



**2021 IRISH STATUTORY ACCOUNTS**

# **MALLINCKRODT PLC**

**(DEBTOR-IN-POSSESSION)**

**(IN EXAMINATION UNDER PART 10 OF THE IRISH COMPANIES ACT 2014)**

**Directors' Report and Consolidated Financial Statements**

**For the Fiscal Year Ended December 31, 2021**

# MALLINCKRODT PLC

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## **DIRECTORS' REPORT**

**For the Fiscal Year Ended December 31, 2021**

*(dollars in millions, except share data and where indicated)*

### ***Basis of Presentation***

The directors present their report on the audited consolidated financial statements for the fiscal year ended December 31, 2021, beginning on page 50, and audited parent company financial statements for the fiscal year ended December 31, 2021, beginning on page 128.

The directors have elected to prepare the Irish statutory Mallinckrodt plc (debtor-in-possession) (in examination under Part 10 of the Irish Companies Act 2014) consolidated financial statements in accordance with Section 279 of the Irish Companies Act 2014, which provides that a true and fair view of the assets and liabilities, financial position and profit or loss may be given by preparing the financial statements in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of Part 6 of the Irish Companies Act 2014.

The directors have elected to prepare the Mallinckrodt plc parent company financial statements in accordance with Financial Reporting Standards applicable in the United Kingdom ("U.K.") and Republic of Ireland ("FRS 102") together with the Irish Companies Act 2014.

The accompanying financial statements reflect the consolidated financial position of the parent company ("Mallinckrodt plc" or the "Company") and its subsidiaries (Mallinckrodt plc and all its subsidiaries, hereinafter referred to as "Mallinckrodt," the "Group," "us," "we," or "our") as an independent, publicly-traded company.

### ***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 2020 consisted of 52 weeks and ended on December 31, 2021, and December 25, 2020, respectively. All references to "fiscal" year are considered to be defined as "financial" year under FRS 102.

### ***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 Directors' Report is "Mallinckrodt," which is a registered trademark or the subject of pending trademark applications in the U.S. and other jurisdictions. Solely for convenience, we only use the ™ or ® symbols the first time any trademark or trade name is mentioned. Such references are not intended to indicate in any way that we will not assert, to the fullest extent permitted under applicable law, our rights to our trademarks and trade names. Each trademark or trade name of any other company appearing in this Directors' Report is, to our knowledge, owned by such other company.

### ***Forward-Looking Statements***

We have made forward-looking statements in this Directors' Report 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 our possible or assumed future results of operations, business strategies, financing plans, competitive position, potential growth opportunities, potential operating performance improvements and 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 principal risks and uncertainties included in this Directors' Report could cause our results to differ materially from those expressed in forward-looking statements. There may be other risks and uncertainties that we are unable to predict at this time or that we currently do not expect to have a material adverse effect on our business.

These forward-looking statements are made as of the issuance date of this Directors' Report. We expressly disclaim any obligation to update these forward-looking statements other than as required by law.

### ***Principal Activities***

Mallinckrodt plc is the parent company of a global business consisting of multiple wholly owned subsidiaries whose principal activity is to 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 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.

The Group is incorporated in Ireland where we maintain our principal executive offices and continues to be subject to the United States ("U.S.") Securities and Exchange Commission ("SEC") reporting requirements.

### ***Significant Events***

#### ***Voluntary Filing Under Chapter 11 and Going Concern***

##### ***Chapter 11 Proceedings***

On October 12, 2020 (the "Petition Date"), 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") in the U.S. Bankruptcy Court for the District of Delaware (the "Bankruptcy Court") to modify our capital structure, including restructuring portions of our debt, and resolve otherwise unmanageable 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<sup>®</sup> 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 Directors' Report shall include, where applicable, such proceedings in Canada and Ireland. Refer to Note 2 of the Notes to the Consolidated Financial Statements for further information on the voluntary petitions for reorganization, the RSA and agreements in principle subsequently memorialized in our Chapter 11 plan of reorganization. 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.

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 an order (the "Confirmation Order") confirming the fourth amended joint plan of reorganization (with technical modifications) proposed by the Debtors (the "Plan"). 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.

#### *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 distribution and administration ("D&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 Bankruptcy Court has entered the Confirmation Order confirming the Plan and the directors remain confident that the transactions contemplated by the Plan have a reasonable prospect of being successfully implemented; however, this is not within the Group's control but rather is subject to approval by the Bankruptcy Court, including completion of the Canadian and Irish proceedings, among other conditions. As such, the directors have concluded that the outcome of the Chapter 11 Cases represents material uncertainty, which casts significant doubt about the Group's ability to continue as a going concern. The Group's ability to continue as a going concern is contingent upon, among other things, its ability to, subject to the approval by 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-related settlements, restructured debt obligations, and operating needs. Refer to Note 29 of the Notes to the Consolidated Financial statements for further information on the examinership process commenced by Mallinckrodt plc with the High Court of Ireland on February 14, 2022.

Although the directors believe that the Group's reorganization through the Chapter 11 proceedings will appropriately position the Group upon emergence, the commencement of these proceedings constituted an event of default under certain of the Group'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 Group's bankruptcy, including, among others that: (a) its prearranged plan of reorganization may never become effective, (b) the Plan 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.

Having reviewed cash flow forecasts prepared by management and approved by the Board of Directors that assume the successful consummation of the transactions contemplated by the Plan and considering the uncertainties described above, the directors have a reasonable expectation that the Group will be able to successfully navigate the Chapter 11 proceedings and that the Group will be able to continue as a going concern for a period of twelve months from the date of approval of these financial statements and are satisfied to prepare the consolidated financial statements on a going concern basis. The consolidated financial statements do not include any adjustments that would be required if the Group were unable to continue as a going concern.

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

#### **StrataGraft®**

On June 15, 2021, we announced that the U.S. Food and Drug Administration ("FDA") had approved the StrataGraft® (allogenic cultured keratinocytes and dermal fibroblasts in murine collagen - dsat) ("StrataGraft biologics") license application ("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.

## ***Amitiza***

During the three months ended December 31, 2021, due to lower anticipated cash flows expected from Amitiza<sup>®</sup> (lubiprostone) ("Amitiza"), we identified an impairment 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.

## ***Likely Future Developments***

### ***Specialty Brands***

Turnover of Ofirmev<sup>®</sup> (acetaminophen injection ("Ofirmev")) decreased \$247.6 million or 89.5%, to \$28.9 million driven primarily by the entrance of generic competition during fiscal 2021.

Turnover 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 novel coronavirus ("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 Pharmaceuticals Inc.'s ("ANI") 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.

Turnover for INOmax<sup>®</sup> (nitric oxide) gas, for inhalation ("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***

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

### ***Terlipressin***

During September 2020, the FDA issued a Complete Response Letter ("CRL") regarding our new drug application ("NDA") seeking approval for the investigational agent terlipressin to treat adults with hepatorenal syndrome ("HRS") type 1 (collectively "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 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 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.

### ***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 turnover 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 the Principal Risks and Uncertainties included within this Director's report.

### ***Key Performance Indicators***

The financial measures discussed below are considered "non-U.S. GAAP" financial measures. The Group has provided these adjusted financial measures because they are used by management, along with financial measures in accordance with U.S. GAAP, to evaluate the Group's operating performance. In addition, management believes that these non-U.S. GAAP financial measures will be used by certain investors to measure the Group's operating results. Management believes that presenting these non-U.S. GAAP financial measures provides useful information about the Group's performance across reporting periods on a consistent basis by excluding items which may be favorable or unfavorable that the Group does not believe are indicative of its core operating performance. These adjusted measures are also utilized in the determination of management incentive compensation.

These non-U.S. GAAP financial measures should be considered supplemental to and not a substitute for financial information prepared in accordance with U.S. GAAP or FRS 102. The Group's definition of these non-U.S. GAAP financial measures may differ from similarly titled measures used by others.

We calculate our key performance indicators based upon results from ordinary activities as they reflect the ongoing operating performance of the Group and provide the best insight into current and future performance.

Adjusted gross profit, adjusted selling, general and administrative ("SG&A") expenses, adjusted research and development ("R&D") expense and adjusted earnings before interest, taxes, depreciation and amortization ("EBITDA") represent amounts prepared in accordance with U.S. GAAP and adjusted for certain items that management believes are not reflective of the operational performance of the business. Adjustments to U.S. GAAP amounts include, as applicable to each measure, depreciation; amortization; restructuring charges, net; non-restructuring impairment charges; discontinued operations; changes in fair value of contingent consideration obligations; significant legal and environmental charges; losses (gains) on divestiture; separation costs, unrealized gain on equity investment; R&D upfront payment; reorganization items, net; share-based compensation and other items identified by the Group. A reconciliation of these historical adjusted financial measures to the most directly comparable U.S. GAAP financial measures is included in the following table:



(in millions)

	Fiscal Year							
	2021				2020			
	Gross Profit	SG&A	R&D	Adjusted EBITDA	Gross Profit	SG&A	R&D	Adjusted EBITDA
<b>U.S. GAAP, as previously reported</b>	\$ 891.7	\$ 608.5	\$ 205.2	\$ (679.6)	\$ 669.4	\$ 868.5	\$ 290.8	\$ (993.5)
Adjustments:								
Interest expense, net	—	—	—	220.7	—	—	—	255.2
Income taxes	—	—	—	(106.3)	—	—	—	8.9
Depreciation <sup>(1)</sup>	70.3	(17.6)	(6.8)	94.7	71.9	(35.1)	(7.0)	114.0
Amortization	577.7	(3.4)	—	581.1	767.8	(3.4)	—	771.2
Restructuring charges, net	—	—	—	26.9	—	—	—	37.5
Non-restructuring impairment charge	—	—	—	90.4	—	—	—	128.0
Income from discontinued operations	—	—	—	(6.1)	—	—	—	(25.1)
Change in contingent consideration fair value	—	(8.2)	—	8.2	—	5.7	—	(5.7)
Significant legal and environmental charges <sup>(2)</sup>	—	(45.4)	—	170.4	536.0	(55.7)	—	653.4
Losses (gains) on divestiture	—	—	—	0.8	—	—	—	(16.6)
Separation costs	—	(1.2)	—	1.2	—	(93.4)	—	93.4
Unrealized gain on equity investment	—	—	—	(4.7)	—	—	—	(3.8)
R&D upfront payment	—	—	—	—	—	—	(5.0)	5.0
Reorganization items, net	—	—	—	428.2	—	—	—	61.4
Share-based compensation	0.5	(8.1)	(1.6)	10.2	1.3	(19.9)	(4.1)	25.3
Japanese consumption tax credit	—	—	—	(6.8)	—	—	—	—
<b>As adjusted:</b>	<b>\$ 1,540.2</b>	<b>\$ 524.6</b>	<b>\$ 196.8</b>	<b>\$ 829.3</b>	<b>\$ 2,046.4</b>	<b>\$ 666.7</b>	<b>\$ 274.7</b>	<b>\$ 1,108.6</b>

(1) Includes \$2.1 million and \$12.3 million of accelerated depreciation in SG&A related to restructuring charges incurred during fiscal 2021 and 2020, respectively.

(2) Fiscal 2021 includes a \$125.0 million charge related to the opioid-related litigation settlement liability and a \$45.4 million increase in environmental liabilities. Fiscal 2020 includes a retrospective one-time charge of \$641.1 million (the "Acthar Gel Medicaid Retrospective Rebate"), of which \$536.0 million and \$105.1 million have been reflected as a component of turnover and operating loss, respectively, in the consolidated profit and loss account. The \$105.1 million reflected as a component of operating loss represents a pre-acquisition contingency related to the portion of the Acthar Gel Medicaid Retrospective Rebate that arose from turnover of Acthar Gel prior to the Group's acquisition of Questcor Pharmaceuticals, Inc. ("Questcor") in August 2014. Fiscal 2020 also includes \$55.7 million of opioid defense costs which are considered to be non-recurring as a result of the opioid-related litigation settlement announced during the three months ended March 27, 2020. These costs were partially offset by a \$43.4 million decrease in the fair value of the opioid settlement warrants.

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

Further information regarding non-U.S. GAAP financial measures can be found on the Investor Relations page of the Group's website.

### Consolidated Results of Operations

Loss after taxation of \$679.6 million and \$993.5 million for fiscal 2021 and 2020, respectively, were recorded to profit and loss account. No profits were distributed as dividends during fiscal 2021 and 2020 and the Group did not make any share repurchases under its authorized share repurchase program during fiscal 2021 and 2020. Refer to Note 328 of the Notes to the Consolidated Financial Statements for further information.

The following table presents the consolidated profit and loss account for fiscal 2021 and 2020 as reported in the Group's 2021 Directors' Report. All discussions below are comparative between fiscal 2021 and 2020.

(in millions)

	Fiscal Year							
	2021				2020			
	Ordinary Activities		Discontinued Operations	Total Group	Ordinary Activities		Discontinued Operations	Total Group
<b>Turnover</b>	\$ 2,208.8	100.0 %	\$ —	\$ 2,208.8	\$ 2,213.4	100.0 %	\$ —	\$ 2,213.4
Cost of sales	1,317.1	59.6	—	1,317.1	1,544.0	69.8	—	1,544.0
<b>Gross profit</b>	891.7	40.4	—	891.7	669.4	30.2	—	669.4
Distribution and administrative expenses	608.5	27.5	—	608.5	868.5	39.2	—	868.5
Research and development costs	205.2	9.3	—	205.2	290.8	13.1	—	290.8
Restructuring charges, net	26.9	1.2	—	26.9	37.5	1.7	—	37.5
Non-restructuring impairment charges	90.4	4.1	—	90.4	128.0	5.8	—	128.0
Loss (profit) on disposal of operations	0.8	—	(1.1)	(0.3)	(16.6)	(0.7)	(8.9)	(25.5)
Opioid-related litigation settlement loss (gain)	125.0	5.7	—	125.0	(43.4)	(2.0)	—	(43.4)
Medicaid lawsuit	—	—	—	—	105.1	4.7	—	105.1
<b>Operating (loss) profit</b>	(165.1)	(7.5)	1.1	(164.0)	(700.5)	(31.6)	8.9	(691.6)
Interest payable and similar expenses	(222.6)	(10.1)	—	(222.6)	(261.1)	(11.8)	—	(261.1)
Interest receivable and similar income	1.9	0.1	—	1.9	5.9	0.3	—	5.9
Other income, net	22.0	1.0	—	22.0	7.4	0.3	—	7.4
Reorganization items, net	(428.2)	(19.4)	—	(428.2)	(61.4)	(2.8)	—	(61.4)
<b>(Loss) profit before taxation</b>	(792.0)	(35.9)	1.1	(790.9)	(1,009.7)	(45.6)	8.9	(1,000.8)
Taxation (credit) charge	(106.3)	(4.8)	(5.0)	(111.3)	8.9	0.4	(16.2)	(7.3)
<b>(Loss) profit after taxation</b>	<u>\$ (685.7)</u>	(31.0)	<u>\$ 6.1</u>	<u>\$ (679.6)</u>	<u>\$ (1,018.6)</u>	(46.0)	<u>\$ 25.1</u>	<u>\$ (993.5)</u>

*Turnover.* Our turnover in fiscal 2021 was \$2,208.8 million, which was relatively flat when compared with \$2,213.4 million in fiscal 2020.

Turnover (excluding the one-time charge related to the Medicaid lawsuit) decreased \$540.6 million, or 19.7%, to \$2,208.8 million in fiscal 2021, 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 turnover of Ofirmev, Acthar Gel and INOmax, as previously discussed.

Turnover generated by our businesses in the U.S. was \$1,991.8 million and \$2,465.5 million in fiscal 2021 and 2020, respectively. Our non-U.S. businesses generated turnover of \$217.0 million and \$283.9 million in fiscal 2021 and 2020, respectively, which represented approximately 9.8% of our turnover in fiscal 2021 and 10.3% of our turnover in fiscal 2020.

*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 decrease was primarily driven by the retrospective one-time charge of \$536.0 million reflected as a component of turnover related to the Medicaid lawsuit in fiscal 2020.

Gross profit (excluding the one-time charge related to the Medicaid lawsuit) decreased \$313.7 million, or 26.0%, to \$891.7 million in fiscal 2021, 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 turnover, as discussed above, as well as the change in product mix.

*Distribution and administrative expenses.* D&A expenses for fiscal 2021 were \$608.5 million, compared with \$868.5 million for fiscal 2020, a decrease of \$260.0 million, or 29.9%. As a percentage of turnover, D&A expenses were 27.5% for fiscal 2021, compared to 39.2%, or 31.6% 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 D&A. These decreases were also driven by cost containment initiatives and lower employee compensation costs. These decreases were partially offset by a \$46.1 million increase to our environmental liabilities during fiscal 2021.

*Research and development costs.* 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 Group 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 turnover, 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 D&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 \$90.4 million for fiscal 2021 representing a partial impairment of the Amitiza intangible asset. Non-restructuring impairment charges were \$128.0 million for fiscal 2020 primarily resulting from a full impairment of \$64.5 million related to the MNK-6105 and MNK-6106 IPR&D asset and a partial impairment of \$63.5 million related to the Ofirmev intangible asset.

*(Profit) loss on disposal of operations.* 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 taxation credit 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. Additionally, 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.

*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. 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 turnover of Acthar Gel prior to our acquisition of Questcor in August 2014.

*Interest payable and similar expenses and interest receivable and similar income, net.* During fiscal 2021 and fiscal 2020, interest payable and similar expenses and interest receivable and similar income, net were \$220.7 million and \$255.2 million, respectively. The \$38.5 million decrease in interest payable and similar expenses 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 payable and similar expenses, respectively, due to lapses of certain statutes of limitations. Interest receivable and similar 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 Therapeutics plc ("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, senior secured term loan due February 2025 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.

*Taxation.* During fiscal 2021, we recognized a taxation credit of \$106.3 million on a loss from ordinary activities before taxation of \$792.0 million. The fiscal 2021 taxation credit was comprised of \$46.4 million of current taxation credit and \$59.9 million of deferred taxation credit. The current taxation credit was primarily the result of an increase to prepaid taxes and a decrease to uncertain tax positions. The deferred taxation credit was predominately related to intangible asset amortization,

partially offset by utilization of loss carryforwards in non-valuation allowance jurisdictions. During fiscal 2020, we recognized a taxation charge of \$8.9 million on a loss from ordinary activities before taxation of \$1,009.7 million. The fiscal 2020 taxation charge was comprised of \$375.3 million of current taxation credit and \$384.2 million of deferred taxation charge. The current taxation credit was primarily the result of the U.S. 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 taxation charge 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 13.4% and negative 0.9% for fiscal 2021 and 2020, respectively. Our effective tax rate for fiscal 2021 was most significantly impacted by the taxation credit of \$274.3 million predominately related to changes in the jurisdictional mix of operating loss resulting from the fiscal 2020 reorganization of the Group's intercompany financing and associated asset and legal entity ownership and a \$9.7 million taxation credit associated with accrued income tax liabilities and uncertain tax positions, partially offset with \$177.7 million of taxation charge 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 taxation credit of \$49.9 million associated with \$428.2 million of reorganization items, net, \$21.1 million of taxation credit associated with the \$125.0 million opioid-related litigation settlement charge, \$20.3 million of taxation credit associated with the \$90.4 million non-restructuring impairment charge and \$10.2 million of taxation credit associated with the \$46.1 million increase to environmental liabilities. These additional impacts are significantly offset with the above referenced valuation allowance, thus resulting in a taxation credit of \$15.0 million included within our jurisdictional mix of operating loss. Our effective tax rate for fiscal 2020 was most significantly impacted by \$632.5 million of taxation charge associated with valuation allowances and an \$82.0 million taxation charge associated with the reorganization of our intercompany financing and associated asset and legal entity ownership, partially offset by a \$281.5 million taxation credit associated with the CARES Act and \$11.9 million of taxation credit associated with accrued income tax liabilities and uncertain tax positions. Additional impacts to the fiscal 2020 effective tax rate included \$32.7 million of taxation credit associated with non-restructuring impairment charges of \$128.0 million, a taxation credit of \$11.8 million associated with \$93.4 million of separation costs, \$5.4 million of taxation credit associated with \$61.4 million of reorganization items, net, \$0.5 million of taxation credit associated with \$25.3 million of share-based compensation, \$0.4 million of taxation credit associated with the \$5.7 million decrease in the fair value of our contingent consideration liabilities and no taxation charge 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 taxation charge or credit.

### ***Financial Position***

Our financial position is set out on page 60. As of December 31, 2021 and December 25, 2020 we had total assets of \$8,916.3 million and \$9,650.9 million, respectively, and total liabilities of \$8,614.0 million and \$8,680.6 million, respectively. As of December 31, 2021 and December 25, 2020 we had net current liabilities of \$3,289.2 million and \$3,402.6 million, respectively. During fiscal 2021, we incurred a loss after taxation of \$679.6 million.

### ***Principal Risks and Uncertainties***

*You should carefully consider the risks described below in addition to all other information provided to you in this Directors' Report and accompanying financial statements. 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 the Group.*

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 Directors' Report. These and other risks could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

## 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 25 of the Notes to Consolidated Financial Statements, 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 (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.***

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 Directors' Report.

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 Group 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 ("CEO"), 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 Group 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 Group.

## **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 April 1, 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 April 1, 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 Controlled Substances Act of 1970 ("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 turnover 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 turnover. A violation of the Operating Injunction may also subject the Group 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 turnover 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 turnover 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 turnover 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 turnover, 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 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 turnover 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 turnover, 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 turnover, marketing and pricing practices, including the Department of Justice ("DOJ") and various other agencies including the Office of Inspector General ("OIG") within the Department of Health and Human Services ("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 U.S. Federal Food, Drug and Cosmetic Act (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 Foreign Corrupt Practices Act of 1977 ("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 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 turnover 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 turnover 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.

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 turnover 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.

***Turnover 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.***

Turnover 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 turnover 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 Group 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 turnover and operating loss, respectively, in the consolidated profit and loss account for fiscal 2020. The \$105.1 million reflected as a component of operating loss represents a pre-acquisition contingency related to the portion of the Acthar Gel Medicaid Retrospective Rebate that arose from turnover 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 Group 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 turnover, 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 corporate integrity agreement ("CIA") 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 "*Turnover 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 turnover, 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 Directors' Report, in May 2019, CMS issued a final decision directing the Group 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 group purchasing organizations ("GPO(s)") 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 turnover to members of that GPO or IDN, having a contract is no assurance that turnover 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 turnover 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 turnover. Distributors of our products are also forming strategic alliances and negotiating terms of turnover more aggressively in an effort

to increase their profitability. Failure to negotiate distribution arrangements having advantageous pricing and other terms of turnover 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 turnover 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, turnover, 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, turnover, 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 Drug Enforcement Administration ("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 turnover, 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 active pharmaceutical ingredients ("API(s)") 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 current good manufacturing practice ("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 turnover, 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 turnover volumes, we may be unable to replace lost turnover 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. Turnover 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 turnover in each of the past two 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<sup>®</sup> photopheresis ("Therakos"), represent a significant percentage of our turnover. Our ability to maintain and increase turnover from these products depends on several factors, including:

- our ability to increase market demand for products through our own marketing and support of our turnover 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 turnover 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, turnover 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 turnover 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 turnover 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 ("ECP"), which is an autologous immune cell therapy that is indicated in the U.S. for skin manifestations of cutaneous T-cell lymphoma ("CTCL") and is available for several additional indications in markets outside the U.S. In the ECP process, blood is drawn from the patient, separating white blood cells from plasma and red blood cells (which are immediately returned to the patient). The separated white blood cells are treated with an Ultraviolet A ("UVA") light activated drug, UVADEX<sup>®</sup> (methoxsalen) Sterile Solution ("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<sup>®</sup> Photopheresis System ("CELLEX"), which is the only FDA-approved closed ECP system, and the UVAR XTS<sup>®</sup> 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 turnover 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 FDCA. This amendment introduced the requirement that drug manufacturers provide proof of the effectiveness (in addition to the previously required proof of safety) of their drugs in order to obtain FDA approval. As such, the FDA's original approval in 1952 was based on safety data as clinical trials evaluating efficacy were not then required. In the 1970s, the FDA reviewed the safety and efficacy of Acthar Gel during its approval of Acthar Gel for the treatment of acute exacerbations in multiple sclerosis ("MS") 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 infantile spasms ("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 turnover 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 turnover 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 good laboratory practices or good clinical practices. 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 Directors' Report, 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 turnover 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 25 of the Notes to Consolidated Financial Statements. 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 turnover 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 \$83.4 million to \$120.9 million. We also concluded that, as of December 31, 2021, the best estimate within this range was \$106.9 million, of which \$63.1 million was classified as liabilities subject to compromise as of December 31, 2021. For further information on our environmental obligations, refer to Note 25 of the Notes to Consolidated Financial Statements. 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 Group from Covidien plc ("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 Group 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 Group (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 turnover 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 turnover 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 turnover and stocks 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 turnover 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 stocks 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 European Union ("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 turnover and operating loss 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 previously, 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 London Inter-Bank Offered Rate ("LIBOR"), could result in higher interest expense and cash payments for us. Although we may enter into interest rate swaps, involving the exchange of floating for fixed-rate interest payments, to reduce interest rate volatility, we cannot provide assurance that we will enter into such arrangements or that they will successfully mitigate such interest rate volatility.

