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 31, 2021
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 25, 2021, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $38.9 million (based upon the closing price of $0.46 per share as reported by the Pink Open Market on that date).

The number of shares of the registrant's common stock outstanding as of March 11, 2022 was 84,734,080.

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 31, 2021, 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 (in examination under Part 10 of the Irish Companies Act 2014), 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, ophthalmology and oncology; immunotherapy and neonatal respiratory critical care therapies; analgesics; cultured skin substitutes 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, where our Specialty Brands global external manufacturing operations are also located. 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. Subsequent to the filing of the Chapter 11 Cases, Chapter 11 proceedings commenced by a limited subset of the Debtors have been recognized and given effect in Canada, and separately Mallinckrodt plc has commenced an examinership process with the High Court of Ireland. The references to the Chapter 11 Cases included within this Annual Report on Form 10-K shall include, where applicable, such proceedings in Canada and Ireland. 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 agreements in principle subsequently memorialized in our Chapter 11 plan of reorganization.

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 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.

Although the Bankruptcy Court entered an order (the "Confirmation Order") confirming the fourth amended plan of reorganization (with technical modifications) proposed by the Debtors (the "Plan"), consummation of such plan of reorganization and the transactions contemplated thereby and emergence from the Chapter 11 proceedings remains subject to the satisfaction of various conditions, including completion of the Canadian and Irish proceedings noted above. Accordingly, no assurance can be given that the Plan or transactions contemplated thereby 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, is publicly available at https://restructuring.primeclerk.com/Mallinckrodt/.

Fiscal Year

We report our results based on a "52-53 week" year ending on the last Friday of December. Fiscal 2021 consisted of 53 weeks and fiscal 2020 and 2019 each consisted of 52 weeks.

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, ophthalmology and oncology; immunotherapy and neonatal respiratory critical care therapies; analgesics; cultured skin substitutes and gastrointestinal products. Our diversified, in-line portfolio of both marketed and development products is focused on patients with significant unmet medical needs.

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, oncologists, neonatologists, surgeons and pharmacy directors) with our own direct sales force of almost 350 sales representatives as of December 31, 2021. 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 a complex mixture of peptides approved by the U.S. Food and Drug Administration ("FDA") for use in 19 indications. The product currently generates substantially all of its net sales from 11 of the on-label indications, including adjunctive therapy for short-term administration for an acute episode or exacerbation in rheumatoid arthritis ("RA"), including juvenile RA; monotherapy for the treatment of infantile spasms in infants and children under 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 that 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 that increases fluid secretion and motility of the intestine, facilitating passage of stool. Of the branded products currently marketed, only Amitiza is approved for three constipation indications in the U.S.

- *StrataGraft® (allogenic cultured keratinocytes and dermal fibroblasts in murine collagen - dsat) ("StrataGraft")* regenerative skin tissue is an allogeneic cellularized scaffold product derived from keratinocytes grown on gelled collagen containing dermal fibroblasts indicated for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns). StrataGraft is designed to deliver viable cells to support the body's own ability to heal. StrataGraft contains metabolically active cells that produce and secrete a variety of growth factors and cytokines. Growth factors and cytokines are known to be involved in wound repair and regeneration. The product is designed with both dermal and epidermal layers composed of well-characterized human cells. StrataGraft is intended to be applied in appropriate aseptic conditions, such as the operating room, and can be sutured, stapled or secured with a tissue adhesive.

  The FDA granted StrataGraft orphan drug designation, and it was among the first products designated by the FDA as a Regenerative Medicine Advanced Therapy (RMAT) under the provisions of the 21st Century Cures Act. At the time of approval, the FDA awarded us a Priority Review Voucher (PRV). In June 2021, the FDA had approved the StrataGraft biologics license application ("BLA") for deep partial-thickness. We are currently conducting a StrataGraft continued access clinical trial under an expanded access program. The trial sites involved in the pivotal Phase 3 trial have the opportunity to participate in this multicenter, open-label study. We also are currently conducting a Phase 2 trial to evaluate StrataGraft for the treatment of adults with full-thickness burns (also referred to as third-degree burns) and a pediatric study evaluating StrataGraft in the treatment of pediatric populations.

The Biomedical Advanced Research and Development Authority ("BARDA") expressed interest in StrataGraft as a medical countermeasure in response to large-scale burn incidents, and provided funding and technical support for the continued development of StrataGraft. These efforts are part of BARDA's strategy to build emergency preparedness in response to mass casualty events involving trauma and thermal burns by developing novel medical countermeasures for adult and at-risk populations. In the case of a mass casualty thermal burn event, the Government Accountability Office estimates that more than 10,000 patients might require thermal burn care. The limited number of specialized burn centers and related medical infrastructure in the U.S. creates a public health need for therapies that could be deployed quickly for use in these and other care sites.

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 several new products in the next few years, 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 with manufacturing facilities exclusively in the U.S. We manufacture controlled substances under the Drug Enforcement Administration ("DEA") quota restrictions, and in calendar 2021, we estimated that we received approximately 36.0% 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

Specialty Brands. Our research and development ("R&D") resources are primarily devoted 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 could not approve the terlipressin NDA in its current form and required 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. On August 18,

2021, we resubmitted our NDA to the FDA and on February 18, 2022 (the Prescription Drug User Fee Act, or "PDUFA", date), the FDA issued a CRL. In the weeks leading up to the PDUFA date, it became necessary for us to identify a new packaging and labeling manufacturing facility, which meant that an inspection of the FDA could not be completed by the PDUFA date. A satisfactory inspection is required before the NDA can be approved. This is the only outstanding issue noted in the CRL, and it is important to note that there were no safety or efficacy issues cited. We are working with the new facility to have it ready for inspection by the FDA. We remain committed to this critically ill patient population, who currently have no approved treatment option in the U.S for HRS-1 and we believe that there is a path to approval in 2022.

- SLN 501 is a ribonucleic acid ("RNA") silencing 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 SLN501, and in September 2020, we exercised an option for two additional complement protein targets under the collaboration. In 2022, we plan to initiate a Phase 1 clinical trial for SLN501 and will continue to advance the additional complement protein targets.

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 five Abbreviated New Drug Applications ("ANDAs") at various stages of review with the FDA and a diverse portfolio of oral, solid and parenteral formulations under development. Our pipeline is focused on applying our capabilities to develop difficult formulations, utilizing our expertise in working with controlled substances to develop potent products, and expanding both our therapeutic and technology platforms into areas with less competitive pressure. We utilize our proven abilities to design around competitor patents to 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. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our branded products offer not only superior health outcomes but also cost and service advantages, as compared with other forms of care. For example, while there is no therapeutically substitutable generic alternative for Acthar Gel, it faces significant competition from alternative forms of treatment, and is generally prescribed when earlier-line treatments have failed to provide positive outcomes or are not well tolerated by the patient. We anticipate that competition will likely intensify following ANI Pharmaceuticals Inc.'s ("ANI") commercial launch of their purified cortrophin gel product during the first quarter of 2022.

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 the next generation delivery system will help to differentiate the product and 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, 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.

Prior to our acquisition of Amitiza in February 2018, the previous owner had entered into agreements to license certain rights to Amitiza to third parties in exchange for royalties on net sales of the product. We receive a double-digit royalty 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 for the agreement with Par Pharmaceuticals, Inc. et al. (collectively "Par") if two or more generics or authorized generics are commercially marketing a generic product in addition to Par. Refer to Note 19 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K for further information regarding patent litigation in relation to Amitiza.

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 addition, commercial durability may also partially depend upon product-related trade secrets, confidentiality agreements and trademark and copyright laws. These additional items may not prevent competitors from independently developing similar technology or a bioequivalent product.

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. 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. 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.

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.

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 approves pharmaceuticals through three distinct pathways. First, in order to market and sell a new prescription non-biologic drug product in the U.S., a drug manufacturer must file a NDA with the FDA 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. Second, 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. Third, 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.

The FDA typically uses different approval pathways for medical devices. To market and sell a new medical device in the U.S., the manufacturer generally must follow one of two paths. First, a manufacturer could follow what is known as pre-market notification or the 510(k) process. This process requires the manufacturer to demonstrate that the medical device is substantially equivalent to a legally marketed medical device. The second process, pre-market approval, is a more stringent time-consuming process. This requires that the medical device is independently proven to be safe and effective for its intended use.

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 good laboratory practice ("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 good clinical practice ("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.

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 PDUFA, 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 2022, the user fee rate has been set at $3,117,220 for a 505(b)(1) NDA and $1,558,610 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 a NDA, a BLA is submitted to the FDA in order to market a new drug in the U.S., 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.

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. 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 2022 user fee rate is set at $225,710 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 2022.

Medical Devices. There are two primary pathways to receive authorization to distribute a new device in the U.S. The first pathway is premarket notification (the 510(k) process). Under this pathway, the applicant must demonstrate to the FDA that the new device is as safe and effective or substantially equivalent to a legally marketed device. The applicant can demonstrate this by submitting data. This data may be from human clinical trials. The FDA will make a determination as to whether the new device is substantially equivalent before commercial distribution occurs. Changes that do not significantly affect the safety or efficacy of a legally marketed device may generally be made without additional 510(k) premarket notifications.

The second primary pathway is a premarket approval application ("PMA"). This pathway is generally more complex, time-consuming and expensive than the 510(k) process. Under the PMA pathway, the applicant must demonstrate that the device is safe and effective for its intended use. This generally requires data from clinical trials to show the safety and efficacy of the device. These trials must be performed in accordance with the applicable Investigational Device Exemption (IDE) regulations. The FDA will approve the application if it finds that the evidence is scientifically valid to demonstrate that the device is safe and effective for its intended use.

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. 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 goal of these programs is to mitigate the risk of abuse, misuse, overdose and accidental exposure as well as educating prescribers, pharmacists, healthcare providers and patients about the safe use of the drug product or class of drug products and the treatment and monitoring of patients. 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. We participate in the Transmucosal Immediate Release Fentanyl (TIRF) REMS Program, Opioid Analgesic REMS, Buprenorphine Transmucosal Products for Opioid Dependence REMS (BTOD REMS), Vigabatrin REMS and other such REMS programs.

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 2021, manufacturing and procurement quotas granted by the DEA were sufficient to meet our sales and inventory requirements on most products. In December 2021, 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 2022. 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 prescription drug coverage program for people with Medicare through a 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 $106.5 million, $665.3 million and $75.9 million in fiscal 2021, 2020 and 2019, respectively. The fiscal 2021 decrease in provision for Medicaid payments was due to the $536.0 million retrospective one-time charge related to the Medicaid lawsuit in fiscal 2020 that is further discussed within Note 19 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K. The remaining $22.8 million decrease in the fiscal 2021 provision for Medicaid payments was primarily due to a $21.7 million decrease in Specialty Brands associated with Acthar Gel. The fiscal 2020 provision was impacted by the aforementioned retrospective one-time charge related to the Medicaid lawsuit. The remaining $53.4 million increase in the fiscal 2020 provision for Medicaid payments, as compared to fiscal 2019, was driven by 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. Our business was also impacted by the annual fee on branded prescription pharmaceutical manufacturers, which is reflected within selling, general and administrative expenses ("SG&A"). During fiscal 2021, we recorded a gain of $1.0 million driven primarily by favorable adjustments by the Internal Revenue Service ("IRS") for prior periods primarily related to the Medicaid lawsuit ruling. Comparatively, during fiscal 2020 and 2019, we recorded an expense of $11.6 million and $20.1 million, respectively.

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 (HIPPA). 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 legal and 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. Department of Justice Guidance on the Evaluation of Corporate Compliance Programs, 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 integrity and compliance reporting hotline with a strict policy of non-retaliation. Our compliance programs are implemented and facilitated by our Chief Compliance Officer, who reports to the Chief Executive Officer ("CEO") and the Governance and Compliance Committee of our Board of Directors. The Compliance function is independent of the manufacturing and commercial operations functions.

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, mislabeling or making false or misleading claims about our products through our promotional efforts. In addition, we monitor business activities through our compliance monitoring program including: sales representatives expenses, promotional speaker activities and a "ride along" program for compliance to observe field sales representatives interacting with healthcare professionals similar to those included in recent Corporate Integrity Agreements from the OIG. 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 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, among other things, 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 SOM and reporting. The Operating Injunction further requires Mallinckrodt to make available certain clinical data through a third-party data archive and publicly disclose certain produced documents related to the opioid litigation. The Operating Injunction provides that Mallinckrodt must retain an independent monitor to evaluate and audit compliance with the Operating Injunction for a term of five to seven years. On February 8, 2021, the Bankruptcy Court entered an order appointing R. Gil Kerlikowske to serve as monitor.

The monitor has since filed four compliance reports with the Bankruptcy Court describing his work and making certain recommendations regarding potential enhancements to the Company's processes that the Company has worked to implement. The Company has, among other actions, retained a consulting firm with expertise in data analytics to consult regarding the Company's SOM program; enhanced the Company's internal system for customer inquiries and concerns to encourage further collaboration across business units; and implemented a plan to audit state and federal lobbying activity to monitor compliance with the Operating Injunction.

In connection with the Proposed Acthar Gel-Related Settlement, the Company entered into a corporate integrity agreement ("CIA") with the OIG of the HHS in March 2022.

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 European Medicines Agency ("EMA") and member states of the European Union ("E.U."), the Therapeutic Goods Administration in Australia, 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 19 to the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

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

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, oncologists, neonatologists and surgeons), other health care providers including respiratory therapists, 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 2021, 2020 and 2019 were as follows:

	Fiscal Year		
	2021	2020	2019
CuraScript, Inc.	26.1 %	27.4 %	29.7 %
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 31, 2021, 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 93.5%, 4.2% and 2.3% of our manufacturing production (as measured by cost of production) was performed within the U.S., Ireland and Japan, respectively, in fiscal 2021.

As of December 31, 2021, 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.

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

At Mallinckrodt, we value our employees as our most important asset. We aim to create a culture and a work environment that is inclusive and that welcomes diverse experiences and perspectives. We work hard to identify, retain and attract a diverse workforce that shares our corporate vision to improve the lives of underserved patients with severe and critical conditions. We believe that in doing this, it will make us stronger and more innovative. We invest in human resources programs designed to develop capabilities to deliver on our critical business priorities. We do this by offering competitive pay and benefit programs, investing in our employees' growth and development and creating a safe and healthy work environment. We embrace diversity and empower each individual employee to bring their whole, authentic self to work. Further, we encourage and support our employees to be active members of their communities.

We employ a multi-national workforce of approximately 2,800 people as of December 31, 2021. As an innovative biopharmaceutical company, 21.7% of our employees are field-based and work across multiple countries engaging with healthcare professionals and facilities. Our products are developed by a workforce with specialized degrees in science, engineering and technology. Our manufacturing and distribution locations across the U.S., Ireland and Japan make up 52.8% of our workforce; 25.5% of our employees work within our science and technology and corporate services locations of Hampton, New Jersey; Hazelwood, Missouri; Webster Groves, Missouri; Staines, U.K. and Dublin, Ireland. Of our total workforce, 99.2% are full time.

Employee Benefits and Well-being

We believe in providing comprehensive and competitive benefits our employees value, designed to be equitable and meet their diverse and unique needs. We are intentional about building inclusivity into our benefits strategy.

In the U.S., Mallinckrodt provides:

- Up to four weeks of paid caregiver leave to help eligible employees deal with family responsibilities;
- Medications at zero employee cost to promote medication adherence for certain chronic medical conditions; and
- Fertility benefits that provide equitable benefits to same-sex couples.

Mallinckrodt also offers a variety of advocacy support resources for employees and their families, including:

- Clinical support for infertility, maternity, oncology, inpatient care, musculoskeletal conditions, congenital heart disease and transplant situation;
- Second opinion services for new or existing medical issues by board-certified, elite specialists at zero cost to employees; and
- Behavioral Health Advocacy to assist employees and their families with complex behavioral health concerns.

Additionally we leverage our well-being platform by collaborating with our diversity focused Business Resource Groups ("BRGs") to provide resources and activities to support their specific goals.

During the pandemic, we have continued to listen to the needs of employees and their families and have responded by implementing new resources and enhanced benefits.

Talent Development and Employee Engagement

We are committed to a culture of continuous learning, aimed at advancing our workforce through personal and professional development. Our talent strategies are aligned to business priorities creating opportunities for our employees to grow and develop. We offer a wide range of leadership and individual development offerings, 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 partner with external organizations and invest in programs specifically aimed at advancing diverse talent. We have established processes to identify and align individual employee aspirations with business needs so that development and succession planning can occur. These processes have yielded positive results in the advancement of high potential and diverse talent. We create opportunities to advance our talent through development assignments, on-the-job training and career advancement. Our learning platforms are designed to provide flexibility to meet the needs, interests and aspirations of all employees.

At Mallinckrodt, we value employee feedback. We are intentional about creating a culture where employees can speak freely and are empowered to ask questions. We create opportunities to solicit feedback from employees through one-on-one sessions, focus groups and employee surveys. These forums have and will continue to provide us the opportunity to ensure our employees are engaged and supported both personally and professionally. The introduction of hybrid working in 2021 is just one example of a program that was derived as a result of employee feedback.

Inclusion and Diversity ("I&D")

We strive to foster an inclusive work environment and a diverse workforce that reflects the customers and patients we serve. We believe the unique and diverse perspectives of our employees enable us to better understand and respond to our patients' needs.

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. Our employee-led I&D Council and BRGs play key roles in cultivating and inspiring a more inclusive culture. These groups are open to anyone and are typically centered on shared interests, identities and affiliations. Our BRGs provide resources for professional development, personal growth, community engagement, well-being and networking, all while fostering connectivity and enhancing our unique culture.

Our approach to I&D continues to receive national recognition, most recently being recognized as a "Best Places to Work for LGBTQ Equality" for six consecutive years from the Human Rights Campaign Foundation's Corporate Equity Index.

Social and Community Responsibility

Giving back to local communities has been a long-standing tradition of ours for more than 150 years. Our culture of philanthropy stretches beyond simply doing good for others; it's about driving meaningful changes in our communities to make a positive impact on the world. Our social impact strategy focuses on improving the health and well-being of patients, building stronger communities, and empowering our employees to dedicate their time and resources to the causes they care about most. We provide grants to nonprofits worldwide and support employees with their own philanthropy through volunteerism and giving programs.

Corporate Charitable Giving Program

Mallinckrodt provides patient-related and philanthropic support to nonprofit organizations that are aligned with our mission to address unmet needs with innovative solutions. Our patient-centric charitable contributions support initiatives and programs that have broad public benefit and advance medical care and/or patient care within the Company's therapeutic areas of focus. Our community-based investments are centered in three strategic areas – improving health and wellness; advancing science, technology, engineering and mathematics ("STEM") education; and stimulating jobs and economic growth in life sciences.

Throughout the pandemic we have contributed to efforts to advance health equity in research, treatment, patient experience and health outcomes for Black, Indigenous and people of color. We are collaborating with patient advocacy organizations to improve engagement with these communities and promote greater awareness of health disparities in our key therapeutic areas of focus. For example, Mallinckrodt has supported:

- *NephCure Kidney International* to launch a new Health Equity Initiative aimed at creating more equitable access to research and care for underrepresented individuals living with, or are at high risk of developing, chronic kidney diseases.
- *The Arthritis Foundation* to improve health outcomes for populations that have traditionally been inadequately represented in research, treatment and policy.

In 2021, we supported STEM education and expanded educational opportunities for minority students to help combat the lingering disparities in education. Examples of 2021 grant support include:

- *Students 2 Science*, a New Jersey-based nonprofit that inspires and educates students in underserved communities to pursue STEM careers.
- *The St. Louis Black Authors of Children's Literature*, a nonprofit in St. Louis, Missouri that spearheads the Believe Project – which builds literacy labs in schools and community centers that provide kids consistent access to black children's literature as a strategy for improving reading proficiency.
- *Maydm, Inc.*, a nonprofit in Madison, Wisconsin that provides girls and youth of color in grades 6-12 with skill-based training in STEM fields.

Employee Giving and Volunteerism

We believe that our employees are the cornerstone of our corporate citizenship efforts, and we provide opportunities for them to embrace their passions and amplify their philanthropic impact. Our volunteerism program provides eight hours of paid time off to eligible employees annually for qualified volunteer activities, in addition to time off to participate in our global month of service that's held every October. To encourage charitable giving, we match U.S. employee donations to eligible nonprofit organizations. We also activate special matching opportunities during times of disaster or crisis.

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 (and related proceedings in Canada and Ireland).
- 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 Plan and the RSA are subject to significant conditions and milestones that may be difficult for us to satisfy. We must also raise financing to fund certain distributions under the Plan, which may not be available on favorable terms or at all.
- If the RSA is terminated, our ability to consummate 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.
- If the confirmed Plan is not consummated, 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.
- Certain key aspects of the plan of reorganization must be implemented through an examinership process in Ireland. The examinership process is overseen by the High Court of Ireland and the outcome of those proceedings is a matter within the discretion of the High Court of Ireland. While we believe that the examinership will result in the implementation of those Irish law aspects of the plan of reorganization, there is no guarantee that such implementation will occur.

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 reputation, business, financial condition, results of operations and cash flows.
- Our business may be adversely affected by public health crises and epidemics/pandemics, including the on-going coronavirus pandemic.
- 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 face significant competition and may not be able to compete effectively.
- We may experience pricing pressure on certain of our products due to competitor's product entries, 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.
- Our customer concentration may materially adversely affect our business.
- Our product concentration may materially adversely affect our business.
- 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 attract and retain 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.
- 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 make ongoing payments in respect of 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 (and related proceedings in Canada and Ireland).

The Chapter 11 Cases could have a material adverse effect on our business, financial condition, results of operations and cash flows. Although the Bankruptcy Court has entered the Confirmation Order confirming the Plan, consummation of the Plan and emergence from the Chapter 11 Cases remains subject to the satisfaction of certain conditions. 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. As described above, subsequent to the filing of Chapter 11 Cases, the Chapter 11 proceedings commenced by a limited subset of the Debtors have been recognized and given effect in Canada, and separately Mallinckrodt plc has commenced an examinership process with the High Court of Ireland. The references to the Chapter 11 Cases included herein shall include, where applicable, such proceedings in Canada and Ireland.

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:

- court rulings in the Chapter 11 Cases or any appeals therefrom, including rulings on appeals of the Bankruptcy Court's orders confirming the Plan, determining that no premium is payable in connection with the reinstatement of certain of our debt and denying the motion of certain Acthar Insurance Claimants, as defined 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, for allowance of an administrative claim and the outcome of any motion seeking a stay in respect of the Bankruptcy Court's order confirming the Plan or any other motions or requests made to the Bankruptcy Court or any other court relating to the Chapter 11 Cases;
- any court determination that the consummation of the Plan does not render moot challenges thereto (including any appeals of the Bankruptcy Court's orders confirming the Plan, determining that no premium is payable in connection with the reinstatement of certain of our debt and denying the motion of certain Acthar Insurance Claimants for allowance of an administrative claim);
- 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 negotiate and enter into definitive documentation regarding the transactions contemplated by the Plan;
- our ability to satisfy the conditions to consummation of the Plan and ultimately consummate the Plan;
- our ability to raise financing, on favorable terms or at all, sufficient to fund the distributions provided for in the Plan, including the repayment of the revolving credit facility;

- 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, that such milestones will not be extended and that the RSA or such cash collateral arrangement will be terminated;
- 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 and the Bankruptcy Court has entered the Confirmation Order, but there can be no assurance that we will be able to satisfy the conditions to consummate the Plan or ultimately 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, results of operations and cash flows 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 Plan and the RSA are subject to significant conditions and milestones that may be difficult for us to satisfy. We must also raise financing to fund certain distributions under the Plan, which may not be available on favorable terms or at all.

Although the Bankruptcy Court has entered the Confirmation Order, there are certain material conditions we must satisfy under the Plan and the RSA, including the timely satisfaction of milestones in the Chapter 11 Cases, which include the consummation of the Plan. Our ability to timely satisfy such conditions and complete such milestones is subject to risks and uncertainties, many of which are beyond our control. In addition, we must raise additional financing to fund certain distributions under the Plan, including the repayment of our revolving credit facility. Such financing may not be available on favorable terms or at all.

If the RSA is terminated, our ability to 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 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.

Until consummation of the Plan, 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. 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. If we are unable to satisfy the conditions to consummate the Plan and ultimately consummate the Plan, we believe that conversion of the Chapter 11 Cases to a case under Chapter 7 of the Bankruptcy Code may become likely. 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.

If the confirmed plan is not consummated, 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 March 8, 2022, and the exclusive right to solicit acceptances of any such plan through May 10, 2022. 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. We filed a motion with the Bankruptcy Court to extend such deadlines to the statutory maximum and such motion is pending. 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 we are unable to satisfy the conditions to consummate the Plan and ultimately consummate the Plan, we believe that such termination or expiration may become more likely.

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 consummation of a plan of reorganization discharges a debtor from substantially all debts arising prior to consummation of such plan of reorganization. Subject to certain exceptions, all claims that arose prior to consummation of such 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 such plan of reorganization (such as claims falling within the exceptions noted above) 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 have experienced and may continue to 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. Furthermore, the new owners of the Company will have the authority to appoint the board of directors upon emergence from bankruptcy, and that new board will also have the authority to appoint a Chief Executive Officer, which could have an impact on the current composition of the senior management team, which could have a material impact on our business. 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.

Until the Plan is consummated, we will continue to operate our business under supervision by the Bankruptcy Court, and in the case of Mallinckrodt plc, the supervision of the examiner appointed by the High Court of Ireland (the "Examiner"). While we do so, we are required to obtain approval of the Bankruptcy Court, and in some cases certain other parties (including the Examiner), 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 (or in the case of Mallinckrodt plc, the Examiner) 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.

Certain key aspects of the plan of reorganization must be implemented through an examinership process in Ireland. The examinership process is overseen by the High Court of Ireland and the outcome of those proceedings is a matter within the discretion of the High Court of Ireland. While we believe that the examinership will result in the implementation of those Irish law aspects of the plan of reorganization, there is no guarantee that such implementation will occur.

The implementation of the plan of reorganization confirmed by the Bankruptcy Court (and consequently the emergence from Chapter 11) is dependent on a number of conditions precedent. Since we are incorporated in Ireland, one of the conditions precedent is the implementation of certain key aspects of the plan through an examinership process under the laws of Ireland. Under this process, the High Court of Ireland has appointed an independent bankruptcy official, known as the Examiner, to review our business, including the plan, and, if considered appropriate by the Examiner, propose a scheme of arrangement to the creditors and members of the Company that will implement certain key Irish law aspects of the plan. If accepted by the majority in number and value of at least one class of impaired creditor, the Examiner will apply to the High Court of Ireland for an order confirming the scheme of arrangement. We also believe that the Examiner will consider it appropriate to propose a scheme of arrangement that is complementary to the plan of reorganization, and that such a scheme of arrangement should be confirmed by the High Court of Ireland. However, any decision to confirm any such scheme of arrangement is subject to the discretion of the High Court of Ireland, and the decision as to whether or not to propose a scheme of arrangement as outlined above is subject to the discretion of the Examiner, and there is no guarantee that such approval will be forthcoming. In the event that such approval is not forthcoming, it may be necessary to amend the plan of reorganization, propose an amended scheme of arrangement and/or consider other restructuring or strategic options, including the liquidation of the Company.

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 reputation, 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 14, 2022, the cases we are aware of include, but are not limited to, approximately 2,619 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 eight 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 14, 2022, 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.

We have implemented steps to comply with an Operating Injunction enjoining certain Mallinckrodt entities from engaging in certain conduct related to the manner in which they operate their opioid business. The Operating Injunction prohibits, among other things, 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 further requires Mallinckrodt to make available certain clinical data through a third-party data archive and publicly disclose certain produced documents related to the opioid litigation. 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 February 8, 2021, the Bankruptcy Court entered an order appointing R. Gil Kerlikowske to serve as monitor. The obligations imposed by the Operating Injunction apply both while Mallinckrodt is in bankruptcy and after Mallinckrodt emerges from bankruptcy and would apply to the operation of Mallinckrodt's opioid business by any subsequent purchaser. The Operating Injunction imposes material limitations on Mallinckrodt's business in addition to those imposed by otherwise applicable law. Those limitations may have an adverse financial impact on Mallinckrodt's opioid business, including but not limited to by increasing overhead costs or reducing product sales. A violation of the Operating Injunction may also subject the company to adverse action by the Bankruptcy Court, state and territory Attorneys General, or other enforcement authorities, as well as increased legal fees and costs associated with such actions.

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 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 filed a petition for certiorari with the Supreme Court, which was denied. On October 21, 2021, the District Court vacated its December 19, 2018 order, except for its invalidation of the "pass through prohibition" on the basis it violates the Commerce Clause. In April 2019, the State of New York passed its 2020 budget, which amended the OSA so that 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, additional states have enacted opioid taxes or enacted increased licensure and registration fees. Other states may consider 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 price increases, 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 captioned "*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 on-going coronavirus pandemic.

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, the novel coronavirus ("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. 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, and such pressures could result in future 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 even though the pandemic may have abated. 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 for documents related to our payments to charitable foundations, the provision of financial and other support by charitable foundations to patients receiving Acthar Gel, and related matters. We have responded to these requests and cooperated in the investigation.

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 reputation, 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. Our failure to compete effectively could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

As to competition for our specific products:

- Acthar Gel—Given the recent approval by the FDA of a competitor's purified cortrophin gel product for the treatment of certain chronic autoimmune disorders (including acute exacerbations of multiple sclerosis and rheumatoid arthritis as well as excess urinary protein due to nephrotic syndrome), we anticipate that competition will likely intensify following the commercial launch of this product during the first quarter of 2022, which could have an adverse effect on our financial condition, results of operations and cash flows.
- INOmax—We have seen increased competition following the launch of a competitive nitric oxide product before the expiration of the last of the listed patents on May 3, 2026 (November 3, 2026 including pediatric exclusivity), which has had an adverse effect on our ability to successfully maximize the value of INOmax, and if it continues, could have an adverse effect on our financial condition, results of operations and cash flows.

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 experience pricing pressure on certain of our products due to competitor's product entries, 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 our acquisition of the product. Acthar Gel represented 26.9% of our net sales for fiscal 2021. 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. On December 10, 2021, the committee issued its final majority report detailing findings from the investigation. 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 effectiveness of the Proposed Acthar Gel-Related Settlement, we will dismiss our D.C. Circuit appeal. We have also entered into a five-year CIA agreement with the OIG of the HHS, which took effect in March 2022. The failure of the settlement 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;
- multiple product launches in a short period of time may be challenging, particularly for an organization that has not launched a new product in many years, and may result in strained resources that could lead to launch delays and cost;
- other 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, marketing and distribution 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.

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.

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, a broader-scale launch of competitive nitric oxide products has taken place in the market which has adversely impacted our business and may continue to 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”). 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 2037.

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. The completion of 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.

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 19 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on

Form 10-K. If any of these legal proceedings, inquiries or investigations were to result in an adverse outcome, the impact could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

With respect to product liability and clinical trial risks, in the ordinary course of business we are subject to liability claims and lawsuits, including potential class actions, alleging that our marketed products or products in development have caused, or could cause, serious adverse events or other injury. Any such claim brought against us, with or without merit, could be costly to defend and could result in an increase in our insurance premiums. We retain liability for $10.0 million per claim of the first $50.0 million of a loss in our primary liability policies and purchase an additional $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 31, 2021, it was probable that we would incur remediation costs in the range of $72.3 million to $120.9 million. We also concluded that, as of December 31, 2021, the best estimate within this range was $95.8 million, of which $52.0 million was classified as liabilities subject to compromise as of December 31, 2021. For further information on our environmental obligations, refer to Note 19 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K. 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. See 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.*"

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

One of our business strategies includes evaluating potential business development opportunities to potentially 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 attract and retain 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.

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 2021, 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 2022, 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 determine to no longer partner with us, 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. anti-bribery laws such as the FCPA and similar 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 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 organizational 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 $5,448.4 million as of December 31, 2021. 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 2,800 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 31, 2021, 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 make ongoing payments in respect of the Proposed Settlements.

We have substantial indebtedness. As of December 31, 2021, total debt principal was $5,145.8 million, of which $1,395.0 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 (including our indebtedness and our obligations in respect of the Proposed Settlements) 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 and our ongoing obligations in respect of the Proposed Settlements;

- 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 or make prepayments of our ongoing obligations in respect of the Proposed Settlements 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," although the Plan has been confirmed, it has not yet been consummated and 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 existing indebtedness contain, and the agreements that will govern our restructured indebtedness following emergence from bankruptcy are expected to 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, junior secured or unsecured debt and, with respect to certain of our restructured indebtedness following emergence from bankruptcy, certain deferred settlement obligations;
- 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 existing 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. Following emergence from the Chapter 11 Cases, we expect to pay interest on all of our indebtedness as it accrues. Certain of our secured indebtedness, including borrowings under our existing senior secured credit facilities, is or is expected to be, as applicable, 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 31, 2021, we had $1,767.2 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 existing indebtedness restrict (and agreements governing our post-emergence indebtedness are expected to 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. The Financial Conduct Authority also announced that certain of the commonly used LIBOR tenors will continue to be published until June 30, 2023; however, the Federal Reserve, Federal Deposit Insurance Corporation and the Office of the Comptroller of Currency (and certain other government agencies) in the U.S. as well as the Financial Conduct Authority announced that all market participants should stop using LIBOR in new contracts after December 31, 2021, subject to limited exemptions. Accordingly, new contracts entered into after December 31, 2021, generally must utilize an alternative reference rate. Certain of our existing indebtedness, including our existing senior secured credit facilities, bears interest (and certain of our post-emergence indebtedness may bear interest) at rates that are indexed to LIBOR. Changes in the method of calculating LIBOR, or the replacement of LIBOR with an alternative rate or benchmark, may adversely affect interest rates on our current or future indebtedness 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, results of operations and cash flows.

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.

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 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 proposed framework of the Biden administration's Build Back Better Act, the OECD's model rules for Pillar Two and the creation of a 15% minimum global effective tax rate 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 managed the affairs of Mallinckrodt plc so that it was effectively managed and controlled in the U.K. and therefore treated as resident only in the U.K. for tax purposes, by operation

of the Double Taxation Convention. However, if subject to any review by applicable tax authorities, 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. The Board of Directors does not currently have such pre-authorization as we did not seek to renew this authority at the 2021 Annual General Meeting. 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. We do not have any such opt-out in place as we did not seek to renew this opt-out at the 2021 Annual General Meeting. The Company currently proposes that a five-year pre-authorization of the Board of Directors to issue shares and opt-out of pre-emption rights be included in the Company's constitution to be adopted with effect from the emergence from Chapter 11 and the effectiveness of the adoption of the scheme of arrangement and the conclusion of the examinership proceedings in Ireland; however the terms of such scheme and revised constitution, including the pre-authorization of the Directors to issue shares and opt-out of pre-emption rights, will be subject to the discretion of the Examiner and, ultimately, approval of the High Court of Ireland. If such an authority is not included in the constitution, it is the Board of Directors' current intention that a pre-authorization of the Directors to issues shares and opt-out of pre-emption rights will be sought at the Annual General Meeting to be held in 2022, assuming the emergence by the Company from Chapter 11 and the examinership proceedings. We cannot guarantee that renewal of the pre-authorization or 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 from the New York Stock Exchange ("NYSE") has resulted 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, which has been confirmed, but consummation of which remains subject to the satisfaction of certain conditions, 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 31, 2021, 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 0.5 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, antitrust matters, securities class action lawsuits, personal injury claims, employment disputes, contractual and other commercial disputes, and other legal proceedings, in the ordinary course of business. 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 19 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K, which is incorporated by reference into this Part I, Item 3.

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 Pink Open Market (formerly known as the OTC Pink Marketplace) on October 13, 2020 under the symbol "MNKKQ."

There were approximately 2,255 shareholders of record of our ordinary shares as of March 11, 2022.

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. For additional information on repurchases of shares, refer to Note 16 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of the Annual Report on Form 10-K.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the accompanying notes included within this Annual Report on Form 10-K. The following discussion may contain forward-looking statements that reflect our plans, estimates and beliefs and involve risks, uncertainties and assumptions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to these differences include those discussed in Item 1A. Risk Factors and "Forward-Looking Statements" included within this Annual Report on Form 10-K.

Fiscal Year

We report our results based on a "52-53 week" year ending on the last Friday of December. Fiscal 2021 consisted of 53 weeks and fiscal 2020 and 2019 each consisted of 52 weeks.

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, ophthalmology and oncology; immunotherapy and neonatal respiratory critical care therapies; analgesics; cultured skin substitutes 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.

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, 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.

Subsequent to the filing of the Chapter 11 Cases, Chapter 11 proceedings commenced by a limited subset of the Debtors have been recognized and given effect in Canada, and separately Mallinckrodt plc has commenced an examinership process with the High Court of Ireland. The references to the Chapter 11 Cases included within this Annual Report on Form 10-K shall include, where applicable, such proceedings in Canada and Ireland. On February 3, 2022, the Bankruptcy Court issued a written ruling confirming the Chapter 11 plan (which was subsequently revised February 8, 2022 to make minor corrections). On March 2, 2022, the Bankruptcy Court entered the Confirmation Order confirming the fourth amended joint plan of reorganization (with technical modifications) proposed by the Debtors. While we have achieved these significant milestones, consummation of the Plan and emergence from the Chapter 11 Cases remains subject to the satisfaction of certain conditions. For further information on the Chapter 11 Cases, 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.

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 ("LSTC") at their estimated allowed claim amounts, as such adjustments are approved by the Bankruptcy Court. During fiscal 2021 and 2020, reorganization items, net were $428.2 million and $61.4 million, respectively.

During fiscal 2020 we incurred $55.7 million and $93.4 million in opioid defense costs and separation costs, respectively, which were both included within SG&A expenses. As of the Petition Date, the majority of these costs are being classified on a go-forward basis as reorganization items, net, as they directly relate to the Chapter 11 proceedings.

Going Concern

The accompanying consolidated financial statements have been prepared assuming we will continue as a going concern. Although the Bankruptcy Court has entered the Confirmation Order confirming the plan of reorganization proposed by the Debtors, consummation of such plan of reorganization and the transactions contemplated thereby and emergence from the Chapter 11 proceedings remains subject to the satisfaction of various conditions, including completion of the Canadian and Irish proceedings. Accordingly, no assurance can be given that the plan of reorganization or the transactions contemplated thereby 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.

StrataGraft

On June 15, 2021, we announced that the FDA had approved the StrataGraft BLA for the treatment of adults with deep partial-thickness burns and during the first quarter of fiscal 2022, we released our first commercial shipment of the product. Concurrent with the approval of StrataGraft, the FDA granted us a Priority Review Voucher ("PRV"). A PRV is a voucher that may be used to obtain an accelerated FDA review of one of our future products or sold to a third party to obtain accelerated review of one of its future products.

