules of Bankruptcy Procedure* [Docket No. 337] (the "**MSGE Signatories**") hereby (a) acknowledges that it has reviewed and understands the Restructuring Support Agreement (as amended, supplemented, or otherwise modified from time to time in accordance with the terms thereof, the "**Agreement**") dated as of October 11, 2020 by and among (i) Mallinckrodt plc and each of its subsidiaries listed on **Annex 1** to the Agreement, (ii) the Supporting Unsecured Noteholders, and (iii) the Supporting Governmental Opioid Claimants; and (b) acknowledges that the MSGE Signatories shall have the rights, and undertake the obligations, as the Supporting Governmental Opioid Claimants (except as otherwise expressly set forth herein) and that such rights and obligations shall be exercised by the MSGE Signatories through the MSGE Group over the matters set forth in the Agreement for which the Governmental Plaintiff Ad Hoc Committee has consent rights or obligations. For the avoidance of doubt, the MSGE Signatories acknowledge that their rights and obligations as Supporting Governmental Opioid Claimants are solely with respect to themselves and no other Supporting Governmental Opioid Claimants and the MSGE Group's rights and obligations are solely with respect to the MSGE Signatories.

In addition to the foregoing, the undersigned counsel to the MSGE Group or the MSGE Signatories agrees as follows as of the date of each of their respective execution of this Joinder Agreement:

1. **Restructuring Support**: The MSGE Signatories shall be subject to the support and other obligations set forth in Section 4(a) of the Agreement as Supporting Governmental Opioid Claimants. In addition, Counsel agrees to recommend that the members of the MSGE Group that do not become MSGE Signatories to this Joinder Agreement take the actions contemplated by clauses (A) and (B) of Section 4(a) of the Agreement.

2. **Breaches by the MSGE Group**: The Company shall be entitled to terminate the Agreement as to all of the MSGE Signatories in the event that any of the MSGE Signatories breach, in any material respect, any of the representations, warranties, or covenants given under the Agreement, and such breach remains uncured for a period of fifteen (15) Business Days after receipt by the MSGE Group from the Company of written notice of such breach, which written notice will set forth in reasonable detail the alleged breach; provided, that any such termination by the Company shall result in the termination of the Agreement solely as to the MSGE Signatories and shall not give rise to a termination right to any other Supporting Party.

3. **Termination of the Agreement by the MSGE Group**: The sole remedy of the MSGE Signatories for any breach by the Supporting Parties of the Agreement shall be termination of this Joinder Agreement by notice in accordance with the Agreement delivered by the MSGE Group with such notice terminating the Agreement as to all MSGE Signatories. If the MSGE Group terminates this Joinder Agreement, such termination shall not result in a termination of the Agreement as to the other Supporting Parties (other than the MSGE Signatories) and shall not give rise to a termination right under Section 6(a)(xix) for any such Supporting Parties or for the Company under Section 6(b)(iv). For the avoidance of doubt, and notwithstanding anything to the contrary in the Agreement or this Joinder Agreement, the MSGE Group only has the power to terminate the Agreement as to Supporting Governmental Opioid Claimants that are MSGE Signatories.

4. **Milestones:**

    a. To the extent that the Company takes any action with respect to a Milestone without the consent of the MSGE Group, the sole remedy afforded to the MSGE Signatories shall be termination of this Joinder Agreement by the MSGE Group.

    b. Counsel agrees to use best efforts to obtain the executed signature pages of the members of the MSGE Group to be appended hereto within two (2) months from the date of execution of this Joinder Agreement, which may be extended with the consent of the Company, the Governmental Plaintiff Ad Hoc Committee and the Required Supporting Unsecured Noteholders (each of whom are intended third-party beneficiaries hereunder). Failure to satisfy the obligation in this paragraph shall result in a breach of this Joinder Agreement as set forth in Section 2 above.

5. **Fees and Expenses**: So long as this Joinder Agreement is in effect, the MSGE Group's reasonable and documented fees and out-of-pocket expenses of (a) Caplin & Drysdale, Chartered, as legal counsel to the MSGE Group; (b) Seitz, Van Ogtrop & Green, P.A. as Delaware legal counsel to the MSGE Group; (c) FTI Consulting, as financial advisor to the MSGE Group; and (d) such other legal, consulting, financial, and/or other professional advisors to which the MSGE Group and the Debtors shall reasonably agree from time to time (collectively, the "**MSGE Group Professionals**") shall be paid pursuant to Section 25 of the Agreement and the Mallinckrodt Restructuring Term Sheet at 8.

6. **Notice Parties**: Notices provided pursuant to the Agreement shall be sent to the MSGE Group to the address set forth on the signature page for the MSGE Group, with copy (which shall not constitute notice) to:

   Caplin & Drysdale, Chartered
   One Thomas Circle, NW
   Suite 1100
   Washington, D.C. 20005
   Attention: Kevin C. Maclay (kmaclay@capdale.com)
   Todd E. Phillips (tphillips@capdale.com)
   Ann Weber Langley (alangley@capdale.com)

7. **Representations and Warranties**: Counsel and the MSGE Signatories hereby makes the same representations and warranties of the Supporting Parties set forth in the Agreement to each other Party, effective as of the date hereof.