***Despite current and anticipated indebtedness levels, we may still be able to incur more debt. This could further exacerbate the risks described above.***

We may be able to incur substantial additional indebtedness in the future. Although agreements governing our 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 Group'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 Group 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 Group's depreciable, amortizable and other assets. Loss of these tax attributes may have an adverse effect on the Group's prospective cash flow.

To the extent, if any, that U.S. NOL carryforwards, other losses and credits generated by the Group prior to emergence from bankruptcy are available as deductions after emergence, the ability of the Group 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 Group 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 Group's stock after bankruptcy to meet certain specific and narrow conditions. Therefore, the Group's U.S. NOLs may be significantly

limited by Section 382 of the IRC. The amount of the Group'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 Group's U.S. affiliate stock immediately prior to implementation of the Plan (the "Annual Limitation"). However, if the value of the Group's U.S. affiliate stock is zero, if the Group 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 Group may be significantly limited in its ability to use any of its pre-emergence U.S. NOLs. In addition, if the Group 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 Group'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 Internal Revenue Service 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 Group's principal executive offices were relocated from the U.K. to Ireland, which resulted in a change in the Group'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 Group 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 Group'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 issue 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 Group 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.

## **Financial Risk Management**

Our operations include activities in the U.S. and countries outside of the U.S. These operations expose us to a variety of market risks, including the effects of changes in interest rates and currency exchange rates. We monitor and manage these financial exposures as an integral part of our overall risk management program and have entered into derivative instruments to mitigate the exposure of movement in certain of these foreign currency transactions.

## **Interest Rate Risk**

Our exposure to interest rate risk relates primarily to our variable-rate debt instruments, which bear interest based on LIBOR plus margin. As of December 31, 2021, our outstanding debt included \$1,767.2 million variable-rate debt on our senior secured term loans and \$900.0 million variable-rate debt on our revolving credit facility. Assuming a one percent increase in the applicable interest rates, in excess of applicable minimum floors, annual interest expense for fiscal 2021 would have increased by approximately \$26.7 million.

The remaining outstanding debt as of December 31, 2021 is fixed-rate debt. Changes in market interest rates generally affect the fair value of fixed-rate debt, but do not impact earnings or cash flows.

## Currency Risk

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

## Non-Financial Reporting

Regulations on non-financial information mean that the Group must report on a series of topics listed below. Information is provided on these matters across this report, as well as in our Directors' Report, including the Principal Activities section on page 5 and the Principal Risks and Uncertainties section on pages 12 to 41.

We believe our corporate responsibility goes beyond the millions of people whose lives we touch each and every day. We have integrated responsible business practices into everything we do. From our broad efforts to encourage responsible and safe use of opioid pain medications to advocating for patient health and access to medicines, our commitment to building a better tomorrow is stronger than ever. A core pillar of our corporate responsibility is giving back to the communities that have helped us grow for more than 150 years. We partner with organizations that are making a tangible difference and driving positive change within local communities through education, economic development and cultural enrichment. For further information on our corporate responsibility approach and programs please visit [mnk.com/corporate-responsibility](http://mnk.com/corporate-responsibility).

*Environmental, Health and Safety ("EHS") Matters.* We believe our commitment to protecting health, safety and our environment starts with a socially responsible culture. In doing so, our expectation is an injury-free workplace and an assurance that our activities do not result in adverse safety, health or environmental impacts either on or off-site. We believe that every employee is responsible for EHS - leading us to continuously improve our EHS performance by recognizing, evaluating and controlling risks. Some of the main features of our EHS efforts include:

- a well-established EHS management system, including internal protocols and standards adapted to meet or exceed compliance with applicable laws;
- continuous improvement to become a more sustainable and responsible business;
- enterprise-wide EHS management software with utilized and established metrics and measures, including both lagging and leading indicators, to evaluate and project company performance; and
- an internal and external auditing program to assure compliance.

The following table sets out key performance indicators that we utilized related to the safety of the employees of our Specialty Brands and Specialty Generics segments in 2021:

Key Performance Indicator	Specialty Brands	Specialty Generics	Total Group
Global Serious Injury Rate per 100 employees	0.8	0.6	0.7
Number of Serious Injuries	11	9	20
Total Number of Hours Worked	2,747,569	2,909,938	5,657,507

In addition, we are committed to designing products and processes that minimize our environmental impact while meeting the needs of our customers. Our product development process spans from extraction of raw materials to final disposition. We are dedicated to understanding product life cycles and their impact. In addition, our purchasing organization is committed to acquiring products and services from suppliers that share our commitment to quality, innovation, customer satisfaction and sustainability. We believe creating a sustainable supply base and deploying environmentally preferable business practices is critical to our long-term success and growth.

We plan on continuing to conserve resources by improving efficiencies, reducing our consumption and reducing waste. We have a policy setting forth our commitment to purchasing and managing energy in the most efficient, cost effective and environmentally friendly manner possible that applies to those facilities, business units and employees falling under Scope 1 and 2 emissions as defined under the Greenhouse Gas protocol.

The following table sets out key performance indicators for both our Specialty Brands and our Specialty Generics segment that we utilized related to our sustainability efforts in 2021:

Key Performance Indicator	Specialty Brands	Specialty Generics	Total Group
Gross Global Scope 1 Emissions (metric tons CO <sub>2</sub> e)	10,762	86,357	97,119
Gross Global Scope 2 Emissions (metric tons CO <sub>2</sub> e)	8,131	68,362	76,493

In addition, we believe that ensuring the highest quality of our products is a critical complement to our EHS efforts, and we are committed to communicating the Group's Quality Policy to all employees and third parties, and to provide the required leadership, management, and resources to achieve our quality objectives. The guiding principles driving our Quality Policy and our corporate commitment to excellence are:

- Patient Safety as the highest priority, pre-eminent in every decision we make.
- Complying with applicable laws and regulations as well as internal requirements to position our company as a model for compliance and integrity.
- Being recognized as an industry leader in providing quality products and services that meet or exceed the requirements and needs of our patients.
- Continuously challenging ourselves to improve the quality management system, our quality processes and operational excellence through the review and analysis of quality objectives and results.
- Encouraging participation and promotion of quality responsibilities among all employees and third parties through education, training and coaching, supervision, and effective communication.

*Social and Employee Matters.* 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.

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, and provide comprehensive benefits for our employees globally. 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. Additionally, 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.

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.

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 Inclusion and Diversity ("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 Lesbian, Gay, Bisexual, Transgender, Queer (LGBTQ) Equality" for six consecutive years from the Human Rights Campaign Foundation's Corporate Equity Index.

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.

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.

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.

We understand and empathize with the concern over the cost of drugs, particularly as patient out-of-pocket costs grow with increasingly higher deductibles in health insurance plans. We take our responsibility as a pharmaceutical manufacturer very seriously, and our pledge on drug pricing and innovation describes our philosophy around responsible pricing. We seek to be a trusted partner with policymakers, healthcare providers, payers, and patient groups to reform America's healthcare system in a manner that is sustainable and patient-centric. For further information on these and other efforts, please visit [mnk.com/corporate-responsibility](http://mnk.com/corporate-responsibility).

For patients who may not be able to afford their medication, we offer Patient Assistance Programs for certain branded pharmaceuticals to those who qualify. For more information on these programs, please visit [mnk.com/products/brands/patient-assistance](http://mnk.com/products/brands/patient-assistance).

We are dedicated to providing safe and effective medications for the treatment of patients with pain and are equally committed to working with policymakers, law enforcement and industry to address the complex issues of opioid addiction and abuse. We advocate for a comprehensive, multi-prong action plan to fight opioid abuse and misuse in the U.S. and we have proactively taken a number of steps to fight opioid abuse and misuse. For example, we have been at the forefront in developing a comprehensive opioid anti-diversion program by working with our customer-distributors, the DEA and other law enforcement officials to prevent prescription drug diversion, misuse and abuse. Additionally, we have supported improved integration of federal and state prescription drug monitoring programs and enhanced addiction rehabilitation and drug take-back programs, including provision of drop boxes to local law enforcement in communities where our major sites reside. Moreover, we donated more than two million drug deactivation pouches to enable responsible drug disposal.

We have implemented an Opioid Product Operating Injunction compliance program that prohibits, among other things, certain promotional activities related to opioid products and pain treatment, financial an in-kind support for third parties

involved with opioids or pain treatment, and certain lobbying activities and communications related to opioids and pain treatment. Further, in connection with the Proposed Acthar Gel-Related Settlement, we entered into a CIA with the OIG of the HHS in March 2022.

As part of our mission to manage complexity and improve lives, we work to conduct our turnover, marketing and promotional activities ethically. Ethical relationships with healthcare professionals are critical to helping patients by developing and marketing new medicines. An important part of achieving this mission is ensuring that healthcare professionals have the latest, most accurate information available regarding prescription medicines, which play an ever-increasing role in patient health care. We have a long-standing policy of abiding by industry ethical codes on our interaction with healthcare professionals.

*Respect for Human Rights.* We are committed to conducting all of our activities in accordance with high standards of business conduct. The large majority of our businesses operate in countries where breaches of human rights do not present a material risk and we have suitable policies and procedures intended to ensure that the rights of our employees are fully respected and are committed to respecting the human rights of our employees and those within the communities in which we work. In particular, we support the human rights of our workers and the treatment of all people with dignity and respect through two core policy documents: the Group's Supplier Code of Conduct and Guide to Business Conduct. To learn more, please visit [mnk.com/corporate-responsibility/corporate-compliance](http://mnk.com/corporate-responsibility/corporate-compliance).

The Supplier Code of Conduct outlines the expectations for the ethical behavior of our suppliers and prohibits child and compulsory labor, human trafficking and slavery, unsafe and hazardous working conditions and environments, and any behavior that does not maintain human dignity and respect. These standards apply to all suppliers of goods and services to any Group business or supplier, regardless of location.

The Guide to Business Conduct reflects our aim for good global citizenship and worldwide social responsibility, in which we must provide clean and safe working environments and conditions free of human rights violations, and forbids forced or child labor at the Group and at the companies with which we work, with no exceptions. The Guide to Business Conduct also prohibits human trafficking or slavery, unsafe or hazardous conditions or environments, or any behavior that does not maintain human dignity and respect. It further states that we must not engage in activities that fail to protect individual dignity and respect, even if permissible under local law, and must pay a fair wage.

Since 2014, we have annually published a Conflict Minerals Report detailing the use of cassiterite, columbite-tantalite (coltan), gold, wolframite, and their derivatives, which are limited to tin, tantalum and tungsten ("3TGs"), emanating from the Democratic Republic of the Congo region and nine adjoining countries ("covered countries"), which are necessary to the functionality or production of our products. For fiscal 2020, we performed a Reasonable Country of Origin Inquiry on our suppliers believed to provide the Group with materials or components containing 3TGs necessary to the manufacture of our products, which are limited to non-drug products (i.e., medical devices). Our suppliers identified 336 valid smelters and refineries ("smelters"), of which we identified 43 as sourcing (or there was reason to believe they may be sourcing) from the covered countries. Our due diligence review indicated that 33 of these smelters have been audited and are conformant to the Responsible Minerals Assurance Process, formerly the Conflict-Free Smelter Program. The remaining 10 smelters were subject to Mallinckrodt's risk mitigation process according to the OECD Due Diligence Guidance for Responsible Supply Chain of Minerals from Conflict-Affected and High-Risk Areas. We are currently preparing a similar report for fiscal 2021, as required by the U.S. SEC. The Group's policy with respect to the sourcing of conflict minerals can be found on our website at [mnk.com/about/partnering/suppliers/conflict-minerals-policy](http://mnk.com/about/partnering/suppliers/conflict-minerals-policy).

Since fiscal 2017, we have published an annual U.K. Modern Slavery Act Disclosure which sets forth information regarding the steps we have taken to mitigate the risks associated with modern slavery in our business and supply chain.

*Anti-bribery and corruption.* Our responsibility to our many stakeholders, including our financial stakeholders, is built on the integrity of our dealings. The Guide to Business Conduct is an expression of our expected standards of behavior for everyone who conducts business on our behalf. The Guide to Business Conduct establishes compliance responsibilities, supports applicable laws and regulations, and reinforces corporate policies and procedures. The Guide to Business Conduct articulates our fundamental principles, values and framework for ethical conduct.

We are committed to compliance with all applicable anti-corruption laws, and maintains an anti-bribery and anti-corruption policy in an effort to ensure that all of our businesses and employees are aware of their responsibilities in terms of complying with applicable global anti-corruption laws, including but not limited to the U.S. FCPA and the U.K. Bribery Act of 2010. A copy of the policy is provided to relevant employees and anti-corruption compliance training on the key provisions of the policy is also provided periodically to relevant employees who are required to certify their compliance with the policy on an annual basis. All of our employees are required to be trained on the Guide to Business Conduct and to certify annually both to their understanding and compliance.

## Research and Development

*Specialty Brands.* Our 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 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 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 CRL regarding the Group'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 Group 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 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 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.

### ***Acquisition of Own Shares***

From time to time, our Board of Directors have authorized share repurchase programs. No shares were repurchased under these programs during fiscal 2021 or 2020.

The following table sets out the ordinary shares of the Group, which have a par value of \$0.20 per share, held by the Group and are classified as treasury shares (*dollars in million*):

	<b>Number of ordinary shares held</b>	<b>Aggregate consideration paid or received</b>
As of December 25, 2020	9,506,147	\$ 1,616.1
Repurchased during the year	63,498	—
As of December 31, 2021	<u>9,569,645</u>	<u>\$ 1,616.1</u>

Further information relating to the acquisition of our shares is set out at Note 28 of the Notes to the Consolidated Financial Statements and Note 8 of the Notes to the Company Financial Statements.

### ***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.

### ***Accounting Records***

The directors are responsible for ensuring that the Company and Group keep adequate accounting records and appropriate accounting systems. The measures taken by the directors to ensure compliance with the Company's and Group's obligation to keep adequate accounting records include the use of appropriate systems and procedures and the employment of competent persons. The directors have appointed a Chief Financial Officer who makes regular reports to the directors and ensures compliance with the requirements of Sections 281 to 285 of the Irish Companies Act 2014. The Group also has a Controller, who works closely with the Chief Financial Officer and who makes regular reports to the Audit Committee. In addition, the head of the Group's internal audit department makes regular reports to the Audit Committee regarding fraud and other financial-related irregularities. The Audit Committee, in turn, briefs the directors on significant financial matters arising from reports of the Chief Financial Officer, the Controller, the head of internal audit and the Company's or Group's external auditor.

The accounting records of Mallinckrodt plc are maintained at College Business & Technology Park, Cruiserath, Blanchardstown, Dublin 15, Ireland.

### ***Important Events Since Year End***

#### ***Bankruptcy Proceedings***

Certain bankruptcy proceeding matters occurred during fiscal 2021, but had subsequent updates through the issuance of this report, including Mallinckrodt plc's commencement of an examinership process with the High Court of Ireland. See further discussion in Note 2 and 29 of Notes to the Consolidated Financial Statements.

#### ***Commitments and Contingencies***

Certain litigation matters occurred during fiscal 2021 or prior. See further discussion in Note 25 of Notes to the Consolidated Financial Statements for subsequent updates to these matters or new litigation through the issuance of this Directors' Report.

## ***Directors***

Directors' remuneration is set forth in Note 12 of Notes to Consolidated Financial Statements. No director or company secretary of the Group had an interest in shares required to be disclosed under Section 329 of the Irish Companies Act 2014 either at the beginning of the financial year, or date of appointment if later, or at the end of the financial year. Note that where the aggregate interest in shares of any director or secretary (and his or her spouse (or civil partner) and children) represents less than 1% in nominal value of the Group's ordinary shares, the only interests of that director or secretary that are required to be disclosed constitute a right to subscribe for shares in the Group or that arise as a result of the exercise of such a right. Performance stock units where the director or secretary is an employee of the Group and does not make any payment to the Group in respect of the shares are not considered to be rights to subscribe for the purposes of this disclosure and no disclosure is required where they form part of an aggregate less than 1% holding.

Set forth below are the names of the individuals serving as directors during fiscal 2021.

<b>Name</b>
Mark C. Trudeau
David R. Carlucci
J. Martin Carroll
Paul R. Carter
David Y. Norton
Carlos V. Paya, M.D., Ph.D.
JoAnn A. Reed
Angus C. Russell
Anne C. Whitaker
Kneeland C. Youngblood, M.D.

## ***Political Donations***

No political contributions that require disclosure under Irish law were made during the year.

## ***Subsidiary Companies and Branches***

Information regarding subsidiary undertakings, including information regarding branches, is provided in Note 30 of Notes to Consolidated Financial Statements.

## ***Audit Committee***

In accordance with Section 167 of the Irish Companies Act 2014, the Group has established an audit committee for the full financial year.

## ***Disclosure of Information to Auditor***

Each of the persons who is a director at the date of approval of this Directors' Report confirms that:

- so far as that director is aware, there is no relevant audit information of which the Group's auditor is unaware, and
- that director has taken all the steps that ought to have been taken as a director in order to be aware of any relevant audit information and to establish that the Group's auditor is aware of that information.

This confirmation is given and should be interpreted in accordance with the provisions of Section 330 of the Irish Companies Act 2014.

## ***Directors' Compliance Statement***

As required by Section 225 of the Irish Companies Act 2014, the directors acknowledge that they are responsible for securing Mallinckrodt plc's compliance with its "relevant obligations" (as defined in that legislation). The directors further confirm that a compliance policy statement has been drawn up, and that appropriate arrangements and structures have been put in place that are, in the directors' opinion, designed to secure material compliance with the relevant obligations. A review of those arrangements and structures was conducted in the financial year to which this Directors' Report relates. In discharging



their responsibilities under Section 225, the directors relied on the advice of persons who the directors believe have the requisite knowledge and experience to advise Mallinckrodt plc on compliance with its relevant obligations.

### ***Going Concern***

The accompanying consolidated financial statements are prepared in accordance with U.S. 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 the Chapter 11 proceedings, 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 25 of the Notes to the Consolidated Financial Statements as *Opioid-Related Matters* and *Acthar Gel-Related Matters*. In connection with the filing of the Chapter 11 Cases, the Group entered into a Restructuring Support Agreement as part of a prearranged plan of reorganization. Refer to Note 29 of the Notes to the Consolidated Financial statements for further information on the examinership process commenced by Mallinckrodt plc with the High Court of Ireland on February 14, 2022.

The Bankruptcy Court has entered the Confirmation Order confirming the Plan and the directors remain confident that the transactions contemplated by the Plan have a reasonable prospect of being successfully implemented; however, this is not within the Group's control but rather is subject to approval by the Bankruptcy Court, including completion of the Canadian and Irish proceedings, among other conditions. As such, the directors have concluded that the outcome of the Chapter 11 Cases represents a material uncertainty, which casts significant doubt about the Group's ability to continue as a going concern. The Group's ability to continue as a going concern is contingent upon, among other things, its ability to, subject to the approval by 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-related settlements, restructured debt obligations, and operating needs.

Although the directors believe that the Group's reorganization through the Chapter 11 proceedings will appropriately position the Group upon emergence, the commencement of these proceedings constituted an event of default under certain of the Group'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 Group's bankruptcy, including, among others that: (a) its prearranged plan of reorganization may never become effective, (b) the Plan 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.

Having reviewed cash flow forecasts prepared by management and approved by the Board of Directors that assume the successful consummation of the transactions contemplated by the Plan and considering the uncertainties described above, the directors have a reasonable expectation that the Group will be able to successfully navigate the Chapter 11 proceedings and that the Group will be able to continue as a going concern for a period of twelve months from the date of approval of these financial statements and are satisfied to prepare the consolidated financial statements on a going concern basis. The consolidated financial statements do not include any adjustments that would be required if the Group were unable to continue as a going concern.

### ***Auditors***

Deloitte Ireland LLP, Chartered Accountants and Statutory Audit Firm, continue in office in accordance with Section 383(2) of the Irish Companies Act 2014.

On behalf of the Directors

/s/ JoAnn A. Reed

JoAnn A. Reed

Director

1 April 2022

/s/ Mark C. Trudeau

Mark C. Trudeau

Director

**MALLINCKRODT PLC**  
**DIRECTORS' RESPONSIBILITIES STATEMENT**

The directors are responsible for preparing the directors' report and financial statements in accordance with the Companies Act 2014 and the applicable regulations.

Irish company law requires the directors to prepare financial statements for each financial year. Under the law, the directors have elected to prepare the Irish statutory Mallinckrodt plc consolidated ("the Group") financial statements in accordance with Section 279 of the Irish Companies Act 2014, which provides that a true and fair view of the assets and liabilities, financial position and profit or loss may be given by preparing the financial statements in accordance with U.S. GAAP to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of Part 6 of the Irish Companies Act 2014.

The directors have elected to prepare the Mallinckrodt plc ("parent" or "Company") financial statements in accordance with the Financial Reporting Standards applicable in the United Kingdom and Republic of Ireland ("FRS 102") together with the Irish Companies Act 2014. Under company law, the directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the assets, liabilities and financial position of the Group and Company for the financial year, the profit or loss of the Group for the year then ended and otherwise comply with the Irish Companies Act 2014.

In preparing the Group and Company financial statements, the directors are required to:

- select suitable accounting policies for the Group and Company financial statements and then apply them consistently;
- make judgments and estimates that are reasonable and prudent;
- state whether the financial statements have been prepared in accordance with the applicable accounting standards, identify those standards, and note the effect and the reasons for any material departure from those standards; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Group and Company will continue in business.

The directors are responsible for ensuring that the company keeps or causes to be kept adequate accounting records which correctly explain and record the transactions of the company; enable at any time the assets, liabilities, financial position and profit or loss of the company to be determined with reasonable accuracy; enable them to ensure that the Group and Company financial statements and directors' report comply with the Irish Companies Act 2014; and enable the financial statements to be audited. They are also responsible for safeguarding the assets of the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

Legislation in Ireland concerning the preparation and dissemination of financial statements may differ from legislation in other jurisdictions. The directors are responsible for the maintenance and integrity of financial information included on the Group's website.

## INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF MALLINCKRODT PLC

### Report on the audit of the financial statements

#### Opinion on the financial statements of Mallinckrodt plc (the 'Group')

In our opinion the Group financial statements:

- give a true and fair view of the assets, liabilities and financial position of the Group as at 31 December 2021 and of the loss of the Group for the financial year then ended; and
- have been properly prepared in accordance with the relevant financial reporting framework and, in particular, with the requirements of the Companies Act 2014.

The financial statements we have audited comprise:

- the Consolidated Profit and Loss Account;
- the Consolidated Statement of Other Comprehensive Loss;
- the Consolidated Balance Sheet;
- the Consolidated Cash Flow Statement;
- the Consolidated Statement of Changes in Equity; and
- the related notes 1 to 30, including a summary of significant accounting policies as set out in note 3.

