2019 IRISH STATUTORY ACCOUNTS

MALLINCKRODT PLC

Directors' Report and Consolidated Financial Statements
For the Fiscal Year Ended December 27, 2019

MALLINCKRODT PLC

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DIRECTORS' REPORT

For the Fiscal Year Ended December 27, 2019

(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 27, 2019, beginning on page 46, and audited parent company financial statements for the fiscal year ended December 27, 2019, beginning on page 120.

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 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 2019 and 2018 both consisted of 52 weeks and ended on December 27, 2019, and December 28, 2018, 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, litigation and 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 and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; analgesics and gastrointestinal products.

We continue to execute on Mallinckrodt's ongoing transformation to become an innovation-driven biopharmaceutical company focused on improving outcomes for underserved patients with severe and critical conditions.

While the Group's principal executive offices are located in the U.K., the Group remains incorporated in Ireland and continues to be subject to the United States ("U.S.") Securities and Exchange Commission ("SEC") reporting requirements and the applicable corporate governance rules of the New York Stock Exchange.

Significant Events

Opioid-Related Matters

As a result of the greater awareness of the public health issue of opioid abuse, there has been increased scrutiny of, and investigation into, the commercial practices of opioid manufacturers by state and federal agencies. We, along with other opioid manufacturers, have been the subject of federal and state government investigations and enforcement actions, focused on the misuse and abuse of opioid medications in the U.S. Similar investigations may be initiated in the future. During fiscal 2019 and 2018, we incurred $56.2 million and $38.8 million in opioid defense costs, respectively, which are included in distribution and administration expenses ("D&A").

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

Litigation Settlement

On February 25, 2020, we, certain of our subsidiaries operating the Specialty Generics business (the "Specialty Generics Subsidiaries") and certain other affiliates announced an agreement in principle on the terms of a global settlement that would resolve all opioid-related claims against us, which we refer to herein as the "Litigation Settlement." The Litigation Settlement was reached with a court-appointed plaintiffs' executive committee representing the interests of thousands of plaintiffs in the MDL and supported by a broad-based group of 48 state and U.S. Territory Attorneys General. The Litigation Settlement would contemplate the filing of voluntary petitions under Chapter 11 of the U.S. Bankruptcy Code ("Chapter 11") by the Specialty Generics Subsidiaries and the establishment of a trust for the benefit of plaintiffs holding opioid-related claims against Mallinckrodt (the "Opioid Claimant Trust"). Under the terms of the proposed settlement, which would become effective upon the Specialty Generics Subsidiaries' emergence from a contemplated Chapter 11 process, subject to court approval and other conditions, we would (1) make cash payments of $1,600.0 million in structured payments over eight years, beginning upon the Specialty Generics Subsidiaries' emergence from the completed Chapter 11 case, the substantial majority of which is expected to be contributed to the Opioid Claimant Trust and (2) issue warrants with an eight year term to the Opioid Claimant Trust exercisable at a strike price of $3.15 per share to purchase our ordinary shares that would represent approximately 19.99% of our fully diluted outstanding shares, including after giving effect to the exercise of the warrants (the "Settlement Warrants"). As a result of the Litigation Settlement, we recorded a charge of $1,643.4 million attributed to the anticipated structured cash payments and the Settlement Warrants to be issued upon effectiveness of the settlement.

The Litigation Settlement included a number of conditions, such as the outcome of our lawsuit against the U.S. Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS" and together with the HHS, the "Agency") regarding our calculation of Medicaid drug rebates for Acthar® Gel (repository corticotropin injection) ("Acthar Gel"). On March 16, 2020, we received an adverse decision from the federal district court for the District of Columbia with respect to the Medicaid lawsuit. We are engaged in constructive dialogue with the plaintiff parties to the

Litigation Settlement to address the impact of the court's decision, but there can be no assurance that such dialogue will result in a modification of or amendment to the Litigation Settlement that will be satisfactory to all parties. Further discussion of the Medicaid lawsuit is included below and in Note 26 of the Notes to the Consolidated Financial Statements.

The court-supervised process would also be expected to provide a fair, orderly, efficient and legally binding mechanism to resolve all opioid-related claims against the Group, Specialty Generics, and all of our other subsidiaries and related entities. Mallinckrodt plc and our Specialty Brands-related subsidiaries would not be part of the Chapter 11 filing. If the Litigation Settlement is consummated, it is expected that Mallinckrodt plc would receive the benefit of a "channeling injunction" that would provide for the release of all opioid-related claims that have been or could have been asserted against Mallinckrodt plc or our subsidiaries related to Specialty Generics' manufacture and sale of opioids prior to the time the Specialty Generics Chapter 11 plan becomes effective. All of our subsidiaries, including Specialty Generics, are operating as normal and would be expected to continue operating normally throughout the court-supervised process contemplated for Specialty Generics. If the Litigation Settlement is consummated, we currently expect that the Specialty Generics Subsidiaries would continue to be an indirect, wholly owned subsidiary of Mallinckrodt plc during and following emergence from the contemplated court-supervised process. Further discussion of this Litigation Settlement is included in Note 30 of the Notes to the Consolidated Financial Statements.

Separation

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

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

Silence Therapeutics

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

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

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

BioVectra

In November 2019, we completed the sale of BioVectra Inc. ("BioVectra") to an affiliate of H.I.G. Capital with total consideration of up to $250.0 million including an upfront payment of $135.0 million and contingent consideration of $115.0 million based on the long-term performance of the business. During fiscal 2019, the Group recorded a loss on the sale of $33.5

million, which excluded any potential proceeds from future milestones, in the event they are achieved. The financial results of BioVectra's operations are presented within continuing operations as this divestiture did not meet the criteria for discontinued operations classification.

Medicaid Lawsuit

In May 2019, we filed a lawsuit in federal district court against the Agency. This lawsuit is in response to a decision by CMS to require that we revert to the original base date average manufacturer price ("AMP") used to calculate Medicaid drug rebates for Acthar Gel. In March 2020, we received an adverse decision from the court, which upheld CMS' decision to reverse its previous determination of the base date AMP used to calculate Acthar Gel rebates. We intend to continue to vigorously defend ourselves in this matter and, on March 16, 2020, filed an Emergency Motion for Reconsideration and Stay of Entry of Judgment Pending Reconsideration Or, Alternatively, Injunction Pending Appeal. In response, the government has agreed that CMS will not require us to change the Medicaid rebate calculation for Acthar Gel until at least the end of May 2020, which will allow the court time to decide the Group's motion. In the event the court denies the motion, we will immediately appeal the decision to the U.S. Court of Appeals for the D.C. Circuit. In the absence of court intervention and based on the effective date of the ruling and change to the base date AMP, we will pay roughly $630.0 million for the period from January 1, 2013 to December 27, 2019. Based on current Medicaid patient volume, we estimate the annualized prospective change to the Medicaid rebate calculation will reduce Acthar Gel annual net sales by roughly $90.0 to $100.0 million. Further discussion of this matter and other related matters are included in Note 26 of the Notes to the Consolidated Financial Statements.

Tax Matters

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

Reorganization of Intercompany Financing and Legal Entity Ownership

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

Likely Future Developments

Specialty Brands. Turnover of Acthar Gel for fiscal 2019 decreased $157.4 million, or 14.2%, to $952.7 million driven primarily by continued reimbursement challenges impacting new and returning patients and continued payer scrutiny on overall specialty pharmaceutical spending. This was partially offset by continued strength in Ofirmev, INOmax® (nitric oxide) gas, for inhalation ("INOmax") and Therakos® photopheresis ("Therakos") and an increase in turnover related to Amitiza® (lubiprostone) ("Amitiza"), which was acquired in the first quarter of 2018.

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

Research and Development. We devote significant resources to R&D of products and proprietary drug technologies. During fiscal 2019, we incurred R&D expenses of $349.4 million. We expect to continue to pursue targeted investments in R&D activities, both for existing products and the development of new portfolio assets. We intend to focus our R&D investments in the specialty pharmaceuticals areas, specifically investments to support our Specialty Brands portfolio, where we believe there is the greatest opportunity for growth and profitability.

We have completed the Phase 3 clinical studies for two of our development programs, terlipressin for the treatment of hepatorenal syndrome ("HRS") type 1 and StrataGraft for the treatment of deep partial thickness burns, both of which had positive top line results. In March 2020, we completed the submission of the new drug application ("NDA") to the U.S. Food and Drug Administration ("FDA") for terlipressin and in April 2020, we initiated our rolling submission of a biologics license application ("BLA") filing for StrataGraft and expect to complete the submission in the coming months. Upon approval we would be responsible for a one-time milestone payment related to terlipressin of $12.5 million. As part of the contingent consideration included in our acquisition of StrataGraft, we are responsible for a $20.0 million payment upon submission and another $20.0 million upon approval.

Non-restructuring Impairment Charges. During fiscal 2019, we recognized non-restructuring impairment charges of $388.0 million on our in-process research and development ("IPR&D") assets related to stannsoporfin and VTS-270. The charge related to stannsoporfin was $113.5 million, resulting from us no longer pursuing this development product and the charge related to VTS-270 was $274.5 million, primarily driven by continued regulatory challenges; however, the Group will continue to engage with the FDA and assess future opportunities for the VTS-270 development program.

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.

Turnover on a constant currency basis, which measures the change in turnover between current and prior year periods using a constant currency (the exchange rate in effect during the applicable prior-year period), was 1.5% during fiscal 2019. A reconciliation of this non-U.S. GAAP financial measure to turnover, the most directly comparable U.S. GAAP financial measure, is as follows *(dollars in millions)*:

	Fiscal Year				
	2019	2018	Decrease in Turnover	Currency Impact	Turnover on a Constant Currency Basis
Turnover from Ordinary Activities	$ 3,162.5	$ 3,215.6	(1.7)%	(0.2)%	(1.5)%

Adjusted net income, adjusted gross profit and adjusted selling, general and administrative ("SG&A") expenses 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. The adjustments for these items are on a pre-tax basis for adjusted gross profit and adjusted SG&A and on an after-tax basis for adjusted net income. Adjustments to U.S. GAAP amounts include, as applicable to each measure, amortization and non-restructuring impairment charges; restructuring and related charges, net; inventory step-up expenses; discontinued operations; changes in fair value of contingent consideration obligations; acquisition-related expenses; significant legal and environmental charges; losses on divestiture; unrealized gain on equity investment; gains on debt extinguishment, net; separation costs; research and development upfront payments; tax effects of aforementioned adjustments; changes in uncertain tax positions, as well as impacts from certain transactions, such as acquisitions or reorganizations; and other items identified by the Group. Adjusted diluted earnings per share represent adjusted net income divided by the number of diluted shares. 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, except per share data)	Fiscal Year							
	2019				2018			
	Gross profit	**SG&A**	**Net (loss) income**	**Diluted net (loss) income per share [1]**	**Gross profit**	**SG&A**	**Net (loss) income**	**Diluted net (loss) income per share [1]**
U.S. GAAP, as previously reported	$ 1,421.4	$ 831.0	$ (996.5)	$ (11.88)	$ 1,471.2	$ 834.1	$ (3,607.0)	$ (42.94)
Adjustments:								
Intangible asset amortization	847.9	(5.5)	853.4	10.14	733.6	(6.6)	740.2	8.69
Restructuring and related charges, net [2]	—	—	(1.7)	(0.02)	3.0	(2.2)	108.2	1.27
Inventory step-up expense	10.0	—	10.0	0.12	120.8	—	120.8	1.42
Income from discontinued operations	—	—	(10.7)	(0.13)	—	—	(14.9)	(0.17)
Change in contingent consideration fair value	—	60.2	(60.2)	(0.71)	—	50.2	(50.2)	(0.59)
Acquisition related expenses	—	—	—	—	—	(5.8)	5.8	0.07
Non-restructuring impairment charges [3]	—	—	388.0	4.61	—	—	3,893.1	45.69
Significant legal and environmental charges [4]	—	(28.2)	1,671.6	19.85	—	(19.7)	19.7	0.23
Divestitures	—	—	33.5	0.40	—	—	0.8	0.01
R&D upfront payment	—	—	20.0	0.24	—	—	—	—
Separation costs	—	(63.9)	63.9	0.76	—	(6.0)	6.0	0.07
Gains on debt extinguishment, net	—	—	(466.6)	(5.54)	—	—	(12.7)	(0.15)
Unrealized gain on equity investment [5]	—	—	(20.2)	(0.24)	—	—	—	—
Legal entity and intercompany financing organization	—	—	(212.8)	(2.53)	—	—	(256.0)	(3.00)
U.S. Tax Reform	—	—	—	—	—	—	(8.5)	(0.10)
Income taxes [6]	—	—	(524.2)	(6.23)	—	—	(263.1)	(3.09)
As adjusted	$ 2,279.3	$ 793.6	$ 747.5	$ 8.88	$ 2,328.6	$ 844.0	$ 682.2	$ 8.01

(1) In periods where losses from continuing operations are incurred, potential ordinary shares outstanding are excluded from the calculation of diluted earnings per share, prepared in accordance with GAAP, as they would be anti-dilutive. These dilutive shares are included in the calculation of adjusted diluted earnings per share if dilutive to adjusted net income. As a result, the adjusted diluted earnings per share utilized a weighted average share count of 84.2 and 85.2 shares for fiscal 2019 and 2018, respectively.

(2) Includes pre-tax accelerated depreciation.

(3) Fiscal 2019 includes IPR&D intangible asset impairments of $274.5 and $113.5 million related to VTS-270 and stannsoporfin, respectively. Fiscal 2018 includes the goodwill impairment of $3,672.8 million and an IPR&D intangible asset impairment of $218.3 million related to MNK-1411.

(4) Includes the opioid-related litigation settlement charge of $1,643.4 million.

(5) Represents an unrealized gain related to the Group's equity investment in Silence.

(6) Includes tax effects of above adjustments (unless otherwise separately stated), changes in related uncertain tax positions, as well as certain installment sale transactions and other intercompany transactions.

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 $996.5 million and $3,607.0 million for fiscal 2019 and 2018, respectively, were recorded to profit and loss account. No profits were distributed as dividends during fiscal 2019 or 2018 and the Group did not make any share repurchases under its authorized share repurchase program during fiscal 2019, compared to $55.2 million spent by the Group to acquire its own shares during fiscal 2018. Refer to Note 29 of the Notes to the Consolidated Financial Statements for further information.

The following tables present the consolidated results of operations for fiscal 2019 and 2018 as reported in the Group's 2019 Annual Report on Form 10-K. A reconciliation of the amounts reported in the Group's 2019 Annual Report on Form 10-K to the amounts reported within the Consolidated Profit and Loss Account included in this Directors' Report are included in the tables below. All discussions below are comparative between fiscal 2019 and 2018.