8. **Governing Law:** This joinder agreement shall be governed by the governing law set forth in the Agreement.

Date: November 13, 2020

THE MULTI-STATE GOVERNMENTAL ENTITIES GROUP
By: /s/ *Kevin C. Maclay*
Name: Kevin C. Maclay
Title: Member, Caplin & Drysdale, Chartered
Address: One Thomas Circle, N.W., Suite 1100
Washington, D.C. 20005

Claims Covered by Joinder Agreement:

Opioid-related Claims as described in the *Verified Statement of the Multi-State Governmental Entities Group Pursuant to Rule 2019 of the Federal Rules of Bankruptcy Procedure* [Docket No. 337].

Schedule A

Exhibit 21.1

SUBSIDIARIES OF MALLINCKRODT PLC

The following is a list of of subsidiaries of Mallinckrodt plc as of December 25, 2020:

Name of Subsidiary	Jurisdiction of Incorporation/Organization
Acthar IP Unlimited Company	Ireland
Cache Holdings Limited	Bermuda
Carnforth Limited	Bermuda
Dritte CORSA Verwaltungsgesellschaft GmbH	Germany
Ikaria Australia Pty Ltd	Australia
Ikaria Canada Inc.	Canada
IMC Exploration Company	Maryland
Infacare Pharmaceutical Corporation	Delaware
INO Therapeutics LLC	Delaware
Ludlow LLC	Massachusetts
MAK LLC	Delaware
Mallinckrodt APAP LLC	Delaware
Mallinckrodt ARD Finance LLC	Delaware
Mallinckrodt ARD Holdings Inc.	Delaware
Mallinckrodt ARD Holdings Limited	United Kingdom
Mallinckrodt ARD IP Unlimited Company	Ireland
Mallinckrodt ARD LLC	California
Mallinckrodt Brand Pharmaceuticals LLC	Delaware
Mallinckrodt Buckingham Unlimited Company	Ireland
Mallinckrodt Canada Cooperatie U.A.	Netherlands
Mallinckrodt Canada ULC	British Columbia
Mallinckrodt CB LLC	Delaware
Mallinckrodt Chemical Holdings (U.K.) Limited	United Kingdom
Mallinckrodt Chemical Limited	United Kingdom
Mallinckrodt Critical Care Finance LLC	Delaware
Mallinckrodt Enterprises Holdings, Inc.	California
Mallinckrodt Enterprises LLC	Delaware
Mallinckrodt Enterprises UK Limited	United Kingdom
Mallinckrodt Equinox Finance LLC	Delaware
Mallinckrodt Equinox Limited	United Kingdom
Mallinckrodt Finance Management Ireland Limited	Ireland
Mallinckrodt Group S.à r.l.	Luxembourg
Mallinckrodt Group S.à r.l., Luxembourg (LU) Schaffhausen Branch	Switzerland
Mallinckrodt Holdings GmbH	Switzerland
Mallinckrodt Hospital Products Inc.	Delaware
Mallinckrodt Hospital Products IP Unlimited Company	Ireland
Mallinckrodt International Finance SA	Luxembourg
Mallinckrodt International Holdings S. à r.l.	Luxembourg
Mallinckrodt IP Unlimited Company	Ireland
Mallinckrodt LLC	Delaware
Mallinckrodt Lux IP S.à r.l.	Luxembourg
Mallinckrodt Manufacturing LLC	Delaware
Mallinckrodt Medical Holdings (UK) Limited	United Kingdom
Mallinckrodt Medical Holdings (UK) Limited, Zweigniederlassung Deutschland (the German Branch)	Germany
Mallinckrodt Netherlands B.V.	Netherlands
Mallinckrodt Petten Holdings B.V.	Netherlands
Mallinckrodt Pharma IP Trading Unlimited Company	Ireland