The relevant financial reporting framework that has been applied in the preparation of the Group financial statements is the Companies Act 2014 and US Generally Accepted Accounting Principles (US GAAP), as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene Part VI of the Companies Act ("the relevant financial reporting framework").

We have reported separately on the parent company financial statements of Mallinckrodt plc for the financial year ended 31 December 2021.

#### Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland) (ISAs (Ireland)) and applicable law. Our responsibilities under those standards are described below in the "*Auditor's responsibilities for the audit of the financial statements*" section of our report.

We are independent of the Group in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, including the Ethical Standard issued by the Irish Auditing and Accounting Supervisory Authority, as applied to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Material uncertainty related to going concern

In auditing the financial statements, we have concluded that the directors' use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

We draw attention to note 1 in the financial statements, which indicates that the Group initiated proceedings under Chapter 11 of the United States Bankruptcy Code to modify its capital structure, including restructuring portions of its debt, and resolve potential legal liabilities. In connection with the filing of the Chapter 11 Cases, the Group entered into a Restructuring Support Agreement 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 Group's ability to continue as a going concern is contingent upon, among other things, its ability to implement a plan of reorganization, emerge from the Chapter 11 proceedings (including the Irish and Canadian proceedings) and generate sufficient liquidity following the reorganization to meet its obligations, most notably its opioid and Acthar Gel related settlements, restructured debt obligations and operating needs.

Our evaluation of the directors' assessment of the Group's ability to continue to adopt the going concern basis of accounting included:

- obtaining an understanding of the relevant controls in place regarding going concern as part of our risk assessment procedures;
- reviewing documentation relating to the Chapter 11 bankruptcy (including proceedings in Ireland & Canada), the Restructuring Support Agreement and the Plan of Reorganization, details of which are included in note 2;
- challenging the reasonableness of the key assumptions applied by the directors in their going concern assessment;
- holding discussions with management on the directors' going concern assessment, the future plans for the Group after Chapter 11 (including proceedings in Ireland & Canada) and the feasibility of those plans;
- obtaining an understanding of the Group's controls over the development and approval of the projections and assumptions used in the cash flow forecasts to support the going concern assumption and assessing the design and determining the implementation of these controls;
- testing the clerical accuracy of the cash flow forecast model;
- completing an assessment of the consistency of the models used to prepare the forecasts in line with other areas of our audit; and
- assessing the adequacy of the disclosures in the financial statements.

As stated in note 1, these events and conditions, along with the other matters as set forth in note 1 to the financial statements, indicate the existence of a material uncertainty on the Group's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

Our responsibilities and the responsibilities of the directors with respect to going concern are described in the relevant sections of this report.

#### **Emphasis of Matter - Bankruptcy Proceedings:**

We draw your attention to Note 2 to the financial statements, which states that the Group has filed for reorganization under Chapter 11 of the Bankruptcy Code in the United States and separately Mallinckrodt plc has commenced Examinership proceedings with the High Court of Ireland. As discussed in note 1 to the financial statements, the financial statements are prepared in accordance with U.S. GAAP applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Our opinion is not modified in respect of this matter.

<b>Summary of our audit approach</b>	
<b>Key audit matters</b>	<p>The key audit matters that we identified in the current year were:</p> <ul style="list-style-type: none"> <li>• <i>Going Concern Basis of Preparation</i> → (see <i>Material Uncertainty Related to Going Concern</i> paragraph above)</li> <li>• <i>Intangible Assets, net - Finite-lived Intangibles</i> †</li> <li>• <i>Chapter 11 Bankruptcy - Liabilities Subject to Compromise</i> †</li> </ul> <p>Within this report, any new key audit matters are identified with † and any key audit matters which are the same as the prior year identified with →. In the prior year, the Medicaid lawsuit was determined to be a key audit matter, however was not a significant matter this year as the level of audit effort required was less in the current year.</p>
<b>Materiality</b>	The materiality that we used in the current year was \$20.0 million which was determined on the basis of loss on ordinary activities before taxation.
<b>Scoping</b>	We have determined the scope of our audit by obtaining an understanding of the Group and its environment, including group wide controls and assessing the risks of material misstatement at the Group level.
<b>Significant changes in our approach</b>	No significant changes to note.

#### **Key audit matters**

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current financial year and include the most significant assessed risks of material misstatement (whether or not

due to fraud) we identified, including those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit; and directing the efforts of the engagement team.

These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. In addition to the matter described in the material uncertainty relating to going concern section, we have determined the matters described below to be the key audit matters to be communicated in our report.

<b>Intangible Assets, net - Finite-lived Intangibles</b>	
<b>Key audit matter description</b>	<p>The Group has finite-lived intangible assets, net of approximately \$5.4 billion at December 31, 2021, comprised of completed technology, licenses and trademarks. The Group recorded a non-restructuring impairment charge of \$90.4 million related to the Amitiza intangible asset in the Statutory Financial Statements 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 Group 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 Group also assesses the remaining useful life and the recoverability of finite-lived intangible assets for impairment, or whenever events of changes in circumstances indicate that the carrying value may not be recoverable by either a qualitative or income approach.</p> <p>We identified finite-lived intangible assets as a key 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 significant 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.</p>
<b>How the scope of our audit responded to the key audit matter</b>	<p>Our audit procedures related to finite-lived intangible assets included the following, among others:</p> <ul style="list-style-type: none"> <li>• We evaluated management's assessment of potential triggering events for consistency with internal and external events and transactions.</li> <li>• We evaluated management's ability to accurately estimate undiscounted future cash flows by comparing actual undiscounted cash flows to management's historical estimates.</li> <li>• We evaluated the reasonableness of management's assumptions by comparing estimated undiscounted future cash flows to historical financial information.</li> <li>• We evaluated the reasonableness of management's assumptions by inspecting external information.</li> <li>• 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.</li> <li>• We inspected internal communications and documentation to corroborate our inquiries with management.</li> </ul>
<b>Key observations</b>	<p>We have no observations that impact on our audit in respect of the finite-lived intangibles.</p>

<b>Chapter 11 Bankruptcy - Liabilities Subject to Compromise</b>	
<b>Key audit matter description</b>	<p>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.</p> <p>We identified liabilities subject to compromise associated with Chapter 11 bankruptcy and the related disclosure as a key 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 Statutory 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.</p>
<b>How the scope of our audit responded to the key audit matter</b>	<p>Our audit procedures related to Chapter 11 bankruptcy included the following, among others:</p> <ul style="list-style-type: none"> <li>• We tested the effectiveness of controls including management's review of the legal background and facts, applicable accounting guidance, and related disclosure.</li> <li>• We inspected Bankruptcy Court documents, including motions and orders.</li> <li>• We corroborated key facts about the bankruptcy proceedings through our inquiries with internal legal counsel and executive members of management.</li> <li>• We requested and received written responses from internal and external legal counsel regarding the bankruptcy proceedings.</li> <li>• With the assistance of professionals in our firm having expertise in complex accounting and reporting matters, we evaluated the Group's conclusions regarding the application of ASC 852 - Reorganizations.</li> <li>• We evaluated the Group's disclosures for consistency with our knowledge of the status of the Chapter 11 bankruptcy proceedings.</li> </ul>
<b>Key observations</b>	<p>We have no observations that impact on our audit in respect of the Chapter 11 Bankruptcy - Liabilities Subject to Compromise.</p>

Our audit procedures relating to these matters were designed in the context of our audit of the financial statements as a whole, and not to express an opinion on individual accounts or disclosures. Our opinion on the financial statements is not modified with respect to any of the risks described above, and we do not express an opinion on these individual matters.

### **Our application of materiality**

We define materiality as the magnitude of misstatement that makes it probable that the economic decisions of a reasonably knowledgeable person, relying on the financial statements, would be changed or influenced. We use materiality both in planning the scope of our audit work and in evaluating the results of our work.

We determined materiality for the Group to be \$20.0 million, which is approximately 2.53% of loss on ordinary activities before taxation. We have considered the benchmark selected to be the critical component for determining materiality because we determined this result to be of most importance to the principal external users of the financial statements. We have considered quantitative and qualitative factors such as understanding the entity and its environment, history of misstatements, complexity of the Group, and the reliability of the control environment in our determination of materiality.

We agreed with the Audit Committee that we would report to them any audit differences in excess of \$1.0 million or 5.0% of materiality, as well as differences below that threshold which, in our view, warranted reporting on qualitative grounds. We also

report to the Audit Committee on disclosure matters that we identified when assessing the overall presentation of the financial statements.

### **An overview of the scope of our audit**

Our Group audit was scoped by obtaining an understanding of the Group and its environment, including Group-wide controls, and assessing the risks of material misstatement at the Group level. Based on that assessment, we focused our Group audit scope primarily on the audit work in two significant components representing the Group's two reportable segments Specialty Brands and Specialty Generics, which were subject to a full scope audit. These two components represent the principal business units and account for the majority of the Group's net assets, revenue and loss before tax. They were also selected to provide an appropriate basis for undertaking audit work to address the risks of material misstatement identified above. Our audit work at the two components was executed at levels of materiality applicable to each individual component which were lower than Group materiality - \$14.4 million for Specialty Brands and \$12.8 million for Specialty Generics.

### **Other information**

The other information comprises the information included in the Directors' Report and Consolidated Financial Statements for the financial year ended 31 December 2021, other than the financial statements and our auditor's report thereon. The directors are responsible for the other information. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

Our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

### **Responsibilities of directors**

As explained more fully in the Directors' Responsibilities Statement, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view and otherwise comply with the Companies Act 2014, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Group or to cease operations, or have no realistic alternative but to do so.

### **Auditor's responsibilities for the audit of the financial statements**

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs (Ireland), we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of the auditor's report. However, future events or conditions may cause the entity (or where relevant, the Group) to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the business activities within the group to express an opinion on the consolidated financial statements. The Group auditor is responsible for the direction, supervision and performance of the Group audit. The Group auditor remains solely responsible for the audit opinion.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that the auditor identifies during the audit.

For listed entities and public interest entities, the auditor also provides those charged with governance with a statement that the auditor has complied with relevant ethical requirements regarding independence, including the Ethical Standard for Auditors (Ireland), and communicates with them all relationships and other matters that may reasonably be thought to bear on the auditor's independence, and where applicable, related safeguards.

Where the auditor is required to report on key audit matters, from the matters communicated with those charged with governance, the auditor determines those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. The auditor describes these matters in the auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, the auditor determines that a matter should not be communicated in the auditor's report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

### **Report on other legal and regulatory requirements Opinion on other matters prescribed by the Companies Act 2014**

Based solely on the work undertaken in the course of the audit, we report that:

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- The financial statements are in agreement with the accounting records.
- In our opinion the information given in those parts of the directors' report as specified for our review is consistent with the financial statements and the directors' report has been prepared in accordance with the Companies Act 2014.

### **Matters on which we are required to report by exception**

Based on the knowledge and understanding of the Group and its environment obtained in the course of the audit, we have not identified material misstatements in those parts of the directors' report as specified for our review.

The Companies Act 2014 also requires us to report to you if, in our opinion, the Group has not provided the information required by Regulation 5(2) to 5(7) of the European Union (Disclosure of Non-Financial and Diversity Information by certain large undertakings and groups) Regulations 2017 (as amended) for the financial year ended 31 December 2021. We have nothing to report in this regard.

We have nothing to report in respect of the provisions in the Companies Act 2014 which require us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by law are not made.



## Use of our report

This report is made solely to the company's members, as a body, in accordance with Section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company and the company's members as a body, for our audit work, for this report, or for the opinions we have formed.



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Richard Howard

For and on behalf of Deloitte Ireland LLP

Chartered Accountants and Statutory Audit Firm

Deloitte & Touche House, Earlsfort Terrace, Dublin 2

Date: 1 April, 2022

**MALLINCKRODT PLC**  
**(DEBTOR-IN-POSSESSION)**  
**(IN EXAMINATION UNDER PART 10 OF THE IRISH COMPANIES ACT 2014)**  
**CONSOLIDATED PROFIT AND LOSS ACCOUNT**  
*(in millions, except per share data)*

	Note	Fiscal Year					
		2021			2020		
		Ordinary Activities	Discontinued Operations	Total	Ordinary Activities	Discontinued Operations	Total
Turnover <sup>1</sup>	4, 5	\$ 2,208.8	\$ —	\$ 2,208.8	\$ 2,213.4	\$ —	\$ 2,213.4
Cost of sales		1,317.1	—	1,317.1	1,544.0	—	1,544.0
<b>Gross profit</b>		891.7	—	891.7	669.4	—	669.4
Distribution and administrative expenses		608.5	—	608.5	868.5	—	868.5
Research and development costs		205.2	—	205.2	290.8	—	290.8
Restructuring charges, net	6	26.9	—	26.9	37.5	—	37.5
Non-restructuring impairment charges	15	90.4	—	90.4	128.0	—	128.0
Loss (profit) on disposal of operations	7	0.8	(1.1)	(0.3)	(16.6)	(8.9)	(25.5)
Opioid-related litigation settlement loss (gain)	25	125.0	—	125.0	(43.4)	—	(43.4)
Medicaid lawsuit	25	—	—	—	105.1	—	105.1
<b>Operating (loss) profit</b>		(165.1)	1.1	(164.0)	(700.5)	8.9	(691.6)
Interest payable and similar expenses	8	(222.6)	—	(222.6)	(261.1)	—	(261.1)
Interest receivable and similar income		1.9	—	1.9	5.9	—	5.9
Other income, net		22.0	—	22.0	7.4	—	7.4
Reorganization items, net	2	(428.2)	—	(428.2)	(61.4)	—	(61.4)
<b>(Loss) profit on ordinary activities before taxation</b>		(792.0)	1.1	(790.9)	(1,009.7)	8.9	(1,000.8)
Taxation (credit) charge	9	(106.3)	(5.0)	(111.3)	8.9	(16.2)	(7.3)
<b>(Loss) profit after taxation</b>		<u>\$ (685.7)</u>	<u>\$ 6.1</u>	<u>\$ (679.6)</u>	<u>\$ (1,018.6)</u>	<u>\$ 25.1</u>	<u>\$ (993.5)</u>
<b>Basic/Diluted (loss) earnings per ordinary share:</b>	10	\$ (8.10)	\$ 0.07	\$ (8.02)	\$ (12.05)	\$ 0.30	\$ (11.76)

(1) Fiscal 2020 includes the refined estimate of the retrospective one-time charge of \$536.0 million related to the Medicaid lawsuit.

**MALLINCKRODT PLC**  
**(DEBTOR-IN-POSSESSION)**  
**(IN EXAMINATION UNDER PART 10 OF THE IRISH COMPANIES ACT 2014)**  
**CONSOLIDATED STATEMENT OF OTHER COMPREHENSIVE LOSS**  
*(in millions)*

	<b>Fiscal Year</b>	
	<b>2021</b>	<b>2020</b>
<b>Loss after taxation</b>	\$ (679.6)	\$ (993.5)
<b>Other comprehensive profit (loss), net of taxation</b>		
Currency translation adjustments	(0.5)	2.1
Unrecognized gain on derivatives, net of tax charge	—	0.4
Unrecognized gain (loss) on benefit plans, net of tax charge	1.8	(4.2)
<b>Total other comprehensive profit (loss), net of taxation</b>	1.3	(1.7)
<b>Comprehensive loss</b>	<u>\$ (678.3)</u>	<u>\$ (995.2)</u>

**MALLINCKRODT PLC**  
**(DEBTOR-IN-POSSESSION)**  
**(IN EXAMINATION UNDER PART 10 OF THE IRISH COMPANIES ACT 2014)**  
**CONSOLIDATED BALANCE SHEET**  
*(in millions)*

	Note	December 31, 2021	December 25, 2020
<b>Fixed Assets</b>			
Intangible assets	15	\$ 5,448.4	\$ 6,120.0
Tangible assets	16	811.0	891.7
Financial assets	17	191.3	175.9
		<u>6,450.7</u>	<u>7,187.6</u>
<b>Current Assets</b>			
Stocks	18	347.2	344.9
Debtors	19	773.4	1,047.8
Cash at bank and in hand		1,345.0	1,070.6
		<u>2,465.6</u>	<u>2,463.3</u>
Creditors (amounts falling due within one year)	20	5,754.8	5,865.9
<b>Net Current Liabilities</b>		<u>(3,289.2)</u>	<u>(3,402.6)</u>
<b>Total Assets Less Current Liabilities</b>		<u>3,161.5</u>	<u>3,785.0</u>
Creditors (amounts falling due after one year)	21	153.5	224.4
Provisions for Liabilities	27	2,705.7	2,590.3
<b>Net Assets</b>		<u>\$ 302.3</u>	<u>\$ 970.3</u>
<b>Capital and Reserves</b>			
Called-up share capital presented as equity	28	\$ 18.9	\$ 18.8
Share premium account		5.7	5.7
Other reserves	28	1,586.9	1,575.4
Profit and loss account	28	(1,309.2)	(629.6)
<b>Shareholders' Funds</b>		<u>\$ 302.3</u>	<u>\$ 970.3</u>

Approved by the Board of Directors on 1 April 2022 and signed on its behalf by:

/s/ JoAnn A. Reed  
 JoAnn A. Reed  
 Director

/s/ Mark C. Trudeau  
 Mark C. Trudeau  
 Director

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

	Fiscal Year	
	2021	2020
<b>Cash Flows From Ordinary Operating Activities:</b>		
Loss after taxation	\$ (679.6)	\$ (993.5)
Adjustments to reconcile net cash provided by ordinary operating activities:		
Depreciation and amortization	675.8	885.2
Share-based compensation	10.2	25.3
Deferred taxation	(59.9)	385.3
Non-cash impairment charges	90.4	128.0
Stocks provisions	11.5	18.5
Losses (gains) on divestiture	0.8	(16.6)
Other non-cash items	(13.1)	(40.2)
Reorganization items, net	22.5	10.2
Changes in assets and liabilities, net of the effects of acquisitions:		
Trade debtors	98.2	37.9
Stocks	(14.0)	(51.1)
Trade creditors	(1.1)	15.7
Taxation	108.5	(433.8)
Opioid-related litigation settlement liability	125.0	—
Medicaid lawsuit	(4.2)	638.9
Other	84.4	(110.9)
Net cash from ordinary operating activities	<u>455.4</u>	<u>498.9</u>
<b>Cash Flows From Ordinary Investing Activities:</b>		
Capital expenditures	(55.3)	(47.7)
Proceeds (payments) from divestitures, net of cash	15.7	(0.7)
Other	1.8	37.2
Net cash from ordinary investing activities	<u>(37.8)</u>	<u>(11.2)</u>
<b>Cash Flows From Ordinary Financing Activities:</b>		
Repayment of external debt	(137.5)	(139.5)
Debt financing costs	—	(9.4)
Repurchase of shares	—	(0.4)
Other	—	(36.3)
Net cash from ordinary financing activities	<u>(137.5)</u>	<u>(185.6)</u>
Effect of currency rate changes on cash at bank and in hand	(1.9)	2.3
<b>Net change in cash at bank and in hand and restricted cash</b>	<u>278.2</u>	<u>304.4</u>
<b>Cash at bank and in hand and restricted cash at beginning of period</b>	<u>1,127.0</u>	<u>822.6</u>
<b>Cash at bank and in hand and restricted cash at end of period</b>	<u>\$ 1,405.2</u>	<u>\$ 1,127.0</u>
<b>Cash at bank and in hand at end of period</b>	1,345.0	\$ 1,070.6
<b>Restricted Cash, current at end of period</b>	24.0	20.2
<b>Restricted Cash, Noncurrent at end of period</b>	36.2	36.2
<b>Cash at bank and in hand at end of period</b>	<u>\$ 1,405.2</u>	<u>\$ 1,127.0</u>
<b>Supplemental Disclosures of Cash Flow Information:</b>		
Cash paid for interest, net	\$ 243.2	\$ 256.1
Cash (received) paid for taxation, net	(160.0)	39.9

**MALLINCKRODT PLC**  
**(DEBTOR-IN-POSSESSION)**  
**(IN EXAMINATION UNDER PART 10 OF THE IRISH COMPANIES ACT 2014)**  
**CONSOLIDATED STATEMENT OF CHANGES IN EQUITY**  
*(in millions)*

	Called-up Share Capital			Other Reserves			Profit and Loss Account	Total
	Number	Amount	Share Premium Account	Capital Redemption Reserve	Other (Note 28)	Accumulated Other Comprehensive Loss		
<b>Balance as of December 27, 2019</b>	93.5	\$ 18.7	\$ 5.7	\$ 5.3	\$ 1,554.6	\$ (7.9)	\$ 364.3	\$ 1,940.7
Loss after taxation	—	—	—	—	—	—	(993.5)	(993.5)
Other comprehensive profit, net of tax	—	—	—	—	—	(1.7)	—	(1.7)
Vesting of restricted shares	0.6	0.1	—	—	(0.2)	—	(0.4)	(0.5)
Share-based compensation	—	—	—	—	25.3	—	—	25.3
<b>Balance as of December 25, 2020</b>	94.1	18.8	5.7	5.3	1,579.7	(9.6)	(629.6)	970.3
Loss after taxation	—	—	—	—	—	—	(679.6)	(679.6)
Other comprehensive loss, net of tax	—	—	—	—	—	1.3	—	1.3
Vesting of restricted shares	0.2	0.1	—	—	—	—	—	0.1
Share-based compensation	—	—	—	—	10.2	—	—	10.2
<b>Balance as of December 31, 2021</b>	94.3	\$ 18.9	\$ 5.7	\$ 5.3	\$ 1,589.9	\$ (8.3)	\$ (1,309.2)	\$ 302.3

**MALLINCKRODT PLC**  
**(DEBTOR-IN-POSSESSION)**  
**(IN EXAMINATION UNDER PART 10 OF THE IRISH COMPANIES ACT 2014)**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
*(dollars in millions, except share data and where indicated)*

## **1. Background and Basis of Presentation**

### ***Background***

Mallinckrodt plc (debtor-in-possession) (in examination under Part 10 of the Irish Companies Act 2014) is a public limited company incorporated in the Republic of Ireland with the registration number 522227. The business address of its registered office and principal executive offices is College Business and Technology Park, Cruiserath, Blanchardstown, Dublin 15, Ireland.

Mallinckrodt plc is a global business of multiple wholly owned subsidiaries (collectively, "Mallinckrodt" or "the Group"), whose principal activities is to 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 Group 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 Group continues to be subject to United States ("U.S.") Securities and Exchange Commission ("SEC") reporting requirements.

### ***Basis of Presentation***

The directors have elected to prepare the Irish statutory Mallinckrodt plc consolidated financial statements in accordance with Section 279 of the Irish Companies Act 2014, which provides that a true and fair view of the assets and liabilities, financial position and profit or loss may be given by preparing the financial statements in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP") to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of Part 6 of the Irish Companies Act 2014.

The directors have elected to prepare the Mallinckrodt plc parent company financial statements in accordance with the Financial Reporting Standards applicable in the Republic of Ireland ("FRS 102") together with the Irish Companies Act 2014 as they are prepared specifically to present to shareholders and file with the Companies Registration Office in Ireland. Accordingly, these consolidated financial statements represent the results and financial position of Mallinckrodt plc and include disclosures required by the Irish Companies Act 2014, in addition to those required under U.S. GAAP as well as any other adjustments required by Irish law.

The consolidated financial statements have been prepared in U.S. dollars and in accordance with U.S. GAAP. The preparation of the consolidated financial statements in conformity with U.S. 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 turnover and expenses. Actual results may differ from those estimates. The consolidated financial statements include the accounts of Mallinckrodt plc, its wholly owned subsidiaries and entities in which they own or control more than 50.0% of the voting shares, or have the ability to control through similar rights. All intercompany balances and transactions have been eliminated in consolidation and all normal recurring adjustments necessary for a fair presentation have been included in the results reported.

The results of entities disposed of are included in the consolidated financial statements up to the date of disposal and, where appropriate, these operations have been reflected as discontinued operations. Divestitures of product lines and businesses not meeting the criteria for discontinued operations have been reflected in operating loss within ordinary activities.