(in millions)	Fiscal Year							
	2019				2018			
	Ordinary Activities		Discontinued Operations	Total Group	Ordinary Activities		Discontinued Operations	Total Group
Turnover	$ 3,162.5	100.0%	$ —	$ 3,162.5	$ 3,215.6	100.0%	$ —	$ 3,215.6
Cost of sales	1,741.1	55.1	—	1,741.1	1,744.4	54.2	—	1,744.4
Gross profit	1,421.4	44.9	—	1,421.4	1,471.2	45.8	—	1,471.2
Distribution and administrative expenses	831.0	26.3	—	831.0	834.1	25.9	—	834.1
Research and development costs	349.4	11.0	—	349.4	361.1	11.2	—	361.1
Restructuring charges, net	(1.7)	(0.1)	—	(1.7)	103.0	3.2	—	103.0
Non-restructuring impairment charges	388.0	12.3	—	388.0	3,893.1	121.1	—	3,893.1
Loss (profit) on disposal of operations	33.5	1.1	(12.4)	21.1	0.8	—	(16.3)	(15.5)
Opioid-related litigation settlement charge	1,643.4	52.0	—	1,643.4	—	—	—	—
Operating (loss) profit	(1,822.2)	(57.6)	12.4	(1,809.8)	(3,720.9)	(115.7)	16.3	(3,704.6)
Interest payable and similar expenses	(309.0)	(9.8)	—	(309.0)	(370.2)	(11.5)	—	(370.2)
Interest receivable and similar income	9.5	0.3	—	9.5	8.2	0.3	—	8.2
Gains on debt extinguishment, net	466.6	14.8	—	466.6	8.5	0.3		8.5
Other income, net	63.6	2.0	—	63.6	22.4	0.7	—	22.4
(Loss) profit before taxation	(1,591.5)	(50.3)	12.4	(1,579.1)	(4,052.0)	(126.0)	16.3	(4,035.7)
Taxation (credit) charge	(584.3)	(18.5)	1.7	(582.6)	(430.1)	(13.4)	1.4	(428.7)
(Loss) profit after taxation	$ (1,007.2)	(31.8)	$ 10.7	$ (996.5)	$ (3,621.9)	(112.6)	$ 14.9	$ (3,607.0)

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

Turnover generated by our businesses in the U.S. was $2,765.6 million and $2,834.5 million in fiscal 2019 and 2018, respectively. Our non-U.S. businesses generated turnover of $396.9 million and $381.1 million in fiscal 2019 and 2018, respectively, which represented approximately 12.6% of our turnover in fiscal 2019 and 11.9% of our turnover in fiscal 2018.

Gross profit. Gross profit for fiscal 2019 decreased $49.8 million, or 3.4%, to $1,421.4 million, compared with $1,471.2 million in fiscal 2018, due in part to the $53.1 million decrease in turnover, as discussed above. Gross profit margin was 44.9% for fiscal 2019, compared with 45.8% in fiscal 2018. The decrease in gross profit and gross profit margin was primarily

attributable to a change in product mix driven by the decrease in Acthar Gel turnover and an additional $107.3 million of amortization for the Ofirmev intangible asset resulting from a change in amortization method on day 1 of fiscal 2019, as discussed further in Note 16 of the Notes to the Consolidated Financial Statements. The additional amortization was partially offset by a decrease in the amortization of the inventory fair value adjustment related to Amitiza, which was fully amortized during the first quarter of 2019.

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

Research and development costs. R&D expenses decreased $11.7 million, or 3.2%, to $349.4 million in fiscal 2019, compared with $361.1 million in fiscal 2018. This decrease was driven by the completion of certain development programs, partially offset by the $20.0 million upfront payment made to Silence during fiscal 2019. The 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 11.0% and 11.2% in fiscal 2019 and 2018, respectively.

Restructuring and related charges, net. During fiscal 2019, we recognized a net benefit of $1.7 million of restructuring and related charges, net. During fiscal 2019, we finalized the settlement of the contract termination costs related to the production of Raplixa resulting in a $14.1 million reversal of the associated restructuring reserve that was previously established in fiscal 2018. This was partially offset by restructuring charges related to employee severance and benefits. During fiscal 2018, we recorded $108.2 million of restructuring and related charges, net, of which $5.2 million related to accelerated depreciation and was included in cost of sales. The remaining $103.0 million primarily related to the estimated contract termination costs related to the production of Raplixa, exiting certain facilities and employee severance and benefits.

Non-restructuring impairment charges. Non-restructuring impairment charges were $388.0 million for fiscal 2019 resulting from the $274.5 million full impairment related to our VTS-270 intangible asset and the $113.5 million full impairment related to our stannsoporfin intangible asset, both as previously discussed. Non-restructuring impairment charges were $3,893.1 million for fiscal 2018 primarily related to the $3,672.8 million full goodwill impairment and the $218.3 million full impairment related to our MNK-1411 intangible asset.

Loss (profit) on disposal of operations. We recorded income of $10.7 million and $14.9 million on discontinued operations, net of income taxes, during fiscal 2019 and 2018, respectively. During fiscal 2019 and 2018, the income from discontinued operations included $9.0 million and $13.6 million of income, net of tax, respectively, from the receipt of contingent consideration related to the sale of the Nuclear Imaging business. The remaining amounts in both periods represented various post-sale adjustments associated with our previous divestitures. Additionally, during fiscal 2019, we completed the sale of BioVectra for a loss of $33.5 million. During fiscal 2018, we sold a portion of our Hemostasis business, inclusive of our PreveLeak and Recothrom products. As a result of this sale, we recorded a loss of $0.8 million.

Opioid-related litigation settlement charge. During fiscal 2019, we recorded a charge of $1,643.4 million attributed to the anticipated structured cash payments and the stock warrants to be issued upon effectiveness of the settlement. For further information, refer to Note 30 of the Notes to the Consolidated Financial Statements.

Interest payable and similar expenses and interest receivable and similar income, net. During fiscal 2019 and 2018, interest payable and similar expenses and interest receivable and similar income, net were $299.5 million and $362.0 million, respectively. This $62.5 million decrease was attributable to a lower average outstanding debt balance during fiscal 2019 that yielded a decrease in interest expense of $26.6 million, a $23.7 million decrease in interest accrued on deferred tax liabilities associated with our previously outstanding installment notes and the recognition of an $8.6 million benefit to interest expense during fiscal 2019 due to a lapse of certain statute of limitations. For further information, refer to Note 26 of the Notes to the Consolidated Financial Statements. Additionally, non-cash interest expense decreased by $2.4 million over the comparable period. Interest income increased to $9.5 million during fiscal 2019, compared to $8.2 million during fiscal 2018, primarily related to interest on preferred equity certificates received as contingent consideration associated with the sale of the Nuclear Imaging business.

Gains on debt extinguishment, net. During fiscal 2019 and 2018, we recorded gains on debt extinguishment, net, of $466.6 million and $8.5 million, respectively. During fiscal 2019, we completed a private exchange of our senior unsecured notes resulting in a gain of $377.4 million, net of the write-off of associated deferred financing fees of $4.9 million. For further information, refer to Note 23 of the Notes to the Consolidated Financial Statements. Fiscal 2019 also included a gain of $98.6

million on debt repurchases that aggregated to a total principal amount of $492.1 million, partially offset by the write-off of associated deferred financing fees of $9.4 million. Fiscal 2018 included a gain of $12.7 million on debt repurchases that aggregated to a total principal amount of $81.8 million, partially offset by the write-off of associated deferred financing fees of $4.2 million.

Other income, net. During fiscal 2019 and 2018, we recorded other income, net, of $63.6 million and $22.4 million, respectively. This was primarily driven by a $23.5 million increase in royalty income related to our license agreement with Advanced Accelerator Applications for turnover of their Lutathera product. In addition, we recorded an unrealized gain on investment of $20.2 million related to our equity investment in Silence. The remaining amounts in both fiscal years represented non-service pension expense and other items, including gains and losses on intercompany financing, foreign currency transactions and related hedging instruments.

Taxation. During fiscal 2019, we recognized a taxation credit of $584.3 million on a loss on ordinary activities before taxation of $1,591.5 million. The fiscal 2019 taxation credit was comprised of $21.8 million of current taxation charge and $606.1 million of deferred taxation credit, which was predominantly related to previously acquired intangibles, the opioid-related litigation settlement charge, the generation of tax loss and credit carryforwards net of valuation allowances, the non-restructuring impairment charge, as well as the reorganization of our intercompany financing and associated legal entity ownership, which eliminated the interest-bearing deferred tax obligation. During fiscal 2018, we recognized a taxation credit of $430.1 million on a loss on ordinary activities before taxation of $4,052.0 million. The fiscal 2018 taxation credit was comprised of $112.8 million of current taxation charge and $542.9 million of deferred taxation credit, which was predominantly related to the reorganization of our intercompany financing and associated legal entity ownership and generation of net operating losses.

Our effective tax rate was 36.7% and 10.6% for fiscal 2019 and 2018, respectively. Our effective tax rate for fiscal 2019 was most significantly impacted by the recognition of $212.8 million taxation credit associated with the reorganization of our intercompany financing and associated legal entity ownership. Further impacts include receiving $211.9 million of taxation credit associated with the $1,643.4 million opioid-related litigation settlement charge, $71.9 million of taxation credit associated with the $386.3 million of restructuring costs and non-restructuring impairment charges, $18.7 million of taxation credit associated with accrued income tax liabilities and uncertain tax positions, $13.5 million of taxation credit primarily associated with U.S. taxation credits, $11.4 million of taxation credit associated with separation costs of $63.9 million, $10.2 million of taxation charges associated with a gain on debt extinguishment of $466.6 million, $8.0 million of taxation credit associated with a legal settlement charge of $28.2 million, $7.6 million of taxation charge associated with $60.2 million of income from the decrease in the fair value of contingent consideration liabilities and zero taxation impact associated with a $33.5 million loss associated with the sale of BioVectra. Any remaining impacts were related to the impact of recent acquisitions. Our effective tax rate for fiscal 2018 was most significantly impacted by the recognition of $256.0 million taxation credit associated with the reorganization of our intercompany financing and associated legal entity ownership; partially offset by a decrease to taxation credit of $73.2 million associated with accrued income tax liabilities and uncertain tax positions. Further impacts include receiving $60.9 million of taxation credit associated with the $4,001.3 million of restructuring costs and non-restructuring impairment charges, $25.9 million of taxation credit primarily associated with U.S. tax credits, $2.7 million of taxation credit associated with a $0.8 million loss associated with the sale of our PreveLeak and Recothrom assets, and $2.2 million of taxation charge associated with $50.2 million of income from the decrease in the fair value of contingent consideration liabilities. Any remaining impacts were related to the impact of recent acquisitions and the reduction in the U.S. federal corporate statutory rate from U.S. Tax Reform.

Financial Position

Our financial position is set out on page 55. At the end of fiscal 2019 and 2018, we had total assets of $10,338.9 million and $10,877.3 million, respectively, and total liabilities of $8,398.2 million and $7,990.0 million, respectively. We incurred a loss after taxation of $996.5 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 our company.

Risks Related to Our Business

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. The following discussion highlights some of these risks and others are discussed elsewhere in this Directors' Report and accompanying financial statements. These and other risks could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

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

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

In addition, a significant number of lawsuits have been filed against us, other opioid manufacturers, distributors and others in the supply chain by cities, counties, state Attorneys General and private persons seeking to hold us and others accountable for opioid misuse and abuse. As of April 7, 2020, the cases we are aware of include, but are not limited to, approximately 2,528 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 259 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers; approximately 117 cases filed by individuals; approximately seven 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 7, 2020, the Mallinckrodt defendants in these cases consist of Mallinckrodt plc and the following subsidiaries of Mallinckrodt plc: Mallinckrodt Enterprises LLC, Mallinckrodt LLC, SpecGx LLC, Mallinckrodt Brand Pharmaceuticals Inc., Mallinckrodt Inc., MNK 2011 Inc. and Mallinckrodt Enterprises Holdings, Inc. However, there can be no assurance that plaintiffs will not assert claims against additional Mallinckrodt plc subsidiaries in the future. The lawsuits assert a variety of claims, including, but not limited to, public nuisance, negligence, civil conspiracy, fraud, violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO") or similar state laws, violations of state Controlled Substances Act of 1970 ("CSA") or state False Claims Act, product liability, consumer fraud, unfair or deceptive trade practices, false advertising, insurance fraud, unjust enrichment and other common law and statutory claims arising from defendants' manufacturing, distribution, marketing and promotion of opioids and seek restitution, damages, injunctive and other relief and attorneys' fees and costs. The claims generally are based on alleged misrepresentations and/or omissions in connection with the sale and marketing of prescription opioid medications and/or an alleged failure to take adequate steps to prevent diversion. Other parties may file similar lawsuits against us in the future.

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

On February 25, 2020, we, the Specialty Generics Subsidiaries and certain other affiliates have reached an agreement in principle on the terms of a global settlement that would resolve all opioid-related claims against us. The Litigation Settlement included certain contingencies and may not go into effect in its current form or at all, as a result of which our business prospects may be adversely impacted. The Litigation Settlement contemplates the filing of voluntary petitions under Chapter 11 by the Specialty Generics Subsidiaries and the Opioid Claimant Trust. Any bankruptcy of the Specialty Generics Subsidiaries (as contemplated by the Litigation Settlement or otherwise) would subject both the Specialty Generics Subsidiaries and us and our other subsidiaries to additional risks and uncertainties that could adversely affect our business prospects and ability to

continue as a going concern, including, but not limited to by causing increased difficulty obtaining and maintaining commercial relationships on competitive terms with customers, suppliers and other counterparts; increased difficulty retaining and motivating key employees, as well as attracting new employees; diversion of management's time and attention to dealing with bankruptcy and restructuring activities rather than focusing exclusively on business operations; incurrence of substantial costs, fees and other expenses associated with bankruptcy proceedings; and loss of ability to maintain or obtain sufficient financing sources for operations or to fund any reorganization plan and meet future obligations. We would in that event also be subject to risks and uncertainties caused by the actions of creditors and other third parties who have interests that may be inconsistent with our plans. Furthermore, depending on developments with respect to the Litigation Settlement and other factors, it may be necessary or advisable for us and/or our subsidiaries other than the Specialty Generics Subsidiaries to seek to restructure our or their obligations in a bankruptcy proceeding. Such a bankruptcy could further exacerbate the foregoing risks.