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. On August 18, 2021, we resubmitted our NDA for terlipressin to the FDA and on February 18, 2022 (the PDUFA date), the FDA issued a CRL. In the weeks leading up to the PDUFA date, it became necessary for us to identify a new packaging and labeling manufacturing facility, which meant that an inspection by the FDA could not be completed by the PDUFA date. A satisfactory inspection is required before the NDA can be approved. This is the only outstanding issue noted in the CRL, and it is important to note that there were no safety or efficacy issues cited. We are working with the new facility to have it ready for inspection by the FDA. We remain committed to this critically ill patient population, who currently have no approved treatment option in the U.S for HRS-1 and we believe that there is a path to approval in 2022. We 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 ("IPR&D") asset of $81.0 million included within intangible assets, net on the consolidated balance sheets as of December 31, 2021 and December 25, 2020.

Amitiza

During the three months ended December 31, 2021, due to lower anticipated cash flows expected from Amitiza, we identified a triggering event with respect to the Amitiza intangible asset within the Specialty Brands segment and assessed the recoverability of the definite-lived asset. We determined that the undiscounted cash flows related to the Amitiza intangible asset were less than its net book value, which required us to record an impairment charge of $90.4 million for the difference between the fair value of the Amitiza intangible asset and its net book value.

MNK-6105 and MNK-6106

During fiscal 2021, we decided that we would no longer pursue further development of this asset. As a result, we recognized a full impairment on our Specialty Brands IPR&D asset related to MNK-6105 and MNK-6106 of $64.5 million.

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 expect the coming months to continue to be challenging due to the impact of COVID-19. Our business performance was significantly impacted by COVID-19 during fiscal 2021 and 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 2022. 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 Ofirmev decreased $247.6 million or 89.5%, to $28.9 million driven primarily by the entrance of generic competition during fiscal 2021.

Net sales of Acthar Gel for fiscal 2021 decreased $174.3 million, or 22.7%, to $593.6 million driven primarily by the marketplace

impact of the COVID-19 pandemic and continued payer scrutiny on overall specialty pharmaceutical spending. We anticipate that competition will likely intensify in relation to our Acthar Gel product following ANI's expected commercial launch of their purified cortrophin gel product during the first quarter of 2022, which could have an adverse effect on our financial condition, results of operations and cash flows. ANI's purified cortrophin gel product was recently approved by the FDA for the treatment of certain chronic autoimmune disorders, including acute exacerbations of multiple sclerosis and rheumatoid arthritis, in addition to excess urinary protein due to nephrotic syndrome. We continue our efforts to extend the value of the Acthar Gel 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 conducting and sponsoring additional studies of the drug.

Net sales for INOmax decreased $125.6 million or 21.9% to $448.5 million driven primarily by increased competition following the launch of a competitive nitric oxide product before the expiration of the last of the listed patents on May 3, 2036 (November 3, 2036 including pediatric exclusivity), which could continue to adversely affect our ability to successfully maximize the value of INOmax and have an adverse effect on our financial condition, results of operations and cash flows. We continue to develop and pursue patent protection of next generation nitric oxide delivery systems and additional uses of nitric oxide. We further intend to vigorously enforce our intellectual property rights relating to our nitric oxide products against any additional parties that may seek to market an alternative version of our INOmax product and/or next generation delivery systems.

Specialty Generics

Net sales from the Specialty Generics segment were $661.8 million for fiscal 2021 compared to $689.8 million for fiscal 2020. This decrease in net sales was driven primarily by increased competition and a change in product mix due to market shifts as a result of COVID-19.

Results of Operations

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 for fiscal 2020. For further information on the Medicaid lawsuit, refer to Note 19 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

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.

Fiscal Year Ended December 31, 2021 Compared with Fiscal Year Ended December 25, 2020

Net Sales

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

	Fiscal Year		
	2021	2020	Percentage Change
U.S.	$ 1,991.8	$ 2,465.5	(19.2)%
Europe, Middle East and Africa	181.8	227.5	(20.1)
Other	35.2	56.4	(37.6)
Geographic area net sales	2,208.8	2,749.4	(19.7)
Medicaid lawsuit (Note 19)	—	(536.0)	*
Net sales	$ 2,208.8	$ 2,213.4	(0.2)%

*Not meaningful

Net sales in fiscal 2021 were $2,208.8 million, which was relatively flat when compared with $2,213.4 million in fiscal 2020.

Net sales (excluding the one-time charge related to the Medicaid lawsuit) in fiscal 2021 decreased $540.6 million, or 19.7%, to $2,208.8 million, compared with $2,749.4 million in fiscal 2020. This decrease was primarily driven by a decrease in our Specialty Brands segment including a significant decrease in net sales of Ofirmev, Acthar Gel and INOmax, as previously discussed. 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 2021 increased $222.3 million, or 33.2%, to $891.7 million, compared with $669.4 million in fiscal 2020. This increase 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 in fiscal 2020.

Gross profit (excluding the one-time charge related to the Medicaid lawsuit) in fiscal 2021 decreased $313.7 million, or 26.0%, to $891.7 million, compared with $1,205.4 million in fiscal 2020. Gross profit margin was 40.4% for fiscal 2021, compared with 43.8% in fiscal 2020. The decrease in gross profit and gross profit margin was primarily attributable to the $540.6 million decrease in net sales, as discussed above, as well as a change in product mix.

Selling, general and administrative expenses. SG&A expenses for fiscal 2021 were $581.8 million, compared with $884.1 million for fiscal 2020, a decrease of $302.3 million, or 34.2%. As a percentage of net sales, SG&A expenses were 26.3% for fiscal 2021, compared to 39.9%, or 32.2% % when excluding the one-time charge related to the Medicaid lawsuit, for fiscal 2020. These decreases were primarily driven by the bankruptcy-related professional fees being classified as reorganization items, net, subsequent to the Petition Date. Comparatively, during fiscal 2020, we incurred $93.4 million and $55.7 million in separation costs and opioid defense costs, respectively, that were reflected in SG&A. These decreases were also driven by cost containment initiatives and lower employee compensation costs, coupled with a $7.4 million decrease in the fair value of our contingent consideration liabilities during fiscal 2021, compared to a $9.9 million increase during fiscal 2020. The decrease was partially offset by a $35.0 million increase to our environmental liabilities during fiscal 2021.

Research and development expenses. R&D expenses decreased $85.6 million, or 29.4%, to $205.2 million in fiscal 2021, compared with $290.8 million in fiscal 2020. This decrease was driven by the completion of certain development programs coupled with the abandonment of the MNK-6105 and MNK-6106 asset in fiscal 2021. 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 9.3% for fiscal 2021 compared to 13.1%, or 10.6% when excluding the one-time charge related to the Medicaid lawsuit, for fiscal 2020, respectively.

Restructuring and related charges, net. During fiscal 2021, we recognized $29.0 million of restructuring and related charges, net, of which $2.1 million related to accelerated depreciation and was included in SG&A. The remaining $26.9 million primarily related to employee severance and benefits. The fiscal 2020 charge of $49.8 million, which included $12.3 million related to accelerated depreciation, primarily related to the exiting of our Bedminster, New Jersey facility as we moved our Specialty Brands commercial headquarters from Bedminster to Hampton, New Jersey, as well as employee severance and benefits.

Non-restructuring impairment charges. Non-restructuring impairment charges were $154.9 million for fiscal 2021 resulting from a partial impairment of $90.4 million related to the Amitiza intangible asset and a full impairment of $64.5 million related to the MNK-6105 and MNK-6106 IPR&D asset. Non-restructuring impairment charges were $63.5 million for fiscal 2020 primarily related to the partial impairment related to the Ofirmev intangible asset.

Losses (gains) on divestiture. During fiscal 2021 and 2020, we incurred a loss on divestiture of $0.8 million and a gain of $16.6 million, respectively. Fiscal 2020 included a gain of $16.5 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").

Opioid-related litigation settlement loss (gain). During fiscal 2021, we recorded a charge of $125.0 million as a result of an additional payment expected to be made on the eighth anniversary of the effective date of the Amended Proposed Opioid-Related Litigation Settlement, in accordance with the agreement in principle reached on September 2, 2021. For further information, refer to Note 2 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of the Annual Report on Form 10-K. For 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 given we cannot reasonably estimate the equity value at emergence.

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 2021 and fiscal 2020, net interest expense was $220.7 million and $255.2 million, respectively. The $38.5 million decrease in interest expense was primarily attributable to a $72.5 million decrease resulting from the cessation of interest accruals as of the Petition Date on outstanding unsecured pre-petition debt classified as LSTC in connection with the Chapter 11 Cases, coupled with a lower average outstanding debt balance and a $7.6 million decrease in the amortization of discount and debt issuance costs. This decrease was partially offset by a $51.4 million increase in expense related to

adequate protection payments in fiscal 2021 as compared to fiscal 2020. Additionally, fiscal 2021 and 2020 included the recognition of a $15.8 million and $19.2 million benefit to interest expense, respectively, due to lapses of certain statutes of limitations. Interest income decreased $4.0 million to $1.9 million during fiscal 2021, compared to $5.9 million during fiscal 2020, primarily driven by interest earned on our preferred equity certificates that were received as contingent consideration related to the sale of the Nuclear Imaging business during fiscal 2020 and lower interest rates during fiscal 2021.

Other income, net. During fiscal 2021 and 2020, we recorded other income, net, of $22.0 million and $7.4 million, respectively. This increase was primarily driven by $9.0 million of one-time milestone receivables in fiscal 2021, coupled with a $6.8 million one-time Japanese consumption tax credit. The remaining activity in both periods represented unrealized gains on our equity investment in Silence, 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 2021 and 2020, we recorded $428.2 million and $61.4 million of reorganization items, net in conjunction with our Chapter 11 proceedings, respectively. The fiscal 2021 charges included $405.6 million of advisor and legal fees directly related to the Chapter 11 Cases and $23.1 million of deferred financing fee write-offs related to the senior secured term loan due September 2024 (the "2017 Term Loan"), senior secured term loan due February 2025 (the "2018 Term Loan") and second lien senior notes in order to reflect the carrying value of the notes within LSTC on the consolidated balance sheet as of December 31, 2021, at their estimated allowed claim amounts. The fiscal 2020 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.

(Benefit) expense from income taxes. During fiscal 2021, we recognized an income tax benefit of $106.3 million on a loss from continuing operations before income taxes of $829.8 million. The fiscal 2021 income tax benefit was comprised of $46.4 million of current tax benefit and $59.9 million of deferred tax benefit. The current tax benefit was primarily the result of an increase to prepaid taxes and a decrease to uncertain tax positions. The deferred tax benefit was predominately related to intangible asset amortization, partially offset by utilization of loss carryforwards in non-valuation allowance jurisdictions. 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.

Our effective tax rate was 12.8% and negative 0.9% for fiscal 2021 and 2020, respectively. Our effective tax rate for fiscal 2021 was most significantly impacted by the tax benefit of $286.3 million predominately related to changes in the jurisdictional mix of operating loss resulting from the fiscal 2020 reorganization of the Company's intercompany financing and associated asset and legal entity ownership and a $9.7 million tax benefit associated with accrued income tax liabilities and uncertain tax positions, partially offset with $189.7 million of tax expense associated with valuation allowances recorded against our net deferred tax assets in applicable tax jurisdictions. Additional impacts to the fiscal 2021 effective tax rate include a tax benefit of $49.9 million associated with $428.2 million of reorganization items, net, $34.8 million of tax benefit associated with an impairment charge of $154.9 million, and $21.1 million of tax benefit associated with the $125.0 million opioid-related litigation settlement charge. These additional impacts are significantly offset with the above referenced valuation allowance, thus resulting in a tax benefit of $15.0 million included within our jurisdictional mix of operating loss. Our effective tax rate for fiscal 2020 was most significantly impacted by $618.2 million of 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, partially offset by 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 fiscal 2020 effective tax rate included a tax benefit of $11.8 million associated with $93.4 million of separation costs, $5.4 million of tax benefit associated with $61.4 million of reorganization items, net, $0.5 million of tax benefit associated with $25.3 million of share-based compensation, and no tax expense associated with a gain of $43.4 million 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.

Income from discontinued operations, net of income taxes. We recorded income of $6.1 million and $25.1 million on discontinued operations, net of income taxes, during fiscal 2021 and 2020, respectively. Fiscal 2021 and 2020 both included the recognition of a tax benefit related to a release of tax and interest on unrecognized tax benefits due to lapses of certain statutes of limitations related to the Nuclear Imaging business. The remaining income during fiscal 2020 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 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		Percentage Change
	2020	2019	
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 19)	(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 an accelerated amortization method, 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%. 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. These increases were 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 target opportunities. These increases were partially offset by decreases in legal expenses driven by a $28.2 million charge during fiscal 2019 associated with the settlement of the MDL Track 1 Cases, as defined within Note 19 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K, decreased professional fees, and a decrease in travel expense due to temporary travel restrictions as a result of COVID-19.

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 moved 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 the Ofirmev 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 the VTS-270 intangible asset and a $113.5 million full impairment related to the 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. 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 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 are 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. 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 lapses of certain statutes of limitations. For further information, refer to Note 19 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K. 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 14 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K. Fiscal 2019 also included a gain of $98.6 million on debt repurchases that aggregated to a total principal amount of $492.1 million, partially offset by the write-off of associated deferred financing fees of $9.4 million.

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 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 LSTC 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 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 $618.2 million of 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, partially offset by 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 fiscal 2020 effective tax rate included a tax benefit of $11.8 million associated with $93.4 million of separation costs, $5.4 million of tax benefit associated with $61.4 million of reorganization items, net, $0.5 million of tax benefit associated with $25.3 million of share-based compensation, and no tax expense associated with a gain of $43.4 million 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 $212.8 million of tax benefit associated with the reorganization of our intercompany financing and associated legal entity ownership. Further impacts included a tax benefit of $211.9 million 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. 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 statutes 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.

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. 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 31, 2021 Compared with Fiscal Year Ended December 25, 2020

Net Sales

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

	Fiscal Year		Percentage Change
	2021	2020	
Specialty Brands	$ 1,547.0	$ 2,059.6	(24.9)%
Specialty Generics	661.8	689.8	(4.1)
Net sales	2,208.8	2,749.4	(19.7)
Medicaid lawsuit (Note 19)	—	(536.0)	*
Net sales	$ 2,208.8	$ 2,213.4	(0.2)

*Not meaningful

Specialty Brands. Net sales for fiscal 2021 decreased $512.6 million, or 24.9%, to $1,547.0 million, compared with $2,059.6 million for fiscal 2020. This decrease was primarily driven by a $247.6 million, or 89.5%, decrease in Ofirmev driven by the loss of exclusivity at the end of fiscal 2020 and the entrance of generic competition during fiscal 2021. The decrease in net sales was also impacted by a $174.3 million, or 22.7%, 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 and a $125.6 million, or 21.9%, decrease in INOmax due to increased competition. These decreases were partially offset by a $27.9 million, or 11.7%, increase in Therakos net sales driven by increased demand as the product begun to see a recovery from the impact of the COVID-19 pandemic during the first half of fiscal 2021 and an $8.1 million, or 4.3%, increase in Amitiza, primarily as a result of the royalty from Par beginning in fiscal 2021.

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

	Fiscal Year		
	2021	2020	Percentage Change
U.S.	$ 1,450.5	$ 1,901.0	(23.7)%
Europe, Middle East and Africa	75.3	116.7	(35.5)
Other	21.2	41.9	(49.4)
Net sales	$ 1,547.0	$ 2,059.6	(24.9)

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

	Fiscal Year		
	2021	2020	Percentage Change
Acthar Gel	$ 593.6	$ 767.9	(22.7)%
INOmax	448.5	574.1	(21.9)
Ofirmev	28.9	276.5	(89.5)
Therakos	266.5	238.6	11.7
Amitiza	196.9	188.8	4.3
Other	12.6	13.7	(8.0)
Specialty Brands	$ 1,547.0	$ 2,059.6	(24.9)

Specialty Generics. Net sales for fiscal 2021 decreased $28.0 million, or 4.1%, to $661.8 million, compared to $689.8 million for fiscal 2020. The decrease in net sales was driven by a $17.2 million, or 5.9%, and $15.3 million, or 15.6%, decrease in other controlled substances and hydrocodone-related products, respectively, driven by an increased competitive environment. These decreases were partially offset by a $2.9 million, or 1.4%, and $1.5 million, or 7.3%, increase in acetaminophen and other products net sales, respectively.

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

	Fiscal Year		
	2021	2020	Percentage Change
U.S.	$ 541.3	$ 564.5	(4.1)%
Europe, Middle East and Africa	106.5	110.8	(3.9)
Other	14.0	14.5	(3.4)
Net sales	$ 661.8	$ 689.8	(4.1)

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

	Fiscal Year		
	2021	2020	Percentage Change
Hydrocodone (API) and hydrocodone-containing tablets	$ 82.7	$ 98.0	(15.6)%
Oxycodone (API) and oxycodone-containing tablets	68.5	68.4	0.1
Acetaminophen (API)	215.9	213.0	1.4
Other controlled substances	272.7	289.9	(5.9)
Other	22.0	20.5	7.3
Specialty Generics	$ 661.8	$ 689.8	(4.1)

Operating Loss

Operating income by segment and as a percentage of segment net sales for fiscal 2021 and 2020 is shown in the following table (dollars in millions):

	Fiscal Year			
	2021		2020	
Specialty Brands	$ 812.8	52.5 %	$ 1,015.7	49.3 %
Specialty Generics	107.9	16.3	206.4	29.9
Segment operating income	920.7	41.7	1,222.1	44.4
Unallocated amounts:				
Corporate and unallocated expenses [1]	(129.6)		(166.1)	
Depreciation and amortization	(675.8)		(885.2)	
Share-based compensation	(10.2)		(25.3)	
Restructuring charges, net	(26.9)		(37.5)	
Non-restructuring impairment charges	(154.9)		(63.5)	
Separation costs [2]	(1.2)		(93.4)	
R&D upfront payment [3]	—		(5.0)	
Opioid-related litigation settlement (loss) gain (Note 19)	(125.0)		43.4	
Medicaid lawsuit (Note 19)	—		(641.1)	
Total operating loss	$ (202.9)		$ (651.6)	

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

(2) Represents costs included in SG&A expenses, primarily related to professional fees and costs incurred in preparation for the Chapter 11 proceedings. As of the Petition Date, professional fees directly related to the Chapter 11 proceedings that were previously reflected as separation costs were classified on a go-forward basis as reorganization items, net.

(3) Represents R&D expense incurred related to an upfront payment made to acquire product rights in Japan for terlipressin in fiscal 2020.

Specialty Brands. Operating income for fiscal 2021 decreased $202.9 million to $812.8 million, compared with $1,015.7 million for fiscal 2020. Operating margin increased to 52.5% for fiscal 2021, compared with 49.3% for fiscal 2020. The decrease in operating income is primarily driven by the $512.6 million, or 24.9%, decrease in net sales over the same period, which resulted in a $410.0 million decrease in gross profit. Partially offsetting the decrease in operating income and serving to increase operating margin was a $125.9 million, or 26.2%, decrease in SG&A expenses primarily driven by cost containment initiatives and lower employee compensation costs in addition to bankruptcy-related legal fees being classified as reorganization items, net, subsequent to the Petition Date, and an $81.3 million, or 33.7%, decrease in R&D expenses driven by the completion of certain development programs during fiscal 2020, coupled with the decision to no longer pursue further development of the MNK-6105 and MNK-6106 asset in fiscal 2021.

Specialty Generics. Operating income for fiscal 2021 decreased $98.5 million to $107.9 million, compared with $206.4 million for fiscal 2020. Operating margin decreased to 16.3% for fiscal 2021, compared with 29.9% for fiscal 2020. The decrease in operating income and operating margin was primarily attributable to a $97.1 million decrease in gross profit, primarily driven by an increased competitive environment with respect to other controlled substances and hydrocodone-related products.

Corporate and unallocated expenses. Corporate and unallocated expenses were $129.6 million and $166.1 million for fiscal 2021 and fiscal 2020, respectively. This decrease was primarily driven by the bankruptcy-related professional fees being classified as reorganization items, net, subsequent to the Petition Date, in addition to cost containment initiatives and lower employee compensation costs. Comparatively, during fiscal 2020, we incurred $55.7 million of opioid defense costs that were reflected in SG&A. The decrease also included changes in the fair value of our contingent consideration liabilities with a $7.4 million gain during fiscal 2021 compared to a $9.9 million charge during fiscal 2020. The decrease was partially offset by a $35.0 million increase to our environmental remediation liabilities during fiscal 2021.

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 19)	(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		Percentage Change	
	2020	2019		
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		Percentage Change	
	2020	2019		
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		Percentage Change
	2020	2019	
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		Percentage Change
	2020	2019	
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 gain (loss) (Note 19)	43.4			(1,643.4)		
Medicaid lawsuit (Note 19)	(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. These decreases were 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 was 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, resulting from 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.

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 legal settlements, 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. Our material cash requirements are highly dependent upon the plan of reorganization and successful emergence from Chapter 11.

Anticipated Sources and Uses for Chapter 11 Emergence

In the event we are able to successfully emerge from Chapter 11, our primary cash sources upon emergence are expected to include cash on hand, which was $1,345.0 million as of December 31, 2021, and proceeds of newly incurred debt.

Our primary cash uses upon emergence are expected to include the following:

- $900.0 million revolving credit facility with a stated maturity of February 28, 2022, for which efforts to enforce payment obligations were automatically stayed during the pendency of the Chapter 11 Cases;
- $450.0 million upfront payment related to our Amended Proposed Opioid-Related Litigation Settlement;
- $135.0 million payment of general unsecured claims in accordance with the agreement in principle with the unsecured creditors committee;
- $15.0 million upfront payment related to our Proposed Acthar Gel-Related Settlement; and
- Payment of administrative, priority and trade claims, for which the amount is not yet finalized due to ongoing claims reconciliation efforts; and
- Fees related to exit-financing activities.

Refer to Note 2 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 on our plan of reorganization and related expected sources and uses.

Cash Requirements and Sources From Existing Contractual Arrangements

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.

Our material cash requirements from known contractual obligations include debt obligations, legal settlements, income taxes, lease obligations, purchase obligations and other liabilities reflected on our balance sheet, as presented and discussed below.

The following table summarizes our contractual obligations as of December 31, 2021 (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]	$ 5,145.8	$ 1,539.2	$ 2,042.4	$ 1,564.2	$ —
Interest on long-term debt obligations [2]	773.4	288.4	429.8	55.2	—
Operating lease obligations [3]	44.4	15.3	18.9	7.3	2.9
Purchase obligations [4]	4.7	3.0	1.1	0.6	—
Total contractual obligations	$ 5,968.3	$ 1,845.9	$ 2,492.2	$ 1,627.3	$ 2.9

(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 is classified as current on the consolidated balance sheets. Certain of our long-term debt instruments are classified as LSTC, for which no principal payments will be made during the pendency of the proceedings. We intend to use the Chapter 11 process to reduce our total debt. For further details on our Chapter 11 proceedings and debt obligations, refer to Notes 2 and 14, respectively 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.

(2) Interest on long-term debt obligations are projected for future periods using interest rates in effect as of December 31, 2021. 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 LSTC, with the corresponding contractual interest reflected above, 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.

We are contractually obligated under the cash collateral order approved by the Bankruptcy Court to make adequate protection payments on the senior secured revolving credit facility and senior secured term loans at a rate that is 200 and 250 basis points, respectively, greater than the otherwise applicable non-default rate based on LIBOR. Under the cash collateral order, we expect to make approximately $15.5 million of adequate protection payments during fiscal 2022, which is subject to change based on ultimate timing of emergence from Chapter 11. This incremental expense, which is classified as interest expense, is reflected above.

For further information regarding the fixed and variable rates of our debt obligations, refer to Note 14 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

(3) Includes obligations for leases with an initial term of 12 months or less and not recorded on the consolidated balance sheet. Refer to Note 12 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K for further information on our lease liabilities.

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

The preceding table does not include our legal settlement obligations of $1,725.0 million for our Amended Proposed Opioid-Related Litigation Settlement and $260.0 million for our Proposed Acthar Gel-Related Settlement, which are further discussed in Note 2 and 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. We may be subject to other legal matters that may require further cash requirements that we are unable to reasonably estimate the expected amount or range of cost at this time.

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 31, 2021, was $83.2 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 8 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

We are obligated to pay royalties under certain agreements with third parties. During fiscal 2021, 2020 and 2019, we made payments under these arrangements of $14.1 million, $81.9 million and $95.7 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 and the ultimate outcome of the Chapter 11 process. The decrease in royalties paid during fiscal 2021 was driven by loss of exclusivity and entrance of competition for our Ofirmev product, which caused a large decline in net sales, coupled with the cessation of Acthar Gel royalty payments as a result of the Chapter 11 process. Accrued royalties related to our Acthar Gel product were $29.0 million as of December 31, 2021 and have been classified as LSTC on the consolidated balance sheet. 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.

As of December 31, 2021, we had net unfunded pension and postretirement benefit obligations of $27.3 million and $37.3 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 2022, but may elect to make voluntary contributions to our defined pension plans or our postretirement benefit plans during fiscal 2022. As a result of our Chapter 11 filing on October 12, 2020, $32.0 million defined benefit obligations have been classified as LSTC on our consolidated balance sheet as of December 31, 2021, which included the U.S. pension benefit plans and a portion of the postretirement benefit plans. For further information regarding pension and postretirement benefit obligations, refer to 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.

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 31, 2021, we

believe that it is probable that we will incur investigation and remediation costs of approximately $95.8 million, of which $0.8 million was included in accrued and other current liabilities, $52.0 million was included in LSTC, and the remaining $43.0 million was included in environmental liabilities on the consolidated balance sheet as of December 31, 2021. Refer to Notes 2 and 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 for additional information regarding LSTC and environmental matters, respectively.

As part of our acquisition of Stratatech Corporation ("Stratatech"), we are subject to a contractual arrangement to pay contingent consideration to former owners of this business. The payment of obligations under this arrangement is uncertain, and even if payments are expected to be made the timing of these payments may be uncertain as well. As of December 31, 2021, we have accrued $27.3 million for these potential payments, which are classified as LSTC. For further information on our contingent consideration arrangement, 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.

In general, we intend to fund capital expenditures with cash generated from operations. As of December 31, 2021, we had no capital expenditure commitments.

Our remaining cash requirements are obligations that arise from the normal course of our business.

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.

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

	Fiscal Year		
	2021	2020	2019
Net cash from:			
Operating activities	$ 455.4	$ 498.9	$ 742.9
Investing activities	(37.8)	(11.2)	(8.3)
Financing activities	(137.5)	(185.6)	(280.1)
Effect of currency exchange rate changes on cash, cash equivalents and restricted cash	(1.9)	2.3	0.6
Net increase in cash, cash equivalents and restricted cash	$ 278.2	$ 304.4	$ 455.1

Operating Activities

Net cash provided by operating activities of $455.4 million for fiscal 2021 included a loss of $717.4 million, adjusted for non-cash items of $802.7 million driven by depreciation and amortization of $675.8 million and a $154.9 million non-cash impairment charge related to the Amitiza asset and the MNK-6105 and MNK-6106 asset, partially offset by a $59.9 million reduction in our deferred income tax liabilities. The net loss was also offset by cash provided from net investment in working capital of $370.1 million, which was primarily driven by an increase to the opioid-related litigation settlement liability of $125.0 million, a $108.5 million decrease in net tax receivables driven by the receipt of CARES Act income tax refunds, partially offset by an increase in prepaid income taxes and a $98.2 million decrease in accounts receivable. These inflows were partially offset by a $14.0 million increase in inventory.

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 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 LSTC. 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 LSTC, 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 (as defined 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) 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.

Investing Activities

Net cash used in investing activities of $37.8 million for fiscal 2021 was primarily attributable to capital expenditures of $55.3 million, partially offset by cash proceeds of $16.5 million related to the sale of a portion of our Hemostasis business in fiscal 2018.

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.

Under our term loan 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 $137.5 million for fiscal 2021, compared with $185.6 million for fiscal 2020. This decrease was primarily attributable to payments of contingent considerations related to the acquisition of Questcor and Stratatech during fiscal 2020 of $25.0 million and $20.0 million, respectively, $9.4 million in debt issuance costs incurred in fiscal 2020 and a $2.0 million decrease in debt repayments. Our fiscal 2021 debt repayments included $137.5 million in aggregate payments on our variable-rate term loans. Our fiscal 2020 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, and $19.7 million in aggregate payments on our variable-rate senior secured term loans.

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. 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.

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.

Capitalization

Shareholders' equity was $313.4 million at December 31, 2021 compared with $1,019.2 million at December 25, 2020. The decrease in shareholders' equity is primarily attributed to the fiscal 2021 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 2021 or fiscal 2020. For further information, refer to Note 16 of the Notes to the Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Dividends

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

Legal Proceedings

We are subject to various legal proceedings and claims, including present and former operations, including those described in Note 19 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K, 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 from time to time provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to the assets, environmental risks involved in the sale of real estate, liability to investigate and remediate environmental contamination at waste disposal sites and manufacturing facilities, and unidentified tax liabilities related to periods prior to disposition. 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 the 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 18 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

As of December 31, 2021, we had various other letters of credit, guarantees and surety bonds totaling $34.7 million and restricted cash of $41.2 million held in segregated accounts primarily to collateralize surety bonds for our environmental liabilities.

Critical Accounting 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 critical accounting estimates 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 confirmed Chapter 11 plan of reorganization 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

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 provide for government-mandated and/or privately-negotiated rebates, sales 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 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 19) [(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
Provisions	2,087.1	23.7	55.2	2,166.0
Payments or credits	(2,041.8)	(28.8)	(58.0)	(2,128.6)
Balance as of December 31, 2021	$ 241.8	$ 21.5	$ 9.5	$ 272.8

(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. For further information, refer to Note 19 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Provisions presented in the table above are recorded as reductions to net sales. As of December 31, 2021, a five percent change in our sales reserve accounts would have led to an approximately $13.6 million impact on our loss from continuing operations before income taxes. For our presentation of net sales by product family, refer to Note 21 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Total provisions for fiscal 2021 decreased $524.3 million compared with fiscal 2020, which was inclusive of the $536.0 million provision for the Medicaid lawsuit incurred in fiscal 2020. Excluding the impact of the Medicaid lawsuit, the increase in rebates and chargebacks of $21.2 million primarily related to an increase of $32.7 million in the Specialty Generics segment as result of pricing pressure on our business, partially offset by an $11.5 million decrease in Specialty Brands. Provisions for returns decreased $5.2 million driven by the Specialty Generics segment, and other sales deductions decreased by $4.3 million from fiscal 2020 to fiscal 2021.

Total provisions for fiscal 2020 increased $252.6 million compared with fiscal 2019, which was 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.

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.

For additional information, refer to Note 4 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Intangible Assets

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. Intangible assets with finite useful lives are subsequently 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, or the asset group they are a 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. We annually test the indefinite-lived intangible assets for impairment, or whenever events or changes in circumstances indicate that the carrying value may not be recoverable by either a qualitative or income approach. We compare the fair value of the assets with their carrying value and record an impairment when the carrying value exceeds the fair value. Changes in economic and operating conditions impacting these assumptions could result in intangible asset impairment in future periods.

For more information on our intangible impairment analyses and the results thereof, refer to Notes 3 and 13 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Acquisitions

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 may be overstated, which may result in an increased risk of impairment in future periods. We perform our intangible asset valuations using an income approach based on the present value of future cash flows. This approach incorporates many assumptions including future growth rates, discount factors and income tax rates. Changes in economic and operating conditions impacting these assumptions could result in impairment in future periods.

Our purchased research and development represents the estimated fair value as of the acquisition date of in-process projects that have not reached technological feasibility. The primary basis for determining technological feasibility of these projects is obtaining regulatory approval.

The fair value of IPR&D is determined using the discounted cash flow method. In determining the fair value of IPR&D, we consider, among other factors, appraisals, the stage of completion of the projects, the technological feasibility of the projects, whether the projects have an alternative future use and the estimated residual cash flows that could be generated from the various projects and technologies over their respective projected economic lives. The discount rate used includes a rate of return that accounts for the time value of money, as well as risk factors that reflect the economic risk that the cash flows projected may not be realized.

The fair value attributable to IPR&D projects at the time of acquisition is capitalized as an indefinite-lived intangible asset and tested annually for impairment until the project is completed or abandoned. Upon completion of the project, the indefinite-lived

intangible asset is then accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is abandoned, the indefinite-lived intangible asset is charged to expense.

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

Contingent Consideration

As part of certain acquisitions, we are subject to contractual arrangements to pay contingent consideration to former owners of these businesses. The payment of obligations under these arrangements are uncertain, and even if payments are expected to be made the timing of these payments may be uncertain as well. These contingent consideration obligations are required to be recorded at fair value within the consolidated balance sheet and adjusted at each respective balance sheet date, with changes in the fair value being recognized in the consolidated statement of operations. The determination of fair value is dependent upon a number of factors, which include projections of future revenues, the probability of successfully achieving certain regulatory milestones, competitive entrants into the marketplace, the timing associated with the aforementioned criteria and market place data (e.g., interest rates). Several of these assumptions require projections several years into the future. Due to these inherent uncertainties, there is risk that the contingent consideration liabilities may be overstated or understated. Changes in economic and operating conditions impacting these assumptions are expected to impact future operating results, with the magnitude of the impact tied to the significance in the change in assumptions. For additional information, refer to Note 20 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Contingencies

We are involved, either as a plaintiff or a defendant, in various legal proceedings that arise in the ordinary course of business, including, without limitation, government investigations, environmental matters, product liability matters, patent infringement claims, antitrust matters, securities class action lawsuits, personal injury claims, employment disputes, contractual and other commercial disputes, and other legal proceedings, all in the ordinary course of business as further discussed in Note 19 of Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K. Accruals recorded for various contingencies, including legal proceedings, self-insurance and other claims, are based on judgment, the probability of losses and, where applicable, the consideration of opinions of internal and/or external legal counsel, internal and/or external technical consultants and actuarially determined estimates. When a range is established but a best estimate cannot be made, we record the minimum loss contingency amount. These estimates are often initially developed substantially earlier than the ultimate loss is known, and the estimates are reevaluated each accounting period as additional information becomes available. When we are initially unable to develop a best estimate of loss, we record the minimum amount of loss, which could be zero. As information becomes known, additional loss provisions are recorded when either a best estimate can be made or the minimum loss amount is increased. When events result in an expectation of a more favorable outcome than previously expected, our best estimate is changed to a lower amount. We record receivables from third-party insurers up to the amount of the related liability when we have determined that existing insurance policies will provide reimbursement. In making this determination, we consider applicable deductibles, policy limits and the historical payment experience of the insurance carriers. Receivables are not netted against the related liabilities for financial statement presentation.

Income Taxes

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

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

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 continue to maintain 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. Refer to Note 8 of 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.

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

We are a smaller reporting company as defined by Item 10 of Regulations S-K and are not required to provide the information otherwise required under this Item.

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) (in examination under Part 10 of the Irish Companies Act 2014) (the "Company") as of December 31, 2021 and December 25, 2020, the related consolidated statements of operations, comprehensive operations, changes in shareholders' equity, and cash flows for the fiscal years ended December 31, 2021, December 25, 2020 and December 27, 2019 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 31, 2021 and December 25, 2020, and the results of its operations and its cash flows for the fiscal years ended December 31, 2021, December 25, 2020 and December 27, 2019, 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 31, 2021, 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 15, 2022, 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"), which raises 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 2 to the financial statements, the Company has filed for reorganization under Chapter 11 of the 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 Matters

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

Intangible Assets, net – Finite-lived Intangibles– Refer to Note 13 to the financial statements

Critical Audit Matter Description

The Company has finite-lived intangible assets, net of approximately $5.4 billion at December 31, 2021, comprised of completed technology, licenses and trademarks. The Company recorded a non-restructuring impairment charge of $90.4 million related to the Amitiza intangible asset in the consolidated statement of operations for the year ended December 31, 2021. In accordance with Accounting Standard Codification ("ASC") 350 – Intangibles – Goodwill and Other, finite-lived intangible assets are assessed for recoverability when events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. When a triggering event occurs, the Company evaluates finite-lived intangible assets for recoverability by comparing estimated undiscounted cash flows to the carrying amount and fair value of the asset. If the carrying amount of the asset exceeds the estimated undiscounted cash flows, the amount of the potential impairment is measured based on the difference between the carrying amount and fair value of the asset. The Company also assesses the remaining useful life and the recoverability of finite-lived intangible assets for impairment, or whenever events or changes in circumstances indicate that the carrying value may not be recoverable by either a qualitative or income approach.

We identified finite-lived intangible assets as a critical audit matter because of the significant judgment by management when developing the assumptions of cash flows. The estimation of cash flows for finite-lived intangible assets requires management to make assumptions regarding operating results, business plans, future growth rates, anticipated future cash flows, and discount rate. This required a higher degree of auditor judgment, subjectivity, and effort in performing procedures to evaluate these assumptions. Our evaluation included assessing whether the assumptions used by management were reasonable and consistent with audit evidence obtained.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to finite-lived intangible assets included the following, among others:

- We evaluated management's assessment of potential triggering events for consistency with internal and external events and transactions.
- We evaluated management's ability to accurately estimate undiscounted future cash flows by comparing actual undiscounted cash flows to management's historical estimates.
- We evaluated the reasonableness of management's assumptions by comparing estimated undiscounted future cash flows to historical financial information.
- We evaluated the reasonableness of management's assumptions by inspecting external information.
- With the assistance of our fair value specialists, we evaluated the reasonableness of the discount rate used in the Amitiza intangible asset fair value calculation.
- We inspected internal communications and documentation to corroborate our inquiries with management.

Chapter 11 Bankruptcy – Liabilities Subject to Compromise – Refer to Note 2 to the financial statements

Critical Audit Matter Description

As a result of the commencement of the Chapter 11 proceedings, 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 confirmed Chapter 11 plan of reorganization becomes effective. 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 based 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.

We identified liabilities subject to compromise associated with Chapter 11 bankruptcy and the related 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”) 852 – Reorganizations when determining how to appropriately measure and classify the liabilities on the consolidated financial statements. 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 Chapter 11 bankruptcy included the following, among others:

- We tested the effectiveness of controls including management's review of the legal background and facts, applicable accounting guidance, and related disclosure.
- We inspected Bankruptcy Court documents, including motions and orders.

- We corroborated key facts about the bankruptcy proceedings through our inquiries with internal legal counsel and executive members of management.
- We requested and received written responses from internal and external legal counsel regarding the bankruptcy proceedings.
- With the assistance of professionals in our firm having expertise in complex accounting and reporting matters, we evaluated the Company's conclusions regarding the application of ASC 852 – Reorganizations.
- We evaluated the Company's disclosures for consistency with our knowledge of the status of the Chapter 11 bankruptcy proceedings.