Under Irish law, the Group can only pay dividends and repurchase shares out of distributable reserves. Net loss after taxation has been included in the profit and loss account and is included in distributable reserves. The format of the consolidated profit and loss account has been adopted where necessary to better reflect the nature of the business.

## ***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 25 as *Opioid-Related Matters* and *Acthar Gel-Related Matters*. In connection with the filing of the Chapter 11 Cases, the Group 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 (as defined in Note 2) 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 Directors' Report 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 Group's Chapter 11 plan of reorganization. See Note 29 for further information on the examinership process commenced by Mallinckrodt plc with the High Court of Ireland on February 14, 2022.

The U.S. Bankruptcy Court for the District of Delaware (the "Bankruptcy Court") has entered an order (the "Confirmation Order") confirming fourth amended plan of reorganizations (with technical modifications) proposed by the Debtors (the "Plan") and the directors remain confident that the transactions contemplated by the Plan have a reasonable prospect of being successfully implemented; however, this is not within the Group's control but rather is subject to approval by the Bankruptcy Court, including completion of the Canadian and Irish proceedings, among other conditions. As such, the directors have concluded that the outcome of the Chapter 11 Cases represents a material uncertainty, which casts significant doubt about the Group's ability to continue as a going concern. The Group's ability to continue as a going concern is contingent upon, among other things, its ability to, subject to the approval by 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<sup>®</sup> Gel (repository corticotropin injection) ("Acthar Gel")-related settlements, restructured debt obligations, and operating needs.

Although the directors believe that the Group's reorganization through the Chapter 11 proceedings will appropriately position the Group upon emergence, the commencement of these proceedings constituted an event of default under certain of the Group'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 Group's bankruptcy, including, among others that: (a) the Group's prearranged plan of reorganization may never become effective, (b) the Plan 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.

Having reviewed cash flow forecasts prepared by management and approved by the Board of Directors that assume the successful consummation of the transactions contemplated by the Plan and considering the uncertainties described above, the directors have a reasonable expectation that the Group will be able to successfully navigate the Chapter 11 proceedings and that the Group will be able to continue as a going concern for a period of twelve months from the date of approval of these financial statements and are satisfied to prepare the consolidated financial statements on a going concern basis. The consolidated financial statements do not include any adjustments that would be required if the Group were unable to continue as a going concern.

Pursuant to sections 1107(a) and 1108 of the Bankruptcy Code, the Debtors 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 Group's consolidated financial statements. For more information regarding the Chapter 11 Cases, see Note 2.

## ***Preferred Shares***

Mallinckrodt plc is authorized to issue 500,000,000 preferred shares, par value of \$0.20 per share, none of which were issued and outstanding as of 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 plc's Board of Directors on or before the time of



issuance. In the event of the liquidation of Mallinckrodt plc, 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.

### ***Fiscal Year***

The Group 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 consisted of 52 weeks. Unless otherwise indicated, fiscal 2021 and 2020 refer to the Group's fiscal years ended December 31, 2021 and December 25, 2020, respectively. All references to "fiscal" year are considered to be defined as "financial" year under FRS 102.

## **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 Group, substantially all of the Group'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 Group's international subsidiaries (together with the Group, 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 Group'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 Group 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 Group'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 Directors' Report, 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 Group 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 Group 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 Group 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:

	<b>Fiscal Year</b>	
	<b>2021</b>	<b>2020</b>
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 Group'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 25 for further discussion.

## ***Restructuring Support Agreement and Plan of Reorganization***

### *Restructuring Support Agreement*

On October 11, 2020, the Group and the other Debtors entered into a RSA with creditors holding approximately 84%, by aggregate principal amount, of the Group's outstanding guaranteed unsecured senior notes and with a group of governmental plaintiffs in the opioid litigation pending against the Group 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 "MSGGE 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 MSGGE Group, the "RSA Supporting Parties") approximately \$1,300.0 million, by aggregate principal amount, of the Group'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 Group'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 29 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 MSGGE Group, and the Official Committee of Opioid Related Claimants appointed in the Chapter 11 Cases (the "OCC" and, together with the GAHC and the MSGGE 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 Group'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 Group 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 Group'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 Group'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 Group'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 Group 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 Group 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 Group entering the Chapter 11 restructuring process, the Group 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 turnover, based on current Acthar Gel pricing. Also in connection with the Proposed Acthar Gel-Related Settlement, the Group 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 Group 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 Group's senior secured term loans.* At the end of the court-supervised process, lenders holding allowed claims in respect of the Group'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 Group's 2017 and 2018 Term Loans on March 19, 2021.

- *The reinstatement or repayment of the Groups 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 Groups 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 Group's 10.00% second lien senior notes.* At the end of the court-supervised process, lenders holding allowed claims in respect of the Group'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 Group'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 29 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 Group's debt agreements. Subject to any applicable provisions of the Bankruptcy Code, the Group's debt instruments and agreements described in Note 22 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 Group 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 profit and loss account. In addition, the Group identified 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 Group 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 as further described below. 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:

	<b>December 31, 2021</b>	<b>December 25, 2020</b>
Intercompany receivables	\$ 119.1	\$ 282.3
Intercompany payables	112.9	120.3

The intercompany balances were primarily attributable to the Group'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 Group is currently assessing whether or not it qualifies for fresh start accounting upon emergence from Chapter 11. If the Group 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
Trade creditors <sup>(1)</sup>	\$ 42.9	\$ 61.9
Accrued interest	35.2	35.2
Debt <sup>(2)</sup>	3,750.8	1,660.7
Accruals and other creditors <sup>(3)</sup>	46.4	51.0
Creditors (amounts falling due within one year)	3,875.3	1,808.8
Lease liabilities <sup>(3)</sup>	—	28.9
Creditors (amounts falling due after one year)	—	28.9
Pensions and similar obligations	32.0	32.4
Environmental provisions <sup>(4)</sup>	63.1	—
Medicaid lawsuit	634.7	638.9
Opioid-related litigation settlement liability <sup>(5)</sup>	1,725.0	1,600.0
Other provisions <sup>(6)</sup>	78.7	68.0
Provisions for liabilities	2,533.5	2,339.3
<b>Total liabilities subject to compromise</b>	<b>\$ 6,408.8</b>	<b>\$ 4,177.0</b>

- (1) Pre-petition trade creditors 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 as of December 31, 2021.
- (3) The decrease in accruals and other creditors (amounts falling due within one year) and lease amounts falling due after one year was attributable to the Bankruptcy Court's approval of the Group'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. The remaining change was attributable to various increases and decreases as a result of adjustments in the ordinary course of business.
- (4) Represents certain environmental liabilities intended to be discharged upon effectiveness of the plan of reorganization.
- (5) 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 Group 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 as of December 31, 2021.
- (6) The increase in other provisions was primarily driven 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 25) administrative claims were without merit. The remaining change 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 Group 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 Group'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 Group's consolidated profit and loss account 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 Group'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	<u>\$ 428.2</u>	<u>\$ 61.4</u>

### **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 within Note 2 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.

#### ***Turnover Recognition***

##### *Product Turnover*

The Group 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 Group 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, turnover incentives, chargebacks, distribution service agreements fees, fees for services and administration fees and discounts with respect to the purchase of the Group's products.

##### *Reserve for Variable Considerations*

Product turnover is recorded at the turnover 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 turnover deductions that are offered within contracts between the Group and its customers, health care providers and payers relating to the Group's turnover of its products. These reserves are based on the amounts earned or to be claimed on the related turnover and are classified as reductions of trade debtors (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 Group's historical experience, estimated future trends, estimated customer stocks levels, current contracted turnover terms with customers, level of utilization of the Group's products and other competitive factors. Overall, these reserves reflect the Group'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 turnover 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 Group adjusts reserves for chargebacks, rebates, product returns and other turnover deductions to reflect differences between estimated and actual experience. Such adjustments impact the amount of turnover recognized in the period of adjustment.

Product turnover are recognized when the customer obtains control of the Group'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 Group'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 Group's determination of the measure that best aligns with how the obligation is satisfied. The Group'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 Group either has:
  1. the right to invoice the customer in an amount that directly corresponds with the value to the customer of the Group'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 Group's product does not vary, regardless of consumption. As a result, the Group'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 Group'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 Group's contracts are short-term in nature, turnover commissions are generally expensed when incurred as the amortization period would have been less than one year. These costs are recorded within distribution and administrative expense ("D&A") in the consolidated profit and loss account. For contracts that extend beyond one year, the incremental expense recognition matches the recognition of related revenue.

#### *Costs to fulfill a contract*

The Group capitalizes the costs associated with the devices used in the Group'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 Group's cost to produce the asset, which is classified in tangible assets on the consolidated balance sheets and expensed to cost of sales over the useful life of the equipment.

#### *Product Royalty Revenues*

The Group licenses certain rights to Amitiza<sup>®</sup> (lubiprostone) ("Amitiza") to third parties in exchange for royalties on turnover of the product. The Group recognizes such royalty revenue as the related turnover occur.

#### *Contract Balances*

Trade debtors are recorded when the right to consideration becomes unconditional. Payments received from customers are typically based upon payment terms of 30 days. The Group does not maintain contract asset balances aside from the trade debtor 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 D&A on the consolidated profit and loss account. Contract liabilities are recorded when cash payments are received in advance of the Group's performance, including amounts which are refundable.

Taxes collected from customers relating to product turnover and remitted to governmental authorities are accounted for on a net basis. Accordingly, such taxes are excluded from both turnover and expenses.

### *Shipping and Handling Costs*

Shipping costs, which are costs incurred to physically move product from the Group's premises to the customer's premises, are classified as D&A expenses. Handling costs, which are costs incurred to store, move and prepare product for shipment, are classified as cost of sales. Shipping costs included in D&A expenses were \$23.6 million and \$20.1 million for fiscal 2021 and 2020, respectively.

### ***Research and Development***

Internal research and development ("R&D") costs are expensed as incurred. R&D costs 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 Group 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.

The information required by paragraph 63(4) of Schedule 3 of the Irish Companies Act 2014 is not provided as it would be prejudicial to the interest of the Group.

### ***Currency Translation***

For the Group'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. Turnover 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 Group 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 loss after taxation.

### ***Cash at Bank and In Hand***

The Group 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 Group of three months or less, as cash at bank and in hand.

### ***Trade Debtors and Allowance for Doubtful Accounts***

Trade debtors are presented net of an allowance for doubtful accounts. The allowance for doubtful accounts reflects an estimate of losses inherent in the Group's portfolio of trade debtors determined on the basis of historical experience, current facts and circumstances, reasonable and supportable forecasts and other available evidence. Trade debtors are written off when management determines they are uncollectible. Trade debtors are also presented net of reserves related to chargebacks and rebates payable to customers with whom the Group has trade debtors and the right of offset exists.

### ***Stocks***

Stocks are recorded at the lower of cost or net realizable value, primarily using the first-in, first-out convention. The Group reduces the carrying value of stocks for those items that are potentially excess, obsolete or slow-moving based on changes in customer demand, technology developments or other economic factors.

## ***Tangible Assets***

### *Owned Tangible Assets*

Tangible assets are 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 tangible assets, other than land and construction in process, is generally based upon the following estimated useful lives, using the straight-line method:

Buildings	10	to	45 years
Leasehold improvements	1	to	20 years
Capitalized software	1	to	10 years
Machinery and equipment	1	to	20 years

The Group capitalizes certain computer software and development costs incurred in connection with developing or obtaining software for internal use.

Upon retirement or other disposal of tangible assets, 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 the profit and loss account.

The Group assesses the recoverability of assets or asset groups using undiscounted cash flows whenever events or circumstances indicate that the carrying value of an asset 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.

### *Lease Assets*

The Group assesses all contracts at inception to determine whether a lease exists. The Group 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 Group recognizes lease expense for these leases on a straight-line basis over the lease term. The Group has lease agreements with lease and non-lease components, which are accounted for separately. The Group'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 Group's leases do not generally provide an implicit rate, the Group utilized 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 Group'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 Group 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 Group allocates any excess purchase price over the fair value of the net tangible and intangible assets acquired to goodwill.

The Group'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 Group 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 Group 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***

Irish company law requires indefinite-lived intangible assets to be amortized; however, the directors do not believe that this gives a true and fair value because not all intangible assets decline in value. Therefore, to present a true and fair value of the economic reality, under U.S. GAAP, certain other intangible assets are considered indefinite-lived and are not amortized.

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 Group'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 Group's ability to sell, market and distribute products is included in D&A expenses.

When an impairment triggering event occurs, the Group 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 Group 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 Group 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 Group 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 Group 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 25. The Group records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. The Group 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 Group 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). For more information about the Group's share-based awards, refer to Note 11.

## Restructuring

The Group recognizes charges associated with the Group'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 Group accrues for costs when they are probable and reasonably estimable.

## Taxation

Deferred tax assets and liabilities are recognized for the expected future taxation 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 Group determines whether it is more likely than not that a tax position will be sustained upon examination. The taxation credit 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, a tax liability, or a reduction to a deferred tax asset is established. Interest and penalties on tax obligations, associated with uncertain tax positions, are included in the provision for taxation.

The calculation of the Group's tax liabilities involves dealing with uncertainties in the application of complex tax regulations in a multitude of jurisdictions across the Group'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 Group'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 taxation credits being recognized in the period when it is determined that the liabilities are no longer necessary. Refer to Note 9 for further information regarding the classification of such amounts in the consolidated balance sheets.

## 4. Turnover from Contracts with Customers

### Product Turnover

See Note 5 for presentation of the Group's turnover 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 Group's turnover reserve accounts, on an ordinary activity basis:

	Rebates and Chargebacks	Product Returns	Other Turnover Deductions	Total
<b>Balance as of December 27, 2019</b>	\$ 295.8	\$ 28.4	\$ 13.2	\$ 337.4
Provisions	2,065.9	28.9	59.5	2,154.3
Provision for Medicaid lawsuit (Note 27) <sup>(1)</sup>	536.0	—	—	536.0
Payments or credits	(2,701.2)	(30.7)	(60.4)	(2,792.3)
<b>Balance as of December 25, 2020</b>	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)
<b>Balance as of December 31, 2021</b>	\$ 241.8	\$ 21.5	\$ 9.5	\$ 272.8

- (1) Excludes the \$105.1 million that is reflected as a component of operating loss as it represents a pre-acquisition contingency related to the portion of the liability that arose from turnover of Acthar Gel prior to the Group's acquisition of Questcor in August 2014. See Note 25 for further detail on the status of the Medicaid lawsuit.

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

	Fiscal Year	
	2021	2020
Product turnover transferred at a point in time	79.4 %	78.9 %
Product turnover transferred over time	20.6	21.1

*Transaction price allocated to the remaining performance obligations*

The following table includes estimated turnover from contracts extending greater than one year for certain of the Group'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 Group's portfolio of drug-device combination products, which are used in satisfying future performance obligations, was \$25.8 million and were classified as tangible assets on the consolidated balance sheets. The associated depreciation expense recognized during fiscal 2021 and 2020 was \$6.1 million and \$5.5 million, respectively.

**Product Royalty Turnover**

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

**5. Segment and Geographical Data**

The Group 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 Group's operating segments based on segment turnover and operating profit. Management excludes corporate expenses from segment operating profit. In addition, certain amounts that management considers to be non-recurring or non-operational are excluded from segment turnover and operating profit 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 (as defined in Note 25) incurred as a result of the Medicaid lawsuit. Although these amounts are excluded from segment turnover and operating profit, as applicable, they are included in reported consolidated turnover and operating loss and are reflected in the reconciliations presented below.

Management manages assets on a total Group basis, not by operating segment. The Group's chief operating decision maker does not regularly review any asset information by operating segment and, accordingly, the Group does not report asset information by operating segment. Total assets were approximately \$8,916.3 million and \$9,650.9 million as of December 31, 2021 and December 25, 2020, respectively.

Selected information by reportable segment was as follows:

	Fiscal Year	
	2021	2020
<b>Turnover:</b>		
Specialty Brands <sup>(1)</sup>	\$ 1,547.0	\$ 2,059.6
Specialty Generics	661.8	689.8
Segment turnover	2,208.8	2,749.4
Medicaid lawsuit (Note 25) <sup>(1)</sup>	—	(536.0)
<b>Turnover</b>	<b>2,208.8</b>	<b>2,213.4</b>
<b>Operating (loss) profit:</b>		
Specialty Brands	\$ 812.8	\$ 1,015.7
Specialty Generics	107.9	206.4
Segment operating profit	920.7	1,222.1
Unallocated amounts:		
Corporate and unallocated expenses <sup>(2)</sup>	(156.3)	(150.5)
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	(90.4)	(128.0)
Separation costs <sup>(3)</sup>	(1.2)	(93.4)
R&D upfront payment <sup>(4)</sup>	—	(5.0)
Opioid-related litigation settlement (loss) gain (Note 25)	(125.0)	43.4
Medicaid lawsuit (Note 25) <sup>(1)</sup>	—	(641.1)
<b>Operating loss</b>	<b>\$ (165.1)</b>	<b>\$ (700.5)</b>
<b>Depreciation and amortization:</b>		
Specialty Brands	\$ 597.7	\$ 799.3
Specialty Generics	78.1	85.9
Depreciation and amortization	<b>\$ 675.8</b>	<b>\$ 885.2</b>

- (1) Specialty Brands turnover for fiscal 2020 includes the prospective change to the Medicaid rebate calculation, which served to reduce Acthar Gel turnover by \$40.4 million for the period from June 15, 2020 through December 25, 2020. See Note 25 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 Group's reportable segments.
- (3) Represents costs included in D&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.

Turnover by product family from continuing activities within the Group's segments was as follows:

	Fiscal Year	
	2021	2020
Acthar Gel <sup>(1)</sup>	\$ 593.6	\$ 767.9
INOmax	448.5	574.1
Ofirmev	28.9	276.5
Therakos	266.5	238.6
Amitiza <sup>(2)</sup>	196.9	188.8
Other	12.6	13.7
Specialty Brands	<u>1,547.0</u>	<u>2,059.6</u>
Hydrocodone (API) and hydrocodone-containing tablets	82.7	98.0
Oxycodone (API) and oxycodone-containing tablets	68.5	68.4
Acetaminophen (API)	215.9	213.0
Other controlled substances	272.7	289.9
Other	22.0	20.5
Specialty Generics	<u>661.8</u>	<u>689.8</u>
Segment turnover	2,208.8	2,749.4
Medicaid lawsuit (Note 25)	—	(536.0)
Turnover	<u>\$ 2,208.8</u>	<u>\$ 2,213.4</u>

(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 25 for further detail on the status of the Medicaid lawsuit.

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

Selected information by geographic area was as follows:

	Fiscal Year	
	2021	2020
<b>Turnover <sup>(1)</sup>:</b>		
U.S.	\$ 1,991.8	\$ 2,465.5
Europe, Middle East and Africa	181.8	227.5
Other	35.2	56.4
Geographic area turnover	<u>2,208.8</u>	<u>2,749.4</u>
Medicaid lawsuit (Note 25)	—	(536.0)
Turnover	<u>\$ 2,208.8</u>	<u>\$ 2,213.4</u>

	December 31, 2021	December 25, 2020
	<b>Long-lived assets <sup>(2)</sup>:</b>	
U.S.	\$ 629.3	\$ 676.3
Europe, Middle East and Africa <sup>(3)</sup>	156.2	165.5
Other	4.7	4.6
Long-lived assets	<u>\$ 790.2</u>	<u>\$ 846.4</u>

(1) Turnover is 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 owned tangible assets.

(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.



## 6. Restructuring and Related Charges

During fiscal 2021, 2018 and 2016, the Group 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 Group has taken restructuring actions to generate synergies from its acquisitions.

Net restructuring and related charges by segment were as follows:

	Fiscal Year	
	2021	2020
Specialty Brands	\$ 0.1	\$ 0.1
Specialty Generics	4.9	0.1
Corporate	24.0	49.6
Restructuring and related charges, net	29.0	49.8
Less: accelerated depreciation	(2.1)	(12.3)
Restructuring charges, net	\$ 26.9	\$ 37.5

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

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

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

	2018 Program	2016 Program	Acquisition Programs	Total
<b>Balance as of December 29, 2019</b>	\$ 2.7	\$ 31.3	\$ 0.2	\$ 34.2
Charges	28.6	0.1	—	28.7
Changes in estimate	(0.4)	(0.4)	(1.9)	(2.7)
Cash payments	(20.1)	(30.7)	(0.2)	(51.0)
Currency translation and other	0.2	(0.3)	1.9	1.8
<b>Balance as of December 25, 2020</b>	11.0	—	—	11.0
Charges	23.7	—	—	23.7
Changes in estimate	(4.3)	—	—	(4.3)
Cash payments	(12.8)	—	—	(12.8)
<b>Balance as of December 31, 2021</b>	17.6	—	—	17.6
Less: Liabilities subject to compromise <sup>(1)</sup>	(6.7)	—	—	(6.7)
Liabilities not subject to compromise	\$ 10.9	\$ —	\$ —	\$ 10.9

- (1) Represents certain restructuring reserve balances as a result of the Group rejecting certain of its executory contracts within provisions for liabilities. Total restructuring reserves included within LSTC in Note 2 was \$6.7 million and \$10.0 million as of December 31, 2021 and December 25, 2020, respectively.

As of December 31, 2021, net restructuring and related charges incurred cumulative to date were as follows:

	<u>2018 Program</u> <sup>(1)</sup>	<u>2016 Program</u> <sup>(2)</sup>
Specialty Brands	\$ 3.1	\$ 68.1
Specialty Generics	15.0	14.6
Corporate	77.9	28.6
	<u>\$ 96.0</u>	<u>\$ 111.3</u>

(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 provision for liabilities on the Group's consolidated balance sheets. Amounts paid in the future may differ from the amount currently recorded.

## 7. Discontinued Operations and Divestitures

### *Discontinued Operations*

*Nuclear Imaging.* The Group received a total of \$9.0 million in contingent consideration in fiscal 2020 related to the 2017 sale of the Nuclear Imaging business, consisting of the issuance of 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 statement of cash flows for fiscal 2020. On December 4, 2020, the issuer elected to redeem 100% of the outstanding preferred equity certificates, and the Group received a cash payment of \$32.5 million, which included \$29.8 million for the outstanding preferred equity certificates and \$2.7 million for accrued interest receivable through the redemption date. In addition, during fiscal 2020, a taxation credit of \$18.1 million, comprised of tax and interest on unrecognized tax benefits related to the Nuclear Imaging business, was recognized due to a lapse of statute of limitations.

### *Divestitures*

*PreveLeak/Recothrom.* In March 2018, the Group 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 Group recorded a \$16.5 million gain on divestiture related to certain commercial milestones for the Recothrom product. This divestiture did not meet the criteria for discontinued operations classification and accordingly was included in continuing operations.

## 8. Interest Payable and Similar Expenses

Interest payable and similar expenses are primarily related to loans made to the Group by credit institutions and were comprised of:

	<u>Fiscal Year</u>	
	<u>2021</u>	<u>2020</u>
Interest on debt repayable within five years, otherwise than by installment	\$ 122.8	\$ 113.3
Interest on debt repayable beyond five years, otherwise than by installment	—	68.1
Interest on debt repayable within five years, by installment <sup>(1)</sup>	110.6	85.6
Amortization of debt issue costs	5.4	13.0
Capitalized interest	(0.5)	(0.4)
Other <sup>(2)</sup>	(15.7)	(18.5)
Interest payable and similar expenses	<u>\$ 222.6</u>	<u>\$ 261.1</u>

(1) Includes interest expense incurred with respect to the incremental adequate protection payments on the senior secured revolving credit facility and the senior secured term loans of \$63.1 million and \$11.7 million during fiscal 2021 and 2020, respectively. Refer to Note 2 for further information.

(2) Includes other non-cash interest and U.S. Internal Revenue Code ("IRC") Section 453A ("Section 453A") interest. Refer to Note 25 for further information regarding Section 453A interest.