In addition, legislative, regulatory or industry measures to address the misuse of prescription opioid medications may also affect our business in ways that we are not able to predict. For example, the State of New York enacted the Opioid Stewardship Act (the "OSA"), which went into effect on July 1, 2018 and established an aggregate $100.0 million annual assessment on turnover of certain opioid medications in New York. The OSA was successfully challenged, and on December 19, 2018, the U.S. District Court for the Southern District of New York ruled that the OSA was unconstitutional and enjoined its enforcement. On January 17, 2019, the State of New York appealed this ruling. The litigation is still pending. In April 2019, the State of New York passed its 2020 budget, which amended the OSA so that if the OSA decision is reversed on appeal, the OSA would apply only to the 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, Rhode Island and Delaware have enacted opioid taxes, Minnesota and Maine have enacted increased licensure and registration fees and other states are considering similar legislation that could require entities to pay an assessment or tax on the 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 operational changes or commercial arrangements, such legislation in the aggregate may have a material adverse effect on our business, financial condition, results of operations and cash flows. See the risk factor “Extensive laws and regulations govern the industry in which we operate, and any failure to comply with such laws and regulations, including any changes to those laws and regulations may materially adversely affect us.” for more information.

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

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

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

The Litigation Settlement is neither final nor binding and there is no assurance that the necessary parties will agree to definitive documentation, that the contingencies to any agreement will be fulfilled or that any potential settlement agreement entered into by us will be on terms as favorable as the Litigation Settlement. In particular, the Litigation Settlement is subject to a number of conditions, many of which may not be satisfied. Among other things, the Litigation Settlement included certain contingencies, such as the outcome of the Medicaid lawsuit, with respect to which we received an adverse decision from the court in March 2020. Moreover, we and the other parties to the Litigation Settlement do not intend to proceed with its implementation absent supermajority support and participation amongst the plaintiffs in the opioid cases, and there is no assurance that such support and participation will be obtained. Furthermore, the Litigation Settlement is intended to be implemented through a filing by the Specialty Generics Subsidiaries of a pre-arranged bankruptcy case under Chapter 11, which will require confirmation of a plan of reorganization by a U.S. Bankruptcy Court. Confirmation of such a plan is uncertain and could be denied.

Furthermore, subject to the satisfaction of the conditions to the Litigation Settlement, the consummation of the Litigation Settlement would become effective upon the emergence of the Specialty Generics Subsidiaries from Chapter 11 bankruptcy, the timing of which emergence is uncertain. The settlement process may use a significant portion of our resources and divert

management's attention from our day-to-day operations, all of which could harm our business. Furthermore, the Litigation Settlement may not be implemented or consummated in its current form, or not at all. In such circumstances, we would be subject to continued litigation with certain plaintiffs with opioid-related claims. If the Litigation Settlement is not fully implemented or consummated, we or our subsidiaries may become subject to some or all of the liabilities that would have otherwise been settled, which could have a material and adverse effect on our business, financial condition, results of operations and cash flows. The failure of the Litigation Settlement may also lead to Mallinckrodt plc's subsequent bankruptcy, which would subject us to additional risks and uncertainties that could adversely affect our business prospects, as further described in the risk factor "Governmental investigations, inquiries, and regulatory actions and lawsuits brought against us by government agencies and private parties with respect to our historical commercialization of opioids could adversely affect our business, financial condition, results of operations and cash flows."

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

A pandemic, epidemic or outbreak of an infectious disease occurring in the U.S., or elsewhere, could result in our business being adversely affected. In December 2019, a novel strain of coronavirus, "COVID-19", was identified in China, which has now spread to countries throughout the world, including Ireland, the U.K. and the U.S. The spread of the COVID-19 virus has resulted in the World Health Organization declaring the outbreak as a pandemic.

We may experience significant and unpredictable increases 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 Ofirmev product is currently the only intravenous formulation of acetaminophen available in the U.S., and 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, both of which could be subject to similar dynamics. Alternatively, due to the deprioritization of non-critical medical treatment in the face of this pandemic, demand for other of our products may be negatively affected. Further, U.S. President Trump recently invoked emergency powers 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, and given the critical nature of some of the products we manufacture, as well as our pharmaceutical and medical device manufacturing capabilities, we may be impacted by governmental action taken under this or similar legislation.

Many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus. Such disruptions could materially delay potential FDA approval with respect to our clinical trials and product candidates, including the FDA's decision on our NDA for terlipressin. Other known and unknown factors caused by the COVID-19 virus could also materially delay our clinical trials that may be required for this or other product candidates, 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. Any delays in our clinical trials or regulatory review resulting from such disruptions could materially affect the development and/or approval of our product candidates.

In addition, the economic impact of the COVID-19 virus' spread, which has caused a broad impact globally, may adversely affect us. In particular, the COVID-19 virus may negatively affect demand for our products by limiting the ability of our sales representatives to meet with physicians and patients to visit their doctors and pharmacists to receive prescriptions for our products. There is also an increased risk of supply interruption at our third-party suppliers to deliver components as well as our manufacturing facilities to produce finished products on a timely basis, which could result in business or operational disruption. Additionally, while the potential economic impact of the COVID-19 virus may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. The extent to which the coronavirus impacts our results will depend on future developments that are highly uncertain and cannot be predicted.

As a result, given the rapid and evolving nature of the COVID-19 virus, which could negatively affect our sales, it is uncertain how the COVID-19 virus will affect our global operations generally if these impacts persist or continue over an extended period of time. Any of these impacts could have a material adverse effect on our business, financial condition and results of operations.

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 U.S. Department of Justice ("DOJ") and various other agencies including the Office of the Inspector General within the HHS, the FDA, the Federal Trade Commission ("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 ("FFDCA"), the False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, data and patient privacy laws, export and import laws, consumer protection laws and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. The DOJ and the SEC have also increased their focus on the enforcement of the Foreign Corrupt Practices Act of 1977 ("FCPA"), particularly as it relates to the conduct of pharmaceutical companies.

Many of these investigations originate as "qui tam" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim, or caused a false claim to be submitted, to the government for payment. The person bringing a “qui tam” suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as “whistleblower suits,” are often brought by current or former employees. In a qui tam suit, the government must decide whether to intervene and prosecute the case. If the government declines to intervene and prosecute the case, the individual may pursue the case alone. If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses in connection with past or future activities, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as the possible exclusion from federal healthcare programs including Medicare and Medicaid, consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions could have an adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Specific to our business, in September 2012, prior to our acquisition of Questcor Pharmaceuticals, Inc. ("Questcor") in August 2014, a subpoena was received from the U.S. Attorney's Office ("USAO") for the Eastern District of Pennsylvania, requesting documents pertaining to an investigation of its promotional practices. On or about March 8, 2019, the U.S. District Court for the Eastern District of Pennsylvania unsealed two qui tam actions involving the allegations under investigation by the USAO for the Eastern District of Pennsylvania. The DOJ intervened in both actions, which have since been consolidated. In September 2019, we executed a settlement agreement to resolve the portion of the investigation and the litigation involving promotional practices for $15.4 million.

In addition, there has recently been enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance. If we are deemed to have failed to comply with relevant laws, regulations or government guidance in any of these areas, we could be subject to criminal and civil sanctions, including significant fines, civil monetary penalties and exclusion from participation in government healthcare programs, including Medicare and Medicaid, actions against executives overseeing our business, and burdensome remediation measures. As discussed above, the USAO for the Eastern District of Pennsylvania is investigating this issue and the U.S. District Court for the Eastern District of Pennsylvania has unsealed two qui tam actions involving the allegations that are the subject of this investigation. In addition, in December 2016, we received a subpoena from the USAO for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to patients and documents concerning our provision of financial assistance to patients prescribed Acthar Gel. Other companies have disclosed similar inquiries. We are cooperating with this inquiry. It is possible that any actions taken by the DOJ or one of the USAOs as a result of this inquiry or any future action taken by federal or local governments, legislative bodies and enforcement agencies on this subject could result in civil penalties or injunctive relief, negative publicity or other negative actions that could harm our reputation, and could reduce demand for our products and/or reduce coverage of our products, including by federal healthcare programs such as Medicare and Medicaid and state health care, which would negatively impact turnover of our products. If any or all of these events occur, it could have an adverse effect on our business, financial condition, results of operations and cash flows.

We may experience pricing pressure on certain of our products due to legal changes or changes in insurers' reimbursement practices resulting from increased public scrutiny of healthcare and pharmaceutical costs, which could reduce our future revenue and profitability.

Public and governmental scrutiny of the cost of healthcare generally and pharmaceuticals in particular, especially in connection with price increases of certain products, could affect our ability to maintain or increase the prices of one or more of our products, which could negatively impact our future revenue and profitability. Certain press reports and other commentary have criticized the substantial increases in the price of Acthar Gel that occurred prior to our acquisition of the product. Acthar Gel represented 30.1% of our turnover for fiscal 2019. In addition, U.S. federal prosecutors have issued subpoenas to certain pharmaceutical companies seeking information about their drug pricing practices, among other issues, and members of the U.S. Congress have sought information from certain pharmaceutical companies relating to drug price increases. We cannot predict whether any particular legislative or regulatory changes or changes in insurers' reimbursement practices may result from any such public scrutiny, what the nature of any such changes might be or what impact they may have on us. If legislative or regulatory action were taken or insurers changed their reimbursement practices to limit our ability to maintain or increase the prices of our products, our financial condition, results of operations and cash flows could be negatively affected.

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, for example with respect to Acthar Gel. We believe the increasing emphasis on managed care in the U.S. has and will continue to put pressure on the usage and reimbursement of Acthar Gel. Our ability to commercialize our products depends, in part, on the extent to which reimbursement for the costs of these products is available from government healthcare programs, such as Medicaid and Medicare, private health insurers and others. We cannot be certain that, over time, third-party reimbursements for our products will be adequate for us to maintain price levels sufficient for realization of an appropriate return on our investment.

Reimbursement of highly-specialized products, such as Acthar Gel, is typically reviewed and approved or denied on a patient-by-patient, case-by-case basis, after careful review of details regarding a patient's health and treatment history that is provided to the insurance carriers through a prior authorization submission, and appeal submission, if applicable. During this case-by-case review, the reviewer may refer to coverage guidelines issued by that carrier. These coverage guidelines are subject to on-going review by insurance carriers. Because of the large number of carriers, there are a large number of guideline updates issued each year.

Furthermore, demand for new products may be limited unless we obtain reimbursement approval from governmental and private third-party payers prior to introduction. Reimbursement criteria, which vary by country, are becoming increasingly stringent and require management expertise and significant attention to obtain and maintain qualification for reimbursement.

In addition, a number of markets in which we operate have implemented or may implement tender systems in an effort to lower prices. Under such tender systems, manufacturers submit bids which establish prices for products. The company that wins the tender receives preferential reimbursement for a period of time. Accordingly, the tender system often results in companies underbidding one another by proposing low pricing in order to win the tender. Certain other countries may consider implementation of a tender system. Even if a tender system is ultimately not implemented, the anticipation of such could result in price reductions. Failing to win tenders, or the implementation of similar systems in other markets leading to price declines, could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We are unable to predict what additional legislation or regulation or changes in third-party coverage and reimbursement policies may be enacted or issued in the future or what effect such legislation, regulation and policy changes would have on our business. In May 2019, CMS issued a decision requiring that we revert to the base date AMP used to calculate Medicaid drug rebates for Acthar Gel. We subsequently filed suit in federal district court against the HHS and CMS seeking to hold unlawful and set aside this decision. In March 2020, we received a decision from the U.S. District Court for the District of Columbia in its suit against HHS and CMS. The court upheld CMS' decision to reverse its previous determination of the base date AMP used to calculate Acthar Gel rebates. We plan to vigorously defend our position. If we are unsuccessful in our efforts to set

aside CMS's decision, Medicaid turnover of Acthar Gel could be substantially eliminated and our efforts to continue building on our investment in non-turnover and marketing activities to modernize Acthar Gel could be significantly undermined.

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

The regulations regarding reporting and payment obligations with respect to Medicare and Medicaid reimbursement programs, and rebates and other governmental programs, are complex. Because our processes for these calculations and the judgments used in making these calculations involve subjective decisions and complex methodologies, these accruals may have a higher inherent risk for material changes in estimates. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material adjustments to amounts previously paid. See "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, in May 2019, CMS issued a decision requiring that we revert to the base date AMP used to calculate Medicaid drug rebates for Acthar Gel and from time to time, state attorneys general have brought cases against us that allege generally that we and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid, resulting in overpayment by state Medicaid programs for those drugs, and generally seek monetary damages and attorneys' fees. Any such penalties or sanctions that we might become subject to in this or other actions could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Cost-containment efforts of our customers, purchasing groups, third-party payers and governmental organizations could materially adversely affect our business.

In an effort to reduce cost, many existing and potential customers for our products within the U.S. have become members of 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 sale more aggressively in an effort to increase their profitability. Failure to negotiate distribution arrangements having advantageous pricing and other terms of sale could cause us to lose market share to our competitors or result in lower pricing on volume we retain, both of which could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. Outside the U.S., we have experienced pricing pressure due to the concentration of purchasing power in centralized governmental healthcare authorities and increased efforts by such authorities to lower healthcare costs. We frequently are required to engage in competitive bidding for the sale of our products to governmental purchasing agents. Our failure to maintain volume and pricing with historical or anticipated levels could materially adversely affect our business, financial condition, results of operations and cash flows.

Extensive laws and regulations govern the industry in which we operate and any failure to comply with such laws and regulations, including any changes to those laws and regulations may materially adversely affect us.

The development, manufacture, marketing, sale, promotion, and distribution of our products are subject to comprehensive government regulations that govern and influence the development, testing, manufacturing, processing, packaging, holding, record keeping, safety, efficacy, approval, advertising, promotion, sale, distribution and import/export of our products.

Under these laws and regulations, we are subject to periodic inspection of our facilities, procedures and operations and/or the testing of our products by the FDA, the U.S. Drug Enforcement Agency ("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") and other key ingredients;

- developing, commercializing and launching a new product is time-consuming, costly and subject to numerous factors, including legal actions brought by our competitors, that may delay or prevent the development, commercialization and/or launch of new products;
- unanticipated costs;
- payment of prescription drug user fees to the FDA to defray the costs of review and approval of marketing applications for branded and generic drugs;
- experiencing delays as a result of limited resources at the FDA or other regulatory authorities;
- changing review and approval policies and standards at the FDA or other regulatory authorities;
- potential delays in the commercialization of generic products by up to 30 months resulting from the listing of patents with the FDA;
- effective execution of the product launches in a manner that is consistent with expected timelines and anticipated costs; and
- identifying appropriate partners for distribution of our products, including any future over-the-counter commercialization opportunities, and negotiating contractual arrangements in a timely manner with commercially reasonable terms.