/s/ DELOITTE & TOUCHE LLP

St. Louis, Missouri
March 15, 2022

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

MALLINCKRODT PLC
(DEBTOR-IN-POSSESSION)
(IN EXAMINATION UNDER PART 10 OF THE IRISH COMPANIES ACT 2014)
CONSOLIDATED STATEMENTS OF OPERATIONS
(in millions, except per share data)

	Fiscal Year		
	2021	**2020**	**2019**
Net sales (includes refined estimate of the retrospective one-time charge of $536.0 related to the Medicaid lawsuit for fiscal 2020)	$ 2,208.8	$ 2,213.4	$ 3,162.5
Cost of sales	1,317.1	1,544.0	1,741.1
Gross profit	891.7	669.4	1,421.4
Selling, general and administrative expenses	581.8	884.1	831.0
Research and development expenses	205.2	290.8	349.4
Restructuring charges, net	26.9	37.5	(1.7)
Non-restructuring impairment charges	154.9	63.5	388.0
Losses (gains) on divestiture	0.8	(16.6)	33.5
Opioid-related litigation settlement loss (gain) (Note 19)	125.0	(43.4)	1,643.4
Medicaid lawsuit (Note 19)	—	105.1	—
Operating loss	(202.9)	(651.6)	(1,822.2)
Interest expense	(222.6)	(261.1)	(309.0)
Interest income	1.9	5.9	9.5
Gains on debt extinguishment, net	—	—	466.6
Other income, net	22.0	7.4	63.6
Reorganization items, net	(428.2)	(61.4)	—
Loss from continuing operations before income taxes	(829.8)	(960.8)	(1,591.5)
(Benefit) expense from income taxes	(106.3)	8.9	(584.3)
Loss from continuing operations	(723.5)	(969.7)	(1,007.2)
Income from discontinued operations, net of tax (benefit) expense of ($5.0), $(16.2) and $1.7	6.1	25.1	10.7
Net loss	$ (717.4)	$ (944.6)	$ (996.5)
Basic loss per share (Note 9):			
Loss from continuing operations	$ (8.54)	$ (11.48)	$ (12.00)
Income from discontinued operations	0.07	0.30	0.13
Net loss	$ (8.47)	$ (11.18)	$ (11.88)
Basic weighted-average shares outstanding	84.7	84.5	83.9
Diluted loss per share (Note 9):			
Loss from continuing operations	$ (8.54)	$ (11.48)	$ (12.00)
Income from discontinued operations	0.07	0.30	0.13
Net loss	$ (8.47)	$ (11.18)	$ (11.88)
Diluted weighted-average shares outstanding	84.7	84.5	83.9

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
(DEBTOR-IN-POSSESSION)
(IN EXAMINATION UNDER PART 10 OF THE IRISH COMPANIES ACT 2014)
CONSOLIDATED STATEMENTS OF COMPREHENSIVE OPERATIONS
(in millions)

	Fiscal Year		
	2021	**2020**	**2019**
Net loss	$ (717.4)	$ (944.6)	$ (996.5)
Other comprehensive income (loss), net of tax			
Currency translation adjustments	(0.5)	2.1	18.3
Unrecognized gain on derivatives	—	0.4	1.8
Unrecognized gain (loss) on benefit plans	1.8	(4.2)	(4.2)
Total other comprehensive income (loss), net of tax	1.3	(1.7)	15.9
Comprehensive loss	$ (716.1)	$ (946.3)	$ (980.6)

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
(DEBTOR-IN-POSSESSION)
(IN EXAMINATION UNDER PART 10 OF THE IRISH COMPANIES ACT 2014)
CONSOLIDATED BALANCE SHEETS
(in millions, except share data)

	December 31, 2021	December 25, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 1,345.0	$ 1,070.6
Accounts receivable, less allowance for doubtful accounts of $4.7 and $4.5	439.1	538.8
Inventories	347.2	344.9
Prepaid expenses and other current assets	178.3	350.0
Total current assets	2,309.6	2,304.3
Property, plant and equipment, net	776.0	833.1
Intangible assets, net	5,448.4	6,184.5
Other assets	382.3	393.5
Total Assets	$ 8,916.3	$ 9,715.4
Liabilities and Shareholders' Equity		
Current Liabilities:		
Current maturities of long-term debt	$ 1,388.9	$ 3,587.9
Accounts payable	123.0	93.3
Accrued payroll and payroll-related costs	84.6	79.4
Accrued interest	17.0	26.9
Accrued and other current liabilities	328.7	331.2
Total current liabilities	1,942.2	4,118.7
Pension and postretirement benefits	30.1	34.6
Environmental liabilities	43.0	59.8
Deferred income taxes	20.9	80.6
Other income tax liabilities	83.2	100.1
Other liabilities	85.8	109.8
Liabilities subject to compromise (Note 2)	6,397.7	4,192.6
Total Liabilities	8,602.9	8,696.2
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; 94,296,235 and 94,111,303 issued; 84,726,590 and 84,605,156 outstanding	18.9	18.8
Ordinary shares held in treasury at cost, 9,569,645 and 9,506,147	(1,616.1)	(1,616.1)
Additional paid-in capital	5,597.8	5,587.6
Retained deficit	(3,678.9)	(2,961.5)
Accumulated other comprehensive loss	(8.3)	(9.6)
Total Shareholders' Equity	313.4	1,019.2
Total Liabilities and Shareholders' Equity	$ 8,916.3	$ 9,715.4

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
(DEBTOR-IN-POSSESSION)
(IN EXAMINATION UNDER PART 10 OF THE IRISH COMPANIES ACT 2014)
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in millions)

	Fiscal Year		
	2021	**2020**	**2019**
Cash Flows From Operating Activities:			
Net loss	$ (717.4)	$ (944.6)	$ (996.5)
Adjustments to reconcile net cash provided by operating activities:			
Depreciation and amortization	675.8	885.2	951.1
Share-based compensation	10.2	25.3	33.8
Deferred income taxes	(59.9)	385.3	(604.3)
Non-cash impairment charges	154.9	63.5	388.0
Inventory provisions	11.5	18.5	18.0
Losses (gains) on divestiture	0.8	(16.6)	33.5
Gain on debt extinguishment, net	—	—	(466.6)
Other non-cash items	(13.1)	(40.2)	(65.7)
Reorganization items, net	22.5	10.2	—
Changes in assets and liabilities, net of the effects of acquisitions:			
Accounts receivable, net	98.2	37.9	31.6
Inventories	(14.0)	(51.1)	(23.1)
Accounts payable	(1.1)	15.7	6.7
Income taxes	108.5	(433.8)	(2.1)
Opioid-related litigation settlement liability	125.0	—	1,600.0
Medicaid lawsuit	(4.2)	638.9	—
Other	57.7	(95.3)	(161.5)
Net cash from operating activities	455.4	498.9	742.9
Cash Flows From Investing Activities:			
Capital expenditures	(55.3)	(47.7)	(133.0)
Proceeds (payments) related to divestiture, net of cash	15.7	(0.7)	95.1
Other	1.8	37.2	29.6
Net cash from investing activities	(37.8)	(11.2)	(8.3)
Cash Flows From Financing Activities:			
Issuance of external debt	—	—	695.0
Repayment of external debt	(137.5)	(139.5)	(945.1)
Debt financing costs	—	(9.4)	(10.1)
Proceeds from exercise of share options	—	—	0.6
Repurchase of shares	—	(0.4)	(2.6)
Other	—	(36.3)	(17.9)
Net cash from financing activities	(137.5)	(185.6)	(280.1)
Effect of currency rate changes on cash	(1.9)	2.3	0.6
Net change in cash, cash equivalents and restricted cash	278.2	304.4	455.1
Cash, cash equivalents and restricted cash at beginning of period	1,127.0	822.6	367.5
Cash, cash equivalents and restricted cash at end of period	$ 1,405.2	$ 1,127.0	$ 822.6
Cash and cash equivalents at end of period	$ 1,345.0	$ 1,070.6	$ 790.9
Restricted cash included in prepaid expenses and other assets at end of period	24.0	20.2	—
Restricted cash included in other long-term assets at end of period	36.2	36.2	31.7
Cash, cash equivalents and restricted cash at end of period	$ 1,405.2	$ 1,127.0	$ 822.6
Supplemental Disclosures of Cash Flow Information:			
Cash paid for interest	$ 243.2	$ 256.1	$ 314.2
Cash (received) paid for income taxes, net	(160.0)	39.9	30.7

See Notes to Consolidated Financial Statements.

MALLINCKRODT PLC
(DEBTOR-IN-POSSESSION)
(IN EXAMINATION UNDER PART 10 OF THE IRISH COMPANIES ACT 2014)
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 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 adoption	—	—	—	—	—	(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 as of December 25, 2020	94.1	$ 18.8	9.5	$ (1,616.1)	$ 5,587.6	$ (2,961.5)	$ (9.6)	$ 1,019.2
Net loss	—	—	—	—	—	(717.4)	—	(717.4)
Other comprehensive income	—	—	—	—	—	—	1.3	1.3
Vesting of restricted shares	0.2	0.1	0.1	—	—	—	—	0.1
Share-based compensation	—	—	—	—	10.2	—	—	10.2
Balance as of December 31, 2021	94.3	$ 18.9	9.6	$ (1,616.1)	$ 5,597.8	$ (3,678.9)	$ (8.3)	$ 313.4

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, ophthalmology and oncology; immunotherapy and neonatal respiratory critical care therapies; analgesics; cultured skin substitutes 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 reported in discontinued operations. Divestitures of product lines and businesses 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 19 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. Subsequent to the filing of the Chapter 11 Cases, Chapter 11 proceedings commenced by a limited subset of the Debtors have been recognized and given effect in Canada, and separately Mallinckrodt plc has commenced an examinership process with the High Court of Ireland. The references to the Chapter 11 Cases included within this Annual Report on Form 10-K shall include, where applicable, such proceedings in Canada and Ireland.

See Note 2 for further information on the voluntary petitions for reorganization, the RSA and agreements in principle subsequently memorialized in the Company's Chapter 11 plan of reorganization.

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 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.

Although the Bankruptcy Court has entered an order (the "Confirmation Order") confirming the plan of reorganization proposed by the Debtors, consummation of such plan of reorganization and the transactions contemplated thereby and emergence from the Chapter 11 proceedings remains subject to the satisfaction of various conditions, including completion of the Canadian and Irish proceedings noted above. Accordingly, no assurance can be given that the plan of reorganization or the transactions contemplated thereby 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 2021 consisted of 53 weeks and fiscal 2020 and 2019 each consisted of 52 weeks. Unless otherwise indicated, fiscal 2021, 2020 and 2019 refer to the Company's fiscal years ended December 31, 2021, December 25, 2020 and December 27, 2019, 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"). Pursuant to orders granted by the Ontario Superior Court of Justice, the Chapter 11 proceedings commenced by a limited subset of the Company's subsidiaries have also been recognized and given effect in Canada. 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 and Plan of Reorganization* 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

The Company obtained an order of the Bankruptcy Court in the Chapter 11 Cases (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 the Company 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. On April 13, 2021, the Debtors received Bankruptcy Court approval of their motion to amend the final cash collateral order as of March 22, 2021 to pay post-petition interest on the senior secured term loans at a rate equal to (1) the adjusted LIBOR, plus (2) the contract-specified applicable margin, and plus (3) an incremental 250 basis points for its senior secured term loans.

Interest expense incurred and paid with respect to the incremental adequate protection payments on the senior secured revolving credit facility and the senior secured term loans, respectively, were as follows:

	Fiscal Year	
	2021	2020
Interest expense incurred for adequate protection payments	$ 63.1	$ 11.7
Cash paid for adequate protection payments	66.7	7.8

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.

Bar Dates

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) for filing claims against the Debtors relating to the period prior to the Petition Date for general claims and government claims, respectively. On May 20, 2021, the Bankruptcy Court entered an order approving a deadline of June 28, 2021 at 5:00 pm (Eastern Time) for filing claims against the Debtors relating to the period from the Petition Date to April 30, 2021 for administrative expense requests by certain creditors. The preceding bar dates do not cover opioid claims (inclusive of voluntary injunction opioid claims). The Company's review and reconciliation of asserted claims and administrative expense requests is ongoing and discussed further below in *Chapter 11 Claims Process*.

Injunctive Litigation Relief

The Bankruptcy Court entered an order extending its prior injunctions against certain opioid and Acthar Gel-related litigation matters proceeding against the Debtors and also against certain covered non-Debtors on August 30, 2021. Refer to Note 19 for further discussion.

Restructuring Support Agreement and Plan of Reorganization

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 "Initial RSA Supporting Parties"). After the bankruptcy filing, the Multi-State Governmental Entities Group (the "MSGE Group") entered into a joinder to the RSA that gained the support of approximately 1,300 cities, municipalities, hospital and school districts, amongst others. On March 11, 2021, an ad hoc group of lenders holding (collectively, together with the Initial RSA Supporting Parties and the MSGE Group, the "RSA Supporting Parties") approximately $1,300.0 million, by aggregate principal amount, of the Company's outstanding senior secured term loan due September 2024 (the "2017 Term Loan") and senior secured term loan due February 2025 (the "2018 Term Loan") agreed to join the RSA as supporting parties and certain of the existing supporting parties agreed to certain amendments thereto (the "Joinder and Amendment").

The restructuring transactions will be effectuated through the Chapter 11 plan of reorganization, which among other things provides for a financial restructuring that would reduce the Company's total debt. Pursuant to the RSA, each of the Debtors and the RSA 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 RSA Supporting Parties' representatives in the bankruptcy process; and satisfy certain other covenants. The RSA Supporting Parties have committed to support and vote for the Chapter 11 plan of reorganization implementing the terms of the RSA and have agreed to use commercially reasonable efforts to take, or refrain from taking, certain actions in furtherance of such support.

The RSA (as supplemented by the above-described joinders, including the Joinder and Amendment) incorporates the terms agreed to by the parties reflected in the term sheets attached to the RSA and such joinders, including the Joinder and Amendment, including an agreement by the RSA Supporting Parties. Each of the parties to the RSA may terminate the agreement (and thereby their support for the associated plan of reorganization) 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 RSA 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 Debtors' Chapter 11 plan that embodies the transactions set forth in the RSA was the subject of a confirmation hearing that commenced on November 1, 2021 and concluded on January 6, 2021. On February 3, 2022, the Bankruptcy Court issued a written ruling confirming the Chapter 11 plan (which was subsequently revised February 8, 2022 to make minor corrections). On March 2, 2022, the Bankruptcy Court entered the Confirmation Order. The consummation of the Chapter 11 plan is subject to satisfaction of certain conditions precedent. Accordingly, no assurance can be given that the transactions described therein will be consummated. Refer to Note 22 for further information on confirmation of the Chapter 11 plan.

Plan of Reorganization

On September 2, 2021, the Debtors reached agreements in principle with (1) the Governmental Plaintiff Ad Hoc Committee (the “GAHC”), the MSGE Group, and the Official Committee of Opioid Related Claimants appointed in the Chapter 11 Cases (the “OCC” and, together with the GAHC and the MSGE Group, the “Opioid Claimants”), (2) the Official Committee of Unsecured Creditors appointed in the Chapter 11 Cases (the “UCC”) and (3) holders of more than two-thirds of the outstanding principal amount of the 10.00% second lien senior secured notes due April 2025 (the "Second Lien Notes") issued by Company's subsidiaries Mallinckrodt International Finance S.A. and Mallinckrodt CB LLC (the “Settling Second Lien Noteholders”) and the trustee for the Second Lien Notes, in each case relating to the treatment of certain claims pursuant to the proposed Joint Chapter 11 Plan of Reorganization of Mallinckrodt plc and Its Debtor Affiliates Under Chapter 11 of the Bankruptcy Code dated as of June 18, 2021 (the "Proposed Plan"), as it was amended to conform to such agreements in principle (the “Amended Plan”) as filed by the Debtors on September 29, 2021.

The RSA Supporting Parties along with the OCC, the UCC and the Settling Second Lien Noteholders (in accordance with the agreements in principle) agree to support the following as memorialized in the Amended Plan, which may be amended, modified or supplemented from time to time:

- *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 $1,725.0 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; (iii) a $150.0 million payment upon each of the third through seventh anniversaries of emergence; and (iv) a $125.0 million payment upon the eighth anniversary of emergence with an eighteen-month 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 sixth 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 has begun to 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 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. Also in connection with the Proposed Acthar Gel-Related Settlement, the Company entered into a five-year corporate integrity agreement ("CIA") with the Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS") in March 2022. As a result of these agreements, upon effectiveness of the settlement, 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 upon consummation of the plan of reorganization and emergence from the Chapter 11 Cases. Similarly, state and territory Attorneys General will also drop related lawsuits. In turn, 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 was filed in the U.S. Court of Appeals for the District of Columbia ("D.C. Circuit").

      Mallinckrodt has entered into the Proposed Acthar Gel-Related Settlement with the DOJ and other governmental parties solely to move past these litigation matters and disputes and does not make any admission of liability or wrongdoing.
- *A modification of the Company's senior secured term loans.* At the end of the court-supervised process, lenders holding allowed claims in respect of the Company's 2017 and 2018 Term Loans are expected to receive either (1) new senior secured term loans in an amount equal to the remaining principal amount of claims (as reduced by, inter alia, the excess cash flow

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. A mandatory prepayment in an amount equal to $114.0 million arising from excess cash flow with respect to fiscal 2020 was paid to the holders of the Company's 2017 and 2018 Term Loans on March 19, 2021.

- *The reinstatement or repayment of the Company's senior secured revolving credit facility*. At the end of the court-supervised process, all allowed claims under such facility would be paid in full in cash with the proceeds of newly incurred debt.
- *The reinstatement of the agreements associated with the Company's 10.00% first lien senior notes*. At the end of the court-supervised process, all allowed claims under these agreements will be reinstated at existing rates and maturities as the applicable holders' purported make-whole claims were disallowed.
- *A modification of the Company's 10.00% second lien senior notes.* At the end of the court-supervised process, lenders holding allowed claims in respect of the Company's 10.00% second lien senior secured notes are expected to receive their pro rata share of new 10.00% second lien senior secured notes due 2025 that will have the same principal amount and other economic terms as the existing second lien senior secured notes.
- *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, certain trade creditors and holders of other allowed general unsecured claims including 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, are expected to share in $135.0 million in cash, plus other potential consideration, in accordance with the allocations as prescribed in the Amended Plan, and equity holders would receive no recovery.

On April 20, 2021, the Debtors filed a joint plan of reorganization of the Debtors (the "Original Plan") reflecting the terms of the RSA, as amended by the Joinder and Amendment and a related proposed Disclosure Statement (the “Original Disclosure Statement”). On each of June 8, 2021 (or, with respect to the Original Disclosure Statement, June 9, 2021), June 15, 2021 and June 17, 2021, the Debtors filed with the Bankruptcy Court amended versions of the Original Plan and the Original Disclosure Statement. Finally, on June 18, 2021, the Debtors filed with the Bankruptcy Court a solicitation version of the Proposed Plan, and a solicitation version of a related Disclosure Statement (the “Disclosure Statement”). Contemporaneously, the Debtors filed a motion requesting that the Bankruptcy Court (i) establish the Proposed Plan solicitation and voting procedures, (ii) approve the forms of ballots, solicitation packages, and related notices to be sent to the various creditors and interest holders in connection with confirmation of the Plan, and (iii) establish certain deadlines in connection with the approval of the disclosure statement (the “Solicitation and Voting Procedures”). On September 29, 2021, the Debtors filed the Amended Plan with the Bankruptcy Court incorporating the Amended Proposed Opioid-Related Litigation Settlement, the settlement with the UCC and the settlement with the Settling Second Lien Noteholders. The Debtors filed a third and fourth amendment to the Amended Plan on December 29, 2021 and January 6, 2022, respectively, and subsequently technical modifications to the fourth amendment on February 18, 2022, in conjunction with the plan confirmation process as described further below.

The Amended Plan and the related Disclosure Statement describe, among other things, the terms of the Amended Plan; the Debtors contemplated financial restructuring (the “Restructuring”); the events leading up to the Chapter 11 Cases; certain events that have occurred or are anticipated to occur during the Chapter 11 Cases, including solicitation of votes to approve the Proposed Plan from certain of the Debtors' creditors and certain other aspects of the Restructuring.

By order dated June 17, 2021, the Bankruptcy Court approved the Disclosure Statement and the Solicitation and Voting Procedures. Pursuant to the Solicitation and Voting Procedures, the Debtors mailed the ballots, solicitation packages and related notices by June 24, 2021, and votes were due by October 13, 2021, with exception of holders of class 8 and 9 whose votes were due October 20, 2021. In accordance with the Debtors' proposed confirmation timeline, which is subject to change by the Bankruptcy Court, a hearing to consider confirmation of the Amended Plan (which may be adjourned or extended from time to time) commenced on November 1, 2021. On February 3, 2022, the Bankruptcy Court issued a written ruling confirming the Chapter 11 plan (which was subsequently revised February 8, 2022 to make minor corrections). On March 2, 2022, the Bankruptcy Court entered the Confirmation Order. Mallinckrodt plc commenced the examinership process with the High Court of Ireland on February 14, 2022. Refer to Note 22 for further details on confirmation of the Amended Plan and the examinership process.

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 14 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 sheets as of December 31, 2021 and 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 liabilities subject to compromise ("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 sheets as of December 31, 2021 and 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.

Non-debtor entity intercompany balances from/due to the debtor entities at the end of each period were:

	December 31, 2021	December 25, 2020
Intercompany receivables	$ 119.1	$ 282.3
Intercompany payables	112.9	120.3

The intercompany balances were 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 sheets as of December 31, 2021 and December 25, 2020.

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 confirmed Chapter 11 plan of reorganization becomes effective. Accordingly, the ultimate amount of such liabilities is not determinable at this time. 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 at the end of each period consisted of the following:

	December 31, 2021	December 25, 2020
Accounts payable [1]	$ 42.9	$ 61.9
Accrued interest	35.2	35.2
Debt [2]	3,750.8	1,660.7
Environmental liabilities [3]	52.0	—
Medicaid lawsuit	634.7	638.9
Opioid-related litigation settlement liability [4]	1,725.0	1,600.0
Other current and non-current liabilities [5]	125.1	163.5
Pension and postretirement benefits	32.0	32.4
Total liabilities subject to compromise	$ 6,397.7	$ 4,192.6

(1) Pre-petition accounts payable balances have been repaid under effectuated trade agreements pursuant to the critical vendor motion approved by the Bankruptcy Court.

(2) Subsequent to December 25, 2020, in accordance with the agreement in principle reached with the Settling Second Lien Noteholders on September 2, 2021 and Joinder and Amendment to the RSA entered into in March 2021, $322.9 million of Second Lien Notes and $1,767.2 million of outstanding senior secured term loans, respectively, were classified as LSTC in the Company's consolidated balance sheet as of December 31, 2021.

(3) Represents certain environmental liabilities intended to be discharged upon effectiveness of the plan of reorganization.

(4) In accordance with the agreement in principle reached with the Opioid Claimants on September 2, 2021, and subsequently memorialized in the Amended Plan on September 29, 2021, the Company recorded an accrual of $125.0 million related to the additional payment expected to be made on the eighth anniversary of the effective date of emergence, which has been classified as LSTC in the Company's consolidated balance sheet as of December 31, 2021.

(5) The decrease in other current and non-current liabilities was attributable to (1) the Bankruptcy Court's approval of the Company's rejection of its Bedminster facility lease, which resulted in a $34.8 million adjustment to the carrying value of the respective lease liability in LSTC to reflect the estimated allowed claim amount and (2) a decrease of $15.6 million in the fair value of contingent consideration related to MNK-6105 and MNK-6106 . These decreases were partially offset by an increase of $17.3 million related to Acthar Gel royalty accruals as a result of the December 2021 Bankruptcy Court ruling, which found that the Acthar Insurance Claimants' (as defined in Note 19) administrative claims were without merit. The remaining change in other current and non-current liabilities was attributable to various increases and decreases as a result of adjustments in the ordinary course of business.

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 payments due under the Company's unsecured debt instruments for fiscal 2021 and 2020, which it did not pay was $93.0 million and $28.8 million, respectively.

Chapter 11 Claims Process

The Debtors have received over 50,000 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 Proposed Opioid-Related Litigation Settlement (collectively, the "Proposed Settlements"). See *Restructuring Support Agreement and Plan of Reorganization* 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 in the period in which they are resolved. The determination of how liabilities will ultimately be resolved cannot be made until the plan of reorganization is consummated or the Bankruptcy Court 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 2021 and 2020 was $333.1 million and $8.7 million, respectively. Reorganization items, for fiscal 2021 and 2020 include the following:

	Fiscal Year	
	2021	2020
Professional fees	$ 405.6	$ 51.1
Debt valuation adjustments	23.1	10.2
Adjustments of other claims	(0.5)	0.1
Total reorganization items, net	$ 428.2	$ 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 confirmed Chapter 11 plan of reorganization 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 directly 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 third parties 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 that 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		
	2021	2020	2019
Shipping costs	$ 23.6	$ 20.1	$ 17.6

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. 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 and impairment. 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 utilizes its incremental borrowing rate based on the information available at commencement date in determining the present value of future lease payments. 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.

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.

Intangible Assets

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 31, 2021 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 legal proceedings and claims, including government investigations, environmental matters, product liability matters, patent infringement claims, antitrust matters, securities class action lawsuits, personal injury claims, employment disputes, contractual and other commercial disputes, and other legal proceedings, in the ordinary course of business as further discussed in Note 19. The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. The Company discounts environmental liabilities using a risk-free rate of return when the obligation is fixed or reasonably determinable. The impact of the discount in the consolidated balance sheets was not material in any period presented. Legal fees, other than those pertaining to environmental and asbestos matters, are expensed as incurred. Insurance recoveries related to potential claims are recognized up to the amount of the recorded liability when coverage is confirmed and the estimated recoveries are probable of payment. Assets and liabilities are not netted for financial statement presentation.

Share-Based Compensation

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

Restructuring

The Company recognizes charges associated with the Company's Board of Directors approved restructuring programs designed to transform its business and improve its cost structure. Restructuring charges can include severance costs, infrastructure charges, distributor contract cancellations and other items. The Company accrues for costs when they are probable and reasonably estimable.

Income Taxes

Deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been reflected in the consolidated financial statements. Deferred tax assets and liabilities are determined based on the differences between the book and tax bases of assets and liabilities and operating loss carryforwards, using tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided to reduce net deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

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 8 for further information regarding the classification of such amounts in the consolidated balance sheets.

4. Revenue from Contracts with Customers

Product Sales Revenue

See Note 21 for presentation of the Company's net sales by product family.

Reserves for variable consideration

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 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 19) [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
Provisions	2,087.1	23.7	55.2	2,166.0
Payments or credits	(2,041.8)	(28.8)	(58.0)	(2,128.6)
Balance as of December 31, 2021	$ 241.8	$ 21.5	$ 9.5	$ 272.8

(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 19 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		
	2021	2020	2019
Product sales transferred at a point in time	79.4 %	78.9 %	81.8 %
Product sales transferred over time	20.6	21.1	18.2

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 31, 2021:

Fiscal 2022	$ 112.1
Fiscal 2023	69.7
Thereafter	14.7

Costs to fulfill a contract

For both December 31, 2021 and December 25, 2020, 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 and reflected in property, plant and equipment, net, on the consolidated balance sheets was $25.8 million. The associated depreciation expense recognized during fiscal 2021 and 2020 was $6.1 million and $5.5 million, respectively.

Product Royalty Revenues

The Company licenses certain rights to Amitiza to third parties in exchange for royalties on net sales of the product. The Company receives a double-digit royalty based on a percentage of the gross profits of the licensed products sold during the term of the agreements. The Company recognizes such royalty revenue as the related sales occur. The associated royalty revenue recognized during fiscal 2021, 2020 and 2019 was $102.4 million, $70.3 million and $81.3 million, respectively.

5. Discontinued Operations and Divestitures

Discontinued Operations

Nuclear Imaging: The Company received a total of $9.0 million in contingent consideration in both fiscal 2020 and 2019, 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. 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 and 2019. In December 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 2021 and 2020, a tax benefit of $5.1 million and $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 statutes 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 and RECOTHROM® Thrombin topical (Recombinant) ("Recothrom") products to Baxter International Inc. During fiscal 2020, the Company recorded a $16.5 million gain on divestiture related to certain commercial milestones for the Recothrom product.

6. License Agreements

Silence Therapeutics

In July 2019, the Company entered into a license and collaboration agreement with Silence Therapeutics plc ("Silence") 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 and made an upfront payment of $20.0 million, recorded within R&D expense. Under the terms of the agreement, the Company obtained an exclusive worldwide license to Silence's SLN501 silencing therapy. 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.

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 was to provide the Company with a royalty based on net sales of the product through January 1, 2020. In early 2018, the U.S. Food and Drug Administration ("FDA") approved Lutathera for treatment of gastroenteropancreatic neuroendocrine tumors and commercial sales commenced. During fiscal 2019, in relation to this agreement, the Company recognized royalty income of $39.0 million, which was recognized within other income, net in the consolidated statement of operations.

7. Restructuring and Related Charges

During fiscal 2021, 2018 and 2016, the Company launched restructuring programs designed to improve its cost structure. Charges of $50.0 million to $100.0 million were provided for under the 2021 program and $100.0 million to $125.0 million were provided for under the 2018 and 2016 programs. Each program will generally commence upon substantial completion of the previous program. The 2021 program has not commenced as of December 31, 2021 and there is no specified time period associated with this 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		
	2021	2020	2019
Specialty Brands	$ 0.1	$ 0.1	$ (13.7)
Specialty Generics	4.9	0.1	10.0
Corporate	24.0	49.6	2.0
Restructuring and related charges, net	29.0	49.8	(1.7)
Less: accelerated depreciation	(2.1)	(12.3)	—
Restructuring charges, net	$ 26.9	$ 37.5	$ (1.7)

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

	Fiscal Year		
	2021	2020	2019
2018 Program	$ 29.0	$ 52.0	$ 9.8
2016 Program	—	(0.3)	(10.6)
Acquisition programs	—	(1.9)	(0.9)
Total programs	29.0	49.8	(1.7)
Less: non-cash charges, including accelerated depreciation	(6.3)	(23.8)	—
Total charges expected to be settled in cash	$ 22.7	$ 26.0	$ (1.7)

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 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
Charges from continuing operations	23.7	—	—	23.7
Changes in estimate from continuing operations	(1.0)	—	—	(1.0)
Cash payments	(12.8)	—	—	(12.8)
Balance as of December 31, 2021	$ 10.9	$ —	$ —	$ 10.9

(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 Accounting Standard Update (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 31, 2021, net restructuring and related charges incurred cumulative to date were as follows:

	2018 Program [1]	2016 Program [2]
Specialty Brands	$ 3.1	$ 68.1
Specialty Generics	15.0	14.6
Corporate	77.9	28.6
	$ 96.0	$ 111.3

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

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

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

8. Income Taxes

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

	Fiscal Year		
	2021	2020	2019
Domestic	$ (512.2)	$ (656.9)	$ (75.3)
International	(317.6)	(303.9)	(1,516.2)
Total	$ (829.8)	$ (960.8)	$ (1,591.5)

(1) Domestic reflects Ireland in fiscal 2021 and 2020, and U.K. in fiscal 2019.

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

	Fiscal Year		
	2021	2020	2019
Current:			
Domestic	$ (33.7)	$ 0.1	$ 0.1
International	(12.7)	(375.4)	21.7
Current income tax (benefit) provision	(46.4)	(375.3)	21.8
Deferred:			
Domestic	(59.5)	102.2	(1.1)
International	(0.4)	282.0	(605.0)
Deferred income tax (benefit) provision	(59.9)	384.2	(606.1)
Total	$ (106.3)	$ 8.9	$ (584.3)

(1) Domestic reflects Ireland in fiscal 2021 and 2020, and the U.K. in fiscal 2019.

The domestic current income tax provision reflects a tax benefit of $2.2 million, $0.2 million and $1.2 million from using net operating loss ("NOL") carryforwards for fiscal 2021, 2020 and 2019, respectively. For fiscal 2021 and 2020, domestic reflects Ireland; and for fiscal 2019, domestic reflects the U.K. The international current income tax provision reflects a tax benefit of $1.2 million, $33.4 million and $0.9 million from using NOL carryforwards for fiscal 2021, 2020 and 2019, respectively. The fiscal 2020 international current income tax provision also included 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.

During fiscal 2021, net cash refunds for income taxes were $160.0 million, and during fiscal 2020 and 2019, net cash payments for income taxes were $39.9 million and $30.7 million, respectively. Included within the net cash refunds of $160.0 million were refunds of $178.8 million received as a result of the provisions in the Coronavirus Aid, Relief and Economic Security ("CARES") Act and net payments of $18.8 million related to operational activity.

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		
	2021	2020	2019
Benefit for income taxes at domestic statutory income tax rate [1]	$ (103.7)	$ (120.1)	$ (302.4)
Adjustments to reconcile to income tax provision:			
Rate difference between domestic and international jurisdictions [2]	(224.9)	(315.3)	(206.3)
Adjustments to accrued income tax liabilities and uncertain tax positions [3]	(9.7)	16.7	(18.7)
Credits, principally research and orphan drug	(4.7)	(11.2)	(13.5)
Permanently nondeductible and nontaxable items [4]	9.8	2.8	98.1
Divestitures [5]	—	—	9.6
U.S. Tax Reform [6]	—	(281.5)	—
Legal entity reorganization [6]	—	82.0	(212.8)
Separation costs	—	8.4	—
Reorganization items, net	36.9	8.8	—
Other	0.3	0.1	—
Valuation allowances [4]	189.7	618.2	61.7
(Benefit) provision for income taxes	$ (106.3)	$ 8.9	$ (584.3)

(1) The statutory tax rate reflects the Irish statutory tax rate of 12.5% for fiscal 2021 and 2020, and the U.K. statutory tax rate of 19.0% for fiscal 2019.

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

(3) Includes interest and penalties on accrued income tax liabilities and uncertain tax positions.

(4) For fiscal 2021, the permanently nondeductible and nontaxable items were primarily driven by the opioid-related litigation settlement loss that is partially permanently nondeductible. 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 due to the Company's substantial doubt about its ability to continue as a going concern, further explained within Note 1. 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 that is partially permanently nondeductible, further explained within Note 19. Additional valuation allowance impacts are netted within other line items, as referenced in the associated footnotes to this table.

(5) The Company completed the sale of its wholly-owned subsidiary BioVectra in November 2019.

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

The rate difference between domestic and international jurisdictions changed to $224.9 million of tax benefit for fiscal 2021 from $315.3 million of tax benefit for fiscal 2020. Of the $90.4 million decrease in the tax benefit, $48.9 million of the decrease is attributable to the Medicaid lawsuit and $92.9 million of decrease is predominately attributable to changes in the jurisdictional mix of operating loss resulting from the fiscal 2020 reorganization of the Company's intercompany financing and associated asset and legal entity ownership, partially offset by $27.6 million of an increase attributable to reorganization items, $13.2 million of an increase attributable to non-restructuring impairment charges and $10.6 million of an increase attributable to the opioid-related litigation settlement loss.

The Company's valuation allowance tax expense was $189.7 million for fiscal 2021, compared to $618.2 million for fiscal 2020. Of the $428.5 million decrease in tax expense, $288.9 million of decrease was attributable to operational activity in applicable tax jurisdictions that are fully offset by a valuation allowance and $204.9 million of decrease was attributable to the discrete valuation allowance recorded in fiscal 2020 on certain beginning-of-the-year net deferred tax assets, partially offset by a $65.3 million increase attributable to deferred remeasurement as a result of tax rate changes. The valuation allowance tax expense mainly offsets impacts included within the benefit for income taxes at the domestic statutory income tax rate and the rate difference between domestic and international jurisdictions.

The rate difference between domestic and international jurisdictions was $315.3 million of tax benefit for fiscal 2020, compared to $206.3 million of tax benefit for fiscal 2019. Of the $109.0 million increase in the tax benefit, $92.7 million of the increase resulted 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 was 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 loss and a $30.0 million decrease attributable to changes in operating loss. The remaining $137.3 million increase was 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 following table summarizes the activity related to the Company's unrecognized tax benefits, excluding interest:

	Fiscal Year		
	2021	2020	2019
Balance at beginning of period	$ 349.0	$ 398.6	$ 287.7
Additions related to current year tax positions	—	71.1	123.5
Additions related to prior period tax positions	9.3	9.8	19.2
Reductions related to prior period tax positions	(2.8)	(14.2)	(5.7)
Settlements	(0.2)	(80.3)	(1.0)
Lapse of statutes of limitations	(21.8)	(36.0)	(25.1)
Balance at end of period	$ 333.5	$ 349.0	$ 398.6

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

	December 31, 2021	December 25, 2020
Other assets [1]	$ 255.7	$ 256.4
Other income tax liabilities	64.1	83.2
Deferred income taxes	13.7	9.4
	$ 333.5	$ 349.0

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

Included within total unrecognized tax benefits as of December 31, 2021, December 25, 2020 and December 27, 2019 were $77.0 million, $85.9 million and $395.9 million, respectively, of unrecognized tax benefits, which if favorably settled would benefit the effective tax rate, of which approximately $20.0 million related to discontinued operations in fiscal 2019. The remaining unrecognized tax benefits are reflected as a write-off of related other tax assets. If these unrecognized tax benefits were recognized, they would be offset by a valuation allowance in fiscal 2021 and 2020. During fiscal 2021 and 2020, due to a lapse of statutes of limitations, $5.1 million and $18.1 million of tax and interest on unrecognized tax benefits related to the Nuclear Imaging business were eliminated, and a benefit of $5.1 million and $18.1 million was recorded in discontinued operations within the consolidated statement of operations, respectively. During fiscal 2021, the Company recorded $6.4 million of additional interest and penalties through tax provision and decreased accrued interest and penalties by $4.2 million related to prior period reductions, settlements and lapse of statutes of limitations. During fiscal 2020 and 2019, the Company had a net decrease of interest and penalties activity of $16.2 million and $4.2 million, respectively. The total amount of accrued interest and penalties related to uncertain tax positions was $18.9 million, $16.7 million and $32.9 million, respectively.

It is reasonably possible that within the next twelve months the unrecognized tax benefits could decrease by up to $139.2 million and the amount of related interest and penalties could decrease by up to $17.2 million as a result of payments or releases due to the resolution of examinations, appeals and litigation, successful emergence from Chapter 11 and the expiration of various statutes of limitation.

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 31, 2021	December 25, 2020
Accrued and other current liabilities	$ 1.7	$ 26.5
Other income tax liabilities	83.2	100.1
	$ 84.9	$ 126.6

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

	December 31, 2021	December 25, 2020
Other assets	$ 141.3	$ 139.4
Prepaid expenses and other current assets	36.5	188.7
	$ 177.8	$ 328.1

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 31, 2021	December 25, 2020
Deferred tax assets:		
Tax loss and credit carryforward	$ 4,147.5	$ 4,026.0
Capital tax loss carryforward and related assets	1,605.0	1,600.1
Opioid-related litigation settlement liability	294.7	269.3
Excess interest	159.5	150.7
Other	292.2	294.9
	6,498.9	6,341.0
Deferred tax liabilities:		
Intangible assets	(108.5)	(191.2)
Investment in partnership	(67.1)	(74.8)
Other	—	(44.8)
	(175.6)	(310.8)
Net deferred tax asset before valuation allowances	6,323.3	6,030.2
Valuation allowances	(6,344.2)	(6,110.8)
Net deferred tax liability	$ (20.9)	$ (80.6)

The net deferred tax asset before valuation allowances was $6,323.3 million as of December 31, 2021, compared to $6,030.2 million as of December 25, 2020. This increase was due to a $178.8 million increase predominately related to tax loss and credit carryforward additions and current and prior years' operational activity, a $21.4 million increase associated with the opioid-related litigation settlement liability and a $92.9 million increase associated with intangible assets.