## 9. Taxation

The domestic and international components<sup>(1)</sup> of loss before taxation were as follows:

	Fiscal Year	
	2021	2020
Domestic	\$ (512.2)	\$ (656.9)
International	(278.7)	(343.9)
Total	<u>\$ (790.9)</u>	<u>\$ (1,000.8)</u>

(1) Domestic reflects Ireland in fiscal 2021 and 2020.

Significant components of taxation were as follows:

	Fiscal Year	
	2021	2020
Current:		
Domestic	\$ (33.7)	\$ 0.1
International	(17.7)	(392.7)
Current taxation (credit) charge	<u>(51.4)</u>	<u>(392.6)</u>
Deferred:		
Domestic	(59.5)	102.2
International	(0.4)	283.1
Deferred taxation charge (credit)	<u>(59.9)</u>	<u>385.3</u>
Total	<u>\$ (111.3)</u>	<u>\$ (7.3)</u>

The domestic current taxation reflects a taxation credit of \$2.2 million and \$0.2 million from using net operating loss ("NOL") carryforwards for fiscal 2021 and 2020, respectively. The international current taxation reflects a taxation credit of \$1.2 million and \$33.4 million from using NOL carryforwards for fiscal 2021 and 2020, respectively. The fiscal 2020 international current taxation also includes a taxation credit of \$1.0 million related to refundable credits and a taxation credit 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, net cash payments for income taxes were \$39.9 million. 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 U.S. Coronavirus Aid, Relief and Economic Security ("CARES") Act and net payments of \$18.8 million related to operational activity.

The reconciliation between domestic taxation at the statutory rate and the Group's taxation was as follows:

	Fiscal Year	
	2021	2020
Taxation credit at domestic statutory income tax rate <sup>(1)</sup>	\$ (98.9)	\$ (125.1)
Adjustments to reconcile to taxation charge (credit):		
Rate difference between domestic and international jurisdictions	(221.0)	(321.4)
Adjustments to accrued income tax liabilities and uncertain tax positions <sup>(2)</sup>	(14.7)	(0.5)
Credits, principally research and orphan drug	(4.7)	(11.2)
Permanently nondeductible and nontaxable items <sup>(3)</sup>	13.0	1.5
U.S. Tax Reform <sup>(4)</sup>	—	(281.5)
Legal entity reorganization <sup>(4)</sup>	—	82.0
Separation costs	—	8.4
Reorganization items, net	36.7	8.8
Other	0.6	0.1
Valuation allowances <sup>(5)</sup>	177.7	631.6
Taxation credit	<u>\$ (111.3)</u>	<u>\$ (7.3)</u>

(1) The statutory tax rate reflects the Irish statutory tax rate of 12.5%.

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

(3) For fiscal 2021, the permanently nondeductible and nontaxable items were primarily driven by the opioid-related litigation settlement loss that is partially permanently nondeductible.

(4) Associated unrecognized tax benefits and valuation allowance are netted within this line.

- (5) For fiscal 2020, an expense of \$204.9 million was included as a discrete valuation allowance on certain net deferred tax assets that were no longer more likely than not realizable, as explained within Note 1. Additional valuation allowance impacts are netted within other line items, as referenced in the associated footnotes to this table.

The rate difference between domestic and international jurisdictions changed to \$221.0 million of taxation credit for fiscal 2021 from \$321.4 million of taxation credit for fiscal 2020. Of the \$100.4 million decrease in the taxation credit, \$48.9 million of the decrease is attributable to the Medicaid lawsuit and \$89.7 million of decrease is predominately attributable to changes in the jurisdictional mix of operating loss resulting from the fiscal 2020 reorganization of the Group's intercompany financing and associated asset and legal entity ownership, partially offset by \$27.6 million of an increase attributable to reorganization items and \$10.6 million of an increase attributable to the opioid-related litigation settlement loss.

The Group's valuation allowance taxation charge was \$177.7 million for fiscal 2021, compared to \$631.6 million for fiscal 2020. Of the \$453.9 million decrease in taxation charge, \$314.3 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 taxation charge mainly offsets impacts included within the taxation credit at the domestic statutory income tax rate and the rate difference between domestic and international jurisdictions.

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

	Fiscal Year	
	2021	2020
Balance at beginning of period	\$ 349.0	\$ 398.6
Additions related to current year tax positions	—	71.1
Additions related to prior period tax positions	9.3	9.8
Reductions related to prior period tax positions	(2.8)	(14.2)
Settlements	(0.2)	(80.3)
Lapse of statute of limitations	(21.8)	(36.0)
Balance at end of period	<u>\$ 333.5</u>	<u>\$ 349.0</u>

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

	December 31, 2021	December 25, 2020
Debtors (falling due after one year) <sup>(1)</sup>	\$ 255.7	\$ 256.4
Creditors (amounts falling due after one year)	64.1	83.2
Provision for liabilities	13.7	9.4
	<u>\$ 333.5</u>	<u>\$ 349.0</u>

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

Included within total unrecognized tax benefits as of December 31, 2021 and December 25, 2020 were \$77.0 million and \$85.9 million, respectively, of unrecognized tax benefits, which if favorably settled would benefit the effective tax rate. The remaining unrecognized tax benefits are reflected as the write-off of related other tax assets. If these unrecognized tax benefits were recognized, they would be offset by a valuation allowance in fiscal 2021 and 2020. During fiscal 2021 and 2020, due to a lapse of the 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 taxation credit of \$5.1 million and \$18.1 million was recorded in discontinued operations within the consolidated profit and loss account, respectively. During fiscal 2021, the Group recorded \$6.4 million of additional interest and penalties through taxation and decreased accrued interest and penalties by \$4.2 million related to prior period reductions, settlements and lapse of statute of limitations. During fiscal 2020, the Group had a net decrease of interest and penalties activity of \$16.2 million. The total amount of accrued interest and penalties related to uncertain tax positions was \$18.9 million and \$16.7 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 Group'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.

Taxation 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
Creditors (amounts falling due within one year)	\$ 1.7	\$ 26.5
Creditors (amounts falling due after one year)	83.2	100.1
	<u>\$ 84.9</u>	<u>\$ 126.6</u>

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

	December 31, 2021	December 25, 2020
Debtors falling due within one year	\$ 36.5	\$ 188.7
Debtors falling due after one year	141.3	139.4
	<u>\$ 177.8</u>	<u>\$ 328.1</u>

Deferred taxation results from temporary differences between the amount of assets and liabilities recognized for financial reporting and tax purposes. The components of the net deferred tax liability 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	294.7	294.9
	<u>6,501.4</u>	<u>6,341.0</u>
Deferred tax liabilities:		
Intangible assets	(108.5)	(176.9)
Investment in partnership	(67.1)	(74.8)
Other	—	(44.8)
	<u>(175.6)</u>	<u>(296.5)</u>
Net deferred tax asset before valuation allowances	6,325.8	6,044.5
Valuation allowances	(6,346.7)	(6,125.1)
Net deferred tax liability	<u>\$ (20.9)</u>	<u>\$ (80.6)</u>

The net deferred tax asset before valuation allowances increased from \$6,044.5 million as of December 25, 2020 to \$6,325.8 million as of December 31, 2021 due to a \$181.3 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 \$78.6 million increase associated with intangible assets.

The deferred tax asset valuation allowances of \$6,346.7 million and \$6,125.1 million as of December 31, 2021 and December 25, 2020, respectively, relate both to the Group's material uncertainty about its ability to continue as a going concern, as well as the uncertainty of the utilization of certain deferred tax assets, driven by domestic and international net operating and capital losses, credits, intangible assets and the opioid-related settlement liability.

Deferred taxation activity for fiscal 2021 was as follows:

As of December 25, 2020	\$ (80.6)
Provisions	59.2
Currency translation and other	0.5
As of December 31, 2021	<u>\$ (20.9)</u>

Deferred taxation of \$20.9 million and \$80.6 million were included in provisions for liabilities on the consolidated balance sheets as of December 31, 2021 and December 25, 2020, respectively.

As of December 31, 2021, the Group 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 Group 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 Group 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 Group 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 Group also had \$83.9 million of tax credits available to reduce future taxation payables, 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 Group'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 Group's legal entity structure as well as the timing, extent, and nature of any hypothetical realization.

## 10. Loss per Ordinary 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 Group reported a net loss after taxation during all periods presented and therefore, the impact would have been anti-dilutive. During fiscal 2021 and 2020 the weighted-average number of shares outstanding used in the computations of basic and diluted loss per ordinary share were 84.7 million and 84.5 million, respectively.

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

## 11. Share Plans

Total share-based compensation cost was \$10.2 million and \$25.3 million for fiscal 2021 and 2020, respectively. These amounts are generally included within D&A expenses in the consolidated profit and loss account.

### *Stock Compensation Plans*

Over the years, the Group 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:

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

*Share options.* Share options are granted to purchase the Group'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
<b>Outstanding as of December 27, 2019</b>	6,890,700	\$ 36.39		
Expired/Forfeited	(820,988)	39.65		
<b>Outstanding as of December 25, 2020</b>	6,069,712	35.95		
Expired/Forfeited	(516,193)	45.63		
<b>Outstanding as of December 31, 2021</b>	<u>5,553,519</u>	35.05	1.7	\$ —
Vested and non-vested expected to vest as of December 31, 2021	<u>5,352,763</u>	35.14	5.5	\$ —
Exercisable as of December 31, 2021	<u>4,616,911</u>	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 Group'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 Group'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.

*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 Group's ordinary shares on the date of grant.

RSU activity was as follows:

	Shares	Weighted-Average Grant-Date Fair Value
<b>Non-vested as of December 27, 2019</b>	1,419,020	\$ 22.68
Exercised	(647,167)	24.23
Expired/Forfeited	(281,182)	22.11
<b>Non-vested as of December 25, 2020</b>	490,671	20.96
Exercised	(186,930)	23.43
Expired/Forfeited	(60,844)	19.58
<b>Non-vested as of December 31, 2021</b>	<u>242,897</u>	19.40

The total vest date fair value of Mallinckrodt plc 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 Group 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 Group'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 Group's Board of Directors.



PSU activity was as follows <sup>(1)</sup>:

	Shares	Weighted-Average Grant-Date Fair Value
<b>Non-vested as of December 27, 2019</b>	1,195,505	23.85
Forfeited	(1,195,505)	23.85
<b>Non-vested as of December 25, 2020</b>	—	—

(1) The number of shares disclosed within this table are at the target number of 100%.

The Group generally uses the Monte Carlo model to estimate the probability of satisfying the performance criteria and the resulting fair value of PSU awards.

### **Employee Stock Purchase Plans**

Effective March 16, 2016, upon approval by the shareholders of Mallinckrodt, the Group adopted a new qualified Mallinckrodt Employee Stock Purchase Plan ("ESPP"). Substantially all full-time employees of the Group'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 under the period by utilizing treasury stock accumulated by the Group. The ESPP was suspended effective June 30, 2019 and remains unavailable as of December 31, 2021.

## **12. Directors' Remuneration**

Directors' remuneration is set forth in the table below. Mr. Trudeau, the Group's President and Chief Executive Officer ("CEO") and Director, is not compensated for his services as a director. Accordingly, the amounts below for "Managerial Services" include compensation for Mr. Trudeau's services as President and CEO. The amounts below also include compensation for all non-executive directors in their capacities as such (referred to as "Director Services").

	Fiscal Year	
	2021	2020
<b>Director Services</b>		
Fees paid in cash	\$ 3.3	\$ 2.7
Benefits under long-term incentive schemes <sup>(1)</sup>	—	1.1
Total <sup>(2)</sup>	<u>\$ 3.3</u>	<u>\$ 3.8</u>
<b>Managerial Services</b>		
Emoluments	\$ 8.2	\$ 14.0
Benefits under long-term incentive schemes <sup>(1)</sup>	3.2	8.6
Group contributions to savings plans and other <sup>(3)</sup>	0.7	0.9
Total <sup>(2)</sup>	<u>\$ 12.1</u>	<u>\$ 23.5</u>

(1) Includes amounts expensed for outstanding equity awards.

(2) The gain on exercise of share options was zero for fiscal 2021 and 2020 for both directors and managerial services

(3) Includes amounts for contributions to retirement and supplemental savings plan, tax reimbursement payments and other benefits. Total contributions for retirement savings plans were less than \$0.1 million for both fiscal 2021 and 2020, respectively.

**Indemnification Agreements.** Mallinckrodt plc has entered into deeds of indemnification with each of its directors and Secretary ("the Deeds of Indemnification"), and Mallinckrodt Brand Pharmaceuticals, Inc., a Delaware corporation and a wholly owned subsidiary of Mallinckrodt plc ("Brand Pharma"), has entered into indemnification agreements with each of Mallinckrodt plc's directors and Secretary ("the Indemnification Agreements"). The Deeds of Indemnification and Indemnification Agreements provide, respectively, that Mallinckrodt plc and Brand Pharma will, to the fullest extent permitted by law, indemnify each indemnitee against claims related to such indemnitee's service to Mallinckrodt, except (i) in respect of any claim as to which a final and non-appealable judgment is rendered against the indemnitee for an accounting of profits made from the purchase or sale by such indemnitee of securities of Mallinckrodt plc pursuant to the provisions of Section 16(b) of the U.S. Securities Exchange Act of 1934 or similar provision of any federal, state or local laws; (ii) in respect of any claim as to



which a court of competent jurisdiction has determined in a final and non-appealable judgment that indemnification is not permitted under applicable law; or (iii) in respect of any claim as to which the indemnitee is convicted of a crime constituting a felony under the laws of the jurisdiction where the criminal action was brought (or, where a jurisdiction does not classify any crime as a felony, a crime for which the indemnitee is sentenced to death or imprisonment for a term exceeding one year).

### 13. Auditor's Remuneration

Auditor's remuneration was as follows:

	Fiscal Year	
	2021 <sup>(1)</sup>	2020 <sup>(1)</sup>
Audit of the group accounts <sup>(2)</sup>	\$ 0.2	\$ 0.2
Other assurance services <sup>(2)</sup>	0.3	0.3
Other non-audit services <sup>(2),(3)</sup>	0.3	—
	<u>\$ 0.8</u>	<u>\$ 0.5</u>

(1) No amounts were incurred for tax advisory services.

(2) The Group incurred additional fees of \$5.0 million and \$6.1 million during fiscal 2021 and 2020, respectively, payable to affiliates of Deloitte Ireland LLP. These additional amounts reflect fees for professional services rendered, including audit fees payable to Deloitte & Touche LLP in the U.S. for the audit of the Group's consolidated financial statements.

(3) Other non-audit services 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.

### 14. Employees

The average number of persons, including executive directors, employed by the Group during the year was as follows:

	Fiscal Year	
	2021	2020
Manufacturing	1,566	1,701
Turnover, marketing and distribution	603	687
Research and development	304	365
General and administrative	526	536
	<u>2,999</u>	<u>3,289</u>

Employee costs consisted of the following:

	Fiscal Year	
	2021	2020
Wages and salaries	\$ 500.7	\$ 571.7
Social insurance costs	30.5	33.6
Pension and postretirement costs	26.2	31.3
	<u>\$ 557.4</u>	<u>\$ 636.6</u>

For information on share based payments not included within the employee costs above, refer to Note 11.

## 15. Intangible Assets

Intangible asset activity for fiscal 2021 was as follows:

	Completed Technology	Licenses	Trademarks	In-process Research and Development	Total Intangible Assets
<b>Cost:</b>					
As of December 25, 2020	\$ 10,394.6	\$ 120.1	\$ 112.7	\$ 180.8	\$ 10,808.2
Impairments	(90.4)	—	—	—	(90.4)
Transfers	99.8	—	—	(99.8)	—
As of December 31, 2021	<u>\$ 10,404.0</u>	<u>\$ 120.1</u>	<u>\$ 112.7</u>	<u>\$ 81.0</u>	<u>\$ 10,717.8</u>
<b>Accumulated Amortization:</b>					
As of December 25, 2020	\$ 4,586.6	\$ 78.1	\$ 23.5	\$ —	\$ 4,688.2
Amortization expense	573.7	4.0	3.4	—	581.1
Currency translation and other	0.1	—	—	—	0.1
As of December 31, 2021	<u>\$ 5,160.4</u>	<u>\$ 82.1</u>	<u>\$ 26.9</u>	<u>\$ —</u>	<u>\$ 5,269.4</u>
<b>Net book value:</b>					
As of December 25, 2020	\$ 5,808.0	\$ 42.0	\$ 89.2	\$ 180.8	\$ 6,120.0
As of December 31, 2021	5,243.6	38.0	85.8	81.0	5,448.4

### Long-Lived Asset Impairment Analysis

The Group recorded impairment charges related to its Specialty Brands segment totaling \$90.4 million and \$128.0 million during fiscal 2021 and 2020, 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 represents a partial impairment of \$90.4 million related to Amitiza, as discussed further below. The fiscal 2020 impairment charges included a full impairment of \$64.5 million related to MNK-6105 and MNK-6106 as the Group decided it would no longer pursue further development of this IPR&D asset and a partial impairment of \$63.5 million related to Ofirmev<sup>®</sup> (acetaminophen) injection ("Ofirmev") 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.

#### Amitiza

During the three months ended December 31, 2021, due to lower anticipated cash flows expected from Amitiza, the Group identified an impairment triggering event with respect to the associated intangible asset within the Specialty Brands segment and assessed the recoverability of the definite-lived asset. The Group determined that the undiscounted cash flows related to the Amitiza intangible asset were less than its net book value, which required the Group 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 Group 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 Group 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 Group made various assumptions regarding estimated future cash flows, the discount rate and other factors in determining the fair value of the intangible asset. The Group's projections in relation to the Amitiza intangible asset included long-term turnover and operating profit 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 Group recorded an impairment charge of \$90.4 million.

#### StrataGraft<sup>®</sup>

On June 15, 2021, the Group announced that the U.S. Food and Drug Administration ("FDA") had approved the StrataGraft<sup>®</sup> (allogenic cultured keratinocytes and dermal fibroblasts in murine collagen - dsat) ("StrataGraft") biologics license application (BLA) for the treatment of adults with deep partial-thickness burns. Upon FDA approval, the Group 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 Group a Priority Review Voucher ("PRV"). A PRV is a voucher that may be used to obtain an accelerated FDA review of one of the

Group'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 Group'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 Group 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 Group 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 Group 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 Group 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 Group 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 Group 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*

Finite-lived intangible asset amortization expense was \$581.1 million and \$771.2 million during fiscal 2021 and 2020, respectively. The estimated aggregate amortization expense on intangible assets owned by the Group 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

## **16. Tangible Assets**

The gross carrying amount and accumulated depreciation of owned tangible assets were comprised of the following at the end of each period:

	<b>December 31, 2021</b>	<b>December 25, 2020</b>
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
	<u>1,886.6</u>	<u>1,910.9</u>
Less: accumulated depreciation	<u>(1,110.6)</u>	<u>(1,077.8)</u>
Total owned tangible assets	<u>776.0</u>	<u>833.1</u>
Lease assets	35.0	58.6
Total tangible assets	<u>\$ 811.0</u>	<u>\$ 891.7</u>

## Owned Tangible Assets

Owned tangible assets activity for fiscal 2021 was as follows:

	Land	Buildings	Capitalized Software	Machinery and Equipment	Construction in Process	Total Owned Tangible Assets
<b>Cost:</b>						
As of December 25, 2020	\$ 43.6	\$ 416.9	\$ 134.0	\$ 1,260.4	\$ 56.0	\$ 1,910.9
Additions	—	—	—	5.2	60.4	65.6
Disposal of tangible owned assets	—	(36.2)	(15.6)	(36.4)	—	(88.2)
Transfers	—	8.7	2.7	25.2	(36.6)	—
Currency translation and other	(0.1)	(1.6)	—	(0.3)	0.3	(1.7)
As of December 31, 2021	<u>\$ 43.5</u>	<u>\$ 387.8</u>	<u>\$ 121.1</u>	<u>\$ 1,254.1</u>	<u>\$ 80.1</u>	<u>\$ 1,886.6</u>
<b>Accumulated Depreciation:</b>						
As of December 25, 2020	\$ —	\$ 172.3	\$ 93.3	\$ 812.2	\$ —	\$ 1,077.8
Depreciation expense	—	33.3	13.2	48.2	—	94.7
Disposal of tangible owned assets	—	(34.9)	(15.6)	(11.9)	—	(62.4)
Currency translation and other	—	(0.2)	0.6	0.1	—	0.5
As of December 31, 2021	<u>\$ —</u>	<u>\$ 170.5</u>	<u>\$ 91.5</u>	<u>\$ 848.6</u>	<u>\$ —</u>	<u>\$ 1,110.6</u>
<b>Net book value:</b>						
As of December 25, 2020	\$ 43.6	\$ 244.6	\$ 40.7	\$ 448.2	\$ 56.0	\$ 833.1
As of December 31, 2021	43.5	217.3	29.6	405.5	80.1	776.0

Depreciation expense was \$94.7 million and \$114.0 million for fiscal 2021 and 2020, respectively. Gain on disposal of owned tangible assets was \$1.2 million and zero for fiscal 2021 and 2020, respectively.

## Lease Assets

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

	December 31, 2021	December 25, 2020
Tangible lease assets	<u>\$ 35.0</u>	<u>\$ 58.6</u>
Creditors (amounts falling due within one year)	\$ 11.1	\$ 13.0
Creditors (amounts falling due after one year)	\$ 20.0	28.0
Creditors (amount falling due within one year) subject to compromise	\$ 0.4	31.9
Total lease liabilities	<u>\$ 31.5</u>	<u>\$ 72.9</u>

Tangible lease assets activity for fiscal 2021 was as follows:

	<b>Lease Assets</b>	
<b>Cost:</b>		
As of December 25, 2020	\$	101.9
Additions		5.3
Disposal of tangible lease assets		(43.2)
Currency translation and other		1.7
As of December 31, 2021	<u>\$</u>	<u>65.7</u>
<b>Accumulated Amortization:</b>		
As of December 25, 2020	\$	43.3
Amortization expense		13.4
Disposal of tangible lease assets		(25.8)
Currency translation and other		(0.2)
As of December 31, 2021	<u>\$</u>	<u>30.7</u>
<b>Net book value:</b>		
As of December 25, 2020	\$	58.6
As of December 31, 2021		35.0

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

	<b>Fiscal Year</b>	
	<b>2021</b>	<b>2020</b>
<b>Lease cost:</b>		
Operating lease cost	\$ 19.6	\$ 21.2
Short-term lease cost	1.1	1.1
Variable lease cost	2.4	3.1
Total lease cost	<u>\$ 23.1</u>	<u>\$ 25.4</u>

Lease terms and discount rates were as follows:

	<b>December 31, 2021</b>	<b>December 25, 2020</b>
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		<u>43.8</u>
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	<u>\$</u>	<u>31.1</u>

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

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

## 17. Financial Assets

The Group's financial asset activity during fiscal 2021 was as follows:

	Assets Held by Rabbi Trusts	Restricted Cash	Other Financial Assets	Total Financial Assets
As of December 25, 2020	\$ 78.0	\$ 56.4	\$ 41.5	\$ 175.9
Unrealized gain	5.5	—	4.7	10.2
Interest	—	—	1.9	1.9
Additions	—	3.8	—	3.8
Cash received, net	—	—	(0.6)	(0.6)
Currency translation and other	—	—	0.1	0.1
As of December 31, 2021	<u>\$ 83.5</u>	<u>\$ 60.2</u>	<u>\$ 47.6</u>	<u>\$ 191.3</u>

Refer to Note 26 for further discussion of the fair value and the valuation techniques utilized to measure the financial assets at fair value.