As a result of these and other difficulties, products currently in development by us may or may not receive timely regulatory approvals, or approvals at all. This risk is heightened with respect to the development of proprietary branded products due to the uncertainties, higher costs and length of time associated with R&D of such products and the inherent unproven market acceptance of such products. Moreover, the FDA regulates the facilities, processes and procedures used to manufacture and market pharmaceutical products in the U.S. Manufacturing facilities must be registered with the FDA and all products made in such facilities must be manufactured in accordance with current good manufacturing practice ("cGMP") regulations enforced by the FDA. Compliance with cGMP regulations requires the dedication of substantial resources and requires significant expenditures. The FDA periodically inspects both our facilities and procedures to ensure compliance with regulatory standards. The FDA may cause a suspension or withdrawal of product approvals if regulatory standards are not maintained. In the event an approved manufacturing facility for a particular drug is required by the FDA to curtail or cease operations, or otherwise becomes inoperable, obtaining the required FDA authorization to manufacture at the same or a different manufacturing site could result in production delays, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Furthermore, the market perception and reputation of our products are important to our business and the continued acceptance of our products. Any negative press reports or other commentary about our products, whether accurate or not, could have a material adverse effect on our business, reputation, financial condition, results of operation or cash flows or could cause the market value of our common shares and/or debt securities to decline.

With respect to generic products for which we are the first developer to have its application accepted for filing by the FDA, and which filing includes a certification that the applicable patent(s) are invalid, unenforceable and/or not infringed (known as a "Paragraph IV certification"), our ability to obtain and realize the full benefits of 180-days of market exclusivity is dependent upon a number of factors, including, being the first to file, the status of any litigation that might be brought against us as a result of our filing or our not meeting regulatory, manufacturing or quality requirements or standards. If any of our products are not approved timely, or if we are unable to obtain and realize the full benefits of the respective market exclusivity period for our products, or if our products cannot be successfully manufactured or commercialized timely, our results of operations could be materially adversely affected. In addition, we cannot guarantee that any investment we make in developing products will be recouped, even if we are successful in commercializing those products. Finally, once developed and approved, new products may fail to achieve commercial acceptance due to the price of the product, third-party reimbursement of the product and the effectiveness of sales and marketing efforts to support the product.

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

From time to time, we may initiate price increases on certain of our pharmaceutical products. There is no guarantee that our customers will be receptive to these price increases and continue to purchase the products at historical quantities. In addition, it is unclear how market participants will react to price increases. For example, following pricing actions in our Specialty Generics segment in fiscal 2015, additional competitors entered the marketplace for several of these products and prices subsequently decreased substantially. If customers do not maintain or increase existing sales volumes, we may be unable

to replace lost sales with orders from other customers, and it could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We face significant competition and may not be able to compete effectively.

The industries in which we operate are highly competitive. Competition takes many forms, such as price reductions on products that are comparable to our own, development of new products with different mechanisms that obviate the need for our treatments, acquisition or in-licensing of new products that may be more cost-effective than or have performance superior to our products, the introduction of generic versions when our proprietary products lose their patent protection or market exclusivity, and the coupling of separate technologies to replicate what our products accomplish through a single system. This competition may limit the effectiveness of any price increases we initiate. Following any price increase by us, competitors may elect to maintain a lower price point that may result in a decline in our sales volume. Our failure to compete effectively could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We may be unable to protect our intellectual property rights, intellectual property rights may be limited or we may be subject to claims that we infringe on the intellectual property rights of others.

We rely on a combination of patents, trademarks, trade secrets, proprietary know-how, market exclusivity gained from the regulatory approval process and other intellectual property to support our business strategy, most notably in relation to Acthar Gel, Ofirmev, INOmax, Therakos and Amitiza products. However, our efforts to protect our intellectual property rights may not be sufficient. If we do not obtain sufficient protection for our intellectual property, or if we are unable to effectively enforce our intellectual property rights, or if there is a change in the way courts and regulators interpret the laws, rules and regulations applicable to our intellectual property, our competitiveness could be impacted, which could adversely affect our competitive position, business, financial condition, results of operations and cash flows.

The composition patent for Acthar Gel has expired and we have no patent-based market exclusivity with respect to any indication or condition we might target. We rely on trade secrets and proprietary know-how to protect the commercial viability and value of Acthar Gel. We currently obtain such protection, in part, through confidentiality and proprietary information agreements. These agreements may not provide meaningful protection or adequate remedies for proprietary technology in the event of unauthorized use or disclosure of confidential and proprietary information. The parties may not comply with or may breach these agreements. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, competitors.

Certain patents related to the use of therapeutic nitric oxide for treating or preventing bronchoconstriction or reversible pulmonary vasoconstriction expired in 2013. Prior to their expiration, we depended, in part, upon these patents to provide us with exclusive marketing rights for our product for some period of time. Since then, we have obtained additional patents, which expire at various dates through 2036, including patents on methods of identifying patients at risk of serious adverse events when nitric oxide is administered to patients with particular heart conditions. Such methods have been approved by the FDA for inclusion in the Warnings and Precautions sections of the INOmax label. Other patents are on inhaled nitric oxide gas delivery systems as well as methods of using such systems, and on use of nitric oxide gas sensors. The Paragraph IV patent litigation trial against Praxair Distribution, Inc. and Praxair, Inc. (collectively "Praxair") to prevent the marketing of its potential infringing nitric oxide drug product delivery system prior to the expiration of the patents covering INOmax was held in March 2017 and a decision was rendered September 5, 2017 that ruled five patents invalid and six patents not infringed. We appealed the decision to the Court of Appeals for the Federal Circuit, which upheld the lower court's decision on August 27, 2019. We filed a petition for en banc review at the Federal Circuit on September 26, 2019, which the Federal Circuit denied on November 19, 2019. We filed a petition for a writ of certiorari with the United States Supreme Court on March 6, 2020 and the petition was denied on April 6, 2020. There has been limited commercial launch activity by Praxair. While Praxair received FDA approval of their Abbreviated New Drug Application ("ANDA") for their Noxivent nitric oxide and clearance of their 510(k) for their NOxBOXi device on October 2, 2018, the Noxivent product received an AA-rating and the Noxivent label states that Noxivent must be delivered using the NOxBOXi device. The adverse final outcome in the appeal of the Praxair litigation decision could result in the broader-scale launch of a competitive nitric oxide product before the expiration of the last of the patents listed in the FDA Orange Book: Approved Drug Products with Therapeutic Equivalence, which could adversely affect our ability to successfully maximize the value of INOmax and have an adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The active ingredient in Ofirmev is acetaminophen. Patent protection is not available for the acetaminophen molecule itself in the territories licensed to us, which include the U.S. and Canada. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredient as Ofirmev so long as the competitors do not infringe any process or formulation patents that we have in-licensed from Bristol Myers Squibb and its licensor, New Pharmatop LLC and any

method-of-use patents that we subsequently obtained. The latest expiration date of the in-licensed patents is 2021 whereas the latest expiration date of the subsequently obtained Group-owned patents is 2032. Settlement agreements have been reached in association with certain challenges to the in-licensed patents, which allow for generic competition to Ofirmev in December 2020, or earlier under certain circumstances.

Our Therakos products focus on extracorporeal photopheresis, which is an autologous immune cell therapy that is indicated in the U.S. for skin manifestations of cutaneous T-cell lymphoma ("CTCL") and is available for several additional indications in markets outside the U.S. In the extracorporeal photopheresis 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® (methoxsalen) Sterile Solution, followed by UVA radiation in the photopheresis instrument, prior to being returned to the patient. Patents related to the methoxsalen composition have expired. Therakos historically manufactured two photopheresis systems, the CELLEX® Photopheresis System ("CELLEX"), which is the only FDA-approved closed ECP system, and the UVAR XTS® Photopheresis System ("UVAR XTS"). While we no longer manufacture the UVAR XTS system, disposable, sterile kits are still supplied to customers for each of the systems. The kits are single use and discarded after a treatment. Certain key patents related to the UVAR XTS system, disposable kit and overall photopheresis method expire in 2020. Key patents related to the CELLEX system, disposable kit and overall photopheresis method expire in 2023. We continue to pursue additional patentable enhancements to the Therakos ECP system. Patent applications were filed in 2016 relating to improvements to the CELLEX system, disposable kit and overall photopheresis method, that, if approved, may offer patent protection through approximately 2036.

Our pending patent applications may not result in the issuance of patents, or the patents issued to or licensed by us in the past or in the future may be challenged or circumvented by competitors. Existing patents may be found to be invalid or insufficiently broad to preclude our competitors from using methods or making or selling products similar or identical to those covered by our patents and patent applications. Regulatory agencies may refuse to grant us the market exclusivity that we were anticipating, or may unexpectedly grant market exclusivity rights to other parties. In addition, our ability to obtain and enforce intellectual property rights is limited by the unique laws of each country. In some countries, it may be particularly difficult to adequately obtain or enforce intellectual property rights, which could make it easier for competitors to capture market share in such countries by utilizing technologies and product features that are similar or identical to those developed or licensed by us. Competitors also may harm our sales by designing products that mirror the capabilities of our products or technology without infringing our patents, including by coupling separate technologies to replicate what our products accomplish through a single system. Competitors may diminish the value of our trade secrets by reverse engineering or by independent invention. Additionally, current or former employees may improperly disclose such trade secrets to competitors or other third parties. We may not become aware of any such improper disclosure, and, in the event we do become aware, we may not have an adequate remedy available to us.

We operate in an industry characterized by extensive patent litigation, and we may from time to time be a party to such litigation.

The pursuit of or defense against patent infringement is costly and time-consuming and we may not know the outcomes of such litigation for protracted periods of time. We may be unsuccessful in our efforts to enforce our patent or other intellectual property rights. In addition, patent litigation can result in significant damage awards, including the possibility of treble damages and injunctions. Additionally, we could be forced to stop manufacturing and selling certain products, or we may need to enter into license agreements that require us to make significant royalty or up-front payments in order to continue selling the affected products. Given the nature of our industry, we are likely to face additional claims of patent infringement in the future. A successful claim of patent or other intellectual property infringement against us could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

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

Our turnover of Acthar Gel, which have and are expected to comprise a significant portion of our overall product portfolio, could be negatively impacted by the level of clinical data available on the product. Acthar Gel was originally approved by the FDA in 1952, prior to the enactment of the 1962 Kefauver Harris Amendment, or the "Drug Efficacy Amendment," to the FFDCA. This amendment introduced the requirement that drug manufacturers provide proof of the effectiveness (in addition to the previously required proof of safety) of their drugs in order to obtain FDA approval. As such, the FDA's original approval in 1952 was based on safety data as clinical trials evaluating efficacy were not then required. In the 1970s, the FDA reviewed the safety and efficacy of Acthar Gel during its approval of Acthar Gel for the treatment of acute exacerbations in multiple sclerosis and evaluated all other previous indications on the label through the Drug Efficacy Study Implementation ("DESI") process. In this process, the medical and scientific merits of the label and each indication on the label were evaluated based on

publications, information from sponsors, and the judgment of the FDA. The label obtained after the DESI review and the addition of the multiple sclerosis indication is the Acthar Gel label that was used until the changes in 2010.

In 2010, in connection with its review of a supplemental NDA for use of Acthar Gel in treatment of 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 multiple sclerosis ("MS") and IS indications. We have initiated Phase 4 clinical trials to supplement the non-clinical evidence supporting the use of Acthar Gel in the treatment of the on-label indications of MS, rheumatoid arthritis, focal segmental glomerular sclerosis, symptomatic sarcoidosis, uveitis and systemic lupus erythematosus and have reported positive results from the open-label part of the Phase 4 clinical trials. The completion of such ongoing or future clinical trials to provide further evidence on the efficacy of Acthar Gel in the treatment of its approved indications could take several years to complete and will require the expenditure of significant time and financial and management resources. Such clinical trials may not result in data that supports the use of Acthar Gel to treat any of its approved indications. In addition, a clinical trial to evaluate the use of Acthar Gel to treat indications not on the current Acthar Gel label may not provide a basis to pursue adding such indications to the current Acthar Gel label. Furthermore, even if prescribed by a physician, third-party payers may implement restrictions on reimbursement of Acthar Gel due, in part, to the limited clinical data of efficacy, which may negatively impact our business, financial condition, results of operations and cash flows.

Clinical studies required for our product candidates and new indications of our marketed products are expensive and time-consuming, and their outcome is highly uncertain. If any such studies are delayed or yield unfavorable results, regulatory approval for our product candidates or new indications of our marketed products may be delayed or become unobtainable.

We must conduct extensive testing of our product candidates and new indications of our marketed products before we can obtain regulatory approval to market and sell them. For example, INOmax is approved for sale in the U.S. only for the treatment of hypoxic respiratory failure associated with pulmonary hypertension in term and near-term infants, and the Therakos systems are approved for sale in the U.S. only for the palliative treatment of the skin manifestations of CTCL in persons who have not been responsive to other forms of treatment. In order to market these products in the U.S. for any other indications, we will need to conduct appropriate clinical trials, obtain positive results from those trials, and obtain regulatory approval for such proposed indications. Conducting such studies is a lengthy, time-consuming, and expensive process and obtaining regulatory approval is uncertain. Even well conducted studies of effective drugs will sometimes appear to be negative in either safety or efficacy results. The regulatory review and approval process to obtain marketing approval for a new indication can take many years, often requires multiple clinical trials and requires the expenditure of substantial resources. This process can vary substantially based on the type, complexity, novelty and indication of the product candidate involved. Success in early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results.

These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate (or prior or concurrent exposure to other products or product candidates), difficulty in enrolling and maintaining subjects in a clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to 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. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of product candidate or a new indication for a product candidate.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new studies, which are expensive and time consuming, or abandon that drug development program. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication(s) would preclude the successful development of

those candidates for such indication(s), which would have a material adverse effect on our business, financial condition, results of operations and cash flows.

We may incur product liability losses and other litigation liability.

We are or may be involved in various legal proceedings and certain government inquiries and investigations, including with respect to, but not limited to, patent infringement, product liability, personal injury, antitrust matters, securities class action lawsuits, breach of contract, Medicare and Medicaid reimbursement claims, opioid related matters, promotional practices and compliance with laws relating to the manufacture and sale of controlled substances. Such proceedings, inquiries and investigations may involve claims for, or the possibility of, fines and penalties involving substantial amounts of money or other relief, including but not limited to civil or criminal fines and penalties, changes in business practices and exclusion from participation in various government healthcare-related programs. Such litigation and related matters are described in Note 26 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 $120.0 million using a combination of umbrella/excess liability policies with respect to any such claims. We believe this coverage level is adequate to address our current risk exposure related to product liability claims and lawsuits. However, some claims, such as those brought against us related to our sale of opioids, might not be covered by our insurance policies. Moreover, where the claim is covered by our insurance, if our insurance coverage is inadequate, we would have to pay the amount of any settlement or judgment that is in excess of our policy limits. We may not be able to obtain insurance on terms acceptable to us or at all since insurance varies in cost and can be difficult to obtain. Our failure to maintain adequate insurance coverage or successfully defend against product liability claims could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our operations expose us to the risk of violations of applicable health, safety and environmental laws and regulations and related liabilities and litigation.

We are subject to numerous federal, state, local and non-U.S. environmental protection and health and safety laws and regulations governing, among other things:

- the generation, storage, use and transportation of hazardous materials;
- emissions or discharges of substances into the environment;
- investigation and remediation of hazardous substances or materials at various sites;
- chemical constituents in products and end-of-life disposal, mandatory recycling and take-back programs; and
- the health and safety of our employees.

We may not have been, or we may not at all times be, in full compliance with environmental and health and safety laws and regulations. In the event a regulatory authority concludes that we are not in full compliance with these laws, we could be fined, criminally charged or otherwise sanctioned. Environmental laws are becoming more stringent, including outside the U.S., resulting in increased costs and compliance burdens.

Certain environmental laws assess liability on current or previous owners of real property and current or previous owners or operators of facilities for the costs of investigation, removal or remediation of hazardous substances or materials at such properties or at properties at which parties have disposed of hazardous substances. Liability for investigative, removal and remediation costs under certain federal and state laws is retroactive, strict (i.e., can be imposed regardless of fault) and joint and several. In addition to cleanup actions brought by governmental authorities, private parties could bring personal injury or other claims due to the presence of, or exposure to, hazardous substances. We have received notification from the U.S. Environmental Protection Agency and similar state environmental agencies that conditions at a number of sites where the disposal of hazardous substances has taken place requires investigation, cleanup and other possible remedial action. These agencies may require that we reimburse the government for its costs incurred at these sites or otherwise pay for the costs of investigation and cleanup of these sites, including by providing compensation for natural resource damage claims arising from such sites.

In the ordinary course of our business planning process, we take into account our known environmental matters as we plan for our future capital requirements and operating expenditures. The ultimate cost of site cleanup and timing of future cash outflows is difficult to predict, given the uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations, and alternative cleanup methods.

We concluded that, as of December 27, 2019, it was probable that we would incur remediation costs in the range of $38.2 million to $86.9 million. We also concluded that, as of December 27, 2019, the best estimate within this range was $61.9 million. For further information on our environmental obligations, refer to Note 26 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 plc 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, we may be subject to substantial liabilities. These potential indemnification obligations could have a material adverse effect on our financial condition, results of operations and cash flows. While the Litigation Settlement requires as a condition precedent that any of our indemnification liabilities to Covidien will be channeled to the Opioid Claimant Trust or otherwise resolved in a manner acceptable to us, there is no guarantee that such condition will be satisfied or that the Litigation Settlement will be effectuated on its current terms or at all.

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

Part of our business strategy includes evaluating potential business development opportunities to grow the business through merger, acquisition, licensing agreements or other strategic transactions. The process to evaluate potential opportunities may be complex, time-consuming and expensive. Once a potential opportunity is identified, we may not be able to conclude negotiations of a potential transaction on terms that are satisfactory to us, which could result in a significant diversion of management and other employee time, as well as substantial out-of-pocket costs. In addition, there are a number of risks and uncertainties relating to our ability to close a potential transaction.

Once an acquisition or licensing transaction is consummated, there are further potential risks related to integration activities, including with regard to operations, personnel, technologies and products. If we are not able to successfully integrate our acquisitions in the expected time frame, we may not obtain the advantages and synergies that such acquisitions were intended to create, which may have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

In addition, we intend to continue to explore opportunities to enter into strategic collaborations with other parties, which may include other pharmaceutical companies, academic and research institutions, government agencies and other public and private research organizations. These third-party collaborators are often directly responsible for certain obligations under these types of arrangements, and we may not have the same level of decision-making capabilities for the prioritization and management of development-related activities as we would for our internal research and development activities. Failures by these partners to meet their contractual, regulatory, or other obligations to us, or any disruption in the relationships with these partners, could have a material adverse effect on our pipeline and business. In addition, these collaborative relationships for research and development could extend for many years and may give rise to disputes regarding the relative rights, obligations and revenues of us versus our partners, including the ownership of intellectual property and associated rights and obligations.

These could result in the loss of intellectual property rights or other intellectual property protections, delay the development and sale of potential products, and lead to lengthy and expensive litigation or arbitration.

Furthermore, the due diligence that we conduct in conjunction with an acquisition or other strategic collaboration may not sufficiently discover risks and contingent liabilities associated with the other party and, consequently, we may consummate an acquisition or otherwise enter into a strategic collaboration for which the risks and contingent liabilities are greater than were projected. In addition, in connection with acquisitions or other strategic collaborations, we could experience disruption in our business, technology and information systems, and our customers, licensors, suppliers and employees and may face difficulties in managing the expanded operations of a larger and more complex company. There is also a risk that key employees of companies that we acquire or key employees necessary to successfully commercialize technologies and products that we acquire or otherwise collaborate on may seek employment elsewhere, including with our competitors. Furthermore, there may be overlap between our products or customers and the companies which we acquire or enter into strategic collaborations with that may create conflicts in relationships or other commitments detrimental to the integrated businesses or impacted products. Additionally, the time between our expenditures to acquire new products, technologies or businesses and the subsequent generation of revenues from those acquired products, technologies or businesses, or the timing of revenue recognition related to licensing agreements and/or strategic collaborations, could cause fluctuations in our financial performance from period to period. Finally, if we are unable to successfully integrate products, technologies, businesses or personnel that we acquire, we could incur significant impairment charges or other adverse financial consequences. Many of these factors are outside of our control and any one of them could result in increased costs, decreases in the amount of expected revenues and diversion of management's time and energy, which could materially impact our business, financial condition, results of operations and cash flows.

If we are unable to retain our key personnel, we may be unable to maintain or expand our business.

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors will remain highly dependent, in large part, upon our ability to attract and retain qualified scientific, technical, regulatory and commercial personnel. The loss of key scientific, technical, regulatory and commercial personnel, or the failure to recruit additional key scientific, technical, regulatory and commercial personnel, could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. There is intense competition for qualified personnel in our industry, and we may not be able to continue to attract and retain the qualified personnel necessary for the development or operation of our business.

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

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. To remain competitive in our industry, we must employ information technologies to support manufacturing processes, quality processes, distribution, financial reporting, as well as R&D and regulatory applications that capture, manage and analyze the large streams of data generated in our clinical trials, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also rely extensively on technology to allow concurrent work sharing around the world. As with all information technology, our systems are vulnerable to potential damage or interruptions from fires, blackouts, telecommunications failures and other unexpected events, as well as physical and electronic break-ins, sabotage, piracy or intentional acts of vandalism. Given the extensive reliance of our business on technology, any substantial disruption or resulting loss of data that is not avoided or corrected by our backup measures could harm our business, financial condition, results of operations and cash flows.

We also have outsourced significant elements of our operations to third parties, some of which are outside the U.S., including significant elements of our information technology infrastructure, and as a result we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of our third-party vendors with whom we contract, make such systems potentially vulnerable to service interruptions. The size and complexity of our and our vendors' systems and the large amounts of confidential information that is present on them also makes them potentially vulnerable to security breaches from inadvertent or intentional actions by our employees, partners or vendors, or from attacks by malicious third parties. We and our vendors could be susceptible to third-party attacks on our information security systems, which attacks are of ever increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including criminal groups, “hackers” and others.

Maintaining the secrecy of all of our confidential, proprietary, and/or trade secret information is important to our competitive business position. However, such information can be difficult to protect. While we have taken steps to protect such

information and invested heavily in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information, including those caused by our own employees or others to whom we have granted access to our systems, that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, human error, sabotage, industrial espionage, fraud, trickery or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology or information, and/or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information, could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

Our customer concentration may materially adversely affect our business.

We sell a significant amount of our products to a limited number of independent wholesale drug distributors, large pharmacy chains and specialty pharmaceutical distributors. In turn, these wholesale drug distributors, large pharmacy chains and specialty pharmaceutical distributors supply products to pharmacies, hospitals, governmental agencies and physicians. Turnover to two of our distributors that supplies our products to many end user customers, CuraScript Inc. and AmerisourceBergen Corporation, accounted for 10.0% or more of our total turnover in the past three fiscal years. If we were to lose the business of these distributors, if these distributors failed to fulfill their obligations, if these distributors were to experience difficulty in paying us on a timely basis, or if these distributors negotiate lower pricing terms, the occurrence of one or more of these factors could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Our product concentration may materially adversely affect our business.

We sell a wide variety of products including specialty branded and specialty generic pharmaceuticals, as well as API. However, a small number of relatively significant products, most notably Acthar Gel and to a lesser extent, INOmax, Ofirmev and Therakos, represent a significant percentage of our 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 sales force;
- our ability to implement and maintain pricing and continue to maintain or increase market demand for these products;
- our ability to achieve hospital and other third-party payer formulary acceptance, and maintain reimbursement levels by third-party payers;
- our ability to maintain confidentiality of the proprietary know-how and trade secrets relating to Acthar Gel;
- our ability to maintain and defend the patent protection and regulatory exclusivity of Ofirmev and INOmax;
- our ability to continue to procure raw materials or finished goods, as applicable, for Acthar Gel, Ofirmev, INOmax and Therakos from internal and third-party manufacturers in sufficient quantities and at acceptable quality and pricing levels in order to meet commercial demand;
- our ability to maintain fees and discounts payable to the wholesalers and distributors and GPOs, at commercially reasonable levels;
- whether the DOJ or other third parties seek to challenge and are successful in challenging patents or patent-related settlement agreements or our sales and marketing practices;
- warnings or limitations that may be required to be added to FDA-approved labeling; and
- the occurrence of adverse side effects related to or emergence of new information related to the therapeutic efficacy of these products, and any resulting product liability claims or product recalls.

Moreover, 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.

The DEA regulates the availability of controlled substances, including API, drug products under development and marketed drug products. At times, the procurement and manufacturing quotas granted by the DEA may be insufficient to meet our needs.

The DEA is the U.S. federal agency responsible for domestic enforcement of the CSA. The CSA classifies drugs and other substances based on identified potential for abuse. Schedule I controlled substances, such as heroin and LSD, have a high abuse potential and have no currently accepted medical use; thus, they cannot be lawfully marketed or sold. Schedule II controlled substances include molecules such as oxycodone, oxymorphone, morphine, fentanyl and hydrocodone. The manufacture, storage, distribution and sale of these controlled substances are permitted, but highly regulated. The DEA regulates the availability of API, products under development and marketed drug products that are in the Schedule II category by setting annual quotas. Every year, we must apply to the DEA for manufacturing quota to manufacture API and procurement quota to manufacture finished dosage products. Given that the DEA has discretion to grant or deny our manufacturing and procurement quota requests, the quota the DEA grants may be insufficient to meet our needs. In 2018, manufacturing and procurement quotas granted by the DEA were sufficient to meet our sales and inventory requirements on most products. In 2018 and 2019, the DEA reduced the amount of opioid medication that may be manufactured in the U.S. by approximately 20% and 10%, respectively. For 2020, the DEA has reduced the amounts that may be produced of the eight most misused opioid molecules by approximately 13% compared to the 2019 amounts. Notably, hydrocodone and oxycodone quotas were reduced by 19% and 15%, respectively, and fentanyl quota was reduced by 31%. In September 2019, the DEA proposed that benzylfentanyl and 4-anilinopiperidine be controlled as list I chemicals under the CSA. Also in September 2019, the DEA proposed to designate norfentanyl as an immediate precursor (i.e., a substance from which another is formed) for fentanyl and to make it a Schedule II controlled substance under the CSA. The DEA could take similar actions in the future. Future delay or refusal by the DEA to grant, in whole or in part, our quota requests could delay or result in stopping the manufacture of our marketed drug products, new product launches or the conduct of bioequivalence studies and clinical trials. Such delay or refusal also could require us to allocate marketed drug products among our customers. These factors, along with any delay or refusal by the DEA to provide customers who purchase API from us with sufficient quota, could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The manufacture of our products is highly exacting and complex, and our business could suffer if we, or our suppliers, encounter manufacturing or supply problems.

The manufacture of our products is highly exacting and complex, due in part to strict regulatory and manufacturing requirements, as well as due to the biologic nature of some of our products, which are inherently more difficult to manufacture than chemical-based products. Problems may arise during manufacturing for a variety of reasons including equipment malfunction, failure to follow specific protocols and procedures, defective raw materials and environmental factors. If a batch of finished product fails to meet quality standards during a production run, then that entire batch of product may have to be discarded. These problems could lead to launch delays, product shortages, backorders, increased costs (including contractual damages for failure to meet supply requirements), lost revenue, damage to our reputation and customer relationships, time and expense spent investigating, correcting and preventing the root causes and, depending on the root causes, similar losses with respect to other products. If manufacturing problems are not discovered before the product is released to the market, we also could incur product recall and product liability costs. If we incur a product recall or product liability costs involving one of our products, such product could receive reduced market acceptance and thus reduced product demand and could harm our reputation and our ability to market our products in the future. Significant manufacturing problems could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We rely on third-party manufacturers to manufacture certain components of our products and certain of our finished products. In the event that these third-party manufacturers cease to manufacture sufficient quantities of our products or components in a timely manner and on terms acceptable to us, we could be forced to locate alternate third-party manufacturers. Additionally, if our third-party manufacturers experience a failure in their production process, are unable to obtain sufficient quantities of the components necessary to manufacture our products or otherwise fail to meet regulatory or quality requirements, we may be forced to delay the manufacture and sale of our products or locate an alternative third-party manufacturer. Several of our products are manufactured at a single manufacturing facility or stored at a single storage site. Loss or damage to a manufacturing facility or storage site due to a natural disaster or otherwise could adversely affect our ability to manufacture sufficient quantities of key products or otherwise deliver products to meet customer demand or contractual requirements, which may result in a loss of revenue and other adverse business consequences. Furthermore, while we work closely with our suppliers to ensure the continuity of supply and to diversify our sources of components and materials, in certain instances we do acquire components and materials from a sole supplier. Although we do carry strategic inventory and maintain insurance to mitigate the potential risk related to any related supply disruption, there can be no assurance that such measures will be effective. Because of the time required to obtain regulatory approval and licensing of a manufacturing facility, an alternate third-party manufacturer may not be available on a timely basis to replace production capacity in the event we lose

manufacturing capacity, experience supply challenges, or products are otherwise not available due to natural disaster, regulatory action or otherwise.

Significant manufacturing problems could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Our global operations expose us to risks and challenges associated with conducting business internationally.

We operate globally with offices or activities in Europe, Africa, Asia, South America, Australia and North America. We face several risks inherent in conducting business internationally, including compliance with international and U.S. laws and regulations that apply to our international operations. These laws and regulations include data privacy requirements, labor relations laws, tax laws, anti-competition regulations, import and trade restrictions, export requirements, U.S. laws such as the FCPA and local laws, which also prohibit corrupt payments to governmental officials or certain payments or remunerations to customers. Given the high level of complexity of these laws, there is a risk that some provisions may be violated, inadvertently or through fraudulent or negligent behavior of individual employees, or through our failure to comply with certain formal documentation requirements or otherwise. Violations of these laws and regulations could result in fines or criminal sanctions against us, our officers or our employees, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts and our ability to attract and retain employees.

In addition to the foregoing, engaging in international business inherently involves a number of other difficulties and risks, including:

- potentially longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain non-U.S. legal systems;
- potential inability to sell products into certain countries given the delay of foreign governments in responding to changes in our U.S. business licensing;
- political and economic instability, including the impact of U.K.'s exit from the 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 expense and intercompany debt financings; and
- potential negative impact of public health epidemics on employees, our supply chain and the global economy, such as the recent coronavirus outbreak previously mentioned.

These or other factors or any combination of them may have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We may not achieve some or all of the expected benefits of any restructuring activities we may undertake and such restructuring activities may adversely affect our business.

From time to time, we may initiate restructuring activities as we continue to realign our cost structure due to the changing nature of our business and look for opportunities to achieve operating efficiencies that will reduce costs. We may not be able to obtain the cost savings and benefits initially anticipated when such restructuring activities were initiated. Additionally, as a result of our restructuring activities we may experience a loss of continuity, loss of accumulated knowledge and/or inefficiency during transitional periods. Reorganizations and restructurings can require a significant amount of management and other employees' time and focus, which may divert attention from operating and growing our business. If we fail to achieve some or all of the expected benefits of such restructuring activities, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We have significant levels of intangible assets, which utilize our future projections of cash flows in impairment testing. Should we experience unfavorable variances from these projections these assets may have an increased risk of future impairment.

Past acquisitions have significantly increased our intangible assets, which were $7,018.0 million at December 27, 2019. At least annually, we review the carrying value of our non-amortizing intangible assets, and for amortizing intangible assets when indicators of impairment are present. Conditions that could indicate impairment and necessitate an evaluation of intangible assets include, but are not limited to, a significant adverse change in the business climate or the legal or regulatory environment.

In performing our impairment tests, we utilize our future projections of cash flows. Projections of future cash flows are inherently subjective and reflect assumptions that may or may not ultimately be realized. Significant assumptions utilized in our projections include, but are not limited to, our evaluation of the market opportunity for our products, the current and future competitive landscape and resulting impacts to product pricing, future legislative and regulatory actions or the lack thereof, planned strategic initiatives, the ability to achieve cost synergies from acquisitions, the realization of benefits associated with our existing and anticipated patents and regulatory approvals. Given the inherent subjectivity and uncertainty in projections, we could experience significant unfavorable variances in future periods or revise our projections downward. This would result in an increased risk that our intangible assets may be impaired. If an impairment were recognized, this could have a material impact to our financial condition and results of operations.

We are subject to labor and employment laws and regulations, which could increase our costs and restrict our operations in the future.

We employ approximately 3,400 employees worldwide. Some of our employees are represented by labor organizations and national works councils. Our management believes that our employee relations are satisfactory. However, further organizing activities or collective bargaining may increase our employment-related costs and we may be subject to work stoppages and other labor disruptions. Moreover, if we are subject to employment-related claims, such as individual and class actions relating to alleged employment discrimination, wage-hour and labor standards issues, and such actions are successful in whole or in part, this may affect our ability to compete or have a material adverse effect on our business, financial condition, 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 are located at a facility in Staines-Upon-Thames, U.K. and our Specialty Brands global manufacturing operations are located in Dublin, Ireland. In addition, we have other locations in the U.S., most notably our corporate shared services facility in Hazelwood, Missouri, our Specialty Brands commercial headquarters in Bedminster, New Jersey and our Specialty Generics headquarters and technical development center in Webster Groves, Missouri. As of December 27, 2019, we owned a total of ten facilities in the U.S., Ireland and Japan. We have 11 manufacturing sites: one in Ireland; two in Japan; and eight in the U.S. Although we have contingency plans in effect for natural disasters or other catastrophic events, these events could still disrupt our operations. Even though we carry business interruption insurance policies, we may suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies. Any natural disaster or catastrophic event at any of our facilities could have a significant negative impact on our business, financial condition, results of operations and cash flows.

Risks Related to Our Indebtedness

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

We have substantial indebtedness, which could adversely affect our ability to fulfill our financial obligations and have a negative impact on our financing options and liquidity position. As of December 27, 2019, total debt principal was $5,422.8 million, of which $634.5 million was classified as current, including $614.8 million aggregate principal amount of 4.875% senior unsecured notes that mature on April 15, 2020 (the "2020 Notes").

Our degree of debt leverage could have significant consequences, including the following:

- making it more difficult for us to satisfy our obligations with respect to our debt;
- limiting our ability to obtain additional financing in the future for working capital, capital expenditures, acquisitions or other corporate requirements;
- requiring a substantial portion of our cash flows to be dedicated to debt service payments instead of other purposes, thereby reducing the amount of cash flows available for working capital, capital expenditures, acquisitions and other general corporate purposes;
- limiting our ability to refinance our indebtedness on terms acceptable to us or at all;
- placing us at a competitive disadvantage to other less leveraged competitors;
- making us more vulnerable to economic downturns and limiting our ability to withstand competitive pressures;
- limiting our flexibility in planning for and reacting to changes in the industry in which we compete; and
- increasing our costs of borrowing.

As discussed in "Important Events Since Year End" of this Directors Report, we have consummated an exchange of certain of our 2020 Notes.

We may not be able to generate sufficient cash to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under our indebtedness, which may not be successful.

Our ability to make scheduled payments on or to refinance our debt obligations depends on our financial condition and operating performance, which are subject to prevailing economic and competitive conditions and to certain financial, business, legislative, regulatory and other factors beyond our control. We may be unable to maintain a level of cash flows from operating activities sufficient to permit us to fund our day-to-day operations or to pay the principal, premium, if any, and interest on our indebtedness.

If our cash flows and capital resources are insufficient to fund our debt service obligations and other cash requirements, we could face substantial liquidity problems and could be forced to reduce or delay investments and capital expenditures or to sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We may not be able to effect any such alternative measures, if necessary, on commercially reasonable terms or at all and, even if successful, such alternative actions may not allow us to meet our scheduled debt service obligations. The agreements governing our indebtedness restrict (a) our ability to dispose of assets and use the proceeds from any such dispositions and (b) our ability to raise debt capital to be used to repay our indebtedness when it becomes due. We may not be able to consummate those dispositions or to obtain proceeds in an amount sufficient to meet any debt service obligations then due.

Our inability to generate sufficient cash flows to satisfy our debt obligations, or to refinance our indebtedness on commercially reasonable terms or at all, would materially and adversely affect our financial position and results of operations.

If we cannot make scheduled payments on our debt, we will be in default and, as a result, lenders under any of our indebtedness could declare essentially all outstanding principal and interest to be due and payable, the lenders under our existing credit facilities could terminate their commitments to loan money, our secured lenders could foreclose against the assets securing such borrowings and we could be forced into bankruptcy or liquidation.

The terms of the agreements that govern our indebtedness restrict our current and future operations, particularly our ability to respond to changes or to pursue our business strategies.

The agreements that govern the terms of our indebtedness contain a number of restrictive covenants that impose significant operating and financial restrictions on us and may limit our ability to engage in acts that may be in our long-term best interest, including limitations or restrictions on our ability to:

- incur, assume or guarantee additional indebtedness;
- declare or pay dividends, make other distributions with respect to equity interests, or purchase or otherwise acquire or retire equity interests;
- make any principal payment on, or redeem or repurchase, subordinated debt;
- make loans, advances or other investments;

- sell or otherwise dispose of assets, including capital stock of subsidiaries;
- incur liens;
- enter into transactions with affiliates;
- enter into sale and lease-back transactions; and
- consolidate or merge with or into, or sell all or substantially all of our assets to, another person or entity.

In addition, the restrictive covenants in the credit agreement governing our senior secured credit facilities require us to comply with a financial maintenance covenant in certain circumstances. Our ability to satisfy this financial maintenance covenant can be affected by events beyond our control and we cannot assure you that we will be able to comply.

A breach of the covenants under the agreements that govern the terms of any of our indebtedness could result in an event of default under the applicable indebtedness. Such default may allow the creditors to accelerate the related debt and may result in the acceleration of any other debt to which a cross-acceleration or cross-default provision applies. In addition, an event of default under the credit agreement that governs our senior secured credit facilities would permit the lenders under such facilities to terminate all commitments to extend further credit thereunder. Furthermore, if we are unable to repay the amounts due and payable under our senior secured credit facilities or other indebtedness, those lenders or investors will be able to proceed against the collateral granted to them to secure that indebtedness. If the holders of our debt accelerate the repayment of our borrowings, we may not have sufficient assets to repay that indebtedness.

As a result of these restrictions, we may be:

- limited in how we conduct our business;
- unable to raise additional debt or equity financing to operate during general economic or business downturns; or
- unable to compete effectively, execute our growth strategy or take advantage of new business opportunities.

These restrictions may affect our ability to grow in accordance with our plans.

Our current debt levels and challenges in the commercial and credit environment may materially adversely affect our ability to issue debt on acceptable terms and our future access to capital.

Our ability to issue debt or enter into other financing arrangements on acceptable terms could be materially adversely affected by our current debt levels or if there is a material decline in the demand for our products or in the solvency of our customers or suppliers or other significantly unfavorable changes in economic conditions occur. In addition, volatility in the world financial markets, including in light of the recent COVID-19 coronavirus outbreak, could increase borrowing costs or affect our ability to access the capital markets, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

A lowering or withdrawal of the ratings assigned to our debt by rating agencies may increase our future borrowing costs and reduce our access to capital.

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

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

Certain of our indebtedness, including borrowings under our senior secured credit facilities and our receivables securitization, are subject to variable rates of interest and expose us to interest rate risk. If interest rates increase, our debt service obligations on the variable-rate indebtedness would increase and our net income would decrease, even though the amount borrowed under the facilities remained the same. As of December 27, 2019, we had $1,924.4 million outstanding variable-rate debt on our senior secured term loans and $900.0 million outstanding on our revolving credit facility. An unfavorable movement in interest rates, primarily London Interbank Offered Rate ("LIBOR"), could result in higher interest expense and cash payments for us. Although we may enter into interest rate swaps, involving the exchange of floating for

fixed-rate interest payments, to reduce interest rate volatility, we cannot provide assurance that we will enter into such arrangements or that they will successfully mitigate such interest rate volatility.

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

We may be able to incur substantial additional indebtedness in the future. Although agreements governing our indebtedness restrict the incurrence of additional indebtedness, these restrictions are and will be subject to a number of qualifications and exceptions and the additional indebtedness incurred in compliance with these restrictions could be substantial. If new debt is added to our current debt levels, the related risks that we now face could intensify.

We may need additional financing in the future to meet our capital needs or to make acquisitions, and such financing may not be available on favorable or acceptable terms, and may be dilutive to existing shareholders.

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

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

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

Risks Related to Tax Matters

A loss of a major tax dispute or a challenge to our operating structure or intercompany pricing policies could result in a higher tax rate on our worldwide earnings, which could result in a material adverse effect on our financial condition and results of operations.

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

In August 2019, the IRS proposed an adjustment to the profit on ordinary activities before taxation of MHP as a result of its findings in the audit of MHP's tax year ended September 26, 2014. MHP, formerly known as Cadence, was acquired as a U.S. subsidiary in March 2014. Following the acquisition of Cadence, we transferred certain rights and risks in Ofirmev intellectual property to one of our wholly owned non-U.S. subsidiaries. The transfer occurred at a price determined in conjunction with our external advisors, in accordance with applicable Treasury Regulations and with reference to the $1,329.0 million taxable consideration we paid to the shareholders of Cadence. The IRS asserts the value of the Transferred IP exceeds the value of the acquired Cadence shares and, further, partially disallows our control premium subtraction. The proposed adjustment to profit on ordinary activities before taxation of $871.0 million, excluding potential associated interest and penalties, is proposed as a multi-year adjustment and may result in a non-cash reduction of our U.S. Federal net operating loss carryforward of $782.0 million. We strongly disagree with the proposed increase to the Transfer Price and intend to contest it through all available administrative and judicial remedies, which may take a number of years to conclude. The final outcome

cannot be reasonably quantified at this time, however, the proposed adjustment may be material. We believe our reserve for income tax contingencies is adequate.

Our status as a foreign corporation for U.S. federal tax purposes could be affected by a change in law.

We believe that, under current law, we are treated as a foreign corporation for U.S. federal tax purposes. However, changes in tax law, such as additional changes to the inversion rules in IRC Section 7874 or the U.S. Treasury Regulations promulgated thereunder or other IRS guidance, could adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any such changes could have prospective or retroactive application to us and our shareholders and affiliates. In addition, previous legislative proposals have aimed to expand the scope of U.S. corporate tax residence, and such legislation, if passed, could have an adverse effect on us. For example, the U.S. Department of the Treasury and Congress have previously issued proposals that would amend the inversion rules. Although the proposals would generally apply to prospective transactions, no assurance can be given that such proposals will not be changed in the legislative process to apply to prior transactions.

Future changes to U.S. and foreign tax laws could adversely affect us.

The European Commission, U.S. Congress and Treasury Department, the Organization for Economic Co-operation and Development ("the OECD"), and other government agencies in jurisdictions where we and our affiliates do business have had an extended focus on issues related to the taxation of multinational corporations, particularly payments made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. As a result, the tax laws in the U.K., Ireland, E.U., Switzerland, U.S. and other countries in which we and our affiliates do business could change on a prospective or retroactive basis, and any such changes could adversely affect us and our affiliates.

Recent examples include the OECD's recommendations on base erosion and profit shifting, the European Commission's Anti-Tax Avoidance Directives ("ATAD I" and "ATAD II"), the Multilateral Convention to Implement Tax Treaty Related Measures to Prevent Base Erosion and Profit Shifting (“Multilateral Instrument”) and Ireland's Budget 2019 published in October 2018 announcing changes to the corporate tax code including implementation of certain provisions of ATAD I. These initiatives include recommendations and proposals that, if enacted in countries in which we and our affiliates do business, could adversely affect us and our affiliates.

We may not be able to maintain a competitive worldwide effective corporate tax rate.

We cannot give any assurance as to what our effective tax rate will be in the future, because of, among other things, uncertainty regarding the tax policies of the jurisdictions where we operate. Our actual effective tax rate may vary from our expectation and that variance may be material. Additionally, the tax laws of the U.K. and other jurisdictions could change in the future, and such changes could cause a material change in our effective tax rate.

A change in our tax residency could have a negative effect on our future profitability and taxes on dividends.

Under current Irish legislation, a company is regarded as resident in Ireland for tax purposes if it is centrally managed and controlled in Ireland, or, in certain circumstances, if it is incorporated in Ireland. Under current U.K. legislation, a company is regarded as resident in the U.K. for tax purposes if it is centrally managed and controlled in the U.K. Where a company is treated as tax resident under the domestic laws of both the U.K. and Ireland then the provisions of article 4(3) of the Double Taxation Convention between Ireland and the U.K. provide that such company shall be treated as resident only in the jurisdiction in which its place of effective management is situated. Since May 2015, we have managed the affairs of Mallinckrodt plc so that it is effectively managed and controlled in the U.K. and therefore be treated as resident only in the U.K. for tax purposes, by operation of the Double Taxation Convention. However, we cannot provide assurance that Mallinckrodt plc will continue to be resident only in the U.K. for tax purposes. It is possible that in the future, whether as a result of a change in law or a change in the practice or conduct of the affairs of any relevant tax authority, Mallinckrodt plc could become, or be regarded as having become resident in a jurisdiction other than the U.K. For example, the new Multilateral Instrument, which has been ratified by both Ireland and the U.K., supersedes the application of article 4(3) of the Double Taxation Convention between Ireland and the U.K. in favor of a new process involving the competent authorities of Ireland and the U.K. If Mallinckrodt plc were considered to be a tax resident of Ireland, in addition to any U.K. tax consequences, it could become liable for Irish corporation tax and any dividends paid by it could be subject to Irish dividend withholding tax.

Risks Related to Our Jurisdiction of Incorporation

Irish law differs from the laws in effect in the U.S. and may afford less protection to holders of our securities.

It may not be possible to enforce court judgments obtained in the U.S. against us in Ireland based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liabilities provisions of the U.S. federal or state securities laws or hear actions against us or those persons based on those laws. We have been advised the U.S. currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland.

A judgment obtained against us will be enforced by the courts of Ireland if the following general requirements are met: (i) U.S. courts must have had jurisdiction in relation to the particular defendant according to Irish conflict of law rules (the submission to jurisdiction by the defendant would satisfy this rule) and (ii) the judgment must be final and conclusive and the decree must be final and unalterable in the court which pronounces it. A judgment can be final and conclusive even if it is subject to appeal or even if an appeal is pending. Where however the effect of lodging an appeal under the applicable law is to stay execution of the judgment, it is possible that in the meantime the judgment may not be actionable in Ireland. It remains to be determined whether final judgment given in default of appearance is final and conclusive. However, Irish courts may refuse to enforce a judgment of the U.S. courts which meets the above requirements for one of the following reasons: (i) if the judgment is not for a definite sum of money; (ii) if the judgment was obtained by fraud; (iii) the enforcement of the judgment in Ireland would be contrary to natural or constitutional justice; (iv) the judgment is contrary to Irish public policy or involves certain U.S. laws which will not be enforced in Ireland; or (v) jurisdiction cannot be obtained by the Irish courts over the judgment debtors in the enforcement proceedings by personal service in Ireland or outside Ireland under Order 11 of the Ireland Superior Courts Rules.

As an Irish company, we are governed by the Irish Companies Act 2014, which differs in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of our securities may have more difficulty protecting their interests than would holders of securities of a corporation incorporated in a jurisdiction of the U.S.

Irish law imposes restrictions on certain aspects of capital management.

Irish law allows our shareholders to pre-authorize shares to be issued by our Board of Directors without further shareholder approval for up to a maximum of five years. Our current authorization approved by shareholders at our 2019 Annual General Meeting is due to expire on the earlier of our 2020 Annual General Meeting or August 15, 2020 unless renewed by shareholders for a further period. We anticipate seeking the renewal of this authority at our 2020 Annual General Meeting and in subsequent years, but we cannot guarantee that such renewal will always be approved. Additionally, subject to specified exceptions, including as opt-out approved by a shareholder vote, Irish law grants statutory pre-emptive rights to existing shareholders to subscribe for new issuances of shares for cash. An opt-out was approved by shareholders at our 2019 Annual General Meeting and is due to expire on the earlier of our 2020 Annual General Meeting or August 15, 2020, unless renewed for a further period. We anticipate seeking the renewal of this opt-out at our 2020 Annual General Meeting and in subsequent years but we cannot guarantee that such renewal of the opt-out from pre-emptive rights will always be approved. We cannot provide assurance that these Irish legal restrictions will not interfere with our capital management.

Risks Related to Our Ordinary Shares

Our share price may fluctuate significantly.

The market price of our ordinary shares may fluctuate significantly due to a number of factors, some of which may be beyond our control, including:

- market reaction to developments related to current litigation involving our Specialty Generics business;

- actual or anticipated fluctuations in our results of operations;
- changes in earnings estimated by securities analysts or our ability to meet those estimates;
- perceived impacts to our results from acquisitions of products, license rights or businesses;
- the operating and share price performance of comparable companies;
- actual or anticipated sales of our ordinary shares;
- allegations by third parties (even if unsubstantiated) regarding our products or business practices;
- publicity and media reports potentially negative about the company or its products/reputation;
- new regulations or legislation in the U.S. relating to the development, sale or pricing of pharmaceuticals or medical devices;
- political pressure to reduce the pricing of pharmaceuticals;
- continued consolidation in pharmacy networks and among insurers that may further increase their competitive market power;
- changes to the regulatory and legal environment in which we operate; and
- U.S. and worldwide economic conditions.

Third parties, some of whom may have taken investment positions that would increase in value if our share price declines (“short sellers”), may make allegations related to our products or business practices. These short sellers make a profit when our shares decline in value, and their actions and public statements, and the resulting publicity, may cause further volatility in our share price. This volatility may cause the value of a shareholder's investment to decline.

In addition, when the market price of a company's ordinary shares drops significantly, shareholders often initiate securities class action lawsuits against the company. A lawsuit against us could cause us to incur substantial costs and could divert the time and attention of our management and other resources.

Furthermore, we cannot guarantee that an active trading market for our ordinary shares will continue to exist.

Our shareholders' percentage of ownership in Mallinckrodt may be diluted.

Our shareholders' percentage ownership in Mallinckrodt may be diluted because of equity issuances for acquisitions, capital market transactions or otherwise, including equity awards granted to our directors, officers and employees. Such issuances may have a dilutive effect on our earnings per share, which could materially adversely affect the market price of our ordinary shares. In addition, our articles of association entitle our Board of Directors, without shareholder approval, to cause us to issue preferred shares with such terms as our Board of Directors may determine. Preferred shares may be preferred as to dividends, rights on a winding up or voting in such a manner as our Board of Directors may resolve. The preferred shares may also be redeemable at the option of the holder of the preferred shares or at the option of us, and may be convertible into or exchangeable for shares of any other class or classes of our shares, depending on the terms of such preferred shares. The terms of one or more classes or series of preferred shares could dilute the voting power or reduce the value of our ordinary shares. For example, we could grant the holders of preferred shares the right to elect some number of our Board of Directors in all events or on the happening of specified events or the right to veto specified transactions. Similarly, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred shares could affect the residual value of our ordinary shares.

Certain provisions in our articles of association, among other things, could prevent or delay an acquisition of us, which could decrease the trading price of our ordinary shares.

Our articles of association contain provisions that could have the effect of deterring coercive takeover practices, inadequate takeover bids and unsolicited offers. These provisions include, among others:

- provisions of our articles of association which allow our Board of Directors to adopt a shareholder rights plan (commonly known as a "poison pill") upon such terms and conditions as the Board of Directors deems expedient and in the best interests of our company;
- a provision of our articles of association which generally prohibits us from engaging in a business combination with an interested shareholder for a period of three years following the date the person became an interested shareholder, subject to certain exceptions;

- rules regarding how shareholders may present proposals or nominate directors for election at shareholder meetings;
- the right of our Board of Directors to issue preferred shares without shareholder approval in certain circumstances, subject to applicable law; and
- the ability of our Board of Directors to fill vacancies on our Board of Directors in certain circumstances.

These provisions are not intended to make us immune from takeovers. However, these provisions will apply even if a takeover offer may be considered beneficial by some shareholders and could delay or prevent an acquisition that our Board of Directors determines is not in the best interests of our company and its shareholders. These provisions may also prevent or discourage attempts to remove and replace incumbent directors.

In addition, several mandatory provisions of Irish law could prevent or delay an acquisition of us. For example, Irish law does not permit shareholders of an Irish public limited company to take action by written consent with less than unanimous consent. We are also subject to various provisions of Irish law relating to mandatory bids, voluntary bids, requirements to make a cash offer and minimum price requirements, as well as substantial acquisition rules and rules requiring the disclosure of interests in our ordinary shares in certain circumstances. Also, Irish companies, including us, may only alter their memorandum of association and articles of association with the approval of the holders of at least 75% of the company's shares present and voting in person or by proxy at a general meeting of the company.

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 27, 2019, our outstanding debt included $1,924.4 million variable-rate debt on our senior secured term loans and $900.0 million variable-rate debt on our revolving credit facility. Assuming a one percent increase in the applicable interest rates, in excess of applicable minimum floors, annual interest expense for fiscal 2019 would increase by approximately $28.2 million.

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

Currency Risk

Certain 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 37.

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.

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 utilize related to the safety of the employees of our Specialty Brands and Specialty Generics segments in 2019:

Key Performance Indicator	Specialty Brands	Specialty Generics	Total Group
Global Serious Injury Rate per 100 employees	0.34	0.65	0.48
Number of Serious Injuries	6	10	16
Total Number of Hours Worked	3,554,921	3,086,607	6,641,528

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 utilize related to our sustainability efforts in 2019:

Key Performance Indicator	Specialty Brands	Specialty Generics	Total Group
Gross Global Scope 1 Emissions (metric tons CO_2e)	7,833	88,705	96,538
Gross Global Scope 2 Emissions (metric tons CO_2e)	21,625	72,857	94,482

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 which 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. We believe every employee has a role in making the Group a more rewarding place to work and expect all employees to treat one another with respect and dignity. Equal opportunity and fair treatment extend to all employees. As a global company, we draw on the diversity of our broad workforce and prohibit discrimination. Additionally, we comply with applicable civil rights, human rights and environmental and labor laws. These principles apply to all employment decisions, including: recruiting, hiring and training; promotions, pay and benefits; and transfers, workforce reductions and terminations.

Inclusion and diversity are at the core of who we are, and as we execute on our strategy to deliver powerful, life-changing treatments for patients, we are strengthened by the value we derive from the varied identities, experiences, cultures and views of our employees. The Group's Guide to Business Conduct sets forth our expectations and standards in relation to our employees and other key stakeholders. In addition to the Guide to Business Conduct, we have a variety of policies setting forth our commitment to equal employment opportunities, an inclusive environment that incorporates diversity and individual respect, and providing a safe and respectful workplace.

As an organization, we know that diverse perspectives and viewpoints will allow for faster and better decision making and having a workforce reflective of the patients and communities we serve is a business imperative. Therefore, in March 2019, we launched a thoughtful and intentional recruitment and retention strategy focused on inclusion. We also worked with our benefits team to alleviate standard, bias language in our policies and plan documents that was creating systemic barriers to access.

Our Inclusion and Diversity Council has been formed with a mission to cultivate and inspire an inclusive and diverse working environment through the engagement of various Business Resource Groups, which are employee-led, volunteer groups open to all employees with the goal to improve attraction, retention, inclusion, and engagement of a diverse and global workforce. Our Business Resource Groups today include the following:

- African American
- Emerging Leaders
- Lesbian, Gay, Bisexual, Transgender, Queer and Allies (LGBTQA)
- Namaste Asia
- Hispanic Heritage
- Veterans
- Wellness
- Women in Business

We have been recognized for our efforts on Inclusion and Diversity matters, including being listed on the Human Right Campaign's Best Places to Work for LGBTQ Equality for the past four years (2016-2020) and three consecutive years in the Top 10 Employee Resource Groups & Council Awards (#6 in 2016, #2 in 2017 and #4 in 2019; there were no recognitions in 2018).

As part of our mission to manage complexity and improve lives, we are committed to strengthening the communities in which our employees live and work. We recognize the importance of employee community involvement to our corporate citizenship efforts. Through our matching gift and employee volunteer programs, we encourage and support the efforts of employees who personally contribute their time and money to causes.

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.

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.

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. For further information on these and other efforts, please visit mnk.com/corporate-responsibility/responsible-use.

As part of our mission to manage complexity and improve lives, we work to conduct our sales, 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.

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 2018, 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 318 valid smelters and refineries ("smelters"), of which we identified 47 as sourcing (or there was reason to believe they may be sourcing) from the covered countries. Our due diligence review indicated that 38 of these smelters have been audited and are conformant to the Responsible Minerals Assurance Process, formerly the Conflict-Free Smelter Program. The remaining 9 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 2019, 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/partnerings/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

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

Specialty Brands. We devote significant R&D resources to our branded products, both inline and pipeline. Our R&D investments center on building a diverse, durable portfolio of innovative therapies that provide value to patients, physicians and payers. Our strategy focuses on growth, including pipeline opportunities related to early- and late-stage development products to meet the needs of underserved patient populations, where we execute on the development process and perform clinical trials to support regulatory approval of new products.

Data generation is an important strategic driver for our key products, both inline and in development, as they extend evidence in approved uses, label enhancements and new indications. Our data strategy is realized through investments in both clinical and health economic activities. We are committed to supporting research that helps advance the understanding and treatment of a variety of different disease states that will further the understanding and development of our currently marketed products, including Acthar Gel, INOmax, Ofirmev and Therakos.

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

- *Terlipressin* is being investigated for the treatment of HRS type 1, an acute, rare and life-threatening condition requiring hospitalization, with no currently approved therapy in the U.S. or Canada. During fiscal 2019 we completed enrollment for the Phase 3 clinical study to evaluate the efficacy and safety of terlipressin (for injection) in subjects with HRS type 1, and announced positive top line results. The study met its primary endpoint of verified HRS type 1 reversal, as well as the statistical value requirements outlined in the FDA completed response letter. This Phase 3 clinical study was conducted under an FDA Special Protocol Assessment ("SPA"). In March 2020, we completed the submission of a NDA to the FDA.
- *StrataGraft* regenerative skin tissue is an investigational product in Phase 3 development for treatment of severe, deep partial thickness burns and Phase 2 development for treatment of severe, full thickness burns. In 2012, the FDA granted StrataGraft orphan product status, conferring seven years exclusivity to be applied upon approval of the drug. The product is being developed as a biologic to be filed under a biologic license application that would confer regulatory protection until 2032. In June 2017, we enrolled the first patient in our Phase 3 clinical study to evaluate the efficacy and safety of StrataGraft regenerative skin tissue in the promotion of autologous skin regeneration of complex skin defects due to thermal burns that contain intact dermal elements. StrataGraft is among the first products to be designated as a Regenerative Medicine Advanced Therapy ("RMAT") by the FDA under the provisions of the 21st Century Cures Act. The RMAT designation allows for earlier and increased interactions with the FDA, including discussions of whether priority review and/or accelerated approval would be appropriate based on surrogate or intermediate endpoints that would be reasonably likely to predict long-term clinical benefit; or reliance upon data obtained from a meaningful number of sites. During fiscal 2019, we completed full enrollment for the Phase 3 clinical study and met both primary endpoints as well as the secondary end point evaluating the safety and efficacy of a single application of StrataGraft in the treatment of severe deep partial thickness burns. In April 2020, we initiated a rolling BLA filing to the FDA and expect to complete the submission in the coming months.

  Building upon the science of StrataGraft, we also maintain ExpressGraft-C9T1 skin tissue, a biologically-active skin tissue with a fully stratified epithelial compartment comprised of human keratinocytes and a dermal compartment containing fibroblasts. This tissue has been genetically modified to up-regulate production of a naturally occurring antimicrobial. It is being evaluated in a first-in-human prospective, open-label trial focused on assessing the safety and tolerability in the treatment of patients with diabetic foot ulcers, a type of wound that is often difficult to heal.
- *MNK-6105 (IV) and MNK-6106 (oral)*, an ammonia scavenger, is being studied for treatment of hepatic encephalopathy ("HE"), a neuropsychiatric syndrome associated with hyperammonemia, a complication of acute or chronic liver disease. If approved, MNK-6105 and MNK-6106 are expected to be effective therapy formulations that rapidly eliminate ammonia in the bloodstream, excreting it through the kidneys, a more effective and less burdensome method of addressing HE than existing treatment options. The intravenous ("IV") formulation of MNK-6105, if approved, is expected to provide rapid reduction in symptoms of acute HE, and potentially reduce hospitalization stay. MNK-6106's oral formulation, if approved, is expected to provide post-discharge continuity of care for the HE patient,

reducing the risk of recurrent HE episodes and rehospitalization. It is also anticipated that patients may transition from the IV to the oral formulation prior to discharge from the hospital setting. The FDA and European Medicines Agency have granted orphan drug designation to MNK-6105/6106. The FDA also granted fast track designation to MNK-6105/6106. We are currently working with the FDA, by way of a SPA, and plan to initiate the Phase 3 trial for the IV formulation of this development product in the first half of 2020. The Phase 2 oral trial is still ongoing.

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

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 2019, compared to $55.2 million in fiscal 2018, due to our shift to debt reduction as one of our primary focuses of our capital allocation strategy for fiscal 2019.

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 *(dollars in million)*:

	Number of ordinary shares held	Aggregate consideration paid or received
As of December 28, 2018	9,381,870	$ 1,617.4
Exercised	160,746	2.6
Reissuance	(189,196)	(4.3)
As of December 27, 2019	9,353,420	$ 1,615.7

Further information relating to the acquisition of our shares is set out at Note 29 of the Notes to the Consolidated Financial Statements and Note 7 of the Notes to the Company Financial Statements.

Dividends

We currently do not anticipate paying any cash dividends for the foreseeable future, as we intend to retain earnings to finance acquisitions, R&D, and the operation and expansion of our business, while executing disciplined capital allocation. The recommendation, declaration and payment of any dividends in the future by us will be subject to the sole discretion of our Board of Directors and will depend upon many factors, including our financial condition, earnings, capital requirements of our operating subsidiaries, covenants associated with certain of our debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by our Board of Directors. Moreover, if we determine to pay dividends in the future, there can be no assurance that we will continue to pay such dividends. The payment of dividends is also subject to compliance with the Irish Companies Act 2014, including the requirement for Mallinckrodt plc to have sufficient realized profits available for distribution.

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 3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG, U.K. In accordance with Section 283(2) of the Irish Companies Act 2014, sufficient accounting records are also maintained in Ireland to disclose, with reasonable accuracy, the financial position of the Company. The accounting records are available at College Business & Technology Park, Cruiserath Road, Blanchardstown, Dublin 15, Ireland.

Important Events Since Year End

Commitments and Contingencies

Certain litigation matters occurred during fiscal 2019 or prior. See further discussion in Note 26 of Notes to the Consolidated Financial Statements for subsequent updates to these matters or new litigation through the issuance of this Directors' Report.

Opioid-Related Matters

On February 25, 2020, we, the Specialty Generics Subsidiaries and certain other affiliates announced an agreement in principle on the terms of a global settlement that would resolve all opioid-related claims against us, the Specialty Generics Subsidiaries and our other subsidiaries. Under the terms of the proposed settlement, which would become effective upon the Specialty Generics Subsidiaries' emergence from a contemplated Chapter 11 process, subject to court approval and other conditions, we would (1) make cash payments of $1,600.0 million in structured payments over eight years, beginning upon the Specialty Generics Subsidiaries' emergence from the completed Chapter 11 case, the substantial majority of which is expected to be contributed to the Opioid Claimant Trust and (2) issue Settlement Warrants. As a result of the Litigation Settlement, during fiscal 2019, we recorded a charge of $1,643.4 million attributed to the anticipated structured cash payments and the Settlement Warrants to be issued upon effectiveness of the settlement. Further discussion of this Litigation Settlement is included in Note 30 of the Notes to Consolidated Financial Statements.

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

Financing Activities

February 25, 2020 Agreements

On February 25, 2020, we announced certain financing activities, including entry by us and the Issuers into a support agreement (the “Support Agreement”) with certain of our existing term lenders, as well as certain of our existing noteholders, as new lenders, relating to a potential amendment to our existing credit agreement and new term loans, and a support and exchange agreement (the “Support and Exchange Agreement”) with Aurelius Capital Master, Ltd., Franklin Advisers, Inc. and Capital Research and Management Company contemplating, among other things, a private offer to exchange the Issuers’ 5.750% senior unsecured notes that mature on August 1, 2022 for new second lien secured notes.

Following the execution of the Support Agreement, we received informal communications from advisors to certain of our existing term lenders that they did not expect to fund the new term loans. The Support Agreement terminated in accordance with its terms on March 20, 2020. The Support and Exchange Agreement was terminated, effective as of April 7, 2020, under the terms of the Exchange Agreement described below.

Exchange Agreement

On April 7, 2020, we and Mallinckrodt International Finance S.A. and Mallinckrodt CB LLC, two of our wholly-owned subsidiaries (“Issuers”), entered into an exchange agreement (the “Exchange Agreement”) with Aurelius Capital Master, Ltd., Franklin Advisers, Inc., as investment manager to certain funds and accounts, Capital Research and Management Company and private funds managed by Columbus Hill Capital Management, L.P. (collectively, the “Exchanging Holders”). Pursuant to the Exchange Agreement, the Exchanging Holders agreed to exchange with the Issuers, on April 7, 2020, their holdings of the 2020 Notes issued by the Issuers (the “Existing Notes”) (consisting of approximately $495.0 million aggregate principal amount of the Existing Notes) for new 10.00% First Lien Senior Secured Notes due 2025 issued by the Issuers (the “New Notes”), at a rate of $1,000 of New Notes for every $1,000 of Existing Notes exchanged (such exchange, the “Exchange”). The Issuers and Exchanging Holders consummated the Exchange on April 7, 2020.

The New Notes issued in the Exchange were issued pursuant to an indenture dated as of April 7, 2020 (the “Indenture”) among the Issuers, the Note Guarantors (as defined below), Wilmington Savings Fund Society, FSB, as first lien trustee, and Deutsche Bank AG New York Branch, as first lien collateral agent.

Interest on the New Notes is payable semi-annually in cash on April 15 and October 15 of each year, commencing on October 15, 2020.

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

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

The Indenture 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 New Notes and could cause a cross-default that could result in the acceleration of other indebtedness of the Company and its subsidiaries.

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

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

Directors

Directors' remuneration is set forth in Note 13 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 2019.

Name
Mark C. Trudeau
David R. Carlucci
J. Martin Carroll
Paul R. Carter
David Y. Norton
Carlos V. Paya, M.D., Ph.D. [(1)]
JoAnn A. Reed
Angus C. Russell
Anne C. Whitaker
Kneeland C. Youngblood, M.D.
Joseph A. Zaccagnino [(2)]

(1) Mr. Paya was appointed to the Board of Directors on May 15, 2019.

(2) Mr. Zaccagnino retired from the Board of Directors on May 15, 2019.

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 31 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 directors have a reasonable expectation that Mallinckrodt plc and the Group have adequate resources to continue in operational existence for the foreseeable future. Accordingly, the directors continue to adopt the going concern basis in preparing the financial statements.

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	/s/ Mark C. Trudeau
JoAnn A. Reed	Mark C. Trudeau
Director	Director
7 April 2020	

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 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 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 27 December 2019 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 Comprehensive Loss;
- the Consolidated Balance Sheet;
- the Consolidated Statement of Changes in Equity;
- the Consolidated Cash Flow Statement; and
- the related notes 1 to 31, including a summary of significant accounting policies as set out in note 2.

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 27 December 2019.

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.

Summary of our audit approach	
Key audit matters	The key audit matters that we identified in the current year were: Taxation - Legal Entity Reorganization Commitments and Contingencies - Opioid Litigation Settlement Going Concern Basis of Preparation
Materiality	The materiality that we used in the current year was $30.0 million, which was determined on the basis of adjusted net income.
Scoping	We 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.
Significant changes in our approach	No significant changes to note.

Conclusions relating to going concern

We have nothing to report in respect of the following matters in relation to which ISAs (Ireland) require us to report to you where:

- the directors' use of the going concern basis of accounting in preparation of the financial statements is not appropriate; or
- the directors have not disclosed in the financial statements any identified material uncertainties that may cast significant doubt about the group's ability to continue to adopt the going concern basis of accounting for a period of at least twelve months from the date when the financial statements are authorised for issue.

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 period 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.

Taxation - Legal Entity Reorganization	
Key audit matter description	The Group completed a reorganization of its intercompany financing and associated legal entity ownership in response to the changing global tax environment, resulting in a $26.2 million current taxation charge and a $239.0 million deferred taxation credit. The reorganization involved the interpretation of multi-jurisdictional tax laws and regulations, supported by third-party tax opinions. Interpretation of tax laws can be inherently uncertain and can be subject to potential challenges by the relevant tax authorities, both of which were considered in assessing its reserves for uncertain tax positions. We identified the income taxes associated with the legal entity reorganization as a key audit matter because of the significant judgments made by management and the complex nature of the reorganization, particularly related to the interpretation of multi-jurisdictional tax laws and regulations. This required a high degree of auditor judgment and an increased extent of effort, including the need to involve our tax specialists when performing audit procedures to evaluate the Group's interpretation of tax laws and regulations for multiple jurisdictions. Refer also to Note 10 Taxation.
How the scope of our audit responded to the key audit matter	In order to assess this key audit matter, we performed the following specific audit procedures, among others: We tested the effectiveness of management's controls over income taxes, including those over the legal entity reorganization and the interpretation of tax laws and regulations. With the assistance of our tax specialists, we evaluated the income taxes associated with the legal entity reorganization by performing the following: Obtaining management and third-party tax opinions or memoranda regarding the analysis of relevant tax laws and regulations and evaluating whether the analysis was consistent with our interpretation. Evaluating the appropriateness of management's conclusions with respect to reserves for uncertain tax positions associated with the legal entity reorganization. Testing the underlying calculations and allocations supporting the tax expense and benefit recorded.
Key observations	We have no observations that impact on our audit in respect of the taxes associated with the Legal Entity Reorganization.

Commitments and Contingencies - Opioid Litigation Settlement	
Key audit matter description	On February 25, 2020, the Group announced that it has reached an agreement in principle on the terms of a global settlement that would resolve all opioid related claims against the Group and its subsidiaries ("Litigation Settlement") for $1,600.0 million in cash payments over eight years and the issuance of warrants to purchase ordinary shares of the Group that would represent approximately 19.99% of the Group's fully diluted outstanding shares. The Litigation Settlement contemplates the filing of voluntary petitions under Chapter 11 of the U.S. Bankruptcy Code ("Chapter 11") by certain subsidiaries of Mallinckrodt plc operating the Specialty Generics business (the "Specialty Generics Subsidiaries"). The Litigation Settlement payments and the issuance of warrants are effective upon the emergence from the contemplated Chapter 11 process and are conditioned upon, among other things, bankruptcy court approval of the bankruptcy plan effectuating the Litigation Settlement, the emergence of the Specialty Generics Subsidiaries from bankruptcy and other material terms. The Group records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. As a result of the Litigation Settlement, the Group recorded an accrual of $1,600.0 million related to the cash payments and $43.4 million related to the warrants in the consolidated balance sheet as of December 27, 2019, with a corresponding non-cash charge to the consolidated profit and loss account as a component of operating expenses.
How the scope of our audit responded to the key audit matter	In order to assess this key audit matter, we performed the following specific audit procedures, among others: We tested the effectiveness of controls over the Litigation Settlement, which included review and approval of the accounting and related disclosures. We requested and received written responses from the Group's external legal counsel regarding opioid litigation and the Litigation Settlement. We evaluated the Group's conclusions regarding the recognition and measurement of the opioid-related litigation settlement by obtaining management's documented accounting treatment and evaluating the accounting based on the terms of the Litigation Settlement and the applicable accounting principles generally accepted in the United States of America. We evaluated the Group's disclosures for consistency with our knowledge of the Litigation Settlement.
Key observations	We have no observations that impact on our audit in respect of the Opioid Litigation Settlement.
Going Concern Basis of Preparation	
Key audit matter description	As set out in the Directors Responsibility Statement on page 46, the Directors are required to prepare the financial statements on a going concern basis of preparation unless it is inappropriate to do so. This requires the Directors to assess the ability of the Group to continue to meet its liabilities as they fall due for the foreseeable future.
How the scope of our audit responded to the key audit matter	In order to assess this key audit matter, we performed the following specific audit procedures, among others, to assess the appropriateness of the going concern basis of preparation: We reviewed the written assessment of going concern as prepared by management and evaluated the conclusion reached. We evaluated if the period considered in the assessment covered an appropriate period of time subsequent to the date of approval of the financial statements. We assessed if information obtained subsequent to the balance sheet date has been adequately assessed by management. We evaluated if adequate disclosure has been provided in the financial statements.
Key observations	We have no observations that impact on our audit in respect of the Going Concern Basis of Preparation

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 $30.0 million which represents approximately 4.0% of adjusted net income and approximately 3.3% of adjusted pre-tax income. We have considered these two benchmarks