The deferred tax asset valuation allowances of $6,344.2 million and $6,110.8 million as of December 31, 2021 and December 25, 2020, 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 litigation settlement liability.

Net deferred tax liabilities of $20.9 million and $80.6 million were included in deferred income taxes on the consolidated balance sheets as of December 31, 2021 and December 25, 2020, respectively.

As of December 31, 2021, the Company had approximately $4,024.0 million of NOL carryforwards in certain international jurisdictions measured at the applicable statutory rates, of which $1,851.3 million have no expiration and the remaining $2,172.7 million will expire in future years through 2042. As of December 31, 2021, the Company had $39.5 million of domestic NOL carryforwards measured at the applicable statutory rates, which have no expiration date.

As of December 31, 2021, the Company had $184.7 million of capital loss carryforwards in certain international jurisdictions measured at the applicable statutory rates, which will expire in future years through 2026. As of December 31, 2021, the Company had approximately $969.5 million of domestic capital loss carryforwards measured at the applicable statutory rates, which have no expiration date.

As of December 31, 2021, the Company also had $83.9 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 2042.

As of December 31, 2021, the Company's financial reporting basis in subsidiaries that may be subject to tax was in excess of its corresponding tax basis by $12.1 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.

9. 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 have been 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		
	2021	2020	2019
Basic	84.7	84.5	83.9

The computation of diluted weighted-average shares outstanding for fiscal 2021, 2020 and 2019 excluded approximately 5.2 million, 5.6 million and 6.3 million, respectively, shares of equity awards because the effect would have been anti-dilutive.

10. Inventories

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

	December 31, 2021	December 25, 2020
Raw materials	$ 59.8	$ 58.1
Work in process	196.4	200.7
Finished goods	91.0	86.1
Inventories	$ 347.2	$ 344.9

11. Property, Plant and Equipment

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

	December 31, 2021	December 25, 2020
Land	$ 43.5	$ 43.6
Buildings	387.8	416.9
Capitalized software	121.1	134.0
Machinery and equipment	1,254.1	1,260.4
Construction in process	80.1	56.0
	1,886.6	1,910.9
Less: accumulated depreciation	(1,110.6)	(1,077.8)
Property, plant and equipment, net	$ 776.0	$ 833.1

Depreciation expense was as follows:

	Fiscal Year		
	2021	2020	2019
Depreciation expense	$ 94.7	$ 114.0	$ 97.7

12. 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 31, 2021	December 25, 2020
Other assets	$ 35.0	$ 58.6
Accrued and other current liabilities	$ 11.1	13.0
Other liabilities	20.0	28.0
Other current and non-current liabilities subject to compromise	0.4	31.9
Total lease liabilities	$ 31.5	$ 72.9

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		
	2021	2020	2019
Lease cost:			
Operating lease cost	$ 19.6	$ 21.2	$ 21.3
Short-term lease cost	1.1	1.1	3.5
Variable lease cost	2.4	3.1	—
Total lease cost	$ 23.1	$ 25.4	$ 24.8

Lease terms and discount rates were as follows:

	December 31, 2021	December 25, 2020
Weighted-average remaining lease term (in years) - operating lease	5.7	6.1
Weighted-average discount rate - operating leases	4.4 %	3.9 %

Contractual maturities of operating lease liabilities as of December 31, 2021 were as follows:

Fiscal 2022	$ 14.7
Fiscal 2023	11.0
Fiscal 2024	7.9
Fiscal 2025	4.5
Fiscal 2026	2.8
Thereafter	2.9
Total lease payments	43.8
Less: Interest	(12.3)
Present value of lease liabilities	31.5
Less: Amounts reclassified to liabilities subject to compromise	(0.4)
Present value of lease liabilities not subject to compromise	$ 31.1

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

	Fiscal Year		
	2021	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 20.4	$ 23.1	$ 23.2
Lease assets obtained in exchange for lease obligations:			
Operating leases	2.6	6.9	7.3

13. Intangible Assets

Intangible Assets

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

	December 31, 2021		December 25, 2020	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortizable:				
Completed technology	$ 10,404.0	$ 5,160.4	$ 10,394.6	$ 4,586.6
License agreements	120.1	82.1	120.1	78.1
Trademarks	77.7	26.9	77.7	23.5
Total	$ 10,601.8	$ 5,269.4	$ 10,592.4	$ 4,688.2
Non-Amortizable:				
Trademarks	$ 35.0		$ 35.0	
In-process research and development	81.0		245.3	
Total	$ 116.0		$ 280.3	

The Company recorded impairment charges related to its Specialty Brands segment totaling $154.9 million, $63.5 million and $388.0 million during fiscal 2021, 2020 and 2019, 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 2021 impairment charge included a partial impairment of $90.4 million related to Amitiza, as discussed further below, and a full impairment of $64.5 million related to MNK-6105 and MNK-6106 as the Company decided it would no longer pursue further development of this IPR&D asset. The fiscal 2020 impairment charge related to Ofirmev® (acetaminophen) injection ("Ofirmev") and was primarily driven by a change in the estimate of the asset's useful life resulting in its undiscounted cash flow being less than its net book value. The fiscal 2019 impairment charge 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.

Amitiza

During the three months ended December 31, 2021, due to lower anticipated cash flows expected from Amitiza, the Company identified a triggering event with respect to the associated intangible asset within the Specialty Brands segment and assessed the recoverability of the definite-lived asset. The Company determined that the undiscounted cash flows related to the Amitiza 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 Amitiza intangible asset and its net book value. In connection with this analysis, the Company concluded that the sum of the years digits method, an accelerated method of amortization, on a prospective basis (beginning with the first quarter of fiscal 2022) would more accurately reflect the consumption of the economic benefits over the remaining useful life of the asset.

The Company determined the fair value of the Amitiza 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 Amitiza 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 Amitiza intangible asset that was less than its net book value. Therefore, the Company recorded an impairment charge of $90.4 million.

StrataGraft®

On June 15, 2021, the Company announced that the FDA had approved the StrataGraft biologics license application (BLA) for the treatment of adults with deep partial-thickness burns. Upon FDA approval, the Company transferred the total $99.8 million of asset value from non-amortized, indefinite-lived acquired IPR&D product rights to amortizable, finite-lived completed technology and will begin amortization of the asset in tandem with the first commercial shipment of the product during the first quarter of fiscal 2022. Concurrent with the approval of StrataGraft, the FDA granted the Company a Priority Review Voucher ("PRV"). A PRV is a voucher that may be used to obtain an accelerated FDA review of one of the Company's future products or sold to a third party to obtain accelerated review of one of its future products.

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. On August 18, 2021, the Company resubmitted its NDA for terlipressin to the FDA and on February 18, 2022 (the Prescription Drug User Fee Act, or "PDUFA date"), the FDA issued a CRL. In the weeks leading up to the PDUFA date, it became necessary for the Company to identify a new packaging and labeling manufacturing facility, which meant that an inspection by the FDA could not be completed by the PDUFA date. A satisfactory inspection is required before the NDA can be approved. This is the only outstanding issue noted in the CRL, and it is important to note that there were no safety or efficacy issues cited. The Company remains committed to this critically ill patient population, who currently have no approved treatment option in the U.S for HRS-1 and believes that there is a path to approval in 2022. The Company 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 31, 2021 and December 25, 2020.

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

Intangible asset amortization expense was as follows:

	Fiscal Year		
	2021	**2020**	**2019**
Amortization expense	$ 581.1	$ 771.2	$ 853.4

The estimated aggregate amortization expense on intangible assets owned by the Company and being amortized as of December 31, 2021, is expected to be as follows:

Fiscal 2022	$ 605.3
Fiscal 2023	585.1
Fiscal 2024	564.8
Fiscal 2025	543.1
Fiscal 2026	517.2

14. Debt

The commencement of the Chapter 11 Cases 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 sheets as of December 31, 2021 and 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 31, 2021		December 25, 2020	
	Principal	Unamortized Discount and Debt Issuance Costs [1]	Principal	Unamortized Discount and Debt Issuance Costs
Secured debt:				
Term loan due September 2024	$ 1,396.5	$ —	$ 1,505.2	$ 12.3
Term loan due February 2025	370.7	—	399.5	5.0
10.00% first lien senior notes due April 2025	495.0	5.9	495.0	7.7
10.00% second lien senior notes due April 2025	322.9	—	322.9	8.0
Revolving credit facility	900.0	0.2	900.0	1.7
Total secured debt	3,485.1	6.1	3,622.6	34.7
Unsecured debt:				
9.50% debentures due May 2022	10.4	—	10.4	—
5.75% senior notes due August 2022	610.3	—	610.3	—
8.00% debentures due March 2023	4.4	—	4.4	—
4.75% senior notes due April 2023	133.7	—	133.7	—
5.625% senior notes due October 2023	514.7	—	514.7	—
5.50% senior notes due April 2025	387.2	—	387.2	—
Total unsecured debt:	1,660.7	—	1,660.7	—
Total debt, prior to reclassification to liabilities subject to compromise	5,145.8	6.1	5,283.3	34.7
Less: Current portion	(1,395.0)	(6.1)	(3,622.6)	(34.7)
Less: Amounts reclassified to liabilities subject to compromise [2]	(3,750.8)	—	(1,660.7)	—
Total long-term debt, net of current portion	$ —	$ —	$ —	$ —

(1) As a result of the Company's Chapter 11 Cases, the Company expensed $23.1 million and $10.2 million of unamortized discount and debt issuance costs, net, recorded in reorganization items, net in the consolidated statements of operations for fiscal 2021 and 2020, respectively.

(2) In connection with the Company's Chapter 11 Cases, $3,750.8 million and $1,660.7 million of outstanding debt instruments have been classified as LSTC in the Company's consolidated balance sheets as of December 31, 2021 and December 25, 2020, respectively. Up to the Petition Date, the Company continued to accrue interest expense in relation to the unsecured debt instruments classified as LSTC. The Company continues to accrue and pay interest on the outstanding secured debt instruments classified as LSTC in conjunction with the cash collateral order. Refer to Note 2 for further information.

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. Efforts to enforce payment obligations under the Revolving Credit Facility were automatically stayed during the pendency of the Chapter 11 Cases. 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 31, 2021. Unused commitments on the Revolving Credit Facility are subject to an annual commitment fee, which was 0.275% as of December 31, 2021, 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 31, 2021, 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	6.00 %	$ 1,396.5
Term loan due February 2025	6.25	370.7
Revolving credit facility	4.42	900.0

(1) Includes the incremental 200 basis points and 250 basis points related to the cash adequate protection payments for the revolving credit facility and senior secured term loans, respectively. Refer to 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 31, 2021. The Company's stated long-term debt principal maturity amounts as of December 31, 2021 are as follows:

Fiscal 2022	$ 1,539.2
Fiscal 2023	671.3
Fiscal 2024	1,371.1
Fiscal 2025	1,564.2

15. 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 31, 2021, U.S. plans represented 36.1% 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 sheets as of December 31, 2021 and 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		
	2021	2020	2019	2021	2020	2019
Service cost	$ 0.2	$ 0.2	$ 0.1	$ —	$ —	$ —
Interest cost	0.3	0.5	0.7	0.7	1.2	1.6
Amortization of net actuarial loss	0.9	0.7	0.5	0.2	—	—
Amortization of prior service cost (credit)	0.1	0.1	0.2	(2.1)	(2.1)	(2.1)
Net periodic benefit cost (credit)	$ 1.5	$ 1.5	$ 1.5	$ (1.2)	$ (0.9)	$ (0.5)

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 31, 2021	December 25, 2020	December 31, 2021	December 25, 2020
Change in benefit obligations:				
Projected benefit obligations at beginning of year	$ 29.4	$ 27.0	$ 40.1	$ 40.5
Service cost	0.2	0.2	—	—
Interest cost	0.3	0.5	0.7	1.2
Actuarial (gain) loss	(0.9)	1.8	(1.7)	1.2
Benefits and administrative expenses paid	(0.7)	(1.5)	(1.8)	(2.8)
Plan settlements	—	(0.1)	—	—
Currency translation	(1.0)	1.5	—	—
Projected benefit obligations at end of year	$ 27.3	$ 29.4	$ 37.3	$ 40.1

	Pension Benefits		Postretirement Benefits	
	December 31, 2021	December 25, 2020	December 31, 2021	December 25, 2020
Amounts recognized on the consolidated balance sheet:				
Current liabilities	$ 0.8	$ 0.8	$ 1.7	$ 1.9
Non-current liabilities	16.7	18.9	13.4	15.5
Liabilities subject to compromise	9.8	9.7	22.2	22.7
Net amount recognized on the consolidated balance sheet	$ 27.3	$ 29.4	$ 37.3	$ 40.1
Amounts recognized in accumulated other comprehensive loss consist of:				
Net actuarial loss	$ (9.7)	$ (11.8)	$ (0.1)	$ (2.0)
Prior service (cost) credit	—	(0.1)	1.7	3.8
Net amount recognized in accumulated other comprehensive loss	$ (9.7)	$ (11.9)	$ 1.6	$ 1.8

The estimated amounts that will be amortized from accumulated other comprehensive loss into net periodic benefit cost (credit) in fiscal 2022 are as follows:

	Pension Benefits	Postretirement Benefits
Amortization of net actuarial loss (gain)	$ 0.6	$ (0.1)
Amortization of prior service credit	—	(1.7)

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		
	2021	2020	2019	2021	2020	2019
Discount rate	1.8 %	2.8 %	4.0 %	1.0 %	1.3 %	2.0 %
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		
	2021	2020	2019	2021	2020	2019
Discount rate	2.3 %	1.8 %	2.8 %	1.3 %	1.0 %	1.3 %
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		
	2021	2020	2019
Net periodic benefit credit	2.0 %	3.0 %	4.1 %
Benefit obligations	2.5	2.0	3.0

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

	December 31, 2021	December 25, 2020
Healthcare cost trend rate assumed for next fiscal year	5.7 %	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 2021 and 2020 the Company made $0.7 million and $1.6 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 2022	$ 2.9	$ 4.7
Fiscal 2023	1.7	3.0
Fiscal 2024	1.7	2.9
Fiscal 2025	1.6	2.8
Fiscal 2026	1.5	2.7
Fiscal 2027 - 2031	6.9	11.7

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 $22.2 million, $26.0 million and $21.9 million for fiscal 2021, 2020 and 2019, respectively.

Rabbi Trusts and Other Investments

The Company maintains several rabbi trusts, the assets of which are used to pay retirement benefits. The rabbi trust assets are subject to the claims of the Company's creditors in the event of the Company's insolvency. Plan participants are general creditors of the Company with respect to these benefits. The trusts primarily hold life insurance policies and debt and equity securities, the value of which is included in other assets on the consolidated balance sheets. Note 20 provides additional information regarding the debt and equity securities. The carrying value of the 57 and 61 life insurance contracts held by these trusts was $43.4 million and $45.0 million as of December 31, 2021 and December 25, 2020, respectively. These contracts had a total death benefit of $86.4 million and $92.7 million as of December 31, 2021 and December 25, 2020, respectively. However, there are outstanding loans against the policies amounting to $20.8 million and $23.2 million as of December 31, 2021 and December 25, 2020, 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 $7.9 million and $7.3 million as of December 31, 2021 and December 25, 2020, respectively. These amounts were included in other assets on the consolidated balance sheets.

16. Equity

Preferred Shares

Mallinckrodt is authorized to issue 500,000,000 preferred shares, par value of $0.20 per share, none of which were issued or outstanding at December 31, 2021. 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. Under the March 2017 Repurchase Program, which has no time limit or expiration date, $1,000.0 million was authorized for share repurchase. No shares were repurchased in fiscal 2021, 2020 and 2019. The remaining amount available for repurchase is $564.2 million, subject to limitations under Chapter 11.

The Company also repurchases shares from certain employees in order to satisfy employee tax withholding requirements in connection with the vesting of restricted shares. In addition, the Company repurchases shares to settle certain option exercises. The Company spent zero, $0.4 million and $2.6 million to acquire shares in connection with equity-based awards in fiscal 2021, 2020 and 2019, respectively.

17. Share Plans

Total share-based compensation cost was $10.2 million, $25.3 million and $33.8 million for fiscal 2021, 2020 and 2019, 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 in both fiscal 2021 and 2020 and $1.2 million in fiscal 2019.

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

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 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		
Expired/Forfeited	(516,193)	45.63		
Outstanding as of December 31, 2021	5,553,519	35.05	1.7	$ —
Vested and non-vested expected to vest as of December 31, 2021	5,352,763	35.14	5.5	$ —
Exercisable as of December 31, 2021	4,616,911	38.56	2.0	—

As of December 31, 2021, there was $1.6 million of total unrecognized compensation cost related to non-vested share option awards, which is expected to be recognized over a weighted-average period of 1.0 year.

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, along with the weighted-average grant-date fair value, were as follows:

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

In fiscal 2019, the total intrinsic value of options exercised was $0.3 million and the related tax benefit was $0.1 million.

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 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
Exercised	(186,930)	23.43
Expired/Forfeited	(60,844)	19.58
Non-vested as of December 31, 2021	242,897	19.40

The total vest date fair value of Mallinckrodt RSUs vested during fiscal 2021 was $4.4 million. As of December 31, 2021, there was $1.9 million of total unrecognized compensation cost related to non-vested RSUs granted, which is expected to be recognized over a weighted-average period of 1.1 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 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 fiscal 2019 were as follows:

Expected stock price volatility	55.2 %
Peer group stock price volatility	41.3
Correlation of returns	47.8

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 31, 2021.

18. Guarantees

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

In connection with the sale of the Specialty Chemical business (formerly known as Mallinckrodt Baker) in fiscal 2010, the Company agreed to indemnify the purchaser with respect to various matters, including certain environmental, health, safety, tax and other matters. The indemnification obligations relating to certain environmental, health and safety matters have a term of 17 years from the sale, while some of the other indemnification obligations have an indefinite term. The amount of the liability relating to all of these indemnification obligations included in LSTC and other liabilities on the Company's consolidated balance sheets as of December 31, 2021 and December 25, 2020, respectively, was $14.9 million and $15.4 million, respectively, of which $12.1 million and $12.7 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 31, 2021 and December 25, 2020. As of December 31, 2021, 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 remained in restricted cash, included in other long-term assets on the consolidated balance sheets as of both December 31, 2021 and December 25, 2020.

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

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

As of December 31, 2021, the Company had various other letters of credit, guarantees and surety bonds totaling $34.7 million and restricted cash of $41.2 million held in segregated accounts primarily to collateralize surety bonds for the Company's environmental liabilities.

19. Commitments and Contingencies

The Company is subject to various legal proceedings and claims, including government investigations, environmental matters, product liability matters, patent infringement claims, antitrust matters, securities class action lawsuits, personal injury claims, employment disputes, contractual and other commercial disputes, and other legal proceedings, all in the ordinary course of business, 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, 2020, 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 14, 2022, the cases the Company is aware of include, but are not limited to, approximately 2,619 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 eight 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 14, 2022, 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 resolved 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 agreed to provide $6.0 million in generic products, including addiction treatment products and a $0.5 million payment upon the two-year anniversary of the settlement agreement 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”).

Amended Proposed 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. On September 2, 2021, the Debtors reached an agreement in principle with the Opioid Claimants, which supersedes the Amended Opioid-Related Litigation Settlement as proposed in the RSA. The agreement in principle 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 $1,725.0 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; (iii) a $150.0 million payment upon each of the third through seventh anniversaries of emergence; and (iv) a $125.0 million payment upon the eighth anniversary of emergence with an eighteen month 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 sixth 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 has begun to comply with an agreed-upon operating injunction with respect to the operation of its opioid business.

In accordance with the announced agreement in principle, the Company recorded an accrual for the additional structured cash payment related to this contingency of $125.0 million during fiscal 2021. As of December 31, 2021 and December 25, 2020, the Company maintained an accrual for this contingency of $1,725.0 million and $1,600.0 million within LSTC, respectively. No value has been ascribed to the warrants as of December 31, 2021 and December 25, 2020 as the Company cannot reasonably estimate the equity value upon emergence. 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, Her Majesty the Queen in right of the Province of British Columbia ("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., Court File 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; (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; or (5) falling within such other class definition as the British Columbia Court may approve. 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 due to Methadose allegedly being a significantly less effective treatment than generic compounded methadone. The suit asserts that the Province, the College and the Mallinckrodt defendants knew (or ought to have known) about, 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) ("Canadian Court") 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 Canadian Court granted a further order on February 25, 2021, staying the British Columbia class action proceedings against all defendants. 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, the Company 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 filed a petition for certiorari with the Supreme Court, which was denied. On October 21, 2021, the District Court vacated its December 19, 2018 order, except for its invalidation of the "pass through prohibition" on the basis it violates the Commerce Clause. In April 2019, the State of New York passed its 2020 budget, which amended the OSA so that 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 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). On January 7, 2022, the SEC issued a subsequent subpoena related to this matter, requesting additional documents from the Company. 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 was 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 represented 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 31, 2021 and December 25, 2020, $634.7 million and $638.9 million related to the Medicaid lawsuit was recorded within LSTC, respectively.

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 effectiveness of the Proposed Acthar Gel-Related Settlement, the Company will dismiss its D.C. Circuit appeal. The Company has also entered into a five-year CIA with the OIG of the HHS, which took effect in March 2022. The Company has entered into the Proposed Acthar Gel-Related Settlement with the DOJ and other governmental parties solely to move past these litigation matters and disputes and does not make any admission of liability or wrongdoing.

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. On December 10, 2021, the Committee issued its final majority report detailing findings from the investigation.

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 consolidated balance sheet as of December 31, 2021 or December 25, 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. The Company expects the DOJ to dismiss the lawsuit after the Company's first payment toward the settlement amount.

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. The Company does not believe that the government will proceed any further with 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. The Company expects the DOJ to dismiss the lawsuit after the Company's first payment toward the settlement amount.

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 included 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. On June 28, 2021, the USAO for EDPA and the entities named as defendants in the qui tam complaint captioned *United States ex. rel. Michael Johnson and Frank Strobl v. Therakos, et al.*, No. 12-cv-0454-JHS, that was filed under seal in 2012 filed a stipulation of dismissal in the United States District Court for the EDPA terminating the matter.

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, and subsequently launched an authorized generic version of Company's Amitiza product in early 2021. 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.

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's 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

City of Rockford and Other Acthar Gel-Related Matters

On March 12, 2021, the plaintiffs in *City of Rockford v. Mallinckrodt ARD, Inc., et al. (“Rockford”), United Ass'n of Plumbers and Pipefitters Local 322 of Southern New Jersey v. Mallinckrodt ARD, LLC, et al. (“Local 322”), Steamfitters Local Union No. 420 v. Mallinckrodt ARD, LLC, et al. (“Steamfitters”), Int'l Union of Operating Engineers Local 542 v. Mallinckrodt ARD Inc., et al. (“Local 542”)* and *Acument Global Technologies, Inc., v. Mallinckrodt ARD Inc., et al. (“Acument”)* filed a motion with the Joint Panel on Multi-District Litigation (“JPML”) under 28 U.S.C. § 1407 requesting that those cases and others alleging claims related to the price of Acthar Gel (including *Health Care Service Corp. v. Mallinckrodt ARD LLC, et al. (“HCSC”), City of Marietta v. Mallinckrodt ARD LLC (“Marietta”), Humana Inc. v. Mallinckrodt ARD LLC (“Humana”), MSP Recovery Claims, Series II, LLC, et al. v. Mallinckrodt ARD, Inc., et al. (“MSP”)* and *U.S. ex rel. Strunck v. Mallinckrodt ARD LLC ("Strunck")*) be transferred to the Northern District of Illinois for coordinated or consolidated pretrial proceedings as a MDL (the “Section 1407 Motion”). The Company opposed the Section 1407 Motion. In April 2021, the U.S. District Courts in the Northern District of Illinois and the EDPA stayed consideration of the Company's motions to transfer *Rockford, MSP* and *Steamfitters* to the District of Delaware pending a decision by the JPML. The EDPA District Court also denied *Local 542*'s motion for reconsideration of the court's order transferring that case to the District of Delaware. On June 7, 2021, the JPML denied the Section 1407 Motion on the grounds that the timing and outcome of the bankruptcy proceedings made centralization premature.

On April 30, 2021, the Company filed several pleadings in the Chapter 11 Cases in respect of Acthar Gel-based claims, including without limitation the following: (a) objections to putative class proofs of claim filed by the City of Rockford, City of Marietta,

Georgia, United Association of Plumbers and Pipefitters Local 322 of Southern New Jersey and Steamfitters Local Union No. 420; (b) objections to all purportedly Acthar Gel-related proofs of claim that state no basis for Acthar Gel-related liability against the named debtor; (c) a motion for establishment of an administrative claims bar date that would require all Acthar Gel claimants, among others, to promptly file any requests for payment of purported administrative claims; and (d) an adversary proceeding seeking a declaratory judgment that the claims of the City of Rockford, as a governmental unit, are dischargeable in the Chapter 11 Cases.

On June 16, 2021, the Bankruptcy Court held that the City of Rockford's claims are dischargeable in the Chapter 11 Cases. On June 29, 2021, the Bankruptcy Court sustained the Company's objections to the putative class proofs of claim filed by City of Rockford, City of Marietta, United Association of Plumbers and Pipefitters Local 322 of Southern New Jersey and Steamfitters Local Union No. 420.

In September 2021, the Company filed a motion in the Bankruptcy Court to assume the exclusive distribution agreement for Acthar Gel that plaintiffs in *Rockford* and the *Rockford*-related litigation matters (together, the "Ad Hoc Acthar Group") allege is anticompetitive. The Ad Hoc Acthar Group moved to dismiss the motion to assume. In October 2021, the Company filed an adversary proceeding in the Bankruptcy Court seeking a declaratory judgment that the exclusive distribution agreement for Acthar Gel is lawful. Subsequently, the Ad Hoc Acthar Group moved to withdraw all of their claims in the bankruptcy case. The Company has objected to the withdrawal motion. The Debtors' motion to assume the exclusive distribution agreement and its adversary proceeding remain pending.

For additional details on *Rockford*, *Local 322*, *Steamfitters*, *Local 542*, *Acument*, *Marietta*, *MSP* and *Strunck*, refer below.

Law Enforcement Health Benefits Litigation. In May 2021, Law Enforcement Health Benefits, Inc. ("LEHB") filed a putative class action complaint in the U.S. District Court for the Northern District of Illinois against the Company and certain of its officers and directors as well as third-party advisors captioned *Law Enforcement Health Benefits, Inc. v. Trudeau, et al.*, No. 3:21-cv-50215 (N.D. Ill.) ("*LEHB*"). The complaint alleges antitrust claims under Section 1 and Section 2 and numerous state laws, RICO claims under 18 U.S.C. §§ 1962(a), 1962(c) and 1962(d), fraud, conspiracy to defraud, and unjust enrichment and incorporates the allegations at issue in *Rockford* and the *Rockford*-related cases discussed above. After the complaint was filed, the Company requested that the district court stay the case in light of the Chapter 11 Cases. The motion to stay was granted. In June 2021, LEHB voluntarily dismissed without prejudice the Mallinckrodt defendant entities that are debtors in the Chapter 11 Cases. In July 2021, LEHB voluntarily dismissed without prejudice most of the Company's officers and directors as named defendants in the case. As of March 10, 2022, the Bankruptcy Court lifted the stay in this matter and established an initial schedule for the proceedings. 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.

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 moved to remand the case back to state court. On June 17, 2021, the district court in California remanded the case back to California 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. On August 23, 2021, the district court in New Jersey granted the Company's motion to transfer the case to the District of Delaware where the Chapter 11 cases are pending.

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 captioned *Humana Inc. v. Mallinckrodt ARD LLC* 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). 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. 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 opposed transfer. On June 28, 2021, the district court in California granted the Company's motion to transfer the case to the District of Delaware where the Chapter 11 cases are pending. Humana, along with an assignee of claims by United Healthcare Services, Inc., Optum Rx Group Holdings and OptumRx Holdings, LLC and CVS Pharmacy, Inc. (together, the "Acthar Insurance Claimants"), has filed similar claims (including claims for administrative expense) in the Chapter 11 Cases. In August 2021, the Company filed a motion for partial summary judgement as to the Acthar Insurance Claimants' antitrust claims. In September 2021, the Bankruptcy Court denied the Company's motion for partial summary judgement in a bench ruling with a written ruling issued in October 2021. In November, 2021, the Bankruptcy Court held a multi-day trial on the Acthar Insurance Claimants' motion for allowance of post-petition administrative antitrust claims filed in the Chapter 11 Cases. In December 2021, the Bankruptcy Court ruled in favor of the Company, finding that the administrative claims were without merit. The Acthar Insurance Claimants are appealing the ruling.

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.

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.

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. In June 2021, the District of Delaware referred this case to the Bankruptcy Court in Delaware.

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.

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.

Other Commercial and Securities Litigation Matters

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. 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 the proceedings against the individual named defendants. The Bankruptcy Court extended

the injunction staying the proceedings against the individual named defendants on August 30, 2021. The plaintiffs subsequently appealed the Bankruptcy Court action to the U.S. District Court in Delaware through an interlocutory appeal, which was denied on November 10, 2021. The Bankruptcy Court further extended the injunction on November 29, 2021. Absent further extension, the injunction will expire on March 18, 2022.

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. The Bankruptcy Court extended the injunction staying the proceedings against the Brandhorst Defendants on August 30, 2021, and further extended the injunction on November 29, 2021. Absent further extension, the injunction will expire on March 18, 2022.

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/or 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 to 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 reconsideration, which was denied by that court on January 27, 2021. The Bankruptcy Court extended the injunction staying the proceedings against the Strougo Defendants on August 30, 2021, and further extended the injunction on November 29, 2021. Absent further extension, the injunction will expire on March 18, 2022.

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 Matthew K. Harbaugh, 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 intend 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 on December 4, 2020, the Bankruptcy Court also enjoined the proceedings against the individual named defendants. The Bankruptcy Court extended the injunction staying the proceedings against the individual named defendants on August 30, 2021, and further extended the injunction on November 29, 2021. Absent further extension, the injunction will expire on March 18, 2022.

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. On February 23, 2022, the Bankruptcy Court approved the Company's entry into the settlement.

Generic Price Fixing Litigation

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 Canada ULC, Mallinckrodt LLC and a predecessor to MNK 2011 LLC, 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. As a result of the Eaton action being served on the Mallinckrodt defendants, Mallinckrodt Canada ULC sought, and the Canadian Court granted, an order on April 20, 2021, among other things: (1) recognizing the Chapter 11 Cases of, and granting Canadian stays with respect to, Mallinckrodt LLC and MNK 2011 LLC; and (2) declaring that the Eaton action is stayed as against each of the Mallinckrodt defendants and the named predecessor to MNK 2011 LLC.

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.

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.

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.

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. An amended complaint was filed in December 2020.

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 and was selected as a bellwether case in May 2021. The Company disagrees with the Attorneys Generals' characterization of the facts and applicable law.

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.

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.

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.

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 200 generic pharmaceutical drugs. Plaintiffs in the Generic Pricing MDL have proceeded with discovery collectively and recently issued subpoenas to former Company employees. On October 18, 2021, the Company agreed to provide limited discovery. 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.

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.

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 31, 2021, it was probable that it would incur remediation costs in the range of $72.3 million to $120.9 million. The Company also concluded that, as of December 31, 2021, the best estimate within this range was $95.8 million, of which $0.8 million was included in accrued and other current liabilities, $52.0 million was included in LSTC, and the remaining $43.0 million was included in environmental liabilities on the consolidated balance sheet as of December 31, 2021. 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.

In March 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. In October 2016, the EPA announced that Occidental Chemicals Corporation ("OCC") had entered into an agreement to develop the remedial design.

In August 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.

On September 28, 2021, the EPA issued the Record of Decision for the upper 9 miles of the River selecting source control as the remedy for the upper 9 miles with an estimated cost of $441.0 million.

As of December 31, 2021, the Company estimated that its remaining liability related to the River was $26.1 million, of which $4.6 million was included in LSTC and the remainder was included within in environmental liabilities on the consolidated balance sheet as of December 31, 2021. Despite the issuance of the revised FFS and the RODs for both the lower and upper River 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. Although the Company was not named as a defendant for the Belleville facility, the Company retains a share of the liability for this suit. 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. However, the mediation process has indefinitely stalled due to an "internal issue" that the U.S. is facing and cannot seem to resolve.

During the three months ended December, 31, 2021, the Company increased the accrual associated with this matter by $34.3 million to $46.3 million, which represents the Company's estimate of its liability related to this environmental site, all of which was reflected within LSTC on the consolidated balance sheet as of December 31, 2021. The non-cash charge of $34.3 million was reflected in the consolidated statement of operations as a component of operating expenses. 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 31, 2021, 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 four 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 maintained a corresponding liability of $12.4 million and $28.2 million as of December 31, 2021 and December 25, 2020, respectively. The decrease of $15.8 million was recognized as a benefit to interest expense during fiscal 2021 due to lapses of certain statutes of limitations. Further favorable resolution of this uncertainty would likely result in a reversal of this liability and a benefit being recorded to interest expense within the consolidated statements of operations.

Other Matters

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

20. Financial Instruments and Fair Value Measurements

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

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

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

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

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

	December 31, 2021	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	$ 38.7	$ 24.9	$ 13.8	$ —
Equity securities	36.5	36.5	—	—
	$ 75.2	$ 61.4	$ 13.8	$ —
Liabilities:				
Deferred compensation liabilities [1]	$ 36.9	$ —	$ 36.9	$ —
Contingent consideration liabilities [2]	27.3	—	—	27.3
	$ 64.2	$ —	$ 36.9	$ 27.3

(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 31, 2021. For further information on executory contracts and LSTC refer to Note 2.

	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 liabilities [2]	34.7	—	—	34.7
	$ 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.

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 2021, 2020 and 2019, the Company recognized an unrealized gain of $4.7 million, $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 liabilities. As part of the acquisition of Stratatech Corporation ("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. 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 $27.3 million and $19.1 million at December 31, 2021 and December 25, 2020, respectively.

As part of the acquisition of Ocera Therapeutics, Inc. ("Ocera"), the Company provided contingent consideration to the prior shareholders of Ocera in the form of both patient enrollment clinical study milestones and sales-based milestones associated with MNK-6105 and MNK-6106. During fiscal 2021, the Company determined it would no longer pursue further development of this asset. The Company determined the fair value of the contingent consideration based on an option pricing model to be zero and $15.6 million as of December 31, 2021 and December 25, 2020, respectively.

All contingent consideration liabilities were classified as LSTC in the consolidated balance sheets as of December 31, 2021 and December 25, 2020. The following table summarizes the fiscal 2021 activity for contingent consideration:

Balance as of December 25, 2020	$ 34.7
Fair value adjustments	(7.4)
Less: Liabilities subject to compromise	(27.3)
Balance as of December 31, 2021	$ —

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 31, 2021 and December 25, 2020:

- 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 $60.2 million and $56.4 million as of December 31, 2021 and December 25, 2020, (level 1), respectively. As of December 31, 2021, $24.0 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 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.
- The Company's life insurance contracts are carried at cash surrender value, which is based on the present value of future cash flows under the terms of the contracts (level 3). Significant assumptions used in determining the cash surrender value include the amount and timing of future cash flows, interest rates and mortality charges. The fair value of these contracts approximates the carrying value of $51.3 million and $52.3 million at December 31, 2021 and December 25, 2020, 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 5.75%, 4.75%, 5.625%, 5.50% 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 9.50% and 8.00% 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 31, 2021		December 25, 2020	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Level 1:				
5.75% senior notes due August 2022	$ 610.3	$ 324.1	$ 610.3	$ 191.2
4.75% senior notes due April 2023	133.7	48.9	133.7	11.1
5.625% senior notes due October 2023	514.7	279.1	514.7	158.9
5.50% senior notes due April 2025	387.2	211.6	387.2	115.4
10.00% first lien senior notes due April 2025	495.0	523.7	495.0	528.4
10.00% second lien senior notes due April 2025	322.9	312.7	322.9	279.0
Revolving credit facility	900.0	900.0	900.0	900.0
Level 2:				
9.50% debentures due May 2022	10.4	7.7	10.4	4.2
8.00% debentures due March 2023	4.4	3.2	4.4	1.3
Term loan due September 2024	1,396.5	1,309.2	1,505.2	1,386.9
Term loan due February 2025	370.7	347.7	399.5	367.9
Total Debt	$ 5,145.8	$ 4,267.9	$ 5,283.3	$ 3,944.3

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		
	2021	2020	2019
CuraScript, Inc.	26.1 %	27.4 %	29.7 %
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 31, 2021	December 25, 2020
AmerisourceBergen Corporation	30.0%	33.6%
McKesson Corporation	15.0	18.2
CuraScript, Inc.	12.7	*

* 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		
	2021	2020	2019
Acthar Gel	26.9 %	27.9 %	30.1 %
INOmax	20.3	20.9	18.1
Therakos	12.1	*	*
Ofirmev	*	10.1	12.1

* Net sales attributable to these products were less than 10.0% of total net sales during the respective periods presented above.

21. Segment and Geographical Data

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

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

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 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. 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 $8,916.3 million and $9,715.4 million as of December 31, 2021 and December 25, 2020, respectively.

Selected information by reportable segment was as follows:

	Fiscal Year		
	2021	2020	2019
Net sales:			
Specialty Brands [1]	$ 1,547.0	$ 2,059.6	$ 2,423.8
Specialty Generics	661.8	689.8	738.7
Segment net sales	2,208.8	2,749.4	3,162.5
Medicaid lawsuit (Note 19) [1]	—	(536.0)	—
Net sales	$ 2,208.8	$ 2,213.4	$ 3,162.5
Operating loss:			
Specialty Brands	$ 812.8	$ 1,015.7	$ 1,210.1
Specialty Generics	107.9	206.4	168.5
Segment operating income	920.7	1,222.1	1,378.6
Unallocated amounts:			
Corporate and unallocated expenses [2]	(129.6)	(166.1)	(102.3)
Depreciation and amortization	(675.8)	(885.2)	(951.1)
Share-based compensation	(10.2)	(25.3)	(33.8)
Restructuring charges, net	(26.9)	(37.5)	1.7
Non-restructuring impairment charges	(154.9)	(63.5)	(388.0)
Separation costs [3]	(1.2)	(93.4)	(63.9)
R&D upfront payment [4]	—	(5.0)	(20.0)
Opioid-related litigation settlement gain (loss) (Note 19)	(125.0)	43.4	(1,643.4)
Medicaid lawsuit (Note 19) [1]	—	(641.1)	—
Operating loss	$ (202.9)	$ (651.6)	$ (1,822.2)
Depreciation and amortization:			
Specialty Brands	$ 597.7	$ 799.3	$ 862.4
Specialty Generics	78.1	85.9	88.7
	$ 675.8	$ 885.2	$ 951.1

(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 19 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 included in SG&A expenses, primarily related to professional fees and costs incurred in preparation for the Chapter 11 proceedings. 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.

(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 6 for further information.

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

	Fiscal Year		
	2021	2020	2019
Acthar Gel [1]	$ 593.6	$ 767.9	$ 952.7
INOmax	448.5	574.1	571.4
Ofirmev	28.9	276.5	384.0
Therakos	266.5	238.6	246.9
Amitiza [2]	196.9	188.8	208.5
Other [3]	12.6	13.7	60.3
Specialty Brands	1,547.0	2,059.6	2,423.8
Hydrocodone (API) and hydrocodone-containing tablets	82.7	98.0	76.3
Oxycodone (API) and oxycodone-containing tablets	68.5	68.4	74.9
Acetaminophen (API)	215.9	213.0	189.9
Other controlled substances	272.7	289.9	352.5
Other	22.0	20.5	45.1
Specialty Generics	661.8	689.8	738.7
Segment net sales	2,208.8	2,749.4	3,162.5
Medicaid lawsuit (Note 19)	—	(536.0)	—
Net Sales	$ 2,208.8	$ 2,213.4	$ 3,162.5

(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 19 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 4 for further details on Amitiza's revenues.

(3) Fiscal 2019 includes $40.1 million of net sales related to BioVectra prior to the completion of the sale of this business in November 2019. Refer to Note 5 for further details.

Selected information by geographic area was as follows:

	Fiscal Year		
	2021	2020	2019
Net sales [1]:			
U.S.	$ 1,991.8	$ 2,465.5	$ 2,765.6
Europe, Middle East and Africa	181.8	227.5	281.8
Other	35.2	56.4	115.1
Geographic area net sales	2,208.8	2,749.4	3,162.5
Medicaid lawsuit (Note 19)	—	(536.0)	—
Net Sales	$ 2,208.8	$ 2,213.4	$ 3,162.5

	December 31, 2021	December 25, 2020
Long-lived assets [2]:		
U.S.	$ 629.3	$ 676.3
Europe, Middle East and Africa [3]	156.2	165.5
Other	4.7	4.6
	$ 790.2	$ 846.4

(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 $154.5 million and $164.0 million as of December 31, 2021 and December 25, 2020, respectively.

22. Subsequent Events

Bankruptcy Proceedings

The Debtors filed a fourth amendment to the Amended Plan on January 6, 2022. On February 3, 2022, the Bankruptcy Court issued a written ruling confirming the Chapter 11 plan (which was subsequently revised February 8, 2022 to make minor corrections).

On March 2, 2022, the Bankruptcy Court entered the Confirmation Order confirming the fourth amended joint plan of reorganization (with technical modifications) proposed by the Debtors (the "Plan").

It is a condition precedent to the consummation of the Plan that the High Court of Ireland shall make an order pursuant to Section 541 of the Companies Act of Ireland confirming a scheme of arrangement with respect to Mallinckrodt plc which is based on and consistent in all respects with the Plan (a “Scheme of Arrangement”), and that such Scheme of Arrangement shall become effective in accordance with its terms (or shall become effective concurrently with the effectiveness of the Plan). As contemplated by the Plan, and in furtherance of the satisfaction of such condition precedent, on February 14, 2022 the directors of Mallinckrodt plc initiated examinership proceedings with respect to Mallinckrodt plc (the “Irish Examinership Proceedings”) by presenting a petition (the “Examinership Petition”) to the High Court of Ireland pursuant to Section 510(1)(b) of the Companies Act of Ireland seeking the appointment of an examiner to Mallinckrodt plc (the “Examiner”). On the same date, following an ex parte application made by the directors of Mallinckrodt plc, the High Court of Ireland made an order appointing the Examiner on an interim basis pending the hearing of the Examinership Petition. The hearing of the Examinership Petition took place before the High Court in Dublin, Ireland on Monday, February 28, 2022. Following that hearing, and on the same date, the High Court of Ireland made an order confirming that appointment of the Examiner. Subsequently, on March 8, 2022, the High Court of Ireland made various orders directing the Examiner to convene meetings of the creditors and shareholders of Mallinckrodt plc for the purposes of considering and voting in relation to a proposed Scheme of Arrangement that, if confirmed by High Court of Ireland, will implement certain Irish law aspects of the Plan. The Examiner is currently in the process of convening such meetings, which are scheduled to be held over the course of April 4, 2022. If the majority in value and number of at least one class of creditors in attendance at the meetings whose interests are impaired by the proposed Scheme of Arrangement vote to accept it, the Examiner will seek a confirmation order from the High Court of Ireland with respect thereto, at a hearing that is currently anticipated to be convened at the end of April 2022.

During the continuance of the Irish Examinership Proceedings, Mallinckrodt plc will be under the protection of the High Court of Ireland. During the period of court protection, no proceedings can be commenced in Ireland to wind up Mallinckrodt plc, and no action can be taken by creditors to enforce security or take possession of any assets of Mallinckrodt plc, without the consent of the Examiner. The period of court protection will subsist for an initial 70 days, which can, in certain circumstances, be extended by order of the High Court of Ireland for a further 30 days, and potentially an additional 50 days after such 30-day period.

Certain bankruptcy proceeding matters occurred in fiscal 2021 or prior but had subsequent updates through the date of this report. See further discussion in Note 2.

Commitments and Contingencies

Certain litigation matters occurred in fiscal 2021 or prior but had subsequent updates through the date of this report. See further discussion in Note 19.

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 31, 2021. 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 31, 2021. 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 31, 2021 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 31, 2021 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") (in examination under Part 10 of the Irish Companies Act 2014) (the "Company") as of December 31, 2021, 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 31, 2021, 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 31, 2021 and December 25, 2020, the related consolidated statements of operations, comprehensive operations, changes in shareholders' equity, and cash flows, for the fiscal years ended December 31, 2021, December 25, 2020 and December 27, 2019, 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 15, 2022, 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 15, 2022

Item 9B. Other Information.

None

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information About Our Directors

Set forth below are the names, ages as of February 2, 2022, and current principal occupations of our directors.

Name	Age	Principal Occupation
David R. Carlucci	67	Former Chairman, Chief Executive Officer and President of IMS Health
J. Martin Carroll	72	Former President and Chief Executive Officer of Boehringer Ingelheim Corporation
Paul R. Carter	61	Former Executive Vice President, Commercial Operations of Gilead Sciences, Inc.
David Y. Norton	70	Former Company Group Chairman, Global Pharmaceuticals of Johnson & Johnson
Carlos V. Paya, M.D.	63	Former President and Chief Executive Officer of Immune Design Corp.
JoAnn A. Reed	66	Healthcare services consultant and former Senior Vice President, Finance and Chief Financial Officer of Medco Health Solutions
Angus C. Russell	66	Former Chief Executive Officer of Shire plc
Mark C. Trudeau	60	President, Chief Executive Officer and Director of Mallinckrodt plc
Anne C. Whitaker	54	Managing Partner of Anne Whitaker Group, LLC
Kneeland C. Youngblood, M.D.	66	Founding Partner of Pharos Capital Group

Each of the directors holds office until the earlier of the Company's next Annual General Meeting and the director's death, retirement, resignation, or removal. Set forth below is a brief description of the position and business experience of each of our directors.

David R. Carlucci has been a director since June 2013 and is a member of Mallinckrodt's Human Resources and Compensation Committee (the "Human Resources and Compensation Committee" or "HRCC"), which he chaired until December 2019. Mr. Carlucci was President and Chief Operating Officer of IMS Health Incorporated, an information services company, from October 2002 until January 2005, when he was named Chief Executive Officer and President. He became Chairman the following year. Mr. Carlucci retired from IMS Health in December 2010. Mr. Carlucci held several senior executive level positions at IBM from 1976 to 2002, including responsibilities for operations in the U.S., Canada and Latin America. Mr. Carlucci served as a director of Mastercard Inc. from 2006 to 2020 and served as Chairman of its Human Resources and Compensation Committee from 2006 to 2014. Mr. Carlucci also served as a member of the advisory board of Mitsui & Co. (USA), Inc., one of the world's most diversified comprehensive trading, investment and service companies. Mr. Carlucci's qualifications to serve on our Board of Directors (the “Board of Directors” or “Board”) include his significant experience as an executive and board member of publicly traded and private companies.

J. Martin Carroll has been a director since June 2013 and is Chair of Mallinckrodt's Governance and Compliance Committee and a member of its Human Resources and Compensation Committee. He served as President and Chief Executive Officer of Boehringer Ingelheim Corporation and of Boehringer Pharmaceuticals, Inc. from 2003 until 2011 and as a director of Boehringer Ingelheim Corporation from 2003 until December 2012. He joined the organization in 2002 as President of Boehringer Pharmaceuticals, Inc. Mr. Carroll worked at Merck & Co., Inc. from 1976 to 2001. From 1972 to 1976, Mr. Carroll served in the United States Air Force where he attained the rank of Captain. He has served as a director of Catalent Pharma Solutions since July 2015. Mr. Carroll served as a director of TherapeuticsMD, Inc. from March 2015 until December 2021 and Inotek Pharmaceuticals Corporation from March 2016 until January 2018, including serving as Chairman of Inotek from June 2016 until January 2018. Mr. Carroll's qualifications to serve on our Board include his significant experience in leadership positions at pharmaceutical companies.

Paul R. Carter has been a director since May 2018 and is a member of Mallinckrodt's Audit Committee and its Science and Technology Committee. Mr. Carter served in various roles at Gilead Sciences, Inc., a research based biopharmaceutical company, from April 2006 to August 2016, most recently serving as Executive Vice President, Commercial Operations. Prior to joining Gilead, Mr. Carter spent 15 years in the pharmaceutical industry with GlaxoSmithKline plc and its legacy companies where he held various roles with increasing levels of senior experience, including General Manager in Europe and as a Regional Head of the International Business in Asia. Mr. Carter also serves as a healthcare advisor to several biotechnology companies. Mr. Carter has served as a director of HUTCHMED (China) Limited (formerly Hutchison China MediTech Ltd.) since 2017, Immatics N.V., VectivBio Holding AG since 2021 and Concentric Analgesics, Inc. since January 2022. He served as a director of Alder Biopharmaceuticals, Inc. from 2015 to 2019. Mr. Carter’s qualifications to serve on our Board include extensive experience with multinational companies in the

pharmaceutical industry, including involvement with the launch and commercialization of various medicines worldwide, as well as his experience as a director of publicly traded pharmaceutical companies.

David Y. Norton has been a director since September 2017 and is Chair of Mallinckrodt's Human Resources and Compensation Committee. He was previously chairman of the board of directors of VIVUS, Inc., a biopharmaceutical company, where he had served as a director from July 2013 through December 2020. Mr. Norton serves on the board of directors of Forepont Capital, LLC, where he has been a director since October 2019 and has also served on the board of directors of COMPASS Pathways plc, since May 2018. Mr. Norton was company group chairman, Global Pharmaceuticals, for Johnson & Johnson, a role in which he led and developed the business' strategic growth agenda, including the strategy for licensing, acquisitions and divestments, and ensuring alignment with the global strategic functions, research and development, and commercial organizations. He retired in 2011 from Johnson & Johnson, where his 32-year tenure spanned marketing and international country management roles; serving as president of the Janssen Pharmaceuticals business in the U.S., group chairman of the Pharmaceuticals Group for Europe, Middle East and Africa, and then for the U.S. and Canada business; as well as the role of company group chairman, worldwide commercial and operations, for Johnson & Johnson's CNS and virology business. He previously served as a director for INC Research Holdings Inc. and Savient Pharmaceuticals Inc. Mr. Norton's qualifications to serve on our Board include his significant experience as an executive and board member of publicly traded pharmaceutical companies.

Carlos V. Paya, M.D. has been a director since May 2019 and is Chair of Mallinckrodt's Science and Technology Committee and a member of its Governance and Compliance Committee. He served as President, Chief Executive Officer of Immune Design Corp. from May 2011 until its acquisition in April 2019. Dr. Paya previously served as president of Elan Pharmaceuticals, and spent a number of years with Eli Lilly and Co. in discovery research and clinical development leadership roles, most recently global leader of the diabetes and endocrine franchise. Prior to his industry roles, Dr. Paya spent nearly a decade at the Mayo Clinic-Rochester, including his role as professor of medicine, immunology and pathology, and vice dean of the clinical investigation program. He has been a director of Fluidigm Corporation since March 2017, a director of Highlight Therapeutics S.L. since April 2020 and a director of Vaxcyte, Inc. since October 2021. He also serves as chairman of all of these boards. He also previously served as a director of Immune Design Corp. from 2011 to 2019. Dr. Paya's qualifications to serve on our Board include his significant experience as an executive and board member of publicly traded pharmaceutical and life sciences companies.

JoAnn A. Reed has been a director since June 2013 and is Chair of Mallinckrodt's Audit Committee. Ms. Reed is a healthcare services consultant. Ms. Reed served as an advisor to the Chief Executive Officer of Medco Health Solutions, Inc., a leading pharmacy benefit manager, from April 2008 to April 2009. She previously served as the Senior Vice President, Finance and Chief Financial Officer of Medco until 2008. Upon joining Medco in 1988, Ms. Reed served in finance and accounting roles of increasing responsibility and was appointed Senior Vice President, Finance in 1992 and Chief Financial Officer in 1996. Prior to joining Medco, Ms. Reed's experience included finance roles at Aetna/American Reinsurance Co., CBS Inc., Standard and Poor's Corporation and Unisys/Timeplex Inc. Ms. Reed has been a director of American Tower Corporation since 2007. She served as a director of Waters Corporation from 2006 to 2021 and Health Management Associates, Inc. from 2013 to 2014 and as a trustee of St. Mary's College of Notre Dame from 2006 to 2015. Ms. Reed's qualifications to serve on our Board include her experience as a healthcare services consultant and her financial expertise and knowledge of financial statements, corporate finance and accounting matters.

Angus C. Russell has been Chairman of the Board since May 2018, and a director since August 2014. He is also a member of Mallinckrodt's Science and Technology Committee and its Audit Committee. Mr. Russell served as a director of Questcor Pharmaceuticals, Inc. (“Questcor”) from June 2013 until Questcor was acquired by us in August 2014. Mr. Russell served as Chief Executive Officer of Shire Plc, a leading global specialty biopharmaceutical company, from 2008 until his retirement in April 2013 and was a member of its Board of Directors from 1999 to 2013. From 1999 to 2008, Mr. Russell served as Chief Financial Officer of Shire. Prior to joining Shire, Mr. Russell served at ICI, Zeneca and AstraZeneca, most recently as VP of Corporate Finance at AstraZeneca. Mr. Russell has served as the non-executive Chairman of Revance Therapeutics, Inc. since March 2014. He has served as a director of Lineage Cell Therapeutics, Inc. (formerly BioTime, Inc.) since December 2014 and as a director of TherapeuticsMD, Inc. since March 2015. Mr. Russell's qualifications to serve on our Board include his significant experience as an executive and/or board member of publicly traded pharmaceutical companies.

Mark C. 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. Mr. Trudeau is familiar with all aspects of our business and has extensive and diverse industry experience and managerial expertise and a proven record of leadership to serve as our President, Chief Executive Officer (“CEO”) and director.

Anne C. Whitaker has been a director since May 2018 and is a member of Mallinckrodt's Human Resources and Compensation Committee. Ms. Whitaker has served as the managing partner of the Anne Whitaker Group, LLC since April 2018. She also held the role of chief executive officer Aerami Therapeutics (formerly Dance Biopharm Holding Inc.) from October 2018 to November 2020. She served as chief executive officer Novoclem Therapeutics, Inc. from February 2017 until April 2018. Previously with Valeant Pharmaceuticals from 2015 to 2017, Ms. Whitaker served as executive vice president and company group chairman with responsibility for the company's branded pharmaceutical segment including key businesses like Salix, Dendreon, and Orapharma as well as the Canadian and Western Europe regions. Prior to that she served as president and chief executive officer of Synta Pharmaceuticals Corp. from 2014 to 2015; as president of North America pharmaceuticals and consumer health at Sanofi S.A. from 2011-2014; and in various commercial and senior leadership roles at GlaxoSmithKline from 1992 to 2011. Ms. Whitaker has been a director of Aerami Therapeutics since August 2018, serving as Chairman since November 2020, and a director of Caladrius Biosciences, Inc. since November 2020, Faron Pharmaceuticals Ltd since April 2021 and OraSure Technologies, Inc. since November 2021. Previously she served as non-executive director of UDG Healthcare plc from October 2020 to August 2021 as well as a director of Cree Inc. from 2013 to January 2021, Vectura Group PLC from 2018 to 2020, and Synta Pharmaceuticals Corp. from 2014 to 2015. Ms. Whitaker's qualifications to serve on our Board include her significant experience in executive positions in the pharmaceutical industry, in both commercial and organizational development roles, as well as her experience as a director of publicly traded and private companies.

Kneeland C. Youngblood, M.D. has been a director since June 2013. He is a member of Mallinckrodt's Governance and Compliance Committee. Dr. Youngblood is a founding partner of Pharos Capital Group, a private equity firm that focuses on buyouts in the healthcare services sector. Dr. Youngblood served as a director of Gap Inc. from 2006 to 2012, a director of Starwood Hotels and Resorts from 2001 to 2012, a director of Burger King Corporation from 2004 to 2010 and a director of iStar Financial from 1998 to 2001. Dr. Youngblood has been serving as a director of Scientific Games Corporation since August 2018. He has been CEO/Chairman of Pharos Capital BDC, Inc. from 2017 to 2019. He also served as a director on the Dallas Police Fire Pension Fund from 2017 to 2019. Prior to that, Dr. Youngblood served as a director of Energy Future Holdings Corp. from 2007 to 2018, as a director of Pace Holdings Corp. from 2015 to 2017 and as a director of TPG Pace Holding Corp. from 2017 to 2019, a director of TPG Pace Solutions Corp during 2021 and TPG Pace Tech Opportunities Corp. from 2020 to 2021. He is currently a director of TPG Pace Beneficial Finance Corp. and TPG Pace Beneficial II Corp., both Special Purpose Acquisition Companies. Dr. Youngblood's qualifications to serve on our Board include his extensive experience in healthcare practice, policy and business.

Information About Our Executive Officers

Set forth below are the names, ages as of February 2, 2022, and current positions of our executive officers.

Name	Age	Title
Mark C. Trudeau	60	President, Chief Executive Officer and Director
Bryan M. Reasons	53	Executive Vice President and Chief Financial Officer
Mark J. Casey	58	Executive Vice President and Chief Legal Officer
Kassie Harrold	42	Senior Vice President and Chief Compliance Officer
Hugh M. O'Neill	58	Executive Vice President and Chief Commercial Officer
Steven J. Romano, MD	62	Executive Vice President and Chief Scientific Officer
Ian Watkins	59	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 C. Trudeau's has been President, Chief Executive Officer and a director since June 2013. Additional information regarding his business experience is provided above under “Information About Our Directors.”

Bryan M. Reasons is our Executive Vice President and Chief Financial Officer (“CFO”). He has executive responsibility for the global finance function as well as the strategy function and Business Insights & Technology Solutions. 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 J. 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.

Kassie Harrold is our Chief Compliance Officer, with responsibility for global ethics and the compliance program, including risk assessment and mitigation, hotline reporting and investigations, program monitoring and governance. Ms. Harrold has more than 15 years of compliance experience in the pharmaceutical and specialty chemical industries, and has assessed, implemented and managed compliance programs in a broad range of subject matter areas. Ms. Harrold has held roles of increasing responsibility since joining Mallinckrodt in 2013, including leading the trade compliance and business support functions and advising senior management on a broad range of business matters as the Senior Staff Liaison to the President and Chief Executive Officer. Previously, Ms. Harrold held several positions, including global compliance, litigation and employment counsel and government affairs, with Solutia Inc., the specialty chemicals spin-off of Monsanto.

Hugh M. 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 J. Romano, M.D. is our Executive Vice President and Chief Scientific Officer. Dr. Romano joined Mallinckrodt in May 2015 and has executive responsibility for research and development ("R&D"), medical affairs and regulatory affairs functions. Dr. Romano is a board-certified psychiatrist with more than 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, facilities management and security. 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.

Involvement in Certain Legal Proceedings

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"). 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 agreements in principle subsequently memorialized in our Chapter 11 plan of reorganization.

Delinquent Section 16(a) Reports

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires our officers and directors and persons who beneficially own more than 10% of our ordinary shares to file reports of ownership and changes in ownership of such

ordinary shares with the SEC. These persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. As a matter of practice, our legal team assists our officers and directors in preparing initial reports of ownership and reports of changes in ownership and files those reports on their behalf. Based on our review of the copies of such forms we have received, as well as information provided and representations made by the reporting persons, we believe that all required Section 16(a) reports were timely filed during our fiscal year ended December 31, 2021.

Code of Business Conduct and Ethics

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. Although our ordinary shares ceased to be listed on the NYSE following our voluntary filing of the Chapter 11 Cases, we have elected to continue to comply with the NYSE listing standards. 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.

Audit Committee and Audit Committee Financial Experts

The Board has a separately designated Audit Committee established in accordance with the Exchange Act. The Audit Committee monitors the integrity of our financial statements, the independence and qualifications of the independent auditors, the performance of our internal auditors and independent auditors, our compliance with certain legal and regulatory requirements and the effectiveness of our internal controls. The Audit Committee is responsible for selecting, retaining, evaluating, setting the remuneration of and, if appropriate, recommending the termination of our independent auditors. The current members of the Audit Committee are Ms. Reed, Mr. Carter, and Mr. Russell. Each of them is independent under SEC rules and NYSE listing standards applicable to audit committee members. Ms. Reed is the Chair of the Audit Committee. The Board has determined that Ms. Reed is an audit committee financial expert. The Audit Committee operates under a charter approved by the Board, which is posted on our website at mallinckrodt.com.

Item 11. Executive Compensation.

Our Named Executive Officers

For purposes of the executive compensation disclosures, the individuals listed below are referred to collectively as our named executive officers ("NEOs").

- Mark C. Trudeau, President and Chief Executive Officer.
- Hugh M. O'Neill, Executive Vice President and Chief Commercial and Operations Officer.
- Steven J. Romano, M.D., Executive Vice President and Chief Scientific Officer.

Fiscal 2021 Compensation Program

The following table summarizes the three major elements of our fiscal 2021 executive compensation program and the objective of each element. They are designed to work together, and the HRCC views the executive compensation program as an integrated total compensation program. The overall value of compensation is competitively benchmarked to the pharmaceutical industry and with peer companies. The mix of compensation elements varies based on an executive's position and responsibilities.

During fiscal 2021, each NEO participated in the 2021 Key Employee Incentive Plan ("2021 KEIP") which is a component of our Stock and Incentive Plan. The HRCC approved the 2021 KEIP on March 8, 2021 followed by the Bankruptcy Court approval on April 5, 2021. The 2021 KEIP was put in place for similar reasons to the 2020 Key Employee Incentive Plan ("2020 KEIP"), which was implemented in the time leading up to the filing of the Chapter 11 Cases in October 2020 in order to replace the annual incentive plan and long-term incentive plan for the Company's NEOs for fiscal 2020. Due to the timing of the commencement of the Chapter 11 Case, the 2020 KEIP contained three separate stand-alone performance periods (First Half, Third Quarter, and Forth Quarter). Since the Chapter 11 proceedings continued into 2021, the 2021 KEIP was structured with the input of various creditor constituencies to include two separate stand-alone performance periods (First Half and Second Half) and added in two additional performance measures, adjusted EBITDA and a multi-faceted pipeline metric. Additional details of the 2021 KEIP can be found under the section "Fiscal 2021 KEIP Awards". After emergence from the Chapter 11 proceedings, the Board of Directors and management of the Company at that time will review and establish the compensation philosophy and program elements appropriate for the business strategy of the emerged organization.

Element	Key Features	Objective
Base salary	Fixed cash compensation	Offer a stable income, intended to reflect the market value of the executive's role, with differentiation for strategic significance, individual capability and experience.
2021 KEIP	Market-competitive, performance-based cash bonus opportunity tied to achievement of Company goals. Calculation for each executive's cash incentive is based on performance versus pre-determined goals tied to financial and operational performance measures. Two separate standalone performance periods and payout schedule (First Half and Second Half).	Focus executives on pre-set patient, employee and stakeholder value objectives and drive specific behaviors that foster short- and long-term growth and profitability.
Retention bonus	Cash-based retention bonus awarded to executives in September 2020 Subject to repayment prior to the earlier of May 15, 2022 or the date the Company emerges from the Chapter 11 Cases in the event the award recipient resigns, retires, voluntarily terminates employment or is terminated by the company for cause	Designed to stabilize the executive leadership team and reduce the possibility of turnover, which could result in the loss of expert knowledge, slow momentum and could impair the Company's ability to navigate its critical challenges, including the Chapter 11 Cases.

Summary Compensation Table

Our NEOs, like our employees generally and our shareholders and other stakeholders, have been significantly impacted by the Chapter 11 Cases. The information presented in the Summary Compensation Table reflects compensation for our NEOs for fiscal year 2021. The impact of the Chapter 11 Cases is not reflected in the Summary Compensation Table. Under the plan of reorganization, each existing equity interest in Mallinckrodt, including our ordinary shares and existing equity-based awards, will be cancelled and extinguished, and our shareholders will not receive any recovery upon our emergence from the Chapter 11 proceedings. Accordingly, upon our emergence from the Chapter 11 proceedings, our NEOs will not receive any value for their RSUs, stock options or any other equity interest in Mallinckrodt.

SUMMARY COMPENSATION TABLE

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($) [1]	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($) [2]	All Other Compensation ($) [3]	Total ($)
Mark C. Trudeau President and Chief Executive Officer	2021	1,090,385	—	—	—	7,148,280	737,318	8,975,983
	2020	1,050,000	1,575,000	—	—	11,407,814	854,724	14,887,538
Hugh M. O'Neill Executive Vice President and Chief Commercial Officer	2021	643,846	—	—	—	2,486,775	159,060	3,289,681
	2020	607,885	930,000	—	—	2,943,675	249,666	4,731,226
Steven J. Romano, M.D. Executive Vice President and Chief Science Officer	2021	643,846	—	—	—	2,486,775	238,439	3,369,060
	2020	620,000	930,000	—	—	2,943,675	283,990	4,777,665

(1) The amounts reported represent cash retention awards paid in 2020 but will not be earned until 2022 for Mr. Trudeau, Mr. O'Neill and Dr. Romano. The terms of the retention payments include repayment of the full amount if the executive voluntarily terminates employment or is terminated for cause earlier of May 15, 2022 or the date the Company emerges from the Chapter 11 proceedings.

(2) The amounts reported for fiscal year 2021 represent incentive cash awards paid to the NEOs under our 2021 KEIP. For information regarding the calculation of these awards, see the Narrative to the Summary Compensation Table.

(3) The amounts reported represent the aggregate dollar amount for each NEO for employer contributions to the Retirement Savings Plan, employer credits to the Supplemental Savings Plan, international assignment benefits for fiscal 2021 and 2020, executive physicals, executive financial planning and tax reimbursements, and tax preparation fees. We also have Company-purchased tickets to athletic or other events which are generally used for business purposes. In limited instances our named executive officers may have personal use of Company-purchased event tickets when they are not being used for business purposes. No amounts are included because there is no incremental cost to us of such personal use. The following table shows the specific amounts included in the All Other Compensation column of the Summary Compensation Table for fiscal 2021.

ALL OTHER COMPENSATION IN 2021

Name	Contributions to Retirement Savings Plan ($)	Credits to Supplemental Savings Plan ($)	Tax Reimbursement Payments ($) [1]	Director Fees ($) [2]	Other ($) [3]	Total ($)
Mark C. Trudeau	18,450	396,842	303,861	—	18,165	737,318
Hugh M. O'Neill	18,450	130,697	9,913	—	—	159,060
Steven J. Romano, M.D.	17,400	130,697	—	74,377	15,965	238,439

(1) Mr. Trudeau is entitled to certain benefits as part of our Tax Equalization Policy due to his service on the Board of Directors and amounts shown represent payments under our Tax Equalization Policy during fiscal 2021. Following the filing of all tax returns, a tax equalization calculation will be prepared to

determine the ultimate amount owed either to the Company or Mr. Trudeau under our Tax Equalization Policy. Mr. O'Neill received tax reimbursement related to spousal travel to the Mallinckrodt's President's Club.

(2) The Company has appointed Mr. Romano as its representative on the Board of Directors of Silence Therapeutics plc. Mr. Romano received director fees of £55,000 from Silence Therapeutics plc for this service in 2021. For purposes of this table, the exchange rate as of December 31, 2021 of one British Pound to 1.35231 U.S. dollars was used.

(3) Includes amounts for executive physicals and executive financial planning and tax preparation fees.

Narrative to Summary Compensation Table

Fiscal 2021 KEIP Awards

For fiscal 2021, the HRCC determined the amount payable to our NEOs under the 2021 KEIP by multiplying the NEO's individual incentive target by the funding based on Company performance for two separate standalone performance periods (First Half and Second Half, the two performance periods together are referred to as the "Full Year").

The HRCC in partnership with independent advisors established award target amounts for each of our NEOs under the 2021 KEIP, detailed in the table below. Based on the assessment of the Company's performance, the HRCC may adjust the bonus funding factor up or down under the maximum determined by our plan.

The 2021 KEIP Full Year target amounts for the NEOs are equal to the sum of their previously approved target annual incentive opportunity for fiscal 2021 and approximately 54% of the CEO's and 77% of the other NEOs previously approved target long-term equity incentive opportunity for fiscal 2021 (a 46% reduction was applied to the CEO and a 23% reduction was applied to the other NEOs to reduce the total cost of the 2021 KEIP, reflect the shorter-term nature of this component of the award and that the award was payable in cash).

Name	2021 KEIP Full Year Target	2020 KEIP Full Year Target	Previously Approved Combined Annual and Long-Term Incentive Target
Mark C. Trudeau	$6,712,000	$9,312,500	$11,312,500
Hugh M. O'Neill	$2,335,000	$2,403,000	$2,903,000
Steven J. Romano, M.D.	$2,335,000	$2,403,000	$2,903,000

Performance Periods and Measures. The 2021 KEIP consisted of two separate standalone performance periods: the first half of fiscal 2021 (50% of award) and the second half of fiscal 2021 (50% of award). The two semi-annual performance periods and semi-annual goals placed a greater emphasis on the results we needed to achieve throughout the year. In addition, this type of incentive plan structure is aligned with market practice for companies operating under similar circumstances to us. The Company's achievement against the following performance measures was assessed for each performance period separately and resulted in two separate award payouts: adjusted EBITDA, adjusted operating cash flow, adjusted net sales, and a pipeline metric. These performance measures were set in relation to our annual budget for the entire enterprise as approved by the Board of Directors.

The HRCC believes these measures are key drivers to preserve and maximize enterprise value and maximize cash generation during a time of significant bankruptcy and litigation overhang.

- Adjusted EBITDA is defined as earnings for the fiscal year before interest, taxes, depreciation and amortization, adjusted (with limitations and governors in place related to research and development expense) to exclude certain non-recurring items considered not a direct reflection of our core operations and our ongoing performance.
- Adjusted operating cash flow represents operating cash flow prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP") adjusted for separation costs, reorganization advisor fees, working capital impacts related to the CARES Act, significant legal and environmental charges and working capital impacts resulting from the Company's Chapter 11 bankruptcy filing, with certain limitations and governors related to research and development expense, days payable outstanding ("DPO"), severance costs and interest payments.
- Adjusted net sales represents net sales calculated in accordance with GAAP, as adjusted for certain items. Net sales is an important measure because it is a leading indicator of performance and value creation and provides a clear focus on top-line growth. For purposes of the 2021 KEIP, adjusted net sales excludes foreign exchange impacts.
- Pipeline metric focused on long-term success with targets related to achievements of operational milestones in the development, execution, and commercialization of key products.

The weighted average funding for the 2021 KEIP could range from 0% to 150% of target based upon performance against these measures for each standalone performance period, which is a reduction to the approved range of 0% to 200% from years prior to 2020. The HRCC maintains discretionary authority to further modify the funding, both negatively and positively.

Fiscal 2021 First Half performance resulted in an overall weighted average funding of 112% and the Second Half performance resulted in an overall weighted average funding of 101%. The following charts summarize the 2021 KEIP design based on the two

separate performance periods with respect to the Company performance measures, including the relative weighting, performance targets, actual results and weighted average funding for our NEOs:

Fiscal 2021 First Half Company Performance Measures (Applicable to all NEOs)

Measure	Weighting	Threshold (50% Payout)	Target (100% Payout)	Maximum (150% Payout)	Fiscal 2021 First Half Results [1]	Weighted Average Funding
Adjusted EBITDA (in millions)	40%	$355	$418	$481	$404	36%
Adjusted Operating Cash Flow (in millions)	40%	$342	$402	$463	$477	60%
Adjusted Net Sales (in millions)	10%	$1,067	$1,186	$1,305	$1,102	6%
Pipeline Metric	10%					10%
						112%

Fiscal 2021 Second Half Company Performance Measures (Applicable to all NEOs)

Measure	Weighting	Threshold (50% Payout)	Target (100% Payout)	Maximum (150% Payout)	Fiscal 2021 Second Half Results [1]	Weighted Average Funding
Adjusted EBITDA (in millions)	40%	$358	$422	$485	$396	32%
Adjusted Operating Cash Flow (in millions)	40%	$263	$310	$356	$352	58%
Adjusted Net Sales (in millions)	10%	$1,081	$1,201	$1,321	$1,103	6%
Pipeline Metric	10%					5%
						101%

The performance measures used for compensation purposes include non-GAAP financial measures which exclude the effects of certain items which the HRCC believes do not represent ongoing operating results and/or business trends.

Strategic Imperatives. In addition to performance against financial and operational measures, the HRCC also considers performance that supported the accomplishment of strategic imperatives, and has the ability to adjust the overall size of the executive bonuses, both negatively and positively. This allows the HRCC to decrease the size of the executive bonuses if, in the HRCC's opinion, such amounts are not appropriately earned or should not be paid.

The HRCC took into account the progress on the strategic imperatives and challenges that faced the business in 2021 when determining the 2021 KEIP award payouts for each of the two performance periods. The following charts show the HRCC approved multipliers for each of the two performance periods.

	Target Performance Multiplier				Payout
	First Half Target KEIP Opportunity	x	Multiplier		First Half KEIP Payout
Mark C. Trudeau	$3,356,000	x	112%	=	$3,758,720
Hugh M. O'Neill	$1,167,500		112%		$1,307,600
Steven J. Romano, M.D.	$1,167,500		112%		$1,307,600

	Target Performance Multiplier				Payout
	Second Half Target KEIP Opportunity	x	Multiplier		Second Half KEIP Payout
Mark C. Trudeau	$3,356,000	x	101%	=	$3,389,560
Hugh M. O'Neill	$1,167,500		101%		$1,179,175
Steven J. Romano, M.D.	$1,167,500		101%		$1,179,175

Executive Retention Bonus Program

In November 2019, the HRCC approved a key executive retention plan, also known as the Executive Retention Bonus Program ("ERBP") for specified employees including the NEOs, and the Board approved an ERBP for the CEO. The ERBP provided a cash-based retention bonus award to specified employees of the Company. In August 2020, the HRCC approved an extension of the ERBP for a small number of employees including the NEOs, and the Board approved an extension for the CEO. The HRCC considered the challenges facing the Company including the opioid litigation, and both the Board and the HRCC believed it critical to continue to stabilize the executive leadership team and reduce the possibility of further turnover during a critical time at the Company. Further turnover would have resulted in the loss of expert knowledge, slowed momentum and could have impaired the Company's ability to

continue to navigate the challenges, including the opioid litigation, and bring pipeline products to market. The HRCC consulted independent advisors on the extension of the program and approaches utilized by other companies facing similar uncertainties for retention of executives in determining the value of the extended ERBP. The HRCC (and the Board with regard to the CEO) approved awards under the extended ERBP for the NEOs in the following amounts.

2020 Executive Retention Bonuses

Mark C. Trudeau	$1,575,000
Hugh M. O'Neill	$930,000
Steven J. Romano, M.D.	$930,000

Awards under the 2019 ERBP, are subject to repayment prior to the 18-month anniversary of the grant date in the event the award recipient resigns, retires, voluntarily terminates employment or is terminated by the Company for cause. Awards under the extended 2020 ERBP, are subject to repayment in the event the award recipient resigns, retires, voluntarily terminates employments or is terminated by the Company for cause until the earlier of May 15, 2022 or the date the Company emerges from bankruptcy proceedings.

Other Benefits

We provide NEOs the same benefits that are provided to all employees, including defined contribution retirement benefits and health and welfare benefits. In addition, our executive officers are provided with certain additional benefits, intended to be competitive with the practices of our peer companies.

Retirement Benefits. The NEOs are eligible to participate in our Retirement Savings and Investment Plan ("Mallinckrodt Retirement Savings Plan"), which is our 401(k) plan available to all eligible U.S. employees, and our Supplemental Savings and Retirement Plan ("Mallinckrodt Supplemental Savings Plan"), our non-qualified deferred compensation plan in which executive officers and other senior employees may participate. The Mallinckrodt Supplemental Savings Plan is a so-called "excess" plan that extends the 401(k) benefits beyond the Internal Revenue Code (the "Code") limitations.

Mallinckrodt Supplemental Savings Plan. Under the Mallinckrodt Supplemental Savings Plan, participants, including NEOs, may defer up to 50% of their base salary and 75% of their annual bonus. We provide matching credits based on the participant's deferred base salary and bonus at the same rate that such participant is eligible to receive matching contributions under the Mallinckrodt Retirement Savings Plan and Company credits on any cash compensation (i.e., base and bonus) that the participant earns during a calendar year in excess of applicable IRS limits ($290,000 for 2021). Participants are fully vested in matching and Company credits (including earnings on such credits) upon completion of two years of service. The Mallinckrodt Supplemental Savings Plan is a non-qualified deferred compensation plan that is maintained as an unfunded "top-hat" plan and is designed to comply with Section 409A of the Code. Amounts credited to the Mallinckrodt Supplemental Savings Plan as participant deferrals or Company credits may also be credited with earnings (or losses) based upon investment selections made by each participant from investments that generally mirror investments offered under the Mallinckrodt Retirement Savings Plan. Participants may elect whether they will receive a distribution of their Mallinckrodt Supplemental Savings Plan account balances upon termination of employment or at a specified date. Distributions can be made in a lump sum or in up to 15 annual installments.

Under the Mallinckrodt Retirement Savings Plan, we make an automatic contribution of three percent (3%) of an employee's eligible pay, irrespective of whether the employee contributes to such plan. Additionally, we match fifty cents ($0.50) for every one dollar ($1.00) employees contribute, up to the first eight percent (8%) of eligible pay. Elective deferrals of compensation were suspended for 2021.

International Assignment Benefits. We ensure that employees who are sent on an assignment outside of their home country are subject to substantially the same income tax liability as they would have paid in the U.S. pursuant to our tax equalization program. Each such employee is responsible for a theoretical U.S. income tax liability based on an estimate of his or her anticipated U.S. income tax liability, and we are responsible for any home country and assignment country taxes in excess of that amount. We deduct hypothetical income taxes from the employee's compensation during the tax year and pay any assignment country taxes on his or her behalf.

Health and Welfare Benefits. The health and welfare benefits we provide to the NEOs are offered to all eligible U.S. based employees and include medical, dental, prescription drug, vision, life insurance, accidental death and dismemberment, business travel accident, personal and family accident, flexible spending accounts, short- and long-term disability coverage and an employee assistance program.

Additional Benefits. We maintain an executive physical examination program and an executive financial and tax planning program for executive officers. These programs are intended to encourage executives to proactively manage their health and complex financial/tax situations, thereby enabling them to focus on the business. The benefits are periodically benchmarked versus comparable companies and intended to be competitive for our industry. In addition, when we request a spouse or partner to attend a business meeting, such as our annual national sales recognition program for top performers, we reimburse executive officers for expenses related to this travel. In these circumstances, we reimburse executive officers for the income taxes associated with these travel

expenses. In addition, certain executives whose permanent residences are located more than 50 miles from our New Jersey executive offices, are reimbursed for commuting expenses and we pay for their lodging when they are working at our New Jersey executive offices.

Severance Benefits. We maintain an executive severance plan that provides benefits to certain senior executives upon an involuntary termination of employment for any reason other than cause, permanent disability or death. We provide this plan to enable our executives to devote their full attention to our business by ensuring they will have some financial security in the event of an involuntary termination of employment without cause. Severance benefits, in the form of a lump sum cash payment equal to 18 months base salary (24 months for our CEO), bonus and health benefits are generally payable following a qualifying termination of employment. Executives whose employment is involuntarily terminated without cause during the first twelve months of employment receive base salary and health benefits equivalent to 9 months (12 months for our CEO) in the form of a lump sum cash payment and do not receive a bonus. Receipt of these benefits is conditioned upon the executive signing a release of any claims against us.

Change in Control Benefits. We maintain a change in control plan that provides benefits to certain senior executives upon an involuntary termination of employment or good reason resignation that occurs during a period shortly before and continuing after a change in control (a double-trigger arrangement). We provide this plan to encourage our executives to remain neutral in the face of a potential transaction that may benefit shareholders but result in the loss of the executive's employment. Benefits are generally payable following a qualifying termination of employment in a lump-sum cash payment equal to 1.5 times (two times for our CEO) the sum of the executive's base salary and the average of the executive's bonus for the previous three fiscal years. Additional benefits provided upon a change in control termination include full vesting of outstanding equity awards (double-trigger), continued subsidy for health plan premiums for an 18-month period (24 months for our CEO) and outplacement services. Receipt of change in control severance benefits is conditioned upon the executive signing a release of any claims against us. The plan does not provide excise tax gross-ups.

Employment Agreements. For our NEOs, we have entered into employment agreements which are intended to codify into a contractual arrangement the severance benefits that each executive officer was already entitled to under the executive severance plan. The term of the employment agreements is three years, with automatic one year renewals, absent notice of non-renewal.

Due to the commencement of the Chapter 11 Cases, the disbursement of severance pay and related benefits during the pendency of the Chapter 11 Cases is subject to, among other things, approval by the Bankruptcy Court and the restrictions regarding severance payments imposed by section 503(c) of the Bankruptcy Code.

Share Ownership Requirements

The Board established share ownership requirements under which executive officers have been expected to hold equity with a value expressed as a multiple of their base salary, with the CEO set at five times base salary and all other executive officers set at three times base salary, with certain allowances for including awarded but unvested equity grants in the calculations. However, as a result of the Chapter 11 Cases and related circumstances, on November 3, 2020, the Board of Directors waived compliance with the stock ownership requirements for the duration of the Chapter 11 Cases.

Anti-Hedging/Anti-Pledging Policy

Our Insider Trading Policy prohibits directors, officers and employees from entering into or trading in puts, calls, cashless collars, options or similar rights and obligations or any other hedging activity involving our securities, other than the exercise of a Company-issued stock option.

Our policy also prohibits directors, officers and employees from purchasing our securities on margin, borrowing against our securities held in a margin account or pledging our securities as collateral for a loan. However, an exception may be granted by our General Counsel if the individual clearly demonstrates the financial capacity to repay the loan without resort to the pledged securities.

Executive Financial Recoupment Program ("Clawback")

Since its separation from Covidien plc in 2013, the Corporate Governance Guidelines have mandated that the Company have a Board-approved policy for recoupment of incentive compensation. This policy was originally implemented by the Board in 2014, and was most recently amended in 2022 in connection with at the Company's corporate integrity agreement entered into with the Office of Inspector General of the Department of Health and Human Services. Mallinckrodt's policy states that in the event of an accounting restatement resulting from material non-compliance with financial reporting requirements under applicable law, the HRCC is authorized to recover any incentive compensation that was overpaid taking into account such factors as the HRCC deems appropriate. In addition, Mallinckrodt's policy states that in the event of certain events of significant misconduct, including a violation of law or regulation or a significant violation of a Company policy, to the extent permitted by law, the Company must seek to recoup cash awards and all or a portion of the realized value of equity awards for the three (3) year period prior to the recoupment determination.

Under Mallinckrodt's policy, the Company agreed to disclose annually whether, at any time during the last completed fiscal year, the Board required recoupment or forfeiture of any incentive compensation received by certain employees, including NEOs, (1) if required by law, and (2) if not required by law, so long as the disclosure (a) would not violate any individual's privacy rights, (b) is not likely to result in or exacerbate any existing or threatened employee, shareholder or other litigation, arbitration, investigation or proceeding against the Company and (c) is not otherwise prohibited. Subject to the exceptions described in the previous sentence, if any such recoupment or forfeiture under this policy occurred, the Company will disclose the general circumstances of the recoupment and/or forfeiture, and if no such recoupment or forfeiture occurred during the last completed fiscal year, the Company will disclose that no such event occurred.

In addition, the Company's Wage Motion which is effective during the Chapter 11 restructuring process, states all parties involved may seek disgorgement of payments from any member in a debtor entity, including the NEOs, if it is determined the member knowingly participated in criminal misconduct in connection with their employment with the Debtors or been aware of acts or omissions of others that such member knew at the time were fraudulent or criminal with respect to the Debtors' commercial practices in connection with the sale of opioids.

In 2021, there was no recoupment or forfeiture applied to the incentive compensation of any executive officer of the Company.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information regarding outstanding stock option awards and unvested restricted unit and performance unit awards held by each NEO as of December 31, 2021 and the corresponding market value based on our closing stock price as of December 31, 2021. For a more complete understanding of the table, please read the footnotes that follow the table.

OUTSTANDING EQUITY AWARDS AT 2021 FISCAL YEAR-END

	Option Awards				Stock Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
Mark C. Trudeau	17,904	— (1)	37.85	1/31/2022	—	—	—	—
	38,875	— (2)	41.73	12/2/2022	—	—	—	—
	234,437	— (3)	44.00	6/30/2023	—	—	—	—
	63,542	— (4)	51.35	1/1/2024	—	—	—	—
	108,014	— (5)	96.96	1/2/2025	—	—	—	—
	175,528	— (6)	72.61	1/4/2026	—	—	—	—
	249,785	— (7)	51.73	1/3/2027	—	—	—	—
	709,502	236,501 (8)	13.80	4/2/2028	—	—	—	—
	257,001	257,001 (9)	22.26	4/1/2029	—	—	—	—
Hugh M. O'Neill	15,062	— (4)	51.35	1/1/2024	—	—	—	—
	9,414	— (10)	51.35	1/1/2024	—	—	—	—
	16,551	— (5)	96.96	1/2/2025	—	—	—	—
	30,605	— (6)	72.61	1/4/2026	—	—	—	—
	40,726	— (7)	51.73	1/3/2027	—	—	—	—
	13,575	— (11)	51.73	1/3/2027	—	—	—	—
	54,301	— (12)	51.73	1/3/2027	—	—	—	—
	96,492	32,165 (8)	13.80	4/2/2028	6,160 (14)	770	—	—
	51,400	51,401 (9)	22.26	4/1/2029	11,231 (13)	1,404	—	—
Steven J. Romano, M.D.	11,275	— (15)	120.27	7/1/2025	—	—	—	—
	22,288	— (6)	72.61	1/4/2026	—	—	—	—
	44,798	— (7)	51.73	1/3/2027	—	—	—	—
	14,933	— (11)	51.73	1/3/2027	—	—	—	—
	59,731	— (12)	51.73	1/3/2027	—	—	—	—
	141,900	47,301 (8)	13.80	4/2/2028	9,058 (14)	1,132	—	—
	51,400	51,401 (9)	22.26	4/1/2029	11,231 (13)	1,404	—	—

(1) Represents stock options granted on February 1, 2012 to Mr. Trudeau in connection with his commencement of employment with Covidien as President of its Pharmaceuticals business, which vest 50% on each of the 3rd and 4th anniversaries of the grant date.

(2) Represents stock options granted on December 3, 2012, which vest one third on each of the 2nd, 3rd and 4th anniversaries of the grant date.

(3) Represents stock options granted on July 1, 2013 in connection with the separation from Covidien, which vest 50% on each of the 3rd and 4th anniversaries of the grant date.

(4) Represents stock options granted on January 2, 2014, which vest 25% on each of the 1st, 2nd, 3rd and 4th anniversaries of the grant date.
(5) Represents stock options granted on January 2, 2015, which vest 25% on each of the 1st, 2nd, 3rd and 4th anniversaries of the grant date.
(6) Represents stock options granted on January 4, 2016, which vest 25% on each of the 1st, 2nd, 3rd and 4th anniversaries of the grant date.
(7) Represents stock options granted on January 3, 2017, which vest 25% on each of the 1st, 2nd, 3rd and 4th anniversaries of the grant date.
(8) Represents stock options granted on April 2, 2018, which vest 25% on each of the 1st, 2nd, 3rd and 4th anniversaries of the grant date.
(9) Represents stock options granted on April 1, 2019, which vest 25% on each of the 1st, 2nd, 3rd and 4th anniversaries of the grant date.
(10) Represents stock options granted on January 2, 2014, which vest 50% each on the 3rd and 4th anniversaries of the grant date.
(11) Represents stock options granted on January 3, 2017 for the transition period, which vest 25% on each of the 1st, 2nd, 3rd and 4th anniversaries of the grant date.
(12) Represents stock options granted to certain NEOs on January 3, 2017, which fully vest on the 4th anniversary of the grant date.
(13) Represents RSUs granted on April 1, 2019, which vest 25% on each of the 1st, 2nd, 3rd and 4th anniversaries of the grant date.
(14) Represents RSUs granted on April 2, 2018, which vest 25% on each of the 1st, 2nd, 3rd and 4th anniversaries of the grant date.
(15) Represents stock options granted on July 1, 2015, which vest 25% on each of the 1st, 2nd, 3rd and 4th anniversaries of the grant date.

Potential Payments upon Termination

Due to the commencement of the Chapter 11 Cases, the disbursement of severance pay and related benefits during the pendency of the Chapter 11 Cases is subject to, among other things, approval by the Bankruptcy Court and the restrictions regarding severance payments imposed by section 503(c) of the Bankruptcy Code. The table below does not take into account changes and restrictions that apply following the commencement of the Chapter 11 Cases.

Employment Agreements. For all of the NEOs, severance benefits are payable pursuant to employment agreements entered into between each of the NEOs and a subsidiary of the Company (the "Employment Agreements"), which were intended to codify into a contractual arrangement the severance benefits that each NEO was already entitled to under the Severance Plan. Under the Employment Agreements, benefits are payable to eligible executives, including NEOs, upon an involuntary termination of employment for any reason other than cause, permanent disability or death. Post-termination benefits consist of:

- Payment of 1.5 times (2x for our CEO) the executive's annual base salary and the average annual bonus received for the previous three fiscal years excluding any amounts paid that were attributable to the component of the award intended to replace a NEOs previously approved target long-term incentive equity opportunity;
- A lump sum payment equal to the employer subsidized portion of the cost of health insurance for the applicable executive and his dependents for 18 months;
- Accelerated vesting of stock options, restricted stock and RSUs scheduled to vest during the 12 months following the date of termination, with vested options remaining exercisable until the one year anniversary of the date of termination, subject to the earlier expiration of the option term. PSUs scheduled to vest during the 12 months following employment termination remain eligible to vest based on actual results.
- If, during the twenty-four months following the date of termination, an executive would reach the age required for early retirement or normal retirement treatment and would otherwise meet the retirement treatment criteria, the executive will be entitled to any more favorable equity award vesting included in any applicable equity award agreement with the executive;
- Outplacement services for up to 12 months; and
- Payment of a pro-rata portion of the executive's annual incentive cash award for the fiscal year in which such executive's employment terminates.

In addition, change in control severance benefits are payable to eligible executives, including NEOs, only if the double-trigger requirements are satisfied, meaning that, in order to receive any of the following benefits, the executive must experience an involuntary termination of employment or good reason resignation during a period that begins upon, and ends two years after, a change in control. Post-termination benefits consist of:

- Payment of 1.5 times (2x for our CEO) the executive's annual base salary and the average annual bonus received for the previous three fiscal years excluding any amounts paid that were attributable to the component of the award intended to replace a NEOs previously approved target long-term incentive equity opportunity;
- A lump sum payment equal to the employer subsidized portion of the cost of health insurance for the applicable executive and his dependents for 18 months;
- Accelerated vesting in full of all stock options, restricted stock, RSUs and PSUs (with vested options remaining exercisable until the one year anniversary of the date of termination), with the vesting level of PSUs to be determined in the sole discretion of the HRCC;
- Outplacement services for up to 12 months; and

- Payment of a pro-rata portion of the executive's annual incentive cash award for the fiscal year in which such executive's employment terminates.

The payment of benefits under the Employment Agreements is conditioned upon the executive executing a general release in favor of us and is subject to the terms of the Non-Competition, Non-Solicitation, and Confidentiality Agreement by and between the executive and us, under which the executive agreed not to disclose confidential Company information at any time and not to compete with us nor solicit our employees or customers, for a period of one year following termination of employment. We may cancel benefits that are payable or seek to recover benefits previously paid if the executive does not comply with these provisions or violates the release of claims. Payments may be delayed until six months after termination of employment if necessary to comply with Section 409A of the Code.

Upon a termination of employment for cause, executives, including NEOs, are not eligible for severance benefits under the Employment Agreements and forfeit all unvested stock options, RSUs and PSUs. In addition, the stock options, RSUs and PSUs include a "clawback" feature pursuant to which we may recover the amount of any profit the NEO realized upon the exercise of stock options, or the vesting of RSUs or PSUs, during the 12-month period that occurs immediately prior to the executive officer's involuntary termination of employment for cause.

For purposes of the Employment Agreements, as well as the "clawback" feature discussed in the preceding sentence, "cause" means substantial failure or refusal of the NEO to perform the duties and responsibilities of his job at a satisfactory level as required by us other than due to permanent disability, a material violation of any fiduciary duty or duty of loyalty owed to us, conviction of misdemeanor (other than a traffic offense) or felony, fraud, embezzlement or theft, violation of a material rule or policy, including a violation of our Guide to Business Conduct, unauthorized disclosure of any of our trade secrets or confidential information or other egregious conduct that has or could have a serious and detrimental impact on us and our employees.

For purposes of the Employment Agreements, "good reason" means any retirement or termination of employment by the NEO that is not initiated by us and that is caused by any one or more of the following events, in each case, without the NEO's written consent during the two-year period following a change in control: (i) assignment to the NEO of any duties inconsistent in any material respect with the NEO's authority, duties or responsibilities as in effect immediately prior to the change in control; (ii) a material diminution in the authority, duties or responsibilities of the supervisor to whom the NEO is required to report as in effect immediately prior to the change in control; (iii) a material change in the geographic location at which the NEO must perform services to a location that is more than 50 miles from the NEO's principal place of business immediately preceding the change in control; (iv) a material reduction in the NEO's compensation and benefits, taken as a whole, as in effect immediately prior to the change in control; (v) our failure to obtain a satisfactory agreement from any successor to assume and agree to perform our obligations to the NEO under such Employment Agreement; or (vi) a material diminution in the budget over which the NEO retains authority. Additionally, "good reason" will only exist if the NEO provides written notice stating the good reason event, we do not cure such event, and the NEO terminates employment within a certain period of time after the end of the cure period.

Other Termination Benefits. The terms of our 2021 KEIP and equity plan provide for certain benefits upon a NEO's termination of employment due to death, disability or retirement. For this purpose, normal retirement occurs where an executive officer terminates employment after attaining age 60 and the sum of the executive's age and years of service equals at least 70. Under the 2021 KEIP, NEOs are eligible to receive a pro-rated annual incentive cash award based on the number of days that the executive officer was employed by us during the fiscal year upon death, disability or normal retirement. Under the equity plan, NEOs are eligible to receive full vesting of stock options, RSUs and PSUs upon death, disability or normal retirement.

Compensation of Non-Employee Directors

The Board of Directors has approved a compensation structure for non-employee directors consisting of an annual cash retainer and supplemental cash retainers. This compensation structure was determined in conjunction with the Governance and Compliance Committee, after reviewing data and analyses from the Governance and Compliance Committee's independent compensation consultant, Willis Towers Watson ("WTW").

Cash Retainers

Board members. Each director receives an annual cash retainer of $336,000, paid in quarterly installments at the end of each quarter. Directors joining the Board other than on the first day of a quarter receive a cash retainer pro-rated for the number of days served during their initial quarter of service.

Committee Chairs. The Chair of the Audit Committee receives a supplemental annual cash retainer of $25,000. The Chair of the Human Resources and Compensation Committee receives a supplemental annual cash retainer of $20,000. The Chairs of the Governance and Compliance Committee and the Science and Technology Committee each receive a supplemental annual cash retainer of $15,000. The Chair of the Strategic Review Committee does not receive any additional retainer for this service.

Committee Members. Each member of a committee (excluding committee chairs) receives a supplemental annual cash retainer of $5,000.

Non-Executive Chairman of the Board. Our non-executive Chairman receives a supplemental annual cash retainer of $139,600.

Equity Awards

RSUs. Historically, at the time of our Annual General Meeting, each non-employee director received an annual grant of RSUs with a value of $295,000. Additionally, our non-executive Chairman received, at the time of our Annual General Meeting, additional RSUs with a value of $112,000. The awards vested on the date of our next succeeding Annual General Meeting.

New directors received a pro-rated annual equity grant. A pro-rated annual equity grant would not be granted to any new director who commences service less than three months prior to the vesting date.

During fiscal 2020, the Board of Directors upon the recommendation of the Governance and Compliance Committee and the Human Resources and Compensation Committee, and with the advice of WTW, approved, in lieu of an annual equity award, an increase in the annual cash retainer for all directors by an amount equal to 80% of the annual equity award value, reflecting a 20% reduction to reflect the shorter-term nature of this component. This change was implemented due to the various uncertainties the Company was facing associated with outstanding legal issues related to opioids and Acthar Gel, and was benchmarked against similar changes implemented at other companies facing such uncertainties and is generally aligned with the approach taken by companies of comparable size to the Company. This compensation structure was again approved in fiscal 2021, as the Company's circumstances had not materially changed.

Other

Pursuant to our company-wide Matching Gift Program, we match employee and director contributions to charitable organizations up to $2,500. Directors are also reimbursed for reasonable out-of-pocket expenses incurred in attending Board meetings, committee meetings and shareholder meetings. Directors are provided with chartered private or commercial aircraft in order to travel to and from such meetings.

Director Share Retention and Ownership Guidelines

Our Corporate Governance Guidelines have provisions requiring all non-employee directors to hold Mallinckrodt ordinary shares with a market value of at least five times the annual cash retainer. Until the required ownership level is achieved, the non-employee directors would be required to retain net after tax shares received upon vesting of RSUs. However, as a result of the Chapter 11 Cases and related circumstances, on November 3, 2020, the Board of Directors waived compliance with the stock ownership guidelines for the duration of the Chapter 11 Cases.

The following table provides information concerning the compensation paid by us to each of our non-employee directors for the fiscal year ended December 31, 2021. Compensation for Mark C. Trudeau, our President and Chief Executive Officer, is shown in the Summary Compensation Table. Mr. Trudeau receives no additional compensation for his services as a director.

2021 Director Compensation Table

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	All Other Compensation ($)	Total ($)
David R. Carlucci	341,000	—	—	341,000
J. Martin Carroll	356,000	—	—	356,000
Paul R. Carter	351,000	—	—	351,000
David Y. Norton	356,000	—	—	356,000
Carlos V. Paya, M.D.	356,000	—	—	356,000
JoAnn A. Reed	361,000	—	—	361,000
Angus C. Russell	490,600	—	—	490,600
Anne C. Whitaker	346,000	—	—	346,000
Kneeland C. Youngblood, M.D.	346,000	—	—	346,000

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

Equity Compensation Plan Information

	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a) [1][2]	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b) [3]	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c) [4]
Equity compensation plans approved by security holders	5,346,512	$34.89	19,788,615
Equity compensation plans not approved by security holders	—	—	—
Total	5,346,512	$34.89	19,788,615

(1) As of December 31, 2021, there were 5,346,512 ordinary shares to be issued upon exercise of outstanding options with a weighted-average exercise price of $34.89, 192,149 ordinary shares to be issued upon settlement of RSUs and PSUs granted pursuant to our Stock and Incentive Plan.

(2) This table does not include information regarding:

- Options converted from Covidien awards in connection with our separation from Covidien in June 2013. We did not assume any equity compensation plans from Covidien, and no grants of Mallinckrodt equity may be made pursuant to any Covidien plans. As of December 31, 2021, there were 190,963 ordinary shares to be issued upon exercise of these converted options with a weighted-average exercise price of $41.49.
- Options, RSAs and RSUs converted from Questcor awards in connection with our acquisition of Questcor in August 2014. We did not assume any equity compensation plans from Questcor, and no grants of Mallinckrodt equity may be made pursuant to any Questcor plans. As of December 31, 2021, there were 28,144 ordinary shares to be issued upon exercise of these converted options with a weighted-average exercise price of $31.31.

(3) Does not take into account RSUs and PSUs, which do not have an exercise price.

(4) As of December 31, 2021, there were 15,315,995 ordinary shares available for issuance pursuant to the Stock and Incentive Plan and 4,472,620 ordinary shares subject to purchase pursuant to the Mallinckrodt Employee Stock Purchase Plan. Ordinary shares subject to purchase pursuant to the Mallinckrodt Employee Stock Purchase Plan may be unissued shares or reacquired shares.

Security Ownership of Management and Certain Beneficial Owners

The following tables show the number of ordinary shares beneficially owned as of February 2, 2022, by (i) each current director, each executive officer named in the Summary Compensation Table and our directors and executive officers as a group; and (ii) each person who we know or have reason to believe is the beneficial owner of more than 5% of our outstanding ordinary shares, based on statements filed by such persons pursuant to Section 13(d) or 13(g) of the Exchange Act, and notices delivered to us pursuant to the Irish Companies Act. The table below does not take into account changes and restrictions that apply following the commencement of the Chapter 11 Cases.

A person is deemed to be a beneficial owner of ordinary shares if he or she, either alone or with others, has the power to vote or to dispose of those ordinary shares or the right to acquire such power within 60 days of February 2, 2022. We have assumed that ordinary shares subject to stock options which by their terms are presently exercisable or exercisable within 60 days of February 2, 2022 and RSUs that by their terms have vested or vest within 60 days of February 2, 2022 are deemed to be outstanding and beneficially owned by the person holding the securities for the purpose of computing the percentage ownership of that person, but are not treated as outstanding for the purpose of computing the percentage of any other person. There were 84,730,100 ordinary shares outstanding as of February 2, 2022 and the calculations of percentage ownership below are based on such number of outstanding shares regardless of the date of the information regarding beneficial ownership reported below.

Directors and Executive Officers

Name of Beneficial Owner	Number of Mallinckrodt Ordinary Shares Beneficially Owned	Percentage Ownership
David R. Carlucci	—	—
J. Martin Carroll	—	—
Paul R. Carter	20,320	*
David Y. Norton	—	—
Carlos V. Paya, M.D.	—	—
JoAnn A. Reed	34,065	*
Angus C. Russell	—	—
Mark C. Trudeau [1]	2,201,684	2.53 %
Anne C. Whitaker	—	—
Kneeland C. Youngblood, M.D.	—	—
Steven J. Romano [2]	483,687	*
Hugh M. O'Neill [3]	454,813	*
All directors and executive officers as a group (16 persons) [4]	3,762,527	4.25 %

* Represents less than 1% of outstanding ordinary shares.

(1) Includes 2,201,684 ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of February 2, 2022.

(2) Includes 29,347 RSUs and 419,325 ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of February 2, 2022. Excludes 8,275 RSUs that vest more than 60 days after February 2, 2022.

(3) Includes 23,550 RSUs and 385,990 ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of February 2, 2022. Excludes 8,033 RSUs that vest more than 60 days after February 2, 2022.

(4) Includes 86,930 RSUs and 3,538,766 ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of February 2, 2022. Excludes 23,839 RSUs that vest more than 60 days after February 2, 2022.

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

Transactions with Related Persons

The Governance and Compliance Committee is responsible for the review and, if appropriate, approval or ratification of "related-person transactions" involving us or our subsidiaries and related persons. Under SEC rules, a related person is a director, nominee for director, executive officer or a beneficial owner of 5% or more of our ordinary shares and their immediate family members. The Board has adopted written policies and procedures that apply to any transaction or series of transactions in which we or one of our subsidiaries is a participant, the amount involved exceeds $120,000 and a related person has a direct or indirect material interest.

Independence of Directors

The Corporate Governance Guidelines include criteria adopted by the Board to guide determinations regarding the independence of its members. The criteria, summarized below, are consistent with the NYSE listing standards regarding director independence. Although our ordinary shares ceased to be listed on the NYSE following our voluntary filing of the Chapter 11 Cases, we have elected to continue to comply with the NYSE listing standards relating to director and audit committee member independence. To be considered independent, a director must be determined by the Board to have no material relationship, directly or indirectly, with us. In assessing independence, the Board considers all relevant facts and circumstances. In particular, when assessing the materiality of a director's relationship with us, the Board considers the issue not just from the standpoint of the director, but also from that of the persons or organizations with which the director has an affiliation. A director will not be considered independent if he or she, at the time of determination:

- Is, or has been within the prior three years, an employee of Mallinckrodt or any of its subsidiaries;
- Has an immediate family member who is, or has been within the prior three years, an executive officer of Mallinckrodt;
- Is a current partner or employee of our external auditor;
- Has an immediate family member who is a current partner of our external auditor or who is an employee of our external auditor and personally works on our audit;
- Has been, or has an immediate family member who has been, within the prior three years, a partner or employee of our external auditor who personally worked on our audit during that time;
- Is, or has an immediate family member who is, or has been within the prior three years, employed as an executive officer of another company that has or had on the compensation committee of its board of directors one of our executive officers (during the same period of time);
- Has, or has an immediate family member who has, received more than $120,000 in direct compensation from Mallinckrodt, other than director and committee fees and pension or other forms of deferred compensation for prior service (provided such compensation is not contingent in any way on continued service), in any 12-month period within the prior three years (compensation received by an immediate family member for service as an employee, other than as an executive officer, is not included for purposes of this determination);
- Is a current employee, or has an immediate family member who is a current executive officer, of a company that does business with Mallinckrodt and has made payments to, or received payments from, Mallinckrodt for property or services in an amount that, in any of the prior three fiscal years, exceeds the greater of $1 million or 2% of such other company's consolidated gross revenues; or
- Is, or his or her spouse is, an executive officer, director or trustee of a charitable organization to which our contributions, not including our matching of charitable contributions by employees, exceed, in any single fiscal year within the prior three years, the greater of $1 million or 2% of such organization's total charitable receipts during that year.

The Board has considered the independence of its members in light of these criteria, has reviewed our relationships with organizations with which our directors are affiliated and has determined that none of these current business relationships is material to us, any of the organizations involved, or our directors. Based on these considerations, the Board has determined that each of our directors, other than Mark C. Trudeau, our President and Chief Executive Officer, satisfies the criteria and is independent. Each independent director is

expected to notify the chair of the Governance and Compliance Committee, as soon as reasonably practicable, of changes in his or her personal circumstances that may affect the Board's evaluation of his or her independence.

Item 14. Principal Accounting Fees and Services.

Audit and Non-Audit Fees

During fiscal 2021 and fiscal 2020, Deloitte & Touche LLP charged fees for services rendered to us as follows:

	Fiscal 2021	Fiscal 2020
Audit Fees	$ 5,438,000	$ 6,573,000
Audit-Related Fees	20,000	—
Tax Fees	67,500	—
All Other Fees	285,000	—
Total	$ 5,810,500	$ 6,573,000

Audit Fees include fees for professional services rendered for the year-end audits of our consolidated financial statements and internal control over financial reporting, reviews of the financial statements included in our Quarterly Reports on Form 10-Q, consents, statutory audits, and procedures related to Chapter 11 proceedings and internal legal entity reorganization.

Audit-Related Fees include fees for attest services not required by statute or regulation.

Tax Fees include fees for tax compliance services.

All Other Fees include fees for professional services rendered in the preparation of an independent expert's report that was submitted to the High Court of Ireland in conjunction with Mallinckrodt plc's commencement of the examinership process.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services

The Audit Committee has adopted a pre-approval policy that provides guidelines for audit, audit-related, tax and other permissible non-audit services that may be provided by our independent auditors. Pursuant to the policy, our Corporate Controller supports the Audit Committee by providing a list of proposed services to the Audit Committee, monitoring the services and fees pre-approved by the Audit Committee, providing periodic reports to the Audit Committee with respect to pre-approved services and coordinating with management and the independent auditors to support compliance with the policy.

Under the policy, the Audit Committee annually pre-approves the audit fee and terms of the engagement, as set forth in the engagement letter. The Audit Committee also annually approves a specified list of audit, audit-related and tax services. Any service not included in the specified list of services must be submitted to the Audit Committee for pre-approval. The independent auditors may not begin work on any engagement without confirmation of Audit Committee pre-approval from our Corporate Controller or their delegate.

Pursuant to the policy, the Audit Committee has delegated to its Chair the authority to pre-approve the engagement of the independent auditors in her discretion. The Chair reports all such pre-approvals to the Audit Committee at the next Audit Committee meeting.

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 31, 2021, December 25, 2020 and December 27, 2019
- Consolidated Statements of Comprehensive Operations for the fiscal year ended December 31, 2021, December 25, 2020 and December 27, 2019
- Consolidated Balance Sheets as of December 31, 2021 and December 25, 2020
- Consolidated Statements of Cash Flows for the fiscal year ended December 31, 2021, December 25, 2020 and December 27, 2019
- Consolidated Statements of Changes in Shareholders' Equity for the period from December 28, 2018 to December 31, 2021
- 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 31, 2021	$ 4.5	$ 1.2	$ —	$ (1.0)	$ 4.7
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
Sales reserve accounts:					
Fiscal year ended December 31, 2021	$ 235.4	$ 2,166.0	$ —	$ (2,128.6)	$ 272.8
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
Tax valuation allowance:					
Fiscal year ended December 31, 2021	$ 6,110.8	$ 233.4	$ —	$ —	$ 6,344.2
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

(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 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.

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 15, 2022

By: /s/ Bryan M. Reasons

Bryan M. Reasons
Executive Vice President and Chief Financial Officer
(principal financial and accounting 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 15, 2022
/s/ Bryan M. Reasons Bryan M. Reasons	Executive Vice President and Chief Financial Officer *(principal financial and accounting officer)*	March 15, 2022
/s/ Angus C. Russell Angus C. Russell	Chairman of the Board of Directors	March 15, 2022
/s/ David R. Carlucci David R. Carlucci	Director	March 15, 2022
/s/ J. Martin Carroll J. Martin Carroll	Director	March 15, 2022
/s/ Paul R. Carter Paul R. Carter	Director	March 15, 2022
/s/ David Y. Norton David Y. Norton	Director	March 15, 2022
/s/ Carlos V. Paya Carlos V. Paya	Director	March 15, 2022
/s/ JoAnn A. Reed JoAnn A. Reed	Director	March 15, 2022
/s/ Anne C. Whitaker Anne C. Whitaker	Director	March 15, 2022
/s/ Kneeland C. Youngblood, M.D. Kneeland C. Youngblood, M.D.	Director	March 15, 2022

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 (incorporated by reference to Exhibit 4.8 to the Company's Annual Report on Form 10-K filed March 10, 2021).
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*	Form of First Amendment to Employment Agreement by and between ST Shared Services LLC and Executive Officers (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed November 2, 2021).
10.15*	Mallinckrodt Pharmaceuticals Severance Plan for U.S. Officers and Executives, amended September 8, 2021 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 10-Q filed November 2, 2021).
10.16*	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).
10.17*	Mallinckrodt Pharmaceuticals Stock and Incentive Plan, as amended and restated effective February 23, 2022.
10.18*	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).
10.19*	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).
10.20*	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).
10.21*	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).
10.22*	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).
10.23*	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).
10.24*	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 (incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the fiscal year ended December 25, 2020).
10.31	Settlement Agreement, dated as of March 7, 2022, among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, Mallinckrodt plc, Mallinckrodt ARD LLC and James Landolt (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 11, 2022).
10.32	Settlement Agreement, dated as of March 7, 2022, among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, Mallinckrodt plc, Mallinckrodt ARD LLC, Charles Strunck, Lisa Pratta and Scott Clark (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed March 11, 2022).
21.1	Subsidiaries of Mallinckrodt plc.
23.1	Consent of Deloitte & Touche LLP.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certifications of the Chief Executive Officer and Interim Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.1	Order Confirming the Fourth Amended Joint Plan of Reorganization (with Technical Modifications) of Mallinckrodt Plc and Its Debtor Affiliates Under Chapter 11 of the Bankruptcy Code, including the full text of the Fourth Amended Joint Plan of Reorganization (with Technical Modifications) as Exhibit A thereto (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed March 3, 2022).
101	The following materials from the Mallinckrodt plc Annual Report on Form 10-K for the fiscal year ended December 31, 2021 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.

MALLINCKRODT PHARMACEUTICALS STOCK AND INCENTIVE PLAN

as amended and restated

This document constitutes part of a prospectus covering securities that have been registered under the United States Securities Act of 1933, as amended.

MALLINCKRODT PHARMACEUTICALS STOCK AND INCENTIVE PLAN

as amended and restated effective February 23, 2022

ARTICLE I

PURPOSE

1.1 *Purpose.* The purposes of this Mallinckrodt Pharmaceuticals Stock and Incentive Plan as amended and restated (the "Plan") are to promote the interests of Mallinckrodt public limited company (and any successor thereto) by (i) aiding in the recruitment and retention of Directors and Employees, (ii) providing incentives to Directors and Employees by means of performance-related incentives to achieve short-term and long-term performance goals, (iii) providing Directors and Employees with an opportunity to participate in the growth and financial success of the Company, and (iv) promoting the growth and success of the Company's business by aligning the financial interests of Directors and Employees with that of the other shareholders of the Company. Toward these objectives, the Plan provides for the grant of Stock Options, Stock Appreciation Rights, Annual Performance Bonuses, Long-Term Performance Awards and Other Stock-Based Awards.

1.2 *Effective Date; Shareholder Approval.* This amendment and restatement of the Plan is effective as of February 23, 2022. To the extent that the performance-based compensation exception under Section 162(m) of the Code is inapplicable or otherwise eliminated for taxable years beginning after December 31, 2017 or otherwise, the provisions relating to such exception herein shall be inapplicable, but only to the extent such exception would not otherwise apply; provided, however, for the avoidance of doubt, compensation resulting from a written binding contract that was in effect on November 2, 2017 and intended to meet the performance-based exception under Section 162(m) of the Code, shall not be materially modified by reason of this amendment and restatement and nothing contained herein shall be construed as such a modification or as permitting such a modification.

ARTICLE II

DEFINITIONS

For purposes of the Plan, the following terms have the following meanings, unless another definition is clearly indicated by particular usage and context:

"Acquired Company" means any business, corporation or other entity acquired by the Company or any Subsidiary.

"Acquired Grantee" means the grantee of a stock-based award of an Acquired Company and may include a current or former Director of an Acquired Company.

"Annual Performance Bonus" means an Award of cash or Shares granted under Section 4.4 of the Plan that is paid solely on account of the attainment of a specified performance target in relation to one or more Performance Measures, and is intended to qualify as "performance-based" compensation under Section 162(m) of the Code.

"Award" means any form of incentive or performance award granted under the Plan, whether singly or in combination, to a Participant by the Committee pursuant to any terms and conditions that the Committee may establish and set forth in the applicable Award Certificate. Awards granted under the Plan may consist of:

Cash Awards:

(a) Cash and other similar awards on an after tax/net basis

Equity Awards:

(a) *"Stock Options"* awarded pursuant to Section 4.3;

(b) *"Stock Appreciation Rights"* awarded pursuant to Section 4.3;

(c) *"Long-Term Performance Awards"* awarded pursuant to Section 4.5;

(d) *"Other Stock-Based Awards"* awarded pursuant to Section 4.6;

(e) *"Director Awards"* awarded pursuant to Section 4.7; and

(f) *"Substitute Awards"* awarded pursuant to Section 4.8.

"Award Certificate" means the document issued, either in writing or an electronic medium, by the Committee or its designee to a Participant evidencing the grant of an Award and which contains, in the same or accompanying document, the terms and conditions applicable to such Award.

"Board" means the Board of Directors of the Company.

"Cause" means, as to any Employee who is a party to an employment agreement with the Company or any Subsidiary which contains a definition of "cause," as set forth in such employment agreement and, if there is no applicable employment agreements, means an Employee's or Director's (i) substantial failure or refusal to perform duties and responsibilities of his or her job at a satisfactory level as required by the Company or Subsidiary, other than due to Disability, (ii) a material violation of any fiduciary duty or duty of loyalty owed to the Company or Subsidiary, conviction of a misdemeanor (other than a traffic offense) or felony, (iv) fraud, embezzlement or theft, (v) violation of a material Company or Subsidiary rule or policy, (vi) unauthorized disclosure of any trade secret or confidential information of the Company or Subsidiary or (vii) other egregious conduct, that has or could have a serious and detrimental impact on the Company or Subsidiary and its employees. The Committee (or the Human Resources and Compensation Committee solely with respect to Director Awards), in its sole and absolute discretion, shall determine Cause.

"Change in Control" means the first to occur of any of the following events:

(a) any "person" (as defined in Section 13(d) and 14(d) of the Exchange Act, excluding for this purpose, (i) the Company or any Subsidiary or (ii) any employee benefit plan of the Company or any Subsidiary (or any person or entity organized, appointed or established by the Company for or pursuant to the terms of any such plan that acquires beneficial ownership of voting securities of the Company), is or becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act) directly or indirectly of securities of the Company representing more than 30 percent of the combined voting power of the Company's then outstanding securities; provided, however, that no Change in Control will be deemed to have occurred as a result of a change in ownership percentage resulting solely from an acquisition of securities by the Company; or

(b) persons who, as of the Effective Date constitute the Board (the "Incumbent Directors") cease for any reason (including without limitation, as a result of a tender offer, proxy contest, merger or similar transaction) to constitute at least a majority thereof, provided that any person becoming a Director of the Company subsequent to the Effective Date shall be considered an Incumbent Director if such person's election or nomination for election was approved by a vote of at least 50 percent of the Incumbent Directors; but provided further, that any such person whose initial assumption of office is in connection with an actual or threatened proxy contest relating to the election of members of the Board or other actual or threatened solicitation of proxies or consents by or on behalf of a "person" (as defined in Section 13(d) and 14(d) of the Exchange Act) other than the Board, including by reason of agreement intended to avoid or settle any such actual or threatened contest or solicitation, shall not be considered an Incumbent Director; or

(c) consummation of a reorganization, merger or consolidation or sale or other disposition of at least 80 percent by value of the assets of the Company (a "Business Combination"), in each case, unless, following such Business Combination, all or substantially all of the individuals and entities who were the beneficial owners of outstanding voting securities of the Company immediately prior to such Business Combination beneficially own directly or indirectly more than 50 percent of the combined voting power of the then outstanding voting securities entitled to vote generally in the election of directors, of the company resulting from such Business Combination (including, without limitation, a company which, as a result of such transaction, owns the Company or all or substantially all of the Company's assets either directly or through one or more Subsidiaries) in substantially the same proportions as their ownership, immediately prior to such Business Combination, of the outstanding voting securities of the Company; or

(d) a complete liquidation or dissolution of the Company.

Any payment of deferred compensation subject to Code Section 409A that is to be made under an Award other than an Annual Performance Bonus upon the occurrence of a Change in Control or any change in the timing and/or form of such payment as a direct result of a Change in Control (including payments made upon a specified date or event occurring after a Change in Control) shall not be made, or such change in timing and/or form shall not occur, unless such Change in Control is also a "change in ownership or effective control" of the Company within the meaning of Code Section 409A(a)(2)(A)(v) and applicable regulations and rulings

thereunder and such payment, or such change in timing and/or form, occurs no later than two (2) years after the date of such change in ownership or effective control of the Company, in each case to the extent required to avoid the recipient of such Award from incurring tax penalties under Code Section 409A in respect of such Award. Notwithstanding the foregoing, if the Committee takes an action pursuant to Section 5.4(b) to accelerate the payment of deferred compensation upon a Change in Control, then any accelerated payment shall occur on a date specified in the applicable Award Certificate, which date shall be no later than ninety (90) days after a "change in ownership or effective control" of the Company. The payment of an Annual Performance Bonus that is to be accelerated pursuant to Subsection 4.4(g) shall occur within thirty (30) days after a "change in ownership or effective control" of the Company within the meaning of Code Section 409A(a)(2)(A)(v).

"*Change in Control Termination*" means such term or concept as defined in an Award Certificate or, if such term is not defined therein, a Participant's involuntary termination of employment that occurs during the twelve (12) month period immediately following a Change in Control. For this purpose, a Participant's involuntary termination of employment includes the following:

(a) termination of the Participant's employment by the Company for any reason other than for Cause, Disability or death;

(b) termination of the Participant's employment by the Participant after one of the following events, provided that the Participant's termination of employment occurs within sixty (60) days after the occurrence of any such event:

(i) the Company, without the Participant's consent, requires the Participant to relocate to a principal place of employment more than fifty (50) miles from his or her existing place of employment, which materially increases the Participant's commuting time; or

(ii) the Company, without the Participant's consent, materially reduces the Participant's base salary, target annual bonus opportunity, or retirement, welfare, target share incentive opportunity, and other benefits taken as a whole, as in effect immediately prior to the Change in Control;

provided that an event described in (i) or (ii) above shall permit a Participant's termination of employment to be deemed a Change in Control Termination only if (x) the Participant provides written notice to the Company specifying in reasonable detail the event upon which the Participant is basing his termination within ninety (90) days after the occurrence of such event, (y) the Company fails to cure such event within thirty (30) days after its receipt of such notice, and (z) the Participant terminates his employment within sixty (60) days after the expiration of such cure period."

"*Code*" means the United States Internal Revenue Code of 1986, as amended.

"*Committee*" means the Compensation and Human Resources Committee of the Board or any successor committee or other committee to which the Compensation and Human Resources Committee delegates its authority under this Plan. The Compensation and Human Resources Committee shall be comprised solely of "non-employee directors" within the meaning of Rule 16b-3(b)(3) under the Exchange Act and two or more persons who are outside directors within the meaning of Section 162(m)(4)(C)(i) of the Code and the applicable regulations.

"*Company*" means Mallinckrodt public limited company, a company incorporated in Ireland under registered number 522227, or any successor thereto.

"*Corporate Integrity Agreement (CIA)*" means the Company's agreement with the U.S. Department of Health and Human Services Officer of Inspector General.

"*Covered Employee*" means an Employee who is a "covered employee" within the meaning of Section 162(m) of the Code or who is reasonably expected to be a "covered employee" at the time the Company would be entitled to claim a tax deduction in respect of an Award but for Section 162(m) of the Code.

"*Deferred Stock Unit*" means a Unit granted under Section 4.6 or 4.7 to acquire Shares upon Termination of Directorship or Termination of Employment, or any other permitted payment event described in the Award Certificate, subject to any restrictions that the Committee, in its discretion, may determine.

"*Director*" means a member of the Board.

"*Disabled*" or "*Disability*" means, subject to Section 7.11(b)(iii), that (1) the Employee meets the requirements for disability benefits under the Social Security law then in effect and/or (2) the Employee is eligible to receive benefits under the Company's long-term disability plan; provided that, to the extent an Award is nonqualified deferred compensation subject to Code Section 409A and the payment of the Award occurs due to Disability, the Employee's will be deemed Disabled under subsection (2) only if he or she has received income replacement benefits for a period of not less than three (3) months under the Company's accident and health plan covering the Employee by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months.

"*Dividend Equivalent*" means an amount equal to the ordinary cash dividend or the fair market value of the share dividend that would be paid on each Share underlying an Award if the Share were duly issued and outstanding on the date on which the dividend is payable. In no event shall Dividend Equivalents be paid with respect to Stock Options or Stock Appreciation Rights.

"*Early Retirement*" means, unless otherwise specified in an Award Certificate, Termination of Employment on or after a Participant has attained age 55, provided that the sum of the Participant's age (in full years) and full years of service with the Company or a Subsidiary is 60 or higher.

"*Effective Date*" means May 16, 2018, unless otherwise provided herein.

"*Employee*" means any individual who performs services as an officer or employee of the Company or a Subsidiary not including "Executives" as defined in this Plan.

"*Equity Award*" means any type of non-cash Award including, but not limited to, Stock Options, Stock Appreciation Rights, Long-Term Performance Awards, and other Stock-Based Awards.

"*Exchange Act*" means the United States Securities Exchange Act of 1934, as amended.

"*Executives*" means all executive officers (as determined pursuant to rule 3b-7 promulgated under the Securities and Exchange Act of 1934, as amended, as well as U.S.-based Executive Vice Presidents and the Chief Executive Officer of the Company.

"*Exercise Price*" means the price of a Share, as fixed by the Committee, which may be purchased under a Stock Option or with respect to which the amount of any payment pursuant to a Stock Appreciation Right is determined.

"*Fair Market Value*" of a Share means the closing sales price on the New York Stock Exchange of a Share on the trading day of the grant or on the date as of which the determination of Fair Market Value is being made or, if no sale is reported for such day, on the next preceding day on which a sale of Shares is reported. Notwithstanding anything to the contrary herein, the Fair Market Value of a Share will in no event be determined to be less than par value.

"*GAAP*" means United States generally accepted accounting principles.

"*HRCC*" means Human Resources and Compensation Committee.

"*Incentive Stock Option*" means a Stock Option granted under Section 4.3 of the Plan that is intended to meet the requirements of Section 422 of the Code and any related regulations and is designated in the Award Certificate as intended to be an Incentive Stock Option.

"*Long-Term Performance Award*" means an Award granted under Section 4.5 of the Plan that is paid solely on account of the attainment of a specified performance target in relation to one or more Performance Measures or other performance criteria as selected in the sole discretion of the Committee.

"*Nonqualified Stock Option*" means any Stock Option granted under Section 4.3 of the Plan that is not an Incentive Stock Option.

"*Normal Retirement*" means, unless otherwise specified in an Award Certificate, Termination of Employment on or after a Participant has attained age 60, provided that the sum of the Participant's age (in full years) and full years of service with the Company or a Subsidiary is 70 or higher.

"*Ordinary Shares*" means the ordinary shares of the Company, $0.20 (U.S.) par value, and such other securities or property as may become subject to Awards pursuant to an adjustment made under Section 5.3 of the Plan.

"*Other Stock-Based Award*" means an Award granted under Section 4.6 of the Plan and denominated in Shares.

"*Participant*" means a Director, Employee or Acquired Grantee who has been granted an Award under the Plan.

"*Performance Cycle*" means, with respect to any Award that vests based on Performance Measures, the period of 12 months or longer, as determined by the Committee in its sole discretion, over which the level of performance will be assessed.

"*Performance Measure*" means, with respect to any Annual Performance Bonus or Long-Term Performance Award, the business criteria selected by the Committee to measure the level of performance of the Company during a Performance Cycle. The Committee may select as the Performance Measure any operating and maintenance expense targets or financial goals as interpreted by the Committee, either individually, alternatively or in any combination, applied to either the Company as a whole or to a business unit or Subsidiary, either individually, alternatively or in any combination, and that are absolute or relative to the performance of one or more comparable companies or an index of comparable companies, and are measured during the Performance Cycle provided that (i) as to an Annual Performance Bonus or Long-Term Performance Award granted to a Covered Employee and intended to be qualified "performance- based" compensation under Section 162(m) of the Code, Performance Measures shall be limited to the criteria set forth on Appendix A (subject to the next sentence), and (ii) as to an Annual Performance Bonus or Long-Term Performance Award granted to a Participant who is not a Covered Employee, Performance Measures may include, but shall not be limited to, the criteria set forth on Appendix A. To the extent that the performance-based exception under Section 162(m) of the Code is inapplicable or otherwise eliminated for fiscal years beginning after December 31, 2017 or otherwise, the Committee shall have the authority to make such other adjustments or establish such other Performance Measures or performance measures for a Covered Employee or otherwise as it so determines in its discretion; provided, however, for the avoidance of doubt, compensation resulting from a written binding contract that was in effect on November 2, 2017 and intended to meet the performance-based exception under Section 162(m) of the Code, shall not be materially modified by reason of this amendment and restatement and nothing contained herein shall be construed as such a modification or as permitting such a modification.

"*Performance Unit*" means a Long-Term Performance Award denominated in Units.

"*Plan*" means this Mallinckrodt Pharmaceuticals Stock and Incentive Plan, as it may be amended from time to time.

"*Reporting Person*" means a Director or an Employee who is subject to the reporting requirements of Section 16(a) of the Exchange Act.

"*Restricted Stock*" means Shares issued pursuant to Section 4.6 that are subject to any restrictions that the Committee, in its discretion, may impose.

"*Restricted Unit*" means a Unit granted under Section 4.5 or Section 4.6 to acquire Shares or an equivalent amount in cash, which Unit is subject to any restrictions that the Committee, in its discretion, may impose.

"*Securities Act*" means the United States Securities Act of 1933, as amended.

"*Share*" means an Ordinary Share of the Company, and "*Shares*" shall be construed accordingly.

"*Significant Misconduct*" means a violation of a law or regulation or a significant violation of a Company policy.

"*Stock Appreciation Right*" means a right granted under Section 4.3 of the Plan of an amount in cash or Shares equal to any excess of the Fair Market Value of a Share as of the date on which the right is exercised over the Exercise Price.

"*Stock Option*" means a right granted under Section 4.3 of the Plan to purchase from the Company a stated number of Shares at a specified price. Stock Options awarded under the Plan may be in the form of Incentive Stock Options or Nonqualified Stock Options.

"*Subsidiary*" means (i) a subsidiary company (wherever incorporated) of the Company, as defined by Section 155 of the Companies Act 1963 of Ireland; (ii) any separately organized business unit, whether or not incorporated, of the Company; (iii) any employer that is required to be aggregated with the Company pursuant to Code Section 414 and the regulations promulgated thereunder; and (iv) any service recipient or employer that is within a controlled group of corporations as defined in Code Sections 1563(a)(1), (2) and (3) which includes the Company, where the phrase "at least 50%" is substituted in each place "at least 80%" appears, and any service recipient or employer within trades or businesses under common control as defined in Code Section 414(c) and Treas. Reg. § 1.414(c)-2, which includes the Company, where the phrase "at least 50%" is substituted in each place "at least 80%" appears, provided, however, that when the relevant determination is to

be based upon legitimate business criteria (as described in Treas. Reg. § 1.409A- 1(b)(5)(iii)(E) and § 1.409A-1(h)(3)), the phrase "at least 20%" shall be substituted in each place "at least 80%" appears as described above with respect to both a controlled group of corporations and trades or business under common control.

"*Target Amount*" means the amount of Performance Units that will be paid if the applicable Performance Measure is fully (100%) attained, as determined in the sole discretion of the Committee.

"*Target Bonus*" means the target Annual Performance Bonus applicable to a Reporting Person in respect of a particular year, as established by the Committee or its delegate.

"*Target Vesting Percentage*" means the percentage of performance-based Restricted Units or Shares of Restricted Stock that will vest if the applicable Performance Measure is fully (100%) attained, as determined in the sole discretion of by the Committee.

"*Termination of Directorship*" means the date of cessation of a Director's membership on the Board for any reason, with or without Cause, as determined in the sole discretion of the HRCC, provided however that if the Director is a member of the HRCC, such determination shall be made by the full Board (excluding such Director). For purposes of any Award which is nonqualified deferred compensation subject to Code Section 409A, a Termination of Directorship shall only occur where such Termination of Directorship is a "separation from service" within the meaning of Code Section 409A(a)(2)(A)(i) and the applicable regulations and rulings thereunder. For purposes of determining whether a Termination of Directorship has occurred, services provided in the capacity of an employee or otherwise shall be excluded.

"*Termination of Employment*" means the date of cessation of an Employee's employment relationship with the Company or a Subsidiary for any reason, with or without Cause, as determined in the sole discretion of the Company. For purposes of any Award which is nonqualified deferred compensation subject to Code Section 409A, a Termination of Employment shall only occur where such Termination of Employment is a "separation from service" within the meaning of Code Section 409A(a)(2)(A)(i) and the applicable regulations and rulings thereunder. For purposes of determining whether a Termination of Employment has occurred, services provided in the capacity of an employee or otherwise shall be excluded.

"*Triggering Event*" means Significant Misconduct (i.e., a violation of a law or regulation or a significant violation of a Company policy) relating to Covered Functions (as defined in the Company's CIA) by Executive that, if discovered prior to payment, would have made Executive ineligible for any Award(s) in the applicable Plan year or subsequent Plan years; Significant Misconduct relating to Covered Functions (as defined in the Company's CIA) by subordinate Employees in the business unit for which Executive had responsibility on or after 150 days after the Effective Date of the CIA that does not constitute an isolated occurrence and which Executive knew or should have known was occurring that, if discovered prior to payment, would have made Executive ineligible for an Award in the applicable Plan year or subsequent Plan years; or Significant Misconduct that results in significant harm to the Company.

"*Unit*" means, for purposes of Performance Units, the potential right to an Award equal to a specified amount denominated in such form as is deemed appropriate in the discretion of the Committee and, for purposes of Restricted Units or Deferred Stock Units, the potential right to acquire one Share.

ARTICLE III

ADMINISTRATION

3.1 *Committee.* The Plan will be administered by the Committee, except as otherwise provided in Section 4.7.

3.2 *Authority of the Committee.* The Committee or, to the extent required by applicable law, the Board will have the authority, in its sole and absolute discretion and subject to the terms of the Plan, to:

(a) Interpret and administer the Plan and any instrument or agreement relating to the Plan;

(b) Prescribe the rules and regulations that it deems necessary for the proper operation and administration of the Plan, and amend or rescind any existing rules or regulations relating to the Plan;

(c) Select Employees to receive Awards under the Plan;

(d) Determine the form of an Award, the number of Shares subject to each Award, all the terms and conditions of an Award, including, without limitation, the conditions on exercise or vesting, the designation of Stock Options as Incentive Stock Options or Nonqualified Stock Options, and the circumstances under which an Award may be settled in cash or Shares or may be cancelled, forfeited or suspended, and the terms of each Award Certificate;

(e) Determine whether Awards will be granted singly, in combination or in tandem;

(f) Establish and interpret Performance Measures (or, as applicable, other performance criteria) in connection with Annual Performance Bonuses and Long-Term Performance Awards, evaluate the level of performance over a Performance Cycle and certify the level of performance attained with respect to Performance Measures (or other performance criteria, as applicable);

(g) Subject to Sections 6.1 and 7.12, waive or amend any terms, conditions, restriction or limitation on an Award, except that the prohibition on the repricing of Stock Options and Stock Appreciation Rights without shareholder approval, as described in Section 4.3(g), may not be waived;

(h) Make any adjustments to the Plan (including but not limited to adjustment of the number of Shares available under the Plan or any Award) and any Award granted under the Plan as shall be appropriate pursuant to Section 5.3;

(i) Determine and set forth in the applicable Award Certificate the circumstances under which Awards may be deferred and the extent to which a deferral will be credited with Dividend Equivalents and interest thereon;

(j) In accordance with Section 7.1, determine and set forth in the applicable Award Certificate whether a Nonqualified Stock Option, Restricted Share or other Award may be transferable to family members, a family trust or a family partnership;

(k) Establish any subplans and make any modifications to the Plan, without amending the Plan, or to Awards made hereunder (including the establishment of terms and conditions in the Award Certificate not otherwise inconsistent with the terms of the Plan) that the Committee may determine to be necessary or advisable for grants made in countries outside the United States to comply with, or to achieve favorable tax treatment under, applicable foreign laws or regulations or tax policies or customs;

(l) Appoint such agents as it shall deem appropriate for the proper administration of the Plan; and

(m) Take any and all other actions it deems necessary or advisable for the proper operation or administration of the Plan.

3.2 *Effect of Determinations.* All determinations of the Committee will be final, binding and conclusive on all persons having an interest in the Plan.

3.3 *Delegation of Authority.* The Board or, if permitted under applicable corporate law and stock exchanges, the Committee, in its discretion and consistent with applicable law, regulations and stock exchange rules, may delegate to a committee or an officer or group of officers, as it deems to be advisable, the authority to select Employees to receive an Award and to determine the number of Shares under any such Award, subject to any terms and conditions that the Board or the Committee may establish. When the Board or the Committee delegates authority pursuant to the foregoing sentence, it will limit, in its discretion, the number or value of Shares that may be subject to Awards that the delegate may grant. Only the Committee has the authority to grant and administer Awards to Reporting Persons or to delegates of the Committee, and to establish and certify Performance Measures (except to the extent that delegation of such authority to another person would not cause an Award to fail to meet the performance-based compensation exception under Section 162(m) of the Code to the extent such section is applicable or otherwise fail to meet the requirements under any applicable tax, securities or other law, rule or regulation).

3.4 *Employment of Advisors.* The Committee may employ attorneys, consultants, accountants and other advisors, the fees and other expenses of which shall be paid by the Company, and the Committee, the Company and the officers and directors of the Company may rely upon the advice, opinions or valuations of the advisors employed.

3.5 *No Liability.* No member of the Committee or the Board or any person acting as a delegate thereof with respect to the Plan will be liable for any losses resulting from any action, interpretation or construction made in good faith with respect to the Plan or any Award granted under the Plan.

ARTICLE IV

AWARDS

4.1 *Eligibility.* All Participants and Employees are eligible to be designated to receive Awards granted under the Plan, except as otherwise provided in this Article IV.

(a) *Prerequisites:* Employees and Executives must meet prerequisites to be eligible to earn Awards. Not successfully meeting the criteria below may impact an Employee's or Executive's Incentive Compensation:

(i) Adherence to applicable laws, the Company Code of Conduct, policies, procedures, and guidelines, which constitutes no documented violations of aforementioned items.

(ii) Completion of the assigned goal in annual Performance Evaluations, which includes successfully completing all assigned training on a timely basis and satisfactory job performance with no significant misconduct or performance-related issues documented.

(b) *Significant Misconduct and Employee Eligibility:* Any Employee found to have violated a law or regulation or a significant, non-minor violation of the Code of Conduct or any other Company policy ("Significant Misconduct") will be ineligible to receive Awards for a two-year period from the date of such determination. In addition, if an Employee is found to have engaged in Significant Misconduct and an Award has been granted but not yet paid, the Award must be suspended for the current Performance Cycle and must be rescinded for any prior Performance Cycle in which such violations occurred or were discovered. To the extent an Award was already paid, the Award is subject to recoupment if not promptly repaid by the Employee.

(c) *Triggering Events and Executive Eligibility:* Effective calendar year 2022, the Company has established an Executive Financial Recoupment Program, which puts at risk of forfeiture and recoupment an amount equivalent to up to three (3) years of Executive's Award(s) if, at the time of a recoupment determination, Executive is either a current Company employee or became a former Company employee 150 days or more after the effective date of the Company's CIA. Any Award(s) are at risk of forfeiture and/or recoupment as a consequence of an Executive's Triggering Event as follows:

(i) The Company reserves the right to pursue recoupment from Executive of all or any portion of a Cash Award paid to Executive in the three (3) years prior to a Triggering Event. The eligibility and recoupment conditions set forth herein shall survive the payment of Executive's Cash Award and the separation of Executive's employment (if applicable) for a period of three (3) years from the payment of the Cash Award. If payment of any portion of a Cash Award is deferred on a mandatory or voluntary basis, the three-year period will be measured from the date the Cash Award would have been paid in the absence of deferral.

(ii) The Company reserves the right to pursue recoupment from Executive of all or a portion of the value of Equity Award(s) provided to Executive for the three (3) years prior to a Triggering Event. The eligibility and recoupment conditions set forth herein shall survive the vesting or distribution of Executive's Equity Awards and the separation of Executive's employment (if applicable) for a period of three (3) years from the vesting or distribution of the Equity Award(s).

(d) *Additional Remedies*: To the extent permitting by controlling law, for the three (3) year period during which Award eligibility and recoupment conditions exist for the Executive, if the Company reasonably anticipates that a Triggering Event has occurred, and the Company has recoupment rights remaining under Paragraphs (c)(i) and (ii) above, the Company reserves the right to toll and thereby extend such rights for an additional three (3) years or until the Company determines that a Triggering Event has not occurred, whichever is earlier, to the extent permitted by controlling law of the relevant jurisdiction.

4.2 *Form of Awards.* Awards will be in the form determined by the Committee, in its discretion, and will be evidenced by an Award Certificate. Awards may be granted singly or in combination or in tandem with other Awards.

4.3 *Stock Options and Stock Appreciation Rights.* The Committee may grant Stock Options and Stock Appreciation Rights under the Plan to those Employees whom the Committee may from time to time select, in the amounts and pursuant to the other terms and conditions that the Committee, in its discretion, may determine and set forth in the Award Certificate, subject to the provisions below:

(a) *Form.* Stock Options granted under the Plan will, at the discretion of the Committee and as set forth in the Award Certificate, be in the form of Incentive Stock Options, Nonqualified Stock Options or a combination of the two. If an Incentive Stock Option and a Nonqualified Stock Option are granted to the same Participant under the Plan at the same time, the form of each will be clearly identified, and they will be deemed to have been granted in separate grants. In no event will the exercise of one Stock Option affect the right to exercise the other Stock Option. Stock Appreciation Rights may be granted either alone or concurrently with Nonqualified Stock Options and the amount of Shares attributable to each Stock Appreciation Right shall be set forth in the applicable Award Certificate on or before the grant date.

(b) *Exercise Price.* Other than with respect to Substitute Awards described in Section 4.8, the Committee will set the Exercise Price of Stock Options or Stock Appreciation Rights granted under the Plan at a price that is equal to or greater than the Fair Market Value of a Share on the date of grant, subject to adjustment as provided in Section 5.3. The Exercise Price of Incentive Stock Options will be equal to or greater than 110 percent of the Fair Market Value of a Share as of the date of grant if the Participant receiving the Incentive Stock Options owns shares possessing more than 10 percent of the total combined voting power of all classes of shares of the Company or any subsidiary or parent corporation of the Company, as defined in Section 424 of the Code. The Exercise Price of a Stock Appreciation Right granted in tandem with a Stock Option will equal the Exercise Price of the related Stock Option. The Committee will set forth the Exercise Price of a Stock Option or Stock Appreciation Right in the Award Certificate or accompanying documentation.

(c) *Term and Timing of Exercise.* Each Stock Option or Stock Appreciation Right granted under the Plan will be exercisable in whole or in part, subject to the following conditions, unless determined otherwise by the Committee:

(i) The term of each Stock Option and Stock Appreciation Right shall be determined by the Committee and set forth in the applicable Award Certificate, but in no event shall the term thereof exceed ten (10) years from the date of its grant. Notwithstanding the foregoing, in the event that on the last business day of the term of a Stock Option (other than an Incentive Stock Option) or Stock Appreciation Right (i) the exercise of the Award is prohibited by applicable law or (ii) Shares may not be purchased or sold by certain employees or directors of the Company due to the "black-out period" of a Company policy or a "lock-up" agreement undertaken in connection with an issuance of securities by the Company, the term of the Stock Option or Stock Appreciation Right shall be extended for a period of thirty (30) days following the end of the legal prohibition, black-out period or lock-up agreement. Moreover, notwithstanding the foregoing, an Award Certificate may provide that if on the last day of the term of a Stock Option or Stock Appreciation Right the Fair Market Value of one Share exceeds the option or grant price per Share, the Participant has not exercised the Stock Option, Stock Appreciation Right or tandem Award, and the Award has not expired, the Stock Option or Stock Appreciation Right shall be deemed to have been exercised by the Participant on such day with payment made by withholding Shares otherwise issuable in connection with the exercise of the Stock Option or Stock Appreciation Right. In such event, the Company shall deliver to the Participant the number of Shares for which the Stock Option or Stock Appreciation Right was deemed exercised, less the number of Shares required to be withheld for the payment of the total purchase price for a Stock Option and required withholding taxes for both Stock Options and Stock Appreciation Rights; provided, however, any fractional Share shall be settled in cash.

(ii) A Stock Option or Stock Appreciation Right will become exercisable at such times and in such manner as determined by the Committee and set forth in the applicable Award Certificate, subject to the minimum vesting limitations of Section 4.10.

(iii) Unless the applicable Award Certificate provides otherwise, and subject to the minimum vesting limitations of Section 4.10, upon the death, Disability, Normal Retirement or a Change in Control Termination of a Participant who has outstanding Stock Options or Stock Appreciation Rights, the unvested Stock Options or Stock Appreciation Rights will fully vest. Unless the applicable Award Certificate or the remainder of this Section 4.3(c) provides otherwise, the Participant's Stock Options and Stock Appreciation Rights will lapse, and will not thereafter be exercisable, upon the earlier of (A) their original expiration date or (B) the date that is three (3) years after the date on which the Participant dies, incurs a Disability or retires due to Normal Retirement.

(iv) Unless the applicable Award Certificate provides otherwise, and subject to the minimum vesting limitations of Section 4.10, upon the Termination of Employment of a Participant for any reason other than the Participant's death, Disability, Normal Retirement or a Change in Control Termination, if the Participant's termination qualifies as Early Retirement, a pro rata portion of the Participant's Stock Options and Stock Appreciation Rights will vest so that the total number of vested Stock Options or Stock Appreciation Rights held by the Participant at Termination of Employment (including those that have already vested as of such date) will be equal to the total number of Stock Options or Stock Appreciation Rights originally granted to the Participant under the applicable Award multiplied by a fraction, the numerator of which is the period of time (in whole months) that have elapsed since the date of grant, and the denominator of which is the number of months set forth in the applicable Award Certificate that is required to attain full

vesting. Unless the Award Certificate provides otherwise, such Participant's Stock Options and Stock Appreciation Rights will lapse, and will not thereafter be exercisable, upon the earlier of (A) their original expiration date or (B) the date that is three (3) years after the date of Termination of Employment.

(v) Unless the applicable Award Certificate provides otherwise, upon the Termination of Employment of a Participant that does not meet the requirements of paragraphs (iii) or (iv) above, any unvested Stock Options or Stock Appreciation Rights will be forfeited. Unless the applicable Award Certificate provides otherwise, any Stock Options or Stock Appreciation Rights that are vested as of such Termination of Employment will lapse, and will not thereafter be exercisable, upon the earlier of (A) their original expiration date or (B) the date that is ninety (90) days after the date of such Termination of Employment.

(vi) Stock Options and Stock Appreciation Rights of a deceased Participant may be exercised only by the estate of the Participant or by the person given authority to exercise the Stock Options or Stock Appreciation Rights by the Participant's will or by operation of law. If a Stock Option or Stock Appreciation Right is exercised by the executor or administrator of a deceased Participant, or by the person or persons to whom the Stock Option or Stock Appreciation Right has been transferred by the Participant's will or the applicable laws of descent and distribution, the Company will be under no obligation to deliver Shares or cash until the Company is satisfied that the person exercising the Stock Option or Stock Appreciation Right is the duly appointed executor or administrator of the deceased Participant or the person to whom the Stock Option or Stock Appreciation Right has been transferred by the Participant's will or by applicable laws of descent and distribution.

(vii) A Stock Appreciation Right granted in tandem with a Stock Option is subject to the same terms and conditions as the related Stock Option and will be exercisable only to the extent that the related Stock Option is exercisable. When either a Stock Option or a Stock Appreciation Right granted in tandem with each other is exercised, the tandem Stock Option or Stock Appreciation Right, as applicable, shall expire.

(d) *Payment of Exercise Price.* The Exercise Price of a Stock Option must be paid in full when the Stock Option is exercised. Shares will be issued and delivered only upon receipt of payment. Payment of the Exercise Price may be made in cash or by certified check, bank draft, wire transfer, or postal or express money order, provided that the format is approved by the Company or a designated third-party administrator. The Committee, in its discretion may also allow payment to be made by any of the following methods, as set forth in the applicable Award Certificate:

(i) Delivering a properly executed exercise notice to the Company or its agent, together with irrevocable instructions to a broker to deliver to the Company, within the typical settlement cycle for the sale of equity securities on the relevant trading market (or otherwise in accordance with the provisions of Regulation T issued by the Federal Reserve Board), the amount of sale proceeds with respect to the portion of the Shares to be acquired having a Fair Market Value on the date of exercise equal to the sum of the applicable portion of the Exercise Price being so paid;

(ii) Subject to any requirements of applicable law and regulations, tendering (actually or by attestation) to the Company or its agent previously acquired Shares that have a Fair Market Value on the day prior to the date of exercise equal to the applicable portion of the Exercise Price being so paid; or

(iii) Subject to any requirements of applicable law and regulations, instructing the Company to reduce the number of Shares that would otherwise be issued by such number of Shares as have in the aggregate a Fair Market Value on the date of exercise equal to the applicable portion of the Exercise Price being so paid.

(e) *Incentive Stock Options.* Incentive Stock Options granted under the Plan will be subject to the following additional conditions, limitations and restrictions:

(i) *Eligibility.* Incentive Stock Options may be granted only to Employees of the Company or a Subsidiary that is a subsidiary or parent corporation of the Company within the meaning of Code Section 424.

(ii) *Timing of Grant.* No Incentive Stock Option will be granted under the Plan after the 10-year anniversary of the date on which the Plan is adopted by the Board or, if earlier, the date on which the Plan was approved by shareholders.

(iii) *Amount of Award.* Subject to Section 5.3 of the Plan, no more than 10 million Shares may be available for grant in the form of Incentive Stock Options. The aggregate Fair Market Value (as of the date of grant) of the Shares with respect to which the Incentive Stock Options awarded to any Employee first become exercisable during any calendar year may not exceed $100,000 (U.S.). For purposes of this $100,000 (U.S.) limit, the Employee's Incentive Stock Options under this Plan and all other plans maintained by the Company and its Subsidiaries will be aggregated. To the extent any Incentive Stock Option would exceed the $100,000 (U.S.) limit, the Incentive Stock Option will afterwards be treated as a Nonqualified Stock Option to the extent required by the Code and underlying regulations and rulings.

(iv) *Timing of Exercise.* If the Committee exercises its discretion in the Award Certificate to permit an Incentive Stock Option to be exercised by a Participant more than three months after the Participant has ceased being an Employee (or more than 12 months if the Participant is permanently and totally disabled, within the meaning of Code Section 22(e)), the Incentive Stock Option will afterwards be treated as a Nonqualified Stock Option to the extent required by the Code and underlying regulations and rulings. For purposes of this paragraph (iv), an Employee's employment relationship will be treated as continuing intact while the Employee is on military leave, sick leave or another approved leave of absence if the period of leave does not exceed 90 days, or a longer period to the extent that the Employee's right to reemployment with the Company or a Subsidiary is guaranteed by statute or by contract. If the period of leave exceeds 90 days and the Employee's right to reemployment is not guaranteed by statute or contract, the employment relationship will be deemed to have ceased on the 91st day of the leave.

(v) *Transfer Restrictions.* In no event will the Committee permit an Incentive Stock Option to be transferred by an Employee other than by will or the laws of descent and distribution, and any Incentive Stock Option awarded under this Plan will be exercisable only by the Employee during the Employee's lifetime.

(f) *Exercise of Stock Appreciation Rights.* Upon exercise of a Participant's Stock Appreciation Rights, the Company will pay cash or Shares or a combination of cash and Shares, in the discretion of the Committee and as described in the Award Certificate. Cash payments will be equal to the excess of the Fair Market Value of a Share on the date of exercise over the Exercise Price, for each Share for which a Stock Appreciation Right was exercised. If Shares are paid for the Stock Appreciation Right, the Participant will receive a number of whole Shares equal to the quotient of the cash payment amount divided by the Fair Market Value of a Share on the date of exercise.

(g) *No Repricing.* Except as otherwise provided in Section 5.3 or in connection with a Change in Control, the terms of outstanding Awards may not be amended to reduce the exercise price of outstanding Stock Options or Stock Appreciation Rights or cancel outstanding Stock Options or Stock Appreciation Rights in exchange for cash, other Awards, or Stock Options or Stock Appreciation Rights with an exercise price that is less than the exercise price of the original Stock Options or Stock Appreciation Rights without shareholder approval.

4.4 *Annual Performance Bonuses.* The Committee may grant annual performance bonuses or other bonus compensation in its discretion outside the terms of this Plan. The Committee may grant Annual Performance Bonuses, intended to qualify as “performance-based compensation” under Section 162(m) of the Code (to the extent the Committee so determines and such performance-based compensation exception continues to apply), under the Plan in the form of cash or Shares to the Reporting Persons that the Committee may from time to time select, in the amounts and pursuant to the terms and conditions that the Committee may determine and set forth in the Award Certificate, subject to the provisions below:

(a) *Section 162(m) of the Code.* The Committee may determine that Annual Performance Bonuses made to Covered Employees should be structured to be “performance-based compensation” for purposes of Section 162(m) of the Code. If the Committee action granting such Awards or the Award Certificates so provide, this Section 4.4 shall be interpreted in a manner that satisfies the applicable requirements of Section 162(m)(4)(C) of the Code and related regulations, and the Plan shall be operated so that the Company may take a full tax deduction for Annual Performance Bonuses. If any provision of this Plan or any Annual Performance Bonus would otherwise frustrate or conflict with this intent, the provision will be interpreted and deemed amended so as to avoid this conflict.

(b) *Performance Cycles.* Annual Performance Bonuses will be awarded in connection with a twelve (12) month Performance Cycle, which will be the fiscal year of the Company.

(c) *Eligible Participants.* Within ninety (90) days after the commencement of a Performance Cycle, the Committee will determine the Reporting Persons who will be eligible to receive an Annual Performance Bonus under the Plan. If an individual becomes a Reporting Person after this ninety (90) day period, the Committee may determine that such Reporting Person is eligible to receive a pro rata Annual Performance Bonus under the Plan.

(d) *Performance Measures; Targets; Award Criteria.*

(i) Within ninety (90) days after the commencement of the service period to which a Performance Cycle relates, the Committee will fix and establish in writing (A) the Performance Measures that will apply to that Performance Cycle; (B) the Target Bonus which may be earned by each Participant; and (C) subject to subsection (d) below, the criteria for computing the amount that will be paid with respect to each level of attained performance. The Committee will also set forth the minimum level of performance, based on the applicable Performance Measures, that must be attained during the Performance Cycle before any Annual Performance Bonus will be paid and the percentage of the Target Bonus that will become payable upon attainment of various levels of performance that equal or exceed the minimum required level.

(ii) The Committee, in its discretion, may, on a case-by-case basis, reduce, but not increase, the amount otherwise payable to any Covered Employee with respect to any given Performance Cycle, provided, however, that no reduction will result in an increase in the amount payable under any Annual Performance Bonus of another Covered Employee.

(e) *Payment, Certification.* No Annual Performance Bonus will be paid to any Reporting Person until the Committee certifies in writing the level of performance attained for the Performance Cycle in relation to the applicable Performance Measures. In applying Performance Measures, the Committee (i) shall make adjustments for events listed in Section 5.3 in accordance therewith and (ii) may, in its discretion, exclude the effect of unusual or infrequently occurring items, including, but not limited to the following, as set forth in the Award Certificate or action of the Committee granting the Award: the cumulative effect of changes in the law, regulations or accounting rules, and other items, all determined in accordance with GAAP (to the extent applicable and unless specified otherwise in the Award Certificate or action of the Committee granting the Award) and identified in financial statements, notes to the financial statements or discussion and analysis of management; asset write downs; litigation or claim judgments or settlements; any reorganization and restructuring programs; acquisitions or divestitures; and foreign exchange gains and losses; provided that the determination by the Committee that Performance Measures shall be adjusted for items in accordance with this clause (ii) shall be made no later than ninety (90) days after the commencement of any applicable Performance Cycle in respect of Annual Performance Bonuses awarded to Covered Employees.

(f) *Form of Payment.* Annual Performance Bonuses will be paid in cash, Shares or such other Awards as determined by the Committee. All such Performance Bonuses shall be paid no later than the 15th day of the third month following the end of the calendar year (or, if later, following the end of the Company's fiscal year) in which such Performance Bonuses are no longer subject to a substantial risk of forfeiture (as determined for purposes of Section 409A of the Code), except to the extent that the Committee determines or a Participant has elected to defer payment under the terms of a duly authorized deferred compensation arrangement or Award, in which case the terms of such arrangement or Award shall govern.

(g) *Acceleration.* Each Participant who is eligible to receive an Annual Performance Bonus with respect to a Performance Cycle during which a Change of Control occurs will, except as otherwise provided below, be deemed to have achieved a level of performance, as of the date of Change in Control, that would cause all (100%) of the Participant's Target Bonus to become payable at such times and in such manner as determined in the sole discretion of the Committee. Notwithstanding the previous sentence, if (i) a surviving entity maintains the Performance Cycle in which a Change in Control occurs, or otherwise provides for the payment of an Annual Performance Bonus based on the level of performance attained for such Performance Cycle in relation to the Performance Measures established for such Performance Cycle (including Performance Measures that were adjusted or modified as a result of the Change in Control) and (ii) the Annual Performance Bonus based on the level of performance attained for such Performance Cycle exceeds all (100%) of the Participant’s Target Bonus, then each Participant who is eligible to receive an Annual Performance Bonus with respect to such Performance Cycle shall receive an Annual Performance Bonus based on the level of performance attained for such Performance Cycle at such times and in such manner as determined in the sole discretion of the Committee, or successor to the Committee. If a Participant’s employment is terminated before the end of the original Performance Cycle due to death, Disability, Normal Retirement, or by the Company without Cause, the Award payable to such Participant

may, in the discretion of the Committee, be proportionately reduced based on the period of actual employment during the applicable Performance Cycle. Notwithstanding the above, the time and manner of any payments made pursuant to this Section 4.4(g) shall comply with Section 4.4(e) above.

4.5 *Long-Term Performance Awards.* The Committee may grant long-term performance awards or other bonus compensation in its discretion outside the terms of this Plan. The Committee may grant Long-Term Performance Awards, intended to be "performance-based compensation" under Section 162(m) of the Code (to the extent the Committee so determines and such performance-based compensation exception continues to apply), under the Plan in the form of Performance Units, Restricted Units or Restricted Stock to any Employee who the Committee may from time to time select, in the amounts and pursuant to the terms and conditions that the Committee may determine and set forth in the Award Certificate, subject to the provisions below:

(a) *Section 162(m) of the Code.* The Committee may determine that Long-Term Performance Awards made to Covered Employees should be structured to be "performance-based compensation" for purposes of Section 162(m) of the Code. If the Committee action granting such Award or the Award Certificates so provide, this Section 4.5 shall be interpreted in a manner that satisfies the applicable requirements of Section 162(m)(4)(C) of the Code and related regulations with respect to Long-Term Performance awards made to Covered Employees, and the Plan shall be operated so that the Company may take a full tax deduction for Long-Term Performance Awards. If any provision of this Plan or any Long-Term Performance Award would otherwise frustrate or conflict with this intent, the provision will be interpreted and deemed amended so as to avoid this conflict.

(b) *Performance Cycles.* Long-Term Performance Awards will be awarded in connection with a Performance Cycle, as determined by the Committee in its discretion, provided, however, that a Performance Cycle may be no shorter than twelve (12) months.

(c) *Eligible Participants.* Within ninety (90) days after the commencement of a Performance Cycle, the Committee will determine the Employees who will be eligible to receive a Long-Term Performance Award for the Performance Cycle, provided that the Committee may determine the eligibility of any Employee other than a Covered Employee after the expiration of this ninety (90) day period.

(d) *Performance Measures; Targets; Award Criteria.*

(i) Within ninety (90) days after the commencement of the service period to which a Performance Cycle relates, the Committee will fix and establish in writing (A) the Performance Measures that will apply to that Performance Cycle; (B) with respect to Performance Units, the Target Amount payable to each Participant; (C) with respect to Restricted Units and Restricted Stock, the Target Vesting Percentage for each Participant; and (D) subject to subsection (d) below, the criteria for computing the amount that will be paid or will vest with respect to each level of attained performance. The Committee will also set forth the minimum level of performance, based on the applicable Performance Measures, that must be attained during the Performance Cycle before any Long-Term Performance Award will be paid or vest, and the percentage of Performance Units that will become payable and the percentage of performance-based Restricted Units or Shares of Restricted Stock that will vest upon attainment of various levels of performance that equal or exceed the minimum required level.

(ii) The Committee, in its discretion, may, on a case-by-case basis, reduce, but not increase, the amount of Long-Term Performance Awards otherwise payable to any Covered Employee with respect to any given Performance Cycle, provided, however, that no reduction will result in an increase in the dollar amount or number of Shares payable under any Long-Term Performance Award of another Covered Employee.

(e) *Payment, Certification.* Long-Term Performance Awards shall only be paid if the Committee certifies in writing the level of performance attained for the Performance Cycle in relation to the applicable Performance Measures. Long-Term Performance Awards awarded to Participants who are not Covered Employees will be based on the Performance Measures, or other applicable performance criteria, and payment formulas that the Committee, in its discretion, may establish for these purposes. These Performance Measures, or other performance criteria, and formulas may be the same as or different than the Performance Measures and formulas that apply to Covered Employees. In applying Performance Measures, the Committee (i) shall make adjustments for events listed in Section 5.3 in accordance therewith and (ii) may, in its discretion, exclude the effect of unusual or infrequently occurring items, including, but not limited to the following, as set forth in the Award Certificate or action of the Committee granting the Award: the cumulative effect of changes in the law, regulations or accounting rules, and other items, all determined in accordance with GAAP (to the extent applicable and unless specified otherwise in the Award

Certificate or action of the Committee granting the Award) and identified in financial statements, notes to the financial statements or discussion and analysis of management; asset write downs; litigation or claim judgments or settlements; any reorganization and restructuring programs; acquisitions or divestitures; and foreign exchange gains and losses.; provided that the determination by the Committee that Performance Measures shall be adjusted for items in accordance with this clause (ii) shall be made no later than ninety (90) days after the commencement of any applicable Performance Cycle in respect of Long-Term Performance Awards awarded to Covered Employees.

(f) *Form of Payment.* Long-Term Performance Awards in the form of Performance Units may be paid in cash or full Shares, in the discretion of the Committee, and as set forth in the applicable Award Certificate. Performance-based Restricted Units and Restricted Stock will be paid in full Shares. Payment with respect to any fractional Share will be in cash in an amount based on the Fair Market Value of the Share as of the date the Performance Unit becomes payable. All Long-Term Performance Awards shall be paid no later than the 15th day of the third month following the end of the calendar year (or, if later, following the end of the Company's fiscal year) in which such Long-Term Performance Awards are no longer subject to a substantial risk of forfeiture (within the meaning of Code Section 409A), except to the extent that a Participant has elected to defer payment under the terms of a duly authorized deferred compensation arrangement, in which case the terms of such arrangement shall govern, or as otherwise provided in Section 4.5(g) below.

(g) *Dividend Equivalents*. At the discretion of the Committee and as set forth in the applicable Award Certificate, dividend equivalents may be earned on Long-Term Performance Awards denominated in Shares, but only to the extent, and shall be payable only at the same time, as the underlying Long-Term Performance Awards may become earned, vested, and payable.

(h) *Special Vesting Provisions.* Unless the applicable Award Certificate provides otherwise, and subject to the minimum vesting limitations of Section 4.10, upon the death, Disability, Normal Retirement or a Change in Control Termination of a Participant who has an outstanding Long-Term Performance Award, the unvested Long-Term Performance Award will fully vest and be paid as if the Participant had continued in active employment with the Company through the date such Long-Term Performance Award would have vested and been paid in the absence of such event. Unless the applicable Award Certificate provides otherwise, upon the Termination of Employment of a Participant for any reason other than the Participant's death, Disability, Normal Retirement or a Change in Control Termination, the unvested Long-Term Performance Award will be forfeited unless the Participant qualifies for Early Retirement, in which case (subject to the minimum vesting limitations of Section 4.10), a pro rata portion of the Participant's Long-Term Performance Awards will vest and be paid as if the Participant had continued in active employment with the Company through the date such Long-Term Performance Award would have vested and been paid in the absence of such event; provided that the number of Long-Term Performance Awards held by the Participant which shall vest under those circumstances shall equal the total number of Long-Term Performance Awards in which such Participant would have vested multiplied by a fraction, the numerator of which is the period of time (in whole months) that have elapsed since the date of grant, and the denominator of which is the number of total months set forth in the applicable Award Certificate for such Performance Period.

4.6 *Other Stock-Based Awards.* The Committee may, from time to time, grant Awards (other than Stock Options, Stock Appreciation Rights, Annual Performance Bonuses or Long-Term Performance Awards) to any Employee who the Committee may from time to time select, which Awards consist of, or are denominated in, payable in, valued in whole or in part by reference to, or otherwise related to, Shares. These Awards may include, among other forms, Restricted Stock, Restricted Units, or Deferred Stock Units. The Committee will determine, in its discretion, the terms and conditions that will apply to Awards granted pursuant to this Section 4.6, which terms and conditions will be set forth in the applicable Award Certificate.

(a) *Vesting.* Restrictions on Other Stock-Based Awards granted under this Section 4.6 will lapse at such times and in such manner as determined by the Committee and set forth in the applicable Award Certificate, subject to the minimum vesting limitations of Section 4.10. Unless the applicable Award Certificate provides otherwise, if the restrictions on Other Stock-Based Awards have not lapsed or been satisfied as of the Participant's Termination of Employment, the Shares will be forfeited by the Participant if the termination is for any reason other than the Normal Retirement, death or Disability of the Participant or a Change in Control Termination, except that the Award will vest pro rata with respect to the portion of the vesting term set forth in the applicable Award Certificate that the Participant has completed if the Participant qualified for Early Retirement (subject to the minimum vesting limitations of Section 4.10). All restrictions on Other Stock- Based Awards granted pursuant to this Section 4.6, subject to the minimum

vesting limitations of Section 4.10, will lapse upon the Normal Retirement, death or Disability of the Participant or a Change in Control Termination.

(b) *Grant of Restricted Stock.* The Committee may grant Restricted Stock to any Employee, which Shares will be registered in the name of the Participant and held for the Participant by the Company. The Participant will have all rights of a shareholder with respect to the Shares, including the right to vote and to receive dividends or other distributions (subject to Section 4.6(e)), except that the Shares may be subject to a vesting schedule and will be forfeited if the Participant attempts to sell, transfer, assign, pledge or otherwise encumber or dispose of the Shares before the restrictions are satisfied or lapse.

(c) *Grant of Restricted Units.* The Committee may grant Restricted Units to any Employee, which Units will be paid in cash or whole Shares or a combination of cash and Shares, in the discretion of the Committee, when the restrictions on the Units lapse and any other conditions set forth in the Award Certificate have been satisfied. For each Restricted Unit that vests, one Share will be paid or an amount in cash equal to the Fair Market Value of a Share as of the date on which the Restricted Unit vests.

(d) *Grant of Deferred Stock Units.* The Committee may grant Deferred Stock Units to any Employee, which Units will be paid in whole Shares upon the Employee's Termination of Employment if the restrictions on the Units have lapsed. One Share will be paid for each Deferred Stock Unit that becomes payable.

(e) *Dividends and Dividend Equivalents.* At the discretion of the Committee and as set forth in the applicable Award Certificate, dividends paid on Shares may, to the extent the underlying Award to which the Shares relate have become fully vested, be paid immediately or withheld and deferred in the Participant's account. In the event of a payment of dividends on the Ordinary Shares, the Committee may credit Restricted Units with Dividend Equivalents in accordance with terms and conditions established in the discretion of the Committee. Dividend Equivalents will be subject to such vesting terms as determined by the Committee and may be distributed immediately or withheld and deferred in the Participant's account as determined by the Committee and set forth in the applicable Award Certificate. Deferred Stock Units may, in the discretion of the Committee and as set forth in the Award Certificate, be credited with Dividend Equivalents or additional Deferred Stock Units. The number of any Deferred Stock Units credited to a Participant’s account upon the payment of a dividend will be equal to the quotient produced by dividing the cash value of the dividend by the Fair Market Value of one Share as of the date the dividend is paid. The Committee will determine any terms and conditions on deferral of a dividend or Dividend Equivalent, including the rate of interest to be credited on deferral and whether interest will be compounded. Notwithstanding anything herein to the contrary, payment of any dividends, Dividend Equivalents or additional Deferred Stock Units granted with respect to an Award shall be subject to the same vesting or performance conditions, as applicable, as the underlying Award.

4.7 *Director Awards.*

(a) Notwithstanding anything herein to the contrary, the HRCC shall have the exclusive authority to issue awards to Directors who are not also employees of the Company or any Subsidiary (Director Awards), which may consist of, but not be limited to, Stock Options, Stock Appreciation Rights, or Other Stock-Based Awards. Each Director Award shall be governed by an Award Certificate approved by the HRCC.

(b) The HRCC shall have the exclusive authority to administer Director Awards and shall have the authority set forth in Section 3.2 and the indemnification set forth in Section 7.7, solely as such provisions apply to the Director Awards. All determinations made by the HRCC hereunder shall be final, binding and conclusive.

(c) Notwithstanding any other provision of the Plan to the contrary, the aggregate grant date Fair Market Value (computed as of the date of grant in accordance with applicable financial accounting rules) of all Awards granted to any Director during any single fiscal year (excluding Awards made at the election of the Director in lieu of all or a portion of annual and committee cash retainers) shall not exceed $750,000.00.

4.8 *Substitute Awards.* The Committee may make Awards under the Plan to Acquired Grantees through the assumption of, or in substitution for, outstanding stock-based awards previously granted to such Acquired Grantees. Such assumed or substituted Awards will be subject to the terms and conditions of the original awards made by the Acquired Company, with such adjustments therein as the Committee considers appropriate to give effect to the relevant provisions of any agreement for the acquisition of the Acquired Company. Any grant of Incentive Stock Options pursuant to this Section 4.8 will be made in accordance with Section 424 of the Code and any final regulations published thereunder.

4.9 *Limit on Individual Grants.* Notwithstanding anything herein to the contrary, the following limits of this Section shall apply only to the extent that the performance-based compensation exception under Section 162(m) of

the Code continues to apply. Subject to Sections 5.1 and 5.3, no Employee may be granted more than six (6) million Shares over any calendar year pursuant to Awards of Stock Options, Stock Appreciation Rights and Long-Term Performance Awards in the form of performance-based Restricted Stock and Restricted Units intended to qualify as "performance-based" under Section 162(m) of the Code, except that an incentive Award of no more than ten (10) million Shares may be made pursuant to Stock Options, Stock Appreciation Rights and performance-based Restricted Stock and Restricted Units intended to qualify as "performance-based" under Section 162(m) of the Code to any person who has been hired within the calendar year as a Covered Employee. The maximum amount that may be paid in cash pursuant to Annual Performance Bonuses or Long- Term Performance Awards paid in Performance Units or settled in cash and which are intended to qualify as "performance- based" under Section 162(m) of the Code to any one Employee is $15 million (U.S.) for any Performance Cycle of twelve (12) months. For any longer Performance Cycle, this maximum will be adjusted proportionally.

4.10 *Minimum Vesting of Awards*. Except with respect to a maximum of five percent (5%) of the Shares authorized in Section 5.1(b) and except to the extent provided in Section 5.4, any Awards shall not provide for vesting which is any more rapid than immediate vesting on the first anniversary of the Award grant date. Notwithstanding the foregoing, the Committee may permit acceleration of vesting of such Awards in certain events, including in the event of the Participant's death or Disability.

4.11 *Termination for Cause.* Notwithstanding anything to the contrary herein and unless the applicable Award Certificate provides otherwise, if a Participant incurs a Termination of Directorship or Termination of Employment for Cause, then all Stock Options, Stock Appreciation Rights, Annual Performance Bonuses, Long-Term Performance Awards, Restricted Units, Restricted Stock and Other Stock-Based Awards will immediately be cancelled. The exercise of any Stock Option or Stock Appreciation Right or the payment of any Award may be delayed, in the Committee's discretion, in the event that a potential termination for Cause is pending. Unless the applicable Award Certificate provides otherwise, if a Participant incurs a Termination of Directorship or Termination of Employment for Cause, then the Participant will be required to deliver to the Company (i) Shares (or, in the discretion of the Committee, cash) equal in value to the amount of any profit the Participant realized upon the exercise of an Option or Stock Appreciation Right during the twelve (12) month period occurring immediately prior to the Participant's Termination of Directorship or Termination of Employment for Cause; and (ii) the number of Shares (or, in the discretion of the Committee, the cash value of Shares) the Participant received for Other Stock Based Awards (including Restricted Stock, Restricted Units and Deferred Stock Units) that vested during the period specified in (i) above. Unless the applicable award certificate provides otherwise, if, after a Participant's Termination of Directorship or Termination of Employment, the Committee determines in its sole discretion that while the Participant was a Company or Subsidiary employee or a Director, such Participant engaged in activity that would have been grounds for a Termination of Directorship or Termination of Employment for Cause, then the Company will immediately cancel all Stock Options, Stock Appreciation Rights, Annual Performance Bonuses, Long-Term Performance Awards, Restricted Units, Restricted Stock and Other Stock-Based Awards and the Participant will be required to deliver to the Company (A) Shares (or, in the discretion of the Committee, cash) equal in value to the amount of any profit the Participant realized upon the exercise of an Option or Stock Appreciate Right during the period that begins twelve (12) months immediately prior to the Participant's Termination of Directorship or Termination of Employment and ends on the date of the Committee's determination that the Participant's conduct would have constituted grounds for a Termination of Directorship or Termination of Employment for Cause; and (B) the number of Shares (or, in the discretion of the Committee, the cash value of said shares) the Participant received for Other Stock Based Awards (including Restricted Stock, Restricted Units and Deferred Stock Units) that vested during the period specified in (A) above.

ARTICLE V

SHARES SUBJECT TO THE PLAN; ADJUSTMENTS

5.1 *Shares Available.*

(a) The Shares issuable under the Plan will be authorized but unissued Shares, and, to the extent permissible under applicable law, Shares acquired by the Company, any Subsidiary or any other person or entity designated by the Company and held as treasury shares.

(b) Subject to the counting rules set forth in Section 5.2 and adjustment in accordance with Section 5.3, the total number of Shares with respect to which Awards may be issued under the Plan shall be 26,769,489.

(c) Incentive Stock Options may be granted under the Plan in respect of no more than 10 million Shares.

5.2 *Counting Rules.*

(a) The total number of Shares with respect to which Awards may be issued under the Plan, as described in Section 5.1(b), shall be reduced by 1.61 Shares per each Share subject to an Award of Restricted Stock, Restricted Units, Deferred Stock Units, Performance Units or Other Stock-Based Awards, or as payment of an Annual Performance Bonus.

(b) The following Shares related to Awards under the Plan will again be available for issuance under the Plan:

(i) Shares related to Awards paid in cash; and

(ii) Shares related to Awards that expire, are forfeited or cancelled or terminate for any other reason without issuance of Shares and any Shares of Restricted Stock that are returned to the Company upon a Participant's Termination of Employment or, if applicable, a Director's Termination of Directorship (including, for clarity, at a rate of 1.61 Shares per each Share related to such an Award in the form of Restricted Stock, Restricted Units, Deferred Stock Units, Performance Units or Other Stock-Based Awards, or as payment of an Annual Performance Bonus).

(c) Any Shares issued in connection with Awards that are assumed, converted or substituted as a result of the acquisition of an Acquired Company by the Company or a combination of the Company with another company shall not count against the total number of Shares set forth in Section 5.1(b). Shares available under a stockholder approved plan of an Acquired Company (as appropriately adjusted to reflect the transaction) may be used for Awards under the Plan to individuals who were not employees or directors of the Company or a subsidiary prior to the transaction (subject to the stock exchange's listing requirements)

5.3 *Adjustments.* In the event of a change in the outstanding Shares by reason of a share split, reverse share split, share dividend or other distribution (whether in the form of cash, Shares, other securities or other property), extraordinary cash dividend, recapitalization, merger, consolidation, split-up, spin-off, reorganization, combination, repurchase or exchange of Shares or other securities or similar corporate transaction or event, the Committee shall make an appropriate adjustment to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan. Any adjustment made by the Committee under this Section 5.3 will be conclusive and binding for all purposes under the Plan.

5.4 *Change in Control.*

(a) *Acceleration.* Unless the applicable Award Certificate provides otherwise, (i) all outstanding Stock Options and Stock Appreciation Rights will become exercisable as of the effective date of a Participant's Change in Control Termination if the Awards are not otherwise vested, and all conditions will be waived with respect to outstanding Restricted Stock and Restricted Units (other than Long-Term Performance Awards) and Deferred Stock Units and (ii) each Participant who has been granted a Long-Term Performance Award that isoutstanding as of the date of such Participant's Change in Control Termination will be deemed to have achieved a level of performance, as of the Change in Control Termination, that would cause all (100%) of the Participant's Target Amounts to become payable and all restrictions on the Participant's performance-based Restricted Units and Shares of Restricted Stock to lapse. Unless the Committee determines otherwise in its discretion (either when an Award is granted or any time thereafter), in the event that Awards outstanding as of the date of a Change in Control that are payable in Ordinary Shares of the Company will not be substituted with comparable awards payable or redeemable in shares of publicly-traded stock after the Change in Control, each such outstanding Award (A) will become fully vested (at target, where applicable) immediately prior to the Change in Control and (B)(i) each such Award that is a Stock Option or Stock Appreciation Right with an exercise price below the Fair Market Value of the Shares subject to such Award will be settled in cash, without the Participant's consent, for an amount equal to the amount that could have been attained upon the exercise of such Award immediately prior to the Change in Control had such Award been exercisable or payable at such time, and (ii) each such Award that is a Stock Option or Stock Appreciation Right with an exercise or grant price above the Fair Market Value of the Shares subject to such Award may be cancelled with no payment without the Participant's consent.

(b) *Permissive Actions*. In addition to the actions described in Section 5.4(a)(A) and (B), in the event of a Change in Control, the Committee may take any one or more of the following actions with respect to any or all outstanding Awards, without the consent of Participants: (i) the Committee may determine that outstanding Stock Options and Stock Appreciation Rights shall be fully vested and exercisable and restrictions on Restricted Stock, Restricted Units, Deferred Stock Units and Other Stock-Based Awards shall lapse as of the date of the Change in Control or such other time (prior to a Participant's Change in Control Termination) as the Committee determines; (ii) the Committee may require that a Participant surrender his or her outstanding Stock Options and Stock Appreciation Rights in exchange for one or more payments by the Company, in cash or Ordinary Shares, as determined by the Committee, in an amount equal to the amount by which the then Fair Market Value of the Shares subject to the Participant's

unexercised Stock Options and Stock Appreciation Rights exceeds the Exercise Price, if any, and on such terms as the Committee determines; (iii) after giving Participants an opportunity to exercise any outstanding Stock Options and Stock Appreciation Rights, the Committee may terminate any or all unexercised Stock Options and Stock Appreciation Rights at such time as the Committee deems appropriate; (iv) the Committee may determine that Annual Performance Bonuses and/or Long-Term Performance Awards will be paid out at their target level, in cash or Ordinary Shares as determined by the Committee; or (v) the Committee may determine that Awards that remain outstanding after the Change in Control shall be converted to similar grants of, or assumed by, the surviving corporation (or a parent or subsidiary of the surviving corporation or successor). Such acceleration, surrender, termination, settlement, payment or conversion shall take place as of the date of the Change in Control or such other date as the Committee determines. The Committee may specify how an Award will be treated in the event of a Change in Control either when the Award is granted or at any time thereafter.

5.5 *Fractional Shares.* No fractional Shares will be issued under the Plan. Except as otherwise provided in Section 4.5(e) and unless otherwise provided by the Committee, if a Participant acquires the right to receive a fractional Share under the Plan, the Participant will receive, in lieu of the fractional Share, a cash payment equal to the Fair Market Value of such fractional share on the date of settlement of the related Award.

ARTICLE VI

AMENDMENT AND TERMINATION

6.1 *Amendment.* The Plan may be amended at any time and from time to time by the Board or authorized Board committee without the approval of shareholders of the Company, except that no material revision to the terms of the Plan will be effective until the amendment is approved by the shareholders of the Company. A revision is “material” for this purpose if it materially increases the number of Shares that may be issued under the Plan (other than an increase pursuant to Section 5.3 of the Plan), expands the types of Awards available under the Plan, materially expands the class of persons eligible to receive Awards under the Plan, materially extends the term of the Plan, constitutes a repricing for which the terms of Section 4.3(g) require shareholder approval or is otherwise an amendment requiring shareholder approval pursuant to any law or the rules of any exchange on which the Company’s Ordinary Shares are listed for trading. No amendment of the Plan or any outstanding Award Certificate made without the Participant's written consent may adversely affect any right of a Participant with respect to an outstanding Award.

6.2 *Termination.* The Plan will terminate upon the earlier of the following dates or events to occur:

(a) The adoption of a resolution of the Board terminating the Plan; or

(b) The day before the tenth (10^{th}) anniversary of the approval of the Plan by the Company’s shareholders as described in Section 1.2.

No Awards will be granted under this Plan after it has terminated. The termination of the Plan, however, will not alter or impair any of the rights or obligations of any person under any Award previously granted under the Plan without such person's consent. After the termination of the Plan, any previously granted Awards will remain in effect and will continue to be governed by the terms of the Plan and the applicable Award Certificate.

ARTICLE VII

GENERAL PROVISIONS

7.1 *Nontransferability of Awards.* No Award under the Plan will be subject in any manner to alienation, anticipation, sale, assignment, pledge, encumbrance or transfer, and no other persons will otherwise acquire any rights therein, except as provided below.

(a) Any Award may be transferred by will or by the laws of descent or distribution.

(b) Unless the applicable Award Certificate provides otherwise, all or any part of a Nonqualified Stock Option or Shares of Restricted Stock may be transferred to a family member without consideration. For purposes of this subsection (b), "family member" includes any child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law of the Participant, including adoptive relationships, any person sharing the Participant's household (other than a tenant or employee), a trust in which these persons have more than fifty percent (50%) of the beneficial interest, a foundation in which these persons (or the

Participant) control the management of assets, and any other entity in which these persons (or the Participant) own more than fifty percent (50%) of the voting interests.

Any transferred Award will be subject to all of the same terms and conditions as provided in the Plan and the applicable Award Certificate. The Participant or the Participant's estate will remain liable for any withholding tax that may be imposed by any federal, state or local tax authority. The Company may, in its sole discretion, disallow all or a part of any transfer of an Award pursuant to this Subsection 7.1(b) unless and until the Participant makes arrangements satisfactory to the Company for the payment of any withholding tax. The Participant must immediately notify the Company, in the form and manner required by the applicable Award Certificate or as otherwise required by the Company, of any proposed transfer of an Award pursuant to this Subsection 7.1(b). No transfer will be effective until the Company consents to the transfer.

(c) Unless the applicable Award Certificate provides otherwise, any Nonqualified Stock Option transferred by a Participant pursuant to subsection (b) may be exercised by the transferee only to the extent that the Award would have been exercisable by the Participant had no transfer occurred. The transfer of Shares upon exercise of the Award will be conditioned on the payment of any withholding tax.

(d) Restricted Stock may be freely transferred after the restrictions lapse or are satisfied and the Shares are delivered, provided, however, that Restricted Stock awarded to an affiliate of the Company may be transferred only pursuant to Rule 144 under the Securities Act, or pursuant to an effective registration for resale under the Securities Act. For purposes of this subsection (d), "affiliate" will have the meaning assigned to that term under Rule 144.

(e) In no event may a Participant transfer an Incentive Stock Option other than by will or the laws of descent and distribution.

7.2 *Withholding of Taxes.* The Committee, in its discretion, may require the satisfaction of a Participant's minimum tax withholding obligations by any of the following methods or any method as it determines to be in accordance with the laws of the jurisdiction in which the Participant resides, has domicile or performs services.

(a) *Stock Options and Stock Appreciation Rights.* As a condition to the delivery of Shares pursuant to the exercise of a Stock Option or Stock Appreciation Right, the Committee may require that the Participant, at the time of exercise, pay to the Company by cash, certified check, bank draft, wire transfer or postal or express money order an amount sufficient to satisfy any applicable tax withholding obligations. The Committee may also, in its discretion, accept payment of the minimum tax withholding obligations through any of the Exercise Price payment methods described in Section 4.3(d).

(b) *Other Awards Payable in Shares.* The Participant shall satisfy the Participant's tax withholding obligations arising in connection with the release of restrictions on Restricted Units, Restricted Stock and Other Stock- Based Awards by payment to the Company in cash or by certified check, bank draft, wire transfer or postal or express money order, provided that the format is approved by the Company or a designated third-party administrator. However, subject to any requirements of applicable law, the Company may also satisfy the Participant's minimum tax withholding obligations by other methods, including selling or withholding Shares that would otherwise be available for delivery.

(c) *Cash Awards.* The Company may satisfy a Participant's tax withholding obligation arising in connection with the payment of any Award in cash by withholding cash from such payment.

7.3 *No Implied Rights.* The establishment and operation of the Plan, including the eligibility of a Participant to participate in the Plan, will not be construed as conferring any legal or other right upon any Director for any continuation of directorship or any Employee for the continuation of employment through the end of any Performance Cycle or other period. The Company expressly reserves the right, which may be exercised at any time and in the Company's sole discretion, to discharge any individual or treat him or her without regard to the effect that discharge might have upon him or her as a Participant in the Plan.

7.4 *No Obligation to Exercise Awards.* The grant of a Stock Option or Stock Appreciation Right will impose no obligation upon the Participant to exercise the Award.

7.5 *No Rights as Shareholders.* A Participant who is granted an Award under the Plan will have no rights as a shareholder of the Company with respect to the Award unless and until certificates for the Shares underlying the Award are registered in the Participant's name and (other than in the case of Restricted Stock) delivered to the Participant. The right of any Participant to receive an Award by virtue of participation in the Plan will be no greater than the right of any unsecured general creditor of the Company.

7.6 *Indemnification of Committee.* The Company will indemnify, to the fullest extent permitted by law, each person made or threatened to be made a party to any civil or criminal action or proceeding by reason of the fact that the person, or the executor or administrator of the person's estate, is or was a member of the Committee or an authorized delegate of the Committee including, for purposes of Director Awards, the HRCC.

7.7 *No Required Segregation of Assets.* Neither the Company nor any Subsidiary will be required to segregate any assets that may at any time be represented by Awards granted pursuant to the Plan.

7.8 *Nature of Payments.* All Awards made pursuant to the Plan are in consideration of services for the Company or a Subsidiary. Any gain realized pursuant to Awards under the Plan constitutes a special incentive payment to the Participant and will not be taken into account as compensation for purposes of any other employee benefit plan of the Company or a Subsidiary, except as the Committee otherwise provides. The adoption of the Plan will have no effect on Awards made or to be made under any other benefit plan covering an employee of the Company or a Subsidiary or any predecessor or successor of the Company or a Subsidiary.

7.9 *Securities Law Compliance.* Awards under the Plan are intended to satisfy the requirements of Rule 16b-3 under the Exchange Act. If any provision of this Plan or any grant of an Award would otherwise frustrate or conflict with this intent, that provision will be interpreted and deemed amended so as to avoid conflict. No Participant will be entitled to a grant, exercise, transfer or payment of any Award if the grant, exercise, transfer or payment would violate the provisions of the Sarbanes-Oxley Act of 2002 or any other applicable law.

7.10 *Coordination with Other Plans.* If this Plan provides a level of benefits with respect to Awards that differs from the level of benefits provided under the Mallinckrodt Pharmaceuticals Severance Plan for U.S. Officers and Executives, the Mallinckrodt Pharmaceuticals Change in Control Severance Plan for Certain U.S. Officers and Executives or the Mallinckrodt Pharmaceuticals Severance Plan for U.S. Employees, then the terms of the plan that provides for the more favorable benefit to the Participant shall govern.

7.11 *Section 409A Compliance*. Notwithstanding any other provision of this Plan or an applicable Award Certificate to the contrary, the provisions of this Section 7.11 shall apply to all Awards that are subject to Code Section 409A, but only with respect to the portion of such Award that is subject to Code Section 409A. To the extent the Committee (or HRCC with respect to Director Awards) determines that any Award granted under the Plan is subject to Code Section 409A, the Award Certificate evidencing such Award will incorporate the terms and conditions required by Code Section 409A. To the extent applicable, the Plan and the Award Certificate will be interpreted in accordance with Code Section 409A and the applicable regulations and rulings thereunder. Notwithstanding any other provision of the Plan to the contrary, in the event that the Committee (or HRCC with respect to Director Awards) determines that any Award may be subject to Code Section 409A, the Committee may adopt such amendments to the Plan and/or the applicable Award Certificate or adopt policies and procedures or take any other action or actions, including an action or amendment with retroactive effect, that the Committee (or HRCC with respect to Director Awards) determines is necessary or appropriate to (i) exempt the Award from the application of Code Section 409A or (ii) comply with the requirements of Code Section 409A.

(a) *Modifications to or Adjustments of Awards*. Any modifications to an Award pursuant to Subsection 3.2(g) or adjustments of an Award pursuant to Subsections 4.8 or 5.3 shall comply with the requirements of Section 409A.

(b) *Specified Employees*. Payments to any Participant who is a "specified employee" of deferred compensation that is subject to Code Section 409A(a)(2) and that becomes payable upon, or that is accelerated upon, such Participant's Termination of Employment (as modified by Subsection 7.12(b)(iv)), shall not be made on or before the date which is six (6) months following such Participant's Termination of Employment (or, if earlier, such Participant's death). A specified employee for this purpose shall be determined by the Committee or its delegate in accordance with the provisions of Code Section 409A and the regulations and rulings thereunder.

7.12 *Section 457A Compliance*. To the extent the Committee (or HRCC with respect to Director Awards) determines that any Award granted under the Plan is subject to Code Section 457A, the Award Certificate evidencing such Award will incorporate the terms and conditions required by Code Section 457A in order to avoid accelerated taxation or tax penalties to the holder thereof in respect of such Award. To the extent applicable, the Plan and the Award Certificate will be interpreted in accordance with Code Section 457A and applicable guidance issued thereunder. Notwithstanding any other provision of the Plan to the contrary, in the event that the Committee (or HRCC with respect to Director Awards) determines that any Award may be subject to Code Section 457A, the Committee may adopt such amendments to the Plan and/or the applicable Award Certificate or adopt policies and procedures or take any other action or actions, including an action or amendment with retroactive effect, that the Committee (or HRCC with respect to Director Awards) determines is necessary or appropriate to (i) exempt the Award from the application of Code Section 457A or (ii) comply with the requirements of Code Section 457A.

7.13 *Governing Law, Severability.* The Plan and all determinations made and actions taken under the Plan will be governed by the law of Ireland and construed accordingly. If any provision of the Plan is held unlawful or otherwise invalid or unenforceable in whole or in part, the unlawfulness, invalidity or unenforceability will not affect any other parts of the Plan, which parts will remain in full force and effect.

APPENDIX A

Net sales; return on sales; revenue, net revenue, product revenue or system-wide revenue (including growth of such revenue measures); operating income (before or after taxes) or net operating income; pre- or after-tax income or loss (before or after allocation of corporate overhead and bonus); earnings or loss per share; income or loss, or net income or loss (before or after taxes); return on equity; total stockholder return; share price performance; return on assets or net assets; appreciation in and/or maintenance of the price of the Shares or any other publicly-traded securities of the Company; market share; gross profits; gross or net profit margin; gross profit growth; operating profit or net operating profit (before or after taxes); operating earnings; earnings or losses or net earnings or losses (including earnings or losses before taxes, before interest and taxes, or before interest, taxes, depreciation and amortization); return on operating revenue; economic value-added models or equivalent metrics; comparisons with various stock market indices; reductions in costs; cash flow (including operating cash flow and free cash flow) or cash flow per share (before or after dividends); return on capital (including return on total capital or return on invested capital); cash flow return on investment; cash flow return on capital; improvement in or attainment of expense levels or working capital levels, including cash, inventory and accounts receivable; general and administrative expense savings; inventory control; operating margin; profit margin; gross margin; year-end cash; cash margin; debt reduction; stockholders equity; operating efficiencies; cost reductions or savings; market share; market segment share; customer satisfaction; customer growth; employee satisfaction; productivity or productivity ratios; regulatory achievements (including submitting or filing applications or other documents with regulatory authorities or receiving approval of any such applications or other documents and passing pre-approval inspections (whether of the Company or the Company's third-party manufacturer) and validation of manufacturing processes (whether the Company's or the Company's third-party manufacturer's)); clinical achievements (including initiating clinical studies; initiating enrollment, completing enrollment or enrolling particular numbers of subjects in clinical studies; completing phases of a clinical study (including the treatment phase); or announcing or presenting preliminary or final data from clinical studies; in each case, whether on particular timelines or generally); strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property; establishing relationships with commercial entities with respect to the marketing, distribution and sale of the Company's products (including with group purchasing organizations, distributors and other vendors); supply chain achievements (including establishing relationships with manufacturers or suppliers of component materials and manufacturers of the Company's products); co-development, co-marketing, profit sharing, joint venture or other similar arrangements); financial ratios, including those measuring liquidity, activity, profitability or leverage; cost of capital or assets under management; financing and other capital raising transactions (including sales of the Company's equity or debt securities; debt level year-end cash position; book value; factoring transactions; competitive market metrics; timely completion of new product roll-outs; product release schedules; timely launch of new facilities; sales or licenses of the Company's assets, including its intellectual property, whether in a particular jurisdiction or territory or globally; or through partnering transactions); royalty income; new product innovation; product cost reduction through advanced technology; brand recognition/acceptance; produce ship targets; implementation, completion or attainment of measurable objectives with respect to research, development, manufacturing, commercialization, products or projects, production volume levels, acquisitions and divestitures, succession and hiring projects, reorganization and other corporate transactions, expansions of specific business operations and meeting divisional or project budgets; factoring transactions; and recruiting and maintaining personnel.

Exhibit 21.1

SUBSIDIARIES OF MALLINCKRODT PLC

The following is a list of subsidiaries of Mallinckrodt plc as of December 31, 2021.

Name of Subsidiary	Jurisdiction of Incorporation/Organizatio
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 AR Finance 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 ("Debtor-in-possiession") (in examination under Part 10 of the Irish Companies Act 2014) (the "Company"), and the effectiveness of the Company's internal control over financial reporting dated March 15, 2022, appearing in the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2021.

/s/ DELOITTE & TOUCHE LLP
St. Louis, Missouri
March 15, 2022

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 15, 2022

By: /s/ Mark C. Trudeau

Mark C. Trudeau

President, 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 15, 2022

By: /s/ Bryan M. Reasons

Bryan M. Reasons

Executive Vice President and Chief Financial Officer, (principal financial and accounting 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 31, 2021 ("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 15, 2022

By: /s/ Bryan M. Reasons
Bryan M. Reasons
Executive Vice President and Chief Financial Officer
March 15, 2022