## 18. Stocks

Stocks 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
Stocks	<u>\$ 347.2</u>	<u>\$ 344.9</u>

## 19. Debtors

At the end of each period, debtors were comprised of:

	December 31, 2021	December 25, 2020
Trade debtors	\$ 439.1	\$ 538.9
Turnover taxation recoverable	11.9	18.4
Taxation receivable (Note 9)	36.5	188.7
Other debtors and prepayments	105.9	122.5
Amounts falling due within one year	<u>593.4</u>	<u>868.5</u>
Taxation receivable (Note 9)	141.3	139.4
Other debtors	38.7	39.9
Amounts falling due after one year	<u>180.0</u>	<u>179.3</u>
Total debtors	<u>\$ 773.4</u>	<u>\$ 1,047.8</u>

## 20. Creditors (amounts falling due within one year)

As of the end of each period, creditors (amounts falling due within one year) were comprised of:

	December 31, 2021	December 25, 2020
Debt (Note 22) <sup>(1)</sup>	\$ 5,139.7	\$ 5,248.6
Trade creditors <sup>(1)</sup>	165.9	155.2
Accrued payroll and employee benefits	84.6	79.4
Other taxes	15.3	30.9
Accrued interest <sup>(1)</sup>	52.2	62.1
Accrued royalties	29.5	14.2
Lease liabilities (Note 16)	11.5	13.0
Accruals and other creditors <sup>(1)</sup>	256.1	262.5
Creditors (amounts falling due within one year)	<u>\$ 5,754.8</u>	<u>\$ 5,865.9</u>

- (1) Of the \$5,754.8 million and \$5,865.9 million classified as creditors (amounts falling due within one year) as of December 31, 2021 and December 25, 2020, respectively, \$3,875.3 million and \$1,808.8 million were classified as liabilities subject to compromise, respectively. For further information on liabilities subject to compromise, refer to Note 2.

## 21. Creditors (amounts falling due after one year)

As of the end of each period, creditors (amounts falling due after one year) were comprised of:

	December 31, 2021	December 25, 2020
Taxation payable (Note 9)	\$ 83.2	\$ 100.1
Deferred compensation	36.9	38.0
Section 453A unrecognized benefit	12.4	28.2
Lease liabilities (Note 16) <sup>(1)</sup>	20.0	56.9
Accruals and other creditors	1.0	1.2
Creditors (amounts falling due after one year)	<u>\$ 153.5</u>	<u>\$ 224.4</u>

- (1) Of the \$153.5 million and \$224.4 million classified as creditors (amounts falling due after one year) as of December 31, 2021 and December 25, 2020, respectively, zero and \$28.9 million were classified as liabilities subject to compromise, respectively. For further information on liabilities subject to compromise, refer to Note 2.

## 22. Debt

The commencement of the Chapter 11 Cases constituted an event of default under certain of the Group's debt agreements. Accordingly, all debt not reclassified as LSTC with original long-term stated maturities was classified as current within Note 2 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 <sup>(1)</sup>	Principal	Unamortized Discount and Debt Issuance Costs
<b>Secured debt:</b>				
Term loan due September 2024 <sup>(2)</sup>	\$ 1,396.5	\$ —	\$ 1,505.2	\$ 12.3
Term loan due February 2025 <sup>(2)</sup>	370.7	—	399.5	5.0
10.00% first lien senior notes due April 2025 <sup>(3)</sup>	495.0	5.9	495.0	7.7
10.00% second lien senior notes due April 2025 <sup>(3)</sup>	322.9	—	322.9	8.0
Revolving credit facility <sup>(3)</sup>	900.0	0.2	900.0	1.7
<b>Total secured debt</b>	<b>3,485.1</b>	<b>6.1</b>	<b>3,622.6</b>	<b>34.7</b>
<b>Unsecured debt:</b>				
9.50% debentures due May 2022 <sup>(3)</sup>	10.4	—	10.4	—
5.75% senior notes due August 2022 <sup>(3)</sup>	610.3	—	610.3	—
8.00% debentures due March 2023 <sup>(3)</sup>	4.4	—	4.4	—
4.75% senior notes due April 2023 <sup>(3)</sup>	133.7	—	133.7	—
5.625% senior notes due October 2023 <sup>(3)</sup>	514.7	—	514.7	—
5.50% senior notes due April 2025 <sup>(3)</sup>	387.2	—	387.2	—
<b>Total unsecured debt:</b>	<b>1,660.7</b>	<b>—</b>	<b>1,660.7</b>	<b>—</b>
<b>Total debt, prior to reclassification to liabilities subject to compromise</b>	<b>5,145.8</b>	<b>6.1</b>	<b>5,283.3</b>	<b>34.7</b>
<b>Less: Current portion</b>	<b>(1,395.0)</b>	<b>(6.1)</b>	<b>(3,622.6)</b>	<b>(34.7)</b>
<b>Less: Amounts reclassified to liabilities subject to compromise <sup>(4)</sup></b>	<b>(3,750.8)</b>	<b>—</b>	<b>(1,660.7)</b>	<b>—</b>
<b>Total long-term debt, net of current portion</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>

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

(2) Includes debt repayable within five years, otherwise than by installment, of \$1,767.2 million as of December 31, 2021.

(3) Includes debt repayable within five years, by installment, of \$3,378.6 million as of December 31, 2021.

(4) In connection with the Group's Chapter 11 Cases, \$3,750.8 million and \$1,660.7 million of outstanding debt instruments have been classified as LSTC within Note 2 as of December 31, 2021 and December 25, 2020, respectively. Up to the Petition Date, the Group continued to accrue interest expense in relation to these debt instruments reclassified to LSTC within Note 2. The Group 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 Group. MIFSA functions as a holding company, established to own, directly or indirectly, substantially all of the operating subsidiaries of the Group, 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 Group pays interest on the April 2023 Notes semiannually in arrears on April 15<sup>th</sup> and October 15<sup>th</sup> 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 Group pays interest on the 2022 Notes semiannually in arrears on February 1<sup>st</sup> and August 1<sup>st</sup> of each year, which commenced on February 1, 2015.

In April 2015, in connection with the Group'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 Group. 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 Group pays interest on the Ikaria Notes semiannually on April 15<sup>th</sup> and October 15<sup>th</sup> of each year, which commenced on October 15, 2015.

In September 2015, in connection with the Group'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 Group. 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 Group pays interest on the October 2023 Notes semiannually on April 15<sup>th</sup> and October 15<sup>th</sup> 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 Group 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 Group, 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 Group, 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 Group 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 Group, the Servicer, and Mallinckrodt Securitization, (iii) the Sale Agreements (together, the "Sale Agreements"), between Mallinckrodt LLC and certain subsidiaries of the Group 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 Group'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 Group 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 Group 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 Group, 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 Group 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 Group's variable-rate debt instruments were as follows:

	Applicable interest rate <sup>(1)</sup>	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 Group'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 Group'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

## 23. Retirement Plans

### *Defined Benefit Plans*

The Group 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 Group's remaining projected benefit obligation. The Group generally does not provide postretirement benefits other than retirement plan benefits for its employees; however, certain of the Group'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 within Note 2 as of December 31, 2021 and December 25, 2020. For further information refer to Note 2.

The amounts included in the Group's financial statements are based on the most recent actuarial valuations, which are generally as of the end of the period. The actuarial valuations are performed by the individual plan's independent and professionally qualified actuaries. These actuarial reports are not available for public inspection.

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, included within the provisions for liabilities, at the end of each period:

	Pension Benefits		Postretirement Benefits	
	Fiscal Year		Fiscal Year	
	2021	2020	2021	2020
<i>Change in benefit obligations:</i>				
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 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
	<i>Amounts recognized in accumulated other comprehensive loss consist of:</i>			
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 Group's pension plans were as follows:

	U.S. Plans		Non-U.S. Plans	
	Fiscal Year		Fiscal Year	
	2021	2020	2021	2020
Discount rate	1.8 %	2.8 %	1.0 %	1.3 %
Rate of compensation increase	—	—	2.5	2.5

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

	U.S. Plans		Non-U.S. Plans	
	Fiscal Year		Fiscal Year	
	2021	2020	2021	2020
Discount rate	2.3 %	1.8 %	1.3 %	1.0 %
Rate of compensation increase	—	—	2.5	2.5

For the Group'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 Group'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 Group's postretirement benefit plans were as follows:

	Fiscal Year	
	2021	2020
Net periodic benefit credit	2.0 %	3.0 %
Benefit obligations	2.5	2.0

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 Group's funding policy is to make contributions in accordance with the laws and customs of the various countries in which the Group operates, as well as to make discretionary voluntary contributions from time to time. During fiscal 2021 and 2020, the Group made \$0.7 million and \$1.6 million in contributions, respectively, to the Group'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 Group 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 Group contribution of 3.0% of an eligible employee's pay, with an additional Group matching contribution generally equal to 50.0% of each employee's elective contribution to the plan up to 8.0% of the employee's eligible pay. The deferred compensation plan permits eligible employees to defer a portion of their compensation. Total defined contribution expense was \$22.2 million and \$26.0 million for fiscal 2021 and 2020, respectively.

### ***Rabbi Trusts and Other Investments***

The Group 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 Group's creditors in the event of the Group's insolvency. Plan participants are general creditors of the Group with respect to these benefits. The trusts primarily hold life insurance policies and debt and equity securities, the value of which is included in financial assets on the consolidated balance sheets. Note 26 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 Group has insurance contracts that serve as collateral for certain of the Group'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 financial assets on the consolidated balance sheets.

## 24. Guarantees

In disposing of assets or businesses, the Group 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 Group 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 Group 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 Group 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 provisions for liabilities, as well as LSTC within Note 2, 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 Group could be required to make under these indemnification obligations was \$70.2 million. The Group was required to pay \$30.0 million into an escrow account as collateral to the purchaser, of which \$19.0 million remained in financial assets on the consolidated balance sheets as of both December 31, 2021 and December 25, 2020.

The Group has recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 25.

The Group is also liable for product performance; however the Group 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 Group 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 Group's environmental liabilities.

## 25. Commitments and Contingencies

The Group 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 Group 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 Group 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 Group have been automatically stayed, subject to certain limited exceptions. In addition, the Bankruptcy Court issued orders enjoining certain litigation against the Group 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 Group, as well as various other manufacturers, distributors, pharmacies, pharmacy benefit managers, individual doctors and/or others, asserting claims relating to defendants' alleged turnover, marketing, distribution, reimbursement, prescribing, dispensing and/or other practices with respect to prescription opioid medications,

including certain of the Group's products. As of April 1, 2022, the cases the Group 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 April 1, 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 Group's President and 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 turnover 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 Group 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 Group paid \$24.0 million in cash on October 1, 2019. In addition, the Group 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 Group 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 turnover 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 Group 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 Group 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 Group (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 Group 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 Group's ordinary shares that would represent approximately 19.99% of the Group'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 Group's Chapter 11 filing on October 12, 2020, the Group entered into a RSA which includes a proposed resolution of all opioid-related claims against the Group 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 Group'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 Group'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 Group'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 Group'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 Group 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 Group 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 Group 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 Group 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 Group have received subpoenas and civil investigative demands ("CID(s)") for information concerning the turnover, marketing and/or distribution of prescription opioid medications and the Group'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 Group 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 Group 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 turnover of generic oxymorphone products. On April 17, 2019, the Group received a grand jury subpoena from the USAO for the Eastern District of New York ("EDNY") for documents related to the turnover and marketing of controlled substances, the policies and procedures regarding controlled substances, and other related documents. On June 4, 2019, the Group received a rider from the USAO for EDNY requesting additional documents regarding the Group's anti-diversion program. On December 15, 2020, the Group received a subpoena from the Western District of Virginia for documents related to services provided by an outside consulting firm. The Group is responding or has responded to these subpoenas, CIDs and any informal requests for documents.

In August 2018, the Group 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 Group completed its response to this letter in December 2018. The Group received a follow-up letter in January 2020 and provided the committee a response. The Group 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 Group. Similar subpoenas and investigations may be brought by others or the foregoing matters may be expanded or result in litigation. The Group intends to vigorously defend itself in these matters. At this stage, the Group 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 Group intends to vigorously defend itself in this matter. At this stage, the Group 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 Group 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 Group 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 Group'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 Group's (and other parties') challenges to the OSA for lack of subject matter jurisdiction. Together with the other plaintiffs, the Group 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 turnover 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 Group received a subpoena from the SEC for documents related to the Group'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 Group 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 Group. The Group is cooperating with the SEC's investigation, which is ongoing.

*Medicaid Lawsuit.* In May 2019, CMS issued a final decision directing the Group 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 Group 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 Group received an adverse decision from the D.C. District Court. The Group immediately sought reconsideration by the D.C. District Court, which was denied. The Group then appealed the D.C. District Court's decision to the D.C. Circuit. In June 2020, while its appeal remained pending, the Group 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 Group 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 turnover and

operating loss, respectively, in the consolidated profit and loss account for fiscal 2020. The \$105.1 million reflected as a component of operating loss represented a pre-acquisition contingency related to the portion of the Acthar Gel Medicaid Retrospective Rebate that arose from turnovers of Acthar Gel prior to the Group'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 provisions for liabilities, respectively.

The D.C. Circuit heard argument on the merits of the Group's appeal in September 2020, prior to the Group'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 Group entering the Chapter 11 restructuring process. Pursuant to the Proposed Acthar Gel-Related Settlement, the Group 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 turnover, based on current Acthar Gel pricing. Additionally, upon effectiveness of the Proposed Acthar Gel-Related Settlement, the Group will dismiss its D.C. Circuit appeal. The Group has also entered into a five-year CIA with the OIG of the HHS, which took effect in March 2022. The Group 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 Group 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 Group has cooperated with the investigation.

*U.S. House Committee Investigation.* In January 2019, the Group along with 11 other pharmaceutical companies, received a letter from the U.S. House Committee on Oversight and Reform requesting information relating to the Group's pricing strategy for Acthar Gel and related matters. The Group cooperated with the Committee's investigation. The Group's President and CEO Mark C. Trudeau accepted an invitation from the Committee to discuss the Group'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 Group received a CID from the USAO for the District of Massachusetts for documents related to the Group's participation in the Medicaid Drug Rebate Program. The Group 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 Group in which the DOJ and 32 states and territories have intervened alleging that the Group had failed to pay the correct amount of rebates for Acthar Gel. Other related legal proceedings involving the Group, including the litigation described as the *Medicaid Lawsuit*, are discussed above. The Group disagrees with the government's characterization of the facts and applicable law. The Group 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 Group 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 Group 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 Group 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 Group expects the DOJ to dismiss the lawsuit after the Group's first payment toward the settlement amount.

*Boston Subpoena.* In December 2016, the Group received a subpoena from the USAO for the District of Massachusetts for documents related to the Group's payments to charitable foundations, the provision of financial and other support by charitable foundations to patients receiving Acthar Gel, and related matters. The Group has responded to these requests and cooperated in the investigation. The Group 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 Group 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 Group 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 Group disagrees with the DOJ's characterization of the facts and applicable law. In January 2020, the court denied the Group's motion to dismiss the Complaint in Intervention.

As discussed above, on October 12, 2020, the Group 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 Group expects the DOJ to dismiss the lawsuit after the Group's first payment toward the settlement amount.

#### Other Related Matters

*Generic Pricing Subpoena.* In March 2018, the Group 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 Group 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 Group's Methylphenidate ER in the Orange Book: Approved Drug Products with Therapeutic Equivalence ("the Orange Book"). In November 2014, the Group 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 Group'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 Group's appeal of the MD Order in abeyance pending the outcome of the withdrawal proceedings. The parties exchanged documents and in April 2018, the Group filed its submission in support of its position in the withdrawal proceedings. A potential outcome of the withdrawal proceedings is that the Group's Methylphenidate ER products may lose their FDA approval and have to be withdrawn from the market.

*Therakos<sup>®</sup> 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<sup>®</sup> 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 Group 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 Group 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 Group'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 Group'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 Group 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 Group'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 Group'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 Group intends to vigorously enforce its intellectual property rights relating to Amitiza against any additional parties that may seek to market a generic version of Group's Amitiza product.

*INOMax Patent Litigation:* The Group 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 Group's patents were invalid and six were not infringed by Praxair. The Group appealed that decision to the Federal Circuit but the District Court decision was substantively affirmed with respect to invalidity and non-infringement. The Group'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 Group'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 Group continues to develop and pursue patent protection of next generation nitric oxide delivery systems and additional uses of nitric oxide. The Group 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 Group's INOMax product and/or next generation delivery systems.

*Generic Products:* The Group continues to pursue development of a portfolio of generic products, some of which require submission of a Paragraph IV certification against patents listed in the FDA Orange Book for the Branded product asserting that the Group'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 Group 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 Group and Pharmascience Inc. ("Pharmascience") relating to the collaboration between Group 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 Group and Pharmascience infringe U.S. Patent No. 9,439,906. The litigation is currently stayed with respect to the Group as a result of the Group's Chapter 11 filing. If the stay is lifted, the Group 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 Group alleging that the Group infringed U.S. Patent Nos. 6,913,768, 8,846,100, and 9,173,857 following receipt of an April 2018 notice from the Group 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 Group 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 Group alleging that the Group 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 Group 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 Group 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 Group 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 Group'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 Group 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 Group'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 Group 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 Group 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 Group 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 Group 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 Group 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 Group's officers and directors as named defendants in the case. As of March 10, 2022, the U.S. District Court lifted the stay in this matter and established an initial schedule for the proceedings. At this stage, the Group 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 Group in California state court alleging improper pricing, marketing and distribution of Acthar Gel, and challenging the acquisition of rights to Synacthen<sup>®</sup> Depot ("Synacthen") by the Group'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 Group intends to vigorously defend itself in this matter and the Group 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 Group disagrees with the court's decision and contests liability. The Group was preparing to move to dismiss an amended complaint when the Group filed the Chapter 11 Cases. In January 2021, the Group removed this case to federal court and moved for transfer to the District of Delaware where the Group'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 Group 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 Group 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 Group has been unjustly enriched as a result. The Group intends to vigorously defend itself in this matter, and has moved to dismiss the complaint. The Group's motion to dismiss was pending when the Group 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 Group 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 turnover 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 Group moved to dismiss or stay the case. On August 18, 2020 the court dismissed all claims against the Group other than Local 322's antitrust claim relating to the Group's predecessor-in-interest's acquisition of Synacthen. The Group disagrees with the court's decision and contests liability. The Group intends to vigorously defend itself in this matter. At this stage, the Group 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 Group's Chapter 11 Cases. In January 2021, the Group moved to transfer this case to the District of Delaware where the Group's Chapter 11 Cases are pending. On August 23, 2021, the district court in New Jersey granted the Group'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 Group 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 Group'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 Group 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 Group'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 Group's motion to dismiss Humana's RICO and other fraud-based claims. Humana filed an amended complaint in May 2020, which the Group moved to dismiss. In August 2020, the court granted-in-part and denied-in-part the Group'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 Group 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 Group moved to transfer this case to the District of Delaware where the Group's Chapter 11 Cases are pending. Humana opposed this transfer. On June 28, 2021, the district court in California granted the Group'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 Group filed a motion for partial summary judgement as to the Acthar Insurance Claimants' antitrust claims. In September 2021, the Bankruptcy Court denied the Group's motion for partial summary 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 Group, 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 Group 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 Group in the U.S. District Court for the EDPA (see *Questcor EDPA Qui 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 Group's motion to dismiss the complaint. The Group disagrees with the court's decision and contests liability. The Group intends to vigorously defend itself in this matter. At this stage, the Group is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit. In January 2021, the Group moved to transfer this case to the District of Delaware where the Group'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 Group 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 Group'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 Group disagrees with the court's decision and contests liability. The Group intends to vigorously defend itself in this matter. At this stage, the Group is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit. In January 2021, the Group removed this case to federal court and moved for transfer to the District of Delaware where the Group'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 Group 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 Group's objections to which were denied by the court. The Group disagrees with the court's decision and contest liability. The Group intends to vigorously defend itself in this matter. At this stage, the Group is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit. In January 2021, the Group removed this case to federal court and moved for transfer to the District of Delaware where the Group'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 Group'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 Group 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 Group 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 Group 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 Group's motion to dismiss the complaint with leave to amend. MSP filed an amended complaint on July 3, 2020. The Group intends to vigorously defend itself in this matter and moved to dismiss the second amended complaint in August 2020. At this stage, the Group 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 Group pursuant to §362 of the Bankruptcy Code. In January 2021, the Group moved for transfer to the District of Delaware where the Group'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 Group 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 turnover of Acthar Gel. In January 2018, the Group

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 Plaintiffs' federal and state antitrust claims. The remaining allegation in the case is that the Group engaged in anti-competitive acts to artificially raise and maintain the price of Acthar Gel. To this end, Plaintiff alleges that the Group 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 Group intends to vigorously defend itself in this matter. At this stage, the Group 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 Group pursuant to §362 of the Bankruptcy Code. In January 2021, the Group moved for transfer to the District of Delaware where the Group'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 Group's stock filed a complaint in the D.C. District Court against the Group, 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 Group is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit. As to the Group, 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 and on March 17, 2022. Absent further extension, the injunction will expire at the earlier of (a) the plan effective date or (b) June 16, 2022, with certain modifications.

*Shareholder Derivative Litigation (Brandhorst).* In September 2019, a purported shareholder of the Group's stock filed a shareholder derivative complaint in the D.C. District Court against the Group, 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 Group 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 Group 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 Group, 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 and on March 17, 2022. Absent further extension, the injunction will expire at the earlier of (a) the plan effective date or (b) June 16, 2022, with certain modifications.

*Putative Class Action Securities Litigation (Strougo).* In July 2019, a putative class action lawsuit was filed against the Group, its CEO Mark C. Trudeau, its CFO Bryan M. Reasons, its former Interim CFO George A. Kegler and its former CFO Matthew K. Harbaugh, in the U.S. District Court for the Southern District of New York, captioned *Barbara Strougo v. Mallinckrodt plc, et al.* The complaint purports to be brought on behalf of all persons who purchased or otherwise acquired Mallinckrodt's securities between February 28, 2018 and July 16, 2019. The lawsuit generally alleges that the defendants made false and misleading statements in violation of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder related to the Group'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 Group and Mark C. Trudeau, Bryan M. Reasons, George A. Kegler and Matthew K. Harbaugh, as well as newly named defendants Kathleen A. Schaefer, Angus C. Russell, Melvin D. Booth, JoAnn A. Reed, Paul R. Carter, and Mark J. Casey (collectively with Trudeau, Reasons, Kegler and Harbaugh, the "Strougo Defendants"). The amended complaint claims that the defendants made false and/or misleading statements and/or failed disclose that: (i) the CMS had informed the Group that it was using the wrong base date AMP for



calculating the Medicaid rebate the Group owed CMS for Acthar Gel each quarter since 2014; (ii) the Group's reported net income was improperly inflated in violation of GAAP; (iii) the Group's contingent liabilities associated with the rebates owed to CMS for Acthar Gel were misrepresented; (iv) the Group's fiscal year 2019 guidance for Acthar Gel turnover was false; (v) the Group 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 Group 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 turnover as a result of the rebates the Group 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 Group is not able to reasonably estimate the expected amount or range of cost or any loss associated with this lawsuit. As to the Group, 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 and March 17, 2022. Absent further extension, the injunction will expire at the earlier of (a) the plan effective date or (b) June 16, 2022, with certain modifications.

*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 Group, its CEO, its former CFO Matthew K. Harbaugh, its Controller Kathleen A. Schaefer, and current and former directors of the Group (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 Group 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 and March 17, 2022. Absent further extension, the injunction will expire at the earlier of (a) the plan effective date or (b) June 16, 2022, with certain modifications.

*Putative Class Action Securities Litigation (Shenk).* In January 2017, a putative class action lawsuit was filed against the Group 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 Group made false or misleading statements related to Acthar Gel and Synacthen to artificially inflate the price of the Group's stock. In particular, the complaint alleges a failure by the Group 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 Group 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 Group, 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 Group, 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 Group 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 Group 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 Group'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 Group's entry into the settlement.

### **Generic Price Fixing Litigation**

*Canadian (Eaton) Litigation.* In December 2020, the Group received a statement of claim filed in federal court in Toronto, Ontario, Canada, naming the Group, 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 Group 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 Group 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 Group 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.