Mallinckrodt Pharma K.K.	Japan
Mallinckrodt Pharmaceuticals Ireland Limited	Ireland
Mallinckrodt Pharmaceuticals Limited	United Kingdom
Mallinckrodt Quincy S.à r.l.	Luxembourg
Mallinckrodt SAG Holdings GmbH	Switzerland
Mallinckrodt Securitization S.à r.l.	Luxembourg
Mallinckrodt UK Finance LLP	United Kingdom
Mallinckrodt UK Ltd	United Kingdom
Mallinckrodt US Holdings LLC	Delaware
Mallinckrodt US Pool LLC	Nevada
Mallinckrodt Veterinary, Inc.	Delaware
Mallinckrodt Windsor Ireland Finance Unlimited Company	Ireland
Mallinckrodt Windsor S.à r.l.	Luxembourg
MCCH LLC	Delaware
MEH, Inc.	Nevada
MHP Finance LLC	Delaware
MKG Medical UK Ltd	United Kingdom
MNK 2011 LLC	Delaware
Montjeu Limited	Ireland
MUSHI UK Holdings Limited	United Kingdom
OCERA Therapeutics, Inc.	Delaware
Petten Holdings Inc.	Delaware
Profibrix B.V.	Netherlands
Questcor International Limited	Ireland
Sonorant Therapeutics Limited	Ireland
SpecGx Holdings LLC	New York
SpecGx LLC	Delaware
ST 2020 LLC	Delaware
ST Operations LLC	Delaware
ST Shared Services LLC	Delaware
ST US Holdings LLC	Nevada
ST US Pool LLC	Delaware
Stratatech Corporation	Delaware
Sucampo Finance Inc.	Delaware
Sucampo GmbH	Switzerland
Sucampo Holdings Inc.	Delaware
Sucampo International Holdings Limited	United Kingdom
Sucampo Pharma Americas LLC	Delaware
Sucampo Pharma, LLC	Japan
Sucampo Pharmaceuticals, Inc.	Delaware
Therakos (Belgium) SPRL	Belgium
Therakos (Canada) Company	Nova Scotia
Therakos (France) SAS	France
Therakos (Italia) S.r.l.	Italy
Therakos (UK) Limited, Dutch Branch	Netherlands
Therakos (UK), Limited, Sucursal en Espana	Spain
Therakos (UK), Ltd	United Kingdom
Therakos (UK), Ltd (Prywatna Spólka Z Ograniczona Odpowiedzialnoscia) Oddzial W Polsce	Poland
Therakos (UK), Ltd, Sweden Filial	Sweden
Therakos EMEA Limited	Ireland
Therakos Europe Limited	Ireland
Therakos Germany GmbH	Germany
Therakos, Inc.	Florida
Vtesse LLC	Delaware

WebsterGx Holdco LLC	New York

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-189711, 333-189712, 333-189716, 333-196054, 333-203912, 333-211117 and 333-230234 on Form S-8 of our reports relating to the consolidated financial statements of Mallinckrodt plc, and the effectiveness of Mallinckrodt plc's internal control over financial reporting dated March 10, 2021, appearing in the Annual Report on Form 10-K of Mallinckrodt plc for the fiscal year ended December 25, 2020.

/s/ DELOITTE & TOUCHE LLP
St. Louis, Missouri
March 10, 2021

POWER OF ATTORNEY

Each person whose signature appears below hereby constitutes and appoints each of Mark C. Trudeau, Bryan M. Reasons and Kathleen A. Schaefer, with full power to each to act without the other, his or her true and lawful attorney-in-fact and agent with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign the Annual Report on Form 10-K of Mallinckrodt plc ("Mallinckrodt") for Mallinckrodt's fiscal year ended December 25, 2020, and any or all amendments to said Annual Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, and to file the same with such other authorities as necessary, granting unto each such attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that each such attorney-in-fact and agent, or his substitute, may lawfully do or cause to be done by virtue hereof.

Signature	Title	Date
/s/ Mark C. Trudeau Mark C. Trudeau	President, Chief Executive Officer and Director *(principal executive officer)*	March 10, 2021
/s/ Bryan M. Reasons Bryan M. Reasons	Executive Vice President and Chief Financial Officer *(principal financial officer)*	March 10, 2021
/s/ Kathleen A. Schaefer Kathleen A. Schaefer	Senior Vice President, Finance and Corporate Controller *(principal accounting officer)*	March 10, 2021
/s/ Angus C. Russell Angus C. Russell	Chairman of the Board of Directors	March 10, 2021
/s/ David R. Carlucci David R. Carlucci	Director	March 10, 2021
/s/ J. Martin Carroll J. Martin Carroll	Director	March 10, 2021
/s/ Paul R. Carter Paul R. Carter	Director	March 10, 2021
/s/ David Y. Norton David Y. Norton	Director	March 10, 2021
/s/ Carlos V. Paya Carlos V. Paya	Director	March 10, 2021
/s/ JoAnn A. Reed JoAnn A. Reed	Director	March 10, 2021
/s/ Anne C. Whitaker Anne C. Whitaker	Director	March 10, 2021
/s/ Kneeland C. Youngblood, M.D. Kneeland C. Youngblood, M.D.	Director	March 10, 2021

Exhibit 31.1

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

I, Mark C. Trudeau, certify that:

1. I have reviewed this annual report on Form 10-K of Mallinckrodt plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in the Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2021

By: /s/ Mark C. Trudeau

Mark C. Trudeau

President and Chief Executive Officer and Director
(principal executive officer)

Exhibit 31.2

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

I, Bryan M. Reasons, certify that:

1. I have reviewed this annual report on Form 10-K of Mallinckrodt plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in the Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2021

By: /s/ Bryan M. Reasons

Bryan M. Reasons

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

Exhibit 32.1

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

The undersigned officers of Mallinckrodt plc ("the Company") hereby certify to their knowledge that the Company's annual report on Form 10-K for the annual period ended December 25, 2020 ("the Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Mark C. Trudeau
Mark C. Trudeau
President and Chief Executive Officer and Director
March 10, 2021

By: /s/ Bryan M. Reasons
Bryan M. Reasons
Executive Vice President and Chief Financial Officer
March 10, 2021