*JM Smith Litigation.* In September 2020, a direct action complaint filed in the U.S. District Court for the EDPA named the Group and several other pharmaceutical manufacturers as new defendants in an action captioned *JM 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 Group 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 Group 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 Group, 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 Group 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 Group 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 Group 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 Group 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 Group employees. On October 18, 2021, the Group agreed to provide limited discovery. The Group intends to vigorously defend itself in this matter. At this stage, the Group 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 Group 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 Group and others by providing substantial consideration to the Group 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 Group intends to vigorously defend itself in this matter. At this stage, the Group 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 Group 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 Group concluded that, as of December 31, 2021, it was probable that it would incur remediation costs in the range of \$83.4 million to \$120.9 million. The Group also concluded that, as of December 31, 2021, the best estimate within this range was \$106.9 million, which was included in provisions for liabilities, of which \$63.1 million was included in LSTC within Note 2 as of December 31, 2021. While it is not possible at this time to determine with certainty the ultimate outcome of these matters, the Group 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 Group 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 Group’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 Group, 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 the December 31, 2021, the Group estimated that its remaining liability related to the River was \$26.1 million and was included within provisions for liabilities, of which \$4.6 million was included in LSTC within Note 2 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 Group’s allocable share of the remediation. Given those uncertainties, the amounts accrued may not be indicative of the amounts for which the Group may be ultimately responsible and will be refined as the remediation progresses.

*Occidental Chemical Corp. v. 21st Century Fox America, Inc.* The Group 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 Group was not named as a defendant for the Belleville facility, the Group 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 Group 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 Group, 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 Group 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 Group increased the accrual associated with this matter by \$45.4 million to \$57.4 million, which represents the Group's estimate of its liability related to this environmental site, all of which was reflected within LSTC within Note 2 as of December 31, 2021. The non-cash charge of \$45.4 million was reflected in the consolidated profit and loss account as a component of operating losses. While it is not possible at this time to determine with certainty the ultimate outcome of this matter, the Group 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 Group 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 Group's property. Each case typically names dozens of corporate defendants in addition to the Group. The complaints generally seek monetary damages for personal injury or bodily injury resulting from alleged exposure to products containing asbestos. The Group's involvement in asbestos cases has been limited because it did not mine or produce asbestos. Furthermore, in the Group's experience, a large percentage of these claims have never been substantiated and have been dismissed by the courts. The Group 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 Group 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 Group.

The Group 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 Group'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 Group 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 Group 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 Group 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 Group has deferred the recognition of the benefit associated with the Group'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 profit and loss account.

### ***Other Matters***

The Group is a defendant in a number of other pending legal proceedings relating to present and former operations, acquisitions and dispositions. The Group 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.

## 26. 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 Group 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)
<b>Assets:</b>				
Debt and equity securities held in rabbi trusts	\$ 38.7	\$ 24.9	\$ 13.8	\$ —
Equity securities	36.5	36.5	—	—
	<u>\$ 75.2</u>	<u>\$ 61.4</u>	<u>\$ 13.8</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Deferred compensation liabilities <sup>(1)</sup>	\$ 36.9	\$ —	\$ 36.9	\$ —
Contingent consideration liabilities <sup>(2)</sup>	27.3	—	—	27.3
	<u>\$ 64.2</u>	<u>\$ —</u>	<u>\$ 36.9</u>	<u>\$ 27.3</u>

(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 as LSTC within Note 2 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)
<b>Assets:</b>				
Debt and equity securities held in rabbi trusts	\$ 33.0	\$ 23.5	\$ 9.5	\$ —
Equity securities	31.1	31.1	—	—
	<u>\$ 64.1</u>	<u>\$ 54.6</u>	<u>\$ 9.5</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Deferred compensation liabilities <sup>(1)</sup>	\$ 38.0	\$ —	\$ 38.0	\$ —
Contingent consideration and acquired contingent liabilities <sup>(2)</sup>	19.1	—	—	19.1
	<u>\$ 57.1</u>	<u>\$ —</u>	<u>\$ 38.0</u>	<u>\$ 19.1</u>

(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 as LSTC within Note 2 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 Group remitted \$5.0 million of consideration to Silence in exchange for equity shares. As part of this equity investment, the Group took a non-executive Director seat on the Silence Board of Directors. The Group's investment in Silence qualifies for equity method accounting given its ability to exercise significant influence; however, the Group elected the fair value method to account for its investment in Silence. During fiscal 2021 and 2020, the Group recognized an unrealized gain of \$4.7 million and \$3.8 million, respectively, related to this investment within other income, net in the consolidated profit and loss account.

*Deferred compensation liabilities.* The Group maintains a non-qualified deferred compensation plan in the U.S., which permits eligible employees of the Group 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 Group'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 Group 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 Group is responsible for a payment upon acceptance of the Group's submission and another upon approval by the FDA. The Group 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 Group 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, and was classified as provisions for liabilities in the consolidated balance sheet, as well as LSTC within Note 2, as of December 31, 2021 and December 25, 2020.

### ***Financial Instruments Not Measured at Fair Value***

The following methods and assumptions were used by the Group 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 at bank and in hand, trade debtors, trade creditors and the majority of other debtors (amounts falling due within one year) and creditors (amounts falling due within one year) approximate fair value because of their short-term nature. The Group 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 Group of three months or less, as cash at bank and on hand (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, respectively (level 1), all of which is included in financial assets on the consolidated balance sheets.
- The Group'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 as of December 31, 2021 and December 25, 2020, respectively. These contracts are included in financial assets on the consolidated balances sheets.
- The carrying value of the Group'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 Group'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 Group'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 Group's debt as of the end of each period:

	December 31, 2021		December 25, 2020	
	Carrying Value	Fair Value	Carrying Value	Fair Value
<b>Level 1:</b>				
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
<b>Level 2:</b>				
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
<b>Total Debt</b>	<b>\$ 5,145.8</b>	<b>\$ 4,267.9</b>	<b>\$ 5,283.3</b>	<b>\$ 3,944.3</b>

### Concentration of Credit and Other Risks

Financial instruments that potentially subject the Group to concentrations of credit risk primarily consist of trade debtors. The Group generally does not require collateral from customers. A portion of the Group's trade debtors outside the U.S. includes turnover 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 turnover attributable to distributors that accounted for 10.0% or more of the Group's total segment turnover, which excludes the one-time charge related to the Medicaid lawsuit:

	Fiscal Year	
	2021	2020
CuraScript, Inc.	26.1 %	27.4 %

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

	December 31, 2021	December 25, 2020
	AmerisourceBergen Corporation	30.0%
McKesson Corporation	15.0%	18.2%
CuraScript, Inc.	12.7%	*

\* Trade debtors attributable to this distributor was less than 10.0% of total gross trade debtors at the end of the respective period presented above.

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

	Fiscal Year	
	2021	2020
Acthar Gel	26.9 %	27.9 %
INOmax	20.3	20.9
Therakos	12.1	*
Ofirmev	*	10.1

\* Turnover attributable to these products were less than 10.0% of total turnover during the respective periods presented above.



## 27. Provisions for Liabilities

As of December 31, 2021 and December 25, 2020, provisions for liabilities was comprised of:

	December 31, 2021	December 25, 2020
Pensions and similar obligations (Note 23) <sup>(1)</sup>	\$ 65.0	\$ 70.2
Deferred taxation (Note 9)	20.9	80.6
Medicaid lawsuit (Note 25) <sup>(1)</sup>	634.7	638.9
Opioid-related litigation settlement liability (Note 25) <sup>(1), (2)</sup>	1,725.0	1,600.0
Other provisions <sup>(1)</sup>	260.1	200.6
	<u>\$ 2,705.7</u>	<u>\$ 2,590.3</u>

(1) Of the \$2,705.7 million and \$2,590.3 million classified as provision for liabilities as of December 31, 2021 and December 25, 2020, respectively, \$2,533.5 million and \$2,339.3 million were classified as liabilities subject to compromise within Note 2, respectively. For further information on liabilities subject to compromise, refer to Note 2.

(2) During fiscal 2021, the Group 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. Refer to Note 2 for further information.

Other provision activity during fiscal 2021 was as follows:

	Environmental (Note 25)	Restructuring Reserves (Note 6)	Guarantees (Note 24)	Contingent Consideration (Note 26)	Other	Total
As of December 25, 2020	\$ 60.8	\$ 11.0	\$ 18.6	\$ 19.1	\$ 91.1	\$ 200.6
Charged to profit and loss account	47.9	19.4	(1.0)	—	128.7	195.0
Accretion	(0.2)	—	—	—	0.1	(0.1)
Fair market value adjustments	—	—	—	8.2	—	8.2
Utilization	(1.6)	(12.8)	—	—	(129.1)	(143.5)
Other, including currency translation	—	—	(0.1)	—	—	(0.1)
As of December 31, 2021	106.9	17.6	17.5	27.3	90.8	260.1
Less: Liabilities subject to compromise	(63.1)	(6.7)	(15.5)	(27.3)	(29.2)	(141.8)
Liabilities not subject to compromise	<u>\$ 43.8</u>	<u>\$ 10.9</u>	<u>\$ 2.0</u>	<u>\$ —</u>	<u>\$ 61.6</u>	<u>\$ 118.3</u>

## 28. Shareholders' Funds

*Other Reserves.* The balance as of December 31, 2021 was primarily comprised of the capital contribution of \$1,095.0 million that was recorded upon the separation from Covidien plc, accumulated other comprehensive loss, contributed surplus on vested restricted stock and accumulated share-based compensation.

*Profit and Loss Account.* During fiscal 2021 and 2020, the profit and loss account activity resulted from accumulated loss after taxation and vesting of restricted shares.

*Dividends.* Historically, the Group has not made any cash dividends payments, as the Group has retained earnings to finance acquisitions, R&D and the operation and expansion of its 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.

Other items affecting shareholders' funds, including *Called-up Share Capital Presented as Equity, Preference Shares and Acquisition of Own Shares* are described in Note 8 to the Company's Notes to the Company Financial Statements.

## 29. Post-Balance Sheet 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 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 Irish Companies Act 2014 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 Irish Companies Act 2014 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 the 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.

On March 30, 2022, the Company sought authorization from the U.S. Bankruptcy Court to reject the CuraScript Inc. (“CuraScript”) distribution agreement, which would have the effect of relieving the Company of certain obligations under such agreement. In turn, the Company has entered into a distribution agreement with FFF Enterprises, Inc. The new distribution agreement covers the same scope of services and products on terms that are at least approximately comparable economically to the CuraScript distribution agreement. As such, the Company believes the transition will result in no material financial or operational disruptions.

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 below in Note 25.

### 30. Subsidiary Undertakings

The Group maintains subsidiary undertakings through ownership of the subsidiaries' ordinary shares. As of December 31, 2021, the Group had the following subsidiary undertakings:

Name	Nature of Business	Group Share %	Registered Office and Country of Incorporation
Acthar IP Unlimited Company	Holding	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Cache Holdings Limited	Holding	100%	Victoria Hall, 5th Floor 31 Victoria Street Hamilton, HM EX Bermuda
Carnforth Limited	Operating	100%	Victoria Hall, 5th Floor 31 Victoria Street Hamilton, HM EX Bermuda
Dritte CORSA Verwaltungsgesellschaft GmbH	Inactive	100%	Josef-Dietzgen-Strasse 1 53773 Hennef, Germany
Ikaria Australia Pty Ltd	Operating	100%	Deacons L 15 485 Bourke Street Melbourne VIC 3000 Australia
Ikaria Canada Inc.	Operating	100%	160 Elgin Street, Suite 2600 Ottawa, Ontario, K1P 13 Canada
IMC Exploration Company	Other	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Infacare Pharmaceutical Corporation	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
INO Therapeutics LLC	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Ludlow LLC	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
MAK LLC	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt APAP LLC	Operating	100%	385 Marshall Ave. Webster Groves, MO 63119 United States
Mallinckrodt ARD Finance, LLC	Finance and Administrative	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt ARD Holdings, Inc.	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt ARD Holdings Limited	Holding	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt ARD IP Unlimited Company	Holding	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt ARD LLC	Operating	100%	53 Frontage Road, STE 300 Hampton, NJ 08827 United States
Mallinckrodt Brand Pharmaceuticals LLC	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Buckingham Unlimited Company	Holding	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland

Mallinckrodt Canada Cooperatie U.A.	Holding	100%	Herikerbergweg 238 Amsterdam 1101CM Netherlands
Mallinckrodt Canada ULC	Operating	100%	400-6500 Trans-Canada Highway Pointe-Claire, Quebec H9R 0A5 Canada
Mallinckrodt CB LLC	Finance and Administrative	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Chemical Holdings (UK) Limited	Inactive	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt Chemical Limited	Operating	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt Critical Care Finance LLC	Finance and Administrative	100%	1209 Orange Street Wilmington, Delaware 19801 United States
Mallinckrodt Enterprises Holdings, Inc.	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Enterprises LLC	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Enterprises UK Limited	Other	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt Equinox Finance LLC	Finance and Administrative	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Equinox Limited	Holding	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt Finance Management Ireland Limited	Operating	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt Group S.a.r.l.	Finance and Administrative	100%	124 Boulevard de la Petrusse L-2330 Luxembourg Grand Duchy of Luxembourg
Mallinckrodt Holdings GmbH	Holding	100%	Solenbergstrasse 5 8207 Schaffhausen, Switzerland
Mallinckrodt Hospital Products Inc.	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Hospital Products IP Unlimited Company	Holding	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt International Finance SA	Finance and Administrative	100%	124 Boulevard de la Petrusse L-2330 Luxembourg Grand Duchy of Luxembourg
Mallinckrodt International Holdings, S.a.r.l.	Holding	100%	124 Boulevard de la Petrusse L-2330 Luxembourg Grand Duchy of Luxembourg
Mallinckrodt IP Unlimited Company	Holding	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt LLC	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Lux IP S.a.r.l.	Finance and Administrative	100%	124 Boulevard de la Petrusse L-2330 Luxembourg Grand Duchy of Luxembourg
Mallinckrodt Manufacturing LLC	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States

Mallinckrodt Medical Holdings (UK) Limited	Holding	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt Netherlands B.V.	Operating	100%	Herikerbergweg 238 Amsterdam 1101CM Netherlands
Mallinckrodt Petten Holdings B.V.	Other	100%	Herikerbergweg 238 Amsterdam 1101CM Netherlands
Mallinckrodt Pharma IP Trading Unlimited Company	Operating	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt Pharma K.K.	Operating	100%	ARK Mori Bldg., 30F 1-12-32 Akasaka, Minato-ku Tokyo, Japan
Mallinckrodt Pharmaceuticals Ireland Limited	Operating	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt Pharmaceuticals Limited	Operating	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt Quincy S.a.r.l.	Holding	100%	124 Boulevard de la Petrusse L-2330 Luxembourg Grand Duchy of Luxembourg
Mallinckrodt SAG Holdings GmbH	Inactive	100%	Solenbergstrasse 5 8207 Schaffhausen, Switzerland
Mallinckrodt Securitization S.a.r.l.	Finance and Administrative	100%	124 Boulevard de la Petrusse L-2330 Luxembourg Grand Duchy of Luxembourg
Mallinckrodt UK Finance LLP	Finance and Administrative	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt UK Ltd	Finance and Administrative	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt US Holdings LLC	Other	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt US Pool LLC	Finance and Administrative	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Veterinary, Inc.	Other	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Windsor Ireland Finance Unlimited Company	Other	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt Windsor S.a.r.l.	Holding	100%	124 Boulevard de la Petrusse L-2330 Luxembourg Grand Duchy of Luxembourg
MCCH LLC	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
MEH, Inc.	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
MHP Finance, LLC	Finance and Administrative	100%	1209 Orange Street Wilmington, Delaware 19801 United States
MKG Medical UK Ltd	Finance and Administrative	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
MNK 2011 LLC	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States

Montjeu Limited	Operating	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
MUSHI UK Holdings Limited	Holding	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
OCERA Therapeutics, Inc.	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Petten Holdings Inc.	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Profibrix B.V.	Inactive	100%	Herikerbergweg 238 Amsterdam 1101CM Netherlands
Questcor International Limited	Other	100%	Arthur Cox Building Earlsfort Terrace Dublin 2 Ireland
Sonorant Therapeutics Limited	Other	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
SpecGx Holdings LLC	Holding	100%	385 Marshall Ave. Webster Groves, MO 63119 United States
SpecGx LLC	Operating	100%	385 Marshall Ave. Webster Groves, MO 63119 United States
ST 2020 LLC	Other	100%	385 Marshall Ave. Webster Groves, MO 63119 United States
ST Operations LLC	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
ST Shared Services LLC	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
ST US AR Finance LLC	Finance and Administrative	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
ST US Holdings LLC	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
ST US Pool LLC	Finance and Administrative	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Stratatech Corporation	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Sucampo Finance Inc.	Finance and Administrative	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Sucampo GmbH	Operating	100%	Baarerstrasse 75 6300 Zug Switzerland
Sucampo Holdings Inc.	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Sucampo International Holdings Limited	Holding	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Sucampo Pharma Americas LLC	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Sucampo Pharma, LLC	Operating	100%	NBF Building 10 F, Uschisaiwai-cho Chiyoda-ku, Tokyo 100-0011 Japan

Sucampo Pharmaceuticals, Inc.	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Therakos (Belgium) SPRL	Operating	100%	Rue Royale 97 (4th Floor) B-1000 Brussels Belgium
Therakos (Canada) Company	Operating	100%	Suite 900, 1959 Upper Water Street P. O. Box 997 Halifax Nova Scotia B3J 3N2 Canada
Therakos (France) SAS	Operating	100%	105 Avenue Raymond Poincare 75116 Paris France
Therakos (Italia) S.r.l	Operating	100%	via Birmania 81 00144 Rome Italy
Therakos (UK), Ltd	Operating	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Therakos EMEA Limited	Operating	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Therakos Europe Limited	Holding	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Therakos Germany GmbH	Operating	100%	Walther-Cronberg-Platz 12 60594 Frankfurt am Main Germany
Therakos, Inc.	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Vtesse Inc.	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
WebsterGx Holdco LLC	Holdings	100%	385 Marshall Ave. Webster Groves, MO 63119 United States

As of December 31, 2021, the Group had the following branches and representative offices outside of Ireland:

<b>Branch</b>	<b>Country</b>
Mallinckrodt Group S.a.r.l. Luxembourg (LU) Schaffhausen Branch	Switzerland
Mallinckrodt Medical Holdings (UK) Limited, Zweigniederlassung Deutschland German Branch	Germany
Therakos (UK), Limited Dutch Branch	Netherlands
Therakos (UK), Limited, Prywatna Spolka Z Ograniczona Odpowiedzialnoscia) Oddzial W Polsce	Poland
Therakos (UK), Ltd Sweden Filial	Sweden
Therakos (UK), Limited, Sucursal en Espana	Spain

# **MALLINCKRODT PLC**

**(DEBTOR-IN-POSSESSION)**

**(IN EXAMINATION UNDER PART 10 OF THE IRISH COMPANIES ACT 2014)**

## **Company Financial Statements**

**For the Fiscal Year Ended December 31, 2021**



# INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF MALLINCKRODT PLC

## Report on the audit of the financial statements

### Opinion on the financial statements of Mallinckrodt plc (the 'Company')

In our opinion the Company financial statements:

- give a true and fair view of the assets, liabilities and financial position of the Company as at 31 December 2021 and of the loss of the Company for the financial year then ended; and
- have been properly prepared in accordance with the relevant financial reporting framework and, in particular, with the requirements of the Companies Act 2014.

The financial statements we have audited comprise:

- the Company Balance Sheet;
- the Company Statement of Changes in Equity;
- the related notes 1 to 13, including a summary of significant accounting policies as set out in note 1.

The relevant financial reporting framework that has been applied in the preparation of the financial statements is the Companies Act 2014 and FRS 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland" ("the relevant financial reporting framework").

### Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland) (ISAs (Ireland)) and applicable law. Our responsibilities under those standards are described below in the "*Auditor's responsibilities for the audit of the financial statements*" section of our report.

We are independent of the Company in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, including the Ethical Standard issued by the Irish Auditing and Accounting Supervisory Authority, as applied to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### Material uncertainty related to going concern

In auditing the financial statements, we have concluded that the directors' use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

We draw attention to note 1 in the financial statements, which indicates that the Company initiated proceedings under Chapter 11 of the United States Bankruptcy Code to modify its capital structure, including restructuring portions of its debt, and resolve potential legal liabilities. In connection with the filing of the Chapter 11 Cases, the Company entered into a Restructuring Support Agreement 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 Company's ability to continue as a going concern is contingent upon, among other things, its ability to implement a plan of reorganization, emerge from the Chapter 11 proceedings (including the Irish and Canadian proceedings) and generate sufficient liquidity following the reorganization to meet its obligations and operating needs.

Our evaluation of the directors' assessment of the Company's ability to continue to adopt the going concern basis of accounting included:

- obtaining an understanding of the relevant controls in place regarding going concern as part of our risk assessment procedures;
- reviewing documentation relating to the Chapter 11 bankruptcy (including proceedings in Ireland & Canada), the Restructuring Support Agreement and the Plan of Reorganization, details of which are included in note 2 of the Group Financial Statements;

- challenging the reasonableness of the key assumptions applied by the directors in their going concern assessment;
- holding discussions with management on the directors' going concern assessment, the future plans for the Group after Chapter 11 (including proceedings in Ireland & Canada) and the feasibility of those plans;
- obtaining an understanding of the Group's controls over the development and approval of the projections and assumptions used in the cash flow forecasts to support the going concern assumption and assessing the design and determining the implementation of these controls;
- testing the clerical accuracy of the cash flow forecast model;
- completing an assessment of the consistency of the models used to prepare the forecasts in line with other areas of our audit; and
- assessing the adequacy of the disclosures in the financial statements.

As stated in note 1, these events and conditions, along with the other matters as set forth in note 1 to the financial statements, indicate the existence of a material uncertainty on the Company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

Our responsibilities and the responsibilities of the directors with respect to going concern are described in the relevant sections of this report.

### **Emphasis of Matter - Bankruptcy Proceedings:**

We draw your attention to Note 2 to the Consolidated financial statements, which states that the company has filed for reorganization under Chapter 11 of the Bankruptcy Code in the United States and separately Mallinckrodt plc has commenced Examinership proceedings with the High Court of Ireland. 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. Our opinion is not modified in respect of this matter.

<b>Summary of our audit approach</b>	
<b>Key audit matter</b>	The key audit matter that we identified in the current year were: <ul style="list-style-type: none"> <li>• <i>Going Concern Basis of Preparation (see Material Uncertainty Related to Going Concern paragraph above).</i></li> </ul>
<b>Materiality</b>	The materiality that we used in the current year was \$4.14 million which was determined on the basis of <i>net liabilities</i> .
<b>Scoping</b>	We have determined the scope of our audit by obtaining an understanding of the Company and its environment, including assessing the risks of material misstatement at the Company level.
<b>Significant changes in our approach</b>	No significant changes to note.

### **Key audit matters**

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current financial year and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, including those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit; and directing the efforts of the engagement team.

Key audit matters are addressed in the context of an audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Other than the Going Concern basis of preparation there were no other key audit matters identified or communicated with those charged with governance.

Our audit procedures relating to this matter were designed in the context of our audit of the financial statements as a whole, and not to express an opinion on individual accounts or disclosures. Our opinion on the financial statements is not modified with respect to any of the risks described above, and we do not express an opinion on these individual matters.

### **Our application of materiality**

We define materiality as the magnitude of misstatement that makes it probable that the economic decisions of a reasonably knowledgeable person, relying on the financial statements, would be changed or influenced. We use materiality both in planning the scope of our audit work and in evaluating the results of our work.

We determined materiality for the Company to be \$4.14 million which is approximately 2.57% of net liabilities. We have considered net liabilities to be the critical component for determining materiality because we determined net liabilities to be of most importance to the principal external users of these financial statements as this is the key balance in this legal entity and holding this investment is the purpose of the entity.

We agreed with the Audit Committee that we would report to them any audit differences in excess of \$0.2 million or 5.0% of materiality, as well as differences below that threshold which, in our view, warranted reporting on qualitative grounds. We also report to the Audit Committee on disclosure matters that we identified when assessing the overall presentation of the financial statements.

### **An overview of the scope of our audit**

Our audit is a risk-based approach taking into account the structure of the Company, our knowledge of the Group and industry in which the company operates and the accounting processes and controls in place.

### **Other information**

The other information comprises the information included in the Directors' Report and Consolidated Financial Statements for the financial year ended 31 December 2021, other than the financial statements and our auditor's report thereon. The directors are responsible for the other information. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

Our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

### **Responsibilities of directors**

As explained more fully in the Directors' Responsibilities Statement, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view and otherwise comply with the Companies Act 2014, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Company or to cease operations, or have no realistic alternative but to do so.

### **Auditor's responsibilities for the audit of the financial statements**

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or

in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs (Ireland), we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of the auditor's report. However, future events or conditions may cause the entity (or where relevant, the Group) to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that the auditor identifies during the audit.

For listed entities and public interest entities, the auditor also provides those charged with governance with a statement that the auditor has complied with relevant ethical requirements regarding independence, including the Ethical Standard for Auditors (Ireland), and communicates with them all relationships and other matters that may reasonably be thought to bear on the auditor's independence, and where applicable, related safeguards.

Where the auditor is required to report on key audit matters, from the matters communicated with those charged with governance, the auditor determines those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. The auditor describes these matters in the auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, the auditor determines that a matter should not be communicated in the auditor's report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

## **Report on other legal and regulatory requirements**

### **Opinion on other matters prescribed by the Companies Act 2014**

Based solely on the work undertaken in the course of the audit, we report that:

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- In our opinion the accounting records of the company were sufficient to permit the financial statements to be readily and properly audited.
- The Company Balance Sheet is in agreement with the accounting records.
- In our opinion the information given in those parts of the directors' report as specified for our review is consistent with the financial statements and the directors' report has been prepared in accordance with the Companies Act 2014.

### **Matters on which we are required to report by exception**

Based on the knowledge and understanding of the Company and its environment obtained in the course of the audit, we have not identified material misstatements in those parts of the directors' report specified for our review.

The Companies Act 2014 also requires us to report to you if, in our opinion, the Company has not provided the information required by Regulation 5(2) to 5(7) of the European Union (Disclosure of Non-Financial and Diversity Information by certain large undertakings and groups) Regulations 2017 (as amended) for the financial year ended 31 December 2021. We have nothing to report in this regard.

We have nothing to report in respect of the provisions in the Companies Act 2014 which require us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by law are not made.

### **Other Matter**

We have reported separately on the Consolidated Financial Statements of Mallinckrodt plc for the financial year ended 31 December 2021.

### **Use of our report**

This report is made solely to the Company's members, as a body, in accordance with Section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the Company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company and the Company's members as a body, for our audit work, for this report, or for the opinions we have formed.



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Richard Howard  
For and on behalf of Deloitte Ireland LLP  
Chartered Accountants and Statutory Audit Firm  
Deloitte & Touche House, Earlsfort Terrace, Dublin 2  
Date: 1 April 2022

**MALLINCKRODT PLC**  
**(DEBTOR-IN-POSSESSION)**  
**(IN EXAMINATION UNDER PART 10 OF THE IRISH COMPANIES ACT 2014)**  
**COMPANY BALANCE SHEET**  
*(in millions)*

	Note	December 31, 2021	December 25, 2020
<b>Current Assets</b>			
Debtors	4	\$ 328.9	\$ 497.3
Cash at bank and in hand		12.7	2.5
		<u>341.6</u>	<u>499.8</u>
<b>Creditors (amounts falling due within one year)</b>			
Amounts owed to subsidiaries	5	10.9	111.4
Accruals and other creditors	5	2.8	0.8
		<u>13.7</u>	<u>112.2</u>
<b>Net Current Assets</b>		<u>327.9</u>	<u>387.6</u>
<b>Total Assets Less Current Liabilities</b>		327.9	387.6
Provision for liabilities	6	488.7	—
<b>Net (Liabilities) Assets</b>		<u>\$ (160.8)</u>	<u>\$ 387.6</u>
<b>Capital and Reserves</b>			
Called-up share capital presented as equity	8	\$ 18.9	\$ 18.8
Share premium account		5.7	5.7
Capital redemption reserve	8	5.3	5.3
Profit and loss account	8	(190.7)	357.8
Shareholders' (Deficit) Funds		<u>\$ (160.8)</u>	<u>\$ 387.6</u>

In accordance with Section 304(2) of the Irish Companies Act 2014, Mallinckrodt plc is availing itself of the exemption from presenting and filing its individual profit and loss account. Mallinckrodt plc's loss as determined in accordance with FRS 102 was \$558.7 million and \$305.1 million for fiscal 2021 and 2020, respectively.

Approved by the Board of Directors on 1 April 2022 and signed on its behalf by:

/s/ JoAnn A. Reed

JoAnn A. Reed

Director

/s/ Mark C. Trudeau

Mark C. Trudeau

Director

**MALLINCKRODT PLC**  
**(DEBTOR-IN-POSSESSION)**  
**(IN EXAMINATION UNDER PART 10 OF THE IRISH COMPANIES ACT 2014)**  
**COMPANY STATEMENT OF CHANGES IN EQUITY**  
*(in millions)*

	<u>Called-up Share Capital</u>		Share Premium Account	Capital Redemption Reserve	Other Reserves	Profit and Loss Account	Total
	Number	Amount					
<b>Balance as of December 27, 2019</b>	93.5	\$ 18.7	\$ 5.7	\$ 5.3	\$ 418.2	\$ 220.0	\$ 667.9
Loss after taxation	—	—	—	—	—	(305.1)	(305.1)
Vesting of restricted shares	0.6	0.1	—	—	(0.2)	(0.4)	(0.5)
Share-based compensation	—	—	—	—	25.3	—	25.3
Transfer to profit and loss account	—	—	—	—	(443.3)	443.3	—
<b>Balance as of December 25, 2020</b>	94.1	18.8	5.7	5.3	—	357.8	387.6
Loss after taxation	—	—	—	—	—	(558.7)	(558.7)
Vesting of restricted shares	0.2	0.1	—	—	—	—	0.1
Share-based compensation	—	—	—	—	10.2	—	10.2
Transfer to profit and loss account	—	—	—	—	(10.2)	10.2	—
<b>Balance as of December 31, 2021</b>	<u>94.3</u>	<u>\$ 18.9</u>	<u>\$ 5.7</u>	<u>\$ 5.3</u>	<u>\$ —</u>	<u>\$ (190.7)</u>	<u>\$ (160.8)</u>

**MALLINCKRODT PLC**  
**(DEBTOR-IN-POSSESSION)**  
**(IN EXAMINATION UNDER PART 10 OF THE IRISH COMPANIES ACT 2014)**  
**NOTES TO COMPANY FINANCIAL STATEMENTS**  
*(dollars in millions, except share data and where indicated)*

**1. Basis of Presentation and Summary of Significant Accounting Policies**

***Basis of Preparation***

Mallinckrodt plc (debtor-in-possession) (in examination under Part 10 of the Irish Companies Act 2014) ("the Company") is a public limited company incorporated in the Republic of Ireland with the registration number 522227. The business address of its registered office and principal executive offices is College Business and Technology Park, Cruiserath, Blanchardstown, Dublin 15, Ireland.

The principal activities of the Company and the Group have been set out on page 5 of the Directors' Report for fiscal year ended December 31, 2021.

The fiscal year ended December 31, 2021 Mallinckrodt plc parent company financial statements have been prepared in accordance with the Financial Reporting Standards applicable in the U.K. and Republic of Ireland ("FRS 102") together with the Irish Companies Act 2014. The directors have elected to prepare the parent company financial statements in a manner different from the consolidated financial statements of Mallinckrodt plc as they are prepared specifically to comply with Irish legislative requirements and represent the results and financial position of the parent company.

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

***Fiscal Year***

The Company reports its results based on a "52-53 week" year ending on the last Friday of December. Fiscal 2021 consisted of 53 weeks and fiscal 2020 consisted of 52 weeks. Unless otherwise indicated, fiscal 2021 and 2020 refer to the Company's fiscal years ended December 31, 2021 and December 25, 2020, respectively. All references to "fiscal" year are considered to be defined as "financial" year under FRS 102.

***Basis of Accounting***

The financial statements have been prepared under the historical cost convention, modified to include certain items at fair value, and in accordance with FRS 102 issued by the Financial Reporting Council.

***Disclosure Exemptions for qualifying entities under FRS 102***

FRS 102 allows a qualifying entity certain disclosure exemptions. As a qualifying entity, the Company has availed of the exemption from the requirements of Section 7 of FRS 102 and FRS 102 paragraph 3.17(d) to present a statement of cash flows.

***Statement of Compliance***

The entity financial statements have been prepared on a going concern basis and comply with FRS 102 and the Irish Companies Act 2014.

***Going Concern***

The accompanying consolidated financial statements are prepared in accordance with FRS 102 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 (the "Debtors") 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 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 (the "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. For more information regarding the *Opioid-Related Matters* and *Acthar Gel-Related Matters*, details of the RSA, and the Chapter 11 Cases, see Note 2 and 25 to the Group's Notes to the Consolidated Financial Statements. Refer to Note 29 of the Group's Notes to the Consolidated Financial statements for further information on the examinership process commenced by Mallinckrodt plc with the High Court of Ireland on February 14, 2022.

The U.S. Bankruptcy Court for the District of Delaware (the "Bankruptcy Court") has entered an order (the "Confirmation Order") confirming the fourth amended plan of reorganizations (with technical modifications) proposed by the Debtors (the "Plan") and the directors remain confident that the transactions contemplated by the Plan have a reasonable prospect of being successfully implemented; however, this is not within the Company's control but rather is subject to approval by the Bankruptcy Court, among other conditions. As such, the directors have concluded that the outcome of the Chapter 11 Cases represents a material uncertainty, which casts significant doubt about the Company's ability to continue as a going concern. 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 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<sup>®</sup> Gel (repository corticotropin injection) ("Acthar Gel")-related settlements, restructured debt obligations, and operating needs.

Although the directors believe that the Company's reorganization 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 Plan 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.

As of December 31, 2021, the Company's financial position had a net liability of \$160.8 million; however, having reviewed cash flow forecasts prepared by management and approved by the Board of Directors that assume the successful consummation of the transactions contemplated by the Plan and considering the uncertainties described above, the directors have a reasonable expectation that the Group will be able to successfully navigate the Chapter 11 proceedings and that the Group will be able to continue as a going concern for a period of twelve months from the date of approval of these financial statements and are satisfied to prepare the consolidated financial statements on a going concern basis. The consolidated financial statements do not include any adjustments that would be required if the Group were unable to continue as a going concern.

The Company 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.

### ***Significant Accounting Policies***

The significant accounting policies used in the preparation of the entity financial statements are set out below. These policies have been consistently applied to all financial periods presented.

#### ***Functional Currency***

Items included in these financial statements are measured using the currency of the primary economic environment in which Mallinckrodt plc operates ("the functional currency"). The financial statements are presented in U.S. dollars ("USD"), which is the Company's functional and presentation currency.

#### ***Currency Translation***

Transactions during the financial period denominated in foreign currencies have been translated at the rate of exchange ruling at the date of the transaction. Assets and liabilities denominated in foreign currencies are translated to USD at the rates of exchange ruling at the balance sheet date. The resulting profits or losses are dealt with in the profit and loss account.

### ***Investments in Subsidiary***

Mallinckrodt plc's investment in subsidiary is recorded at fair value of consideration given plus any directly attributable costs less impairment charges or recovery of the investment via dividend receipts. The investment is tested for impairment if circumstances or indicators suggest that impairment may exist.

### ***Debtors***

Debtor balances are carried at the original invoice or agreement amount, less any allowance for potentially uncollectable debts. A provision is recorded where there is evidence that the Company will not be in a position to collect the associated debt.

### ***Dividends***

Historically, Mallinckrodt plc has not made any cash dividends payments, as it has retained earnings to finance acquisitions, research and development and the operation and expansion of its subsidiaries' 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.

### ***Financial Instruments***

The Company has chosen to adopt Section 11 and 12 of FRS 102 with respect to financial instruments.

Financial assets and financial liabilities are recognized when the company becomes a party to the contractual provisions of the instrument.

Financial liabilities and equity instruments are classified according to the substance of the contractual arrangements entered into. An equity instrument is any contract that evidences a residual interest in the assets of the company after deducting all of its liabilities.

All financial assets and liabilities are initially measured at transaction price (including transaction costs), except for those financial assets classified at fair value through profit or loss, which are initially measured at fair value (which is normally the transaction price excluding transaction costs), unless the arrangement constitutes a financing transaction. If an arrangement constitutes a financing transaction, the financial asset or financial liability is measured at the present value of the future payments discounted at a market rate of interest for a similar debt instrument.

Financial assets are derecognised when and only when a) the contractual rights to the cash flows from the financial asset expire or are settled, b) the company transfers to another party substantially all of the risks and rewards of ownership of the financial asset, or c) the company, despite having retained some, but not all, significant risks and rewards of ownership, has transferred control of the asset to another party.

Financial liabilities are derecognised only when the obligation specified in the contract is discharged, canceled or expires.

## **2. Critical accounting judgements and key sources of estimation uncertainty**

In the application of the Company's accounting policies, which are described in Note 1, the directors are required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates. The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.

### ***Critical judgements in applying the Company's accounting policies***

The following are the critical judgements that the directors have made in the process of applying the Company's accounting policies and that have the most significant effect on the amounts recognized in the financial statements.

### Going concern

Refer to Note 1 for further information.

### Guarantee provision

The directors assessed the Company's full and unconditional guarantee of substantially all of the Group's debt. The view was formed that it was appropriate to make a provision with respect to these guarantees based on reference to the 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), and the subsequent amendments (the "Amended Plan"). When assessing the guarantee provision, the directors considered the fair value of the guaranteed unsecured notes, which are classified as level 1 given the availability of quoted prices in an active market as discussed further in Note 26 to the Group's Notes to the Consolidated Financial Statements. Refer to Note 6.

## 3. Financial Assets

Mallinckrodt plc owns 100% of the share capital of Mallinckrodt International Finance S.A. ("MIFSA"), a company incorporated in the Grand Duchy of Luxembourg. MIFSA functions as a holding company, established to own, directly or indirectly, substantially all of the operating subsidiaries of the Group, as well as to issue debt securities and to perform treasury operations.

Mallinckrodt plc owns 100% of the share capital of Mallinckrodt Inc., a company incorporated in the State of Delaware, in the United States of America. No activity occurred in Mallinckrodt Inc., during fiscal 2021.

As of December 31, 2021 and December 25, 2020, the carrying amount of the Company's investments in subsidiary was zero reflective of the market capitalization of the Group and the uncertainties regarding the outcome of the Chapter 11 and Irish examinership proceedings.

## 4. Debtors

Debtors were comprised of the following at the end of each financial period:

	December 31, 2021	December 25, 2020
Due from subsidiary undertakings	\$ 314.9	\$ 456.4
Other debtors and prepayments	6.5	7.2
Amounts falling due within one year	321.4	463.6
Due from subsidiary undertakings	—	24.0
Other debtors and prepayments	7.5	9.7
Amounts falling due after one year	7.5	33.7
Total debtors	\$ 328.9	\$ 497.3

Amounts due from subsidiary undertakings of \$302.9 million and \$278.3 million as of December 31, 2021 and December 25, 2020, respectively, relate to balances due from MIFSA as part of a cash management agreement. The balance is repayable on demand and is interest bearing.

Intercompany trade receivables of \$12.0 million and \$202.1 million as of December 31, 2021 and December 25, 2020, respectively, related to transactions in the normal course of business.

Within the Amended Plan, each intercompany claim will either be reinstated or canceled and released at the option of the Debtors. As a result, the Company has provided for a \$24.0 million provision on an intercompany claim with a wholly owned subsidiary.

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. Refer to Note 2 to the Group's Notes to the Consolidated Financial Statements for further information.

## 5. Creditors (amounts falling due within one year)

### Amounts Owed to Subsidiaries

Amounts due to subsidiary undertakings were comprised of the following at the end of each financial period:

	December 31, 2021	December 25, 2020
Due to subsidiary undertakings	\$ 10.9	\$ 111.4

Intercompany trade payables of \$10.9 million and \$111.4 million as of December 31, 2021 and December 25, 2020, respectively, relate to transactions in the normal course of business.

### Accruals and other creditors

Accruals and other creditors payable was \$2.8 million and \$0.8 million as of December 31, 2021 and December 25, 2020, respectively. As a result of the commencement of the Chapter 11 Cases, the payment of pre-petition liabilities are subject to compromise or other treatment pursuant to a plan of reorganization. As of both December 31, 2021 and December 25, 2020, \$0.2 million is classified as liabilities subject to compromise within Note 2 to the Group's Notes to the Consolidated Financial Statements.

## 6. Guarantees and Contingencies

Mallinckrodt plc, along with certain of its direct or indirect wholly-owned subsidiaries, has fully and unconditionally guaranteed substantially all of the Group's debt, as discussed in Note 22 to the Group's Notes to the Consolidated Financial Statements. The directors have formed the view that it is appropriate to make a provision of \$488.7 million with respect to these guarantees based on reference to the Amended Plan, under which 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 and taking into account the aggregate fair value of the guaranteed unsecured notes as of December 31, 2021, which was estimated to be \$863.7 million. Refer to Note 26 to the Group's Notes to the Consolidated Financial Statements for further information.

Mallinckrodt plc has entered into guarantee arrangements with various banks and third parties that provide Mallinckrodt Group companies with extensions of credit, including overdraft facilities, foreign exchange facilities and bank guaranty facilities. Under these arrangements, Mallinckrodt plc has unconditionally guaranteed all obligations of these Group companies to the banks and third parties, up to a maximum amount outstanding of approximately \$34.7 million as of December 31, 2021. The Company has assessed the fair value of these guarantees and determined them to be insignificant.

Mallinckrodt plc is subject to various legal proceedings and claims. These legal proceedings involving the Company, including the litigation described as the *Putative Class Action Securities Litigation (Shenk) and (Strougo)*, are described in Note 25 to the Group's Notes to the Consolidated Financial Statements.

## 7. Financial Instruments

The carrying value of the Company's financial assets and liabilities are summarized by category below:

	Note	December 31, 2021	December 25, 2020
<b>Financial Assets</b>			
<i>Measured at undiscounted amount receivable</i>			
Amount due from subsidiary undertakings	4	\$ 314.9	\$ 480.4
<b>Financial liabilities</b>			
<i>Measured at undiscounted amount payable</i>			
Trade and other payables		\$ 2.8	\$ 0.8
Amount owed to subsidiary undertakings	5	10.9	111.4
		<u>\$ 13.7</u>	<u>\$ 112.2</u>

## 8. Shareholders' Funds

*Called-up Share Capital presented as equity.* Mallinckrodt plc has authorized 500,000,000 ordinary shares, par value of \$0.20 per share, 94,296,235 and 94,111,303 of which were issued as of December 31, 2021 and December 25, 2020, respectively. Changes during fiscal 2021 are associated with shares issued under employee capital programs.

*Preference Shares.* Mallinckrodt plc is authorized to issue 500,000,000 preferred shares, par value of \$0.20 per share, none of which were issued and outstanding as of December 31, 2021 or December 25, 2020. Rights as to dividends, return of capital, redemption, conversion, voting and otherwise with respect to these shares may be determined by the Board of Directors on or before the time of issuance. In the event of the liquidation of the Group, holders of any preferred shares then outstanding would, if the shares were issued on such terms that they carry a preferential distribution entitlement on liquidation, be entitled to receive payment of the amount for which the preferred shares were subscribed and any unpaid dividends, prior to any payment to ordinary shareholders.

*Acquisition of Own Shares.* On March 1, 2017, the Board of Directors authorized a \$1.0 billion share repurchase program (the "March 2017 Program"). The March 2017 Program has no time limit or expiration date. The number of shares acquired and the timing of repurchases of ordinary shares under the March 2017 Program will depend on a number of factors, including share price, trading volume and general market conditions along with working capital requirements, general business conditions and other factors.

During fiscal 2021, Mallinckrodt plc acquired 63,498 shares at an average market price of \$0.33, which were accounted for as treasury shares within shareholders' funds and represent deemed acquisitions of shares issued in connection with the vesting of share-based awards to satisfy minimum statutory tax withholding obligations and are presented as "*Vesting of restricted shares*" in the statement of changes in equity. As of December 31, 2021, the Company had repurchased a total of 1,030,160 shares to satisfy minimum statutory tax withholding obligations.

No shares were acquired under the March 2017 Program during fiscal 2021. As of December 31, 2021, the Company had acquired 35,566,865 shares (with a par value of \$0.20 per share) for \$1,586.6 million under share buyback programs. The average market price of treasury shares purchased to date under share repurchase programs was \$44.61.

The Group operates an Employee Share Purchase Plan ("ESPP") for U.S. based employees. Mallinckrodt plc reissues treasury shares to satisfy obligations in relation to the plan. As of December 31, 2021, Mallinckrodt plc had reissued a total of 527,380 treasury shares in relation to the ESPP. The ESPP was suspended effective June 20, 2019 and remains unavailable as of December 31, 2021.

Mallinckrodt plc held 9,569,645 and 9,506,147 treasury shares which both had a nominal value of \$1.9 million as of December 31, 2021 and December 25, 2020, respectively. Treasury shares represent 7.9% of Company capital as of both December 31, 2021 and December 25, 2020. As of both December 31, 2021 and December 25, 2020, the total cost of treasury shares acquired under both the share repurchase program and shares repurchased to cover statutory tax withholding obligations was \$1,616.1 million.

*Undistributable Reserves.* As of December 31, 2021, the share premium account and capital redemption reserve amounted to \$5.7 million and \$5.3 million, respectively, both of which are considered undistributable reserves. Under Irish law, dividends and distributions cannot be made from undistributable reserves.

*Other Reserves.* The balance in other reserves is comprised of the contributed surplus on vested restricted stock and share-based compensation. The share-based compensation reflected in other reserves was \$10.2 million and \$25.3 million for fiscal 2021 and 2020, respectively. During fiscal 2021 and 2020, the Company transferred \$10.2 million and \$443.3 million from the other reserve to the profit and loss account reserve, respectively. Under Irish law, the Company can only pay dividends and repurchase shares out of distributable reserves. The Company did not declare or pay any dividends and the Company does not currently intend to pay dividends in the foreseeable future.

## 9. Directors' Remuneration and Key Management Personnel Compensation

Note 12 to the Group's Notes to Consolidated Financial Statements provides details of directors' remuneration. There were no other payments made to key management personnel from the Company during fiscal 2021 and 2020, respectively.

## 10. Auditor's Remuneration

Auditor's remuneration was as follows:

	Fiscal Year	
	2021	2020
Other assurance services	\$ 0.2	\$ 0.2
Other non-audit services	0.3	—
	<u>\$ 0.5</u>	<u>\$ 0.2</u>

Auditor's remuneration was less than \$0.1 million for the audit of individual accounts for both fiscal 2021 and 2020. Other non-audit services 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. No amounts were incurred for tax advisory services. Note 13 to the Group's Notes to Consolidated Financial Statements provides additional details of fees paid by the Group.

## 11. Related Party Transactions

The Company is availing itself of the exemption provided under Schedule 3, paragraph 67 (3), Irish Companies Act 2014, which exempts disclosure of transactions entered into between two or more members of a group, provided that any subsidiary undertaking which is party to the transaction is wholly owned by a member of the group.

## 12. Subsidiary Undertakings

Mallinckrodt plc owns Mallinckrodt Inc. and MIFSA. Details of the subsidiaries are included in Note 30 to the Group's Notes to Consolidated Financial Statements.

## 13. Post-Balance Sheet Events

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 Plan.

As detailed in Note 29 to the Group's Notes to Consolidated Financial Statements, following an 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 on February 28, 2022. The Examiner is currently in the process of convening such meetings of the creditors and shareholders of Mallinckrodt plc for the purposes of considering and voting to a proposed Scheme of Arrangement.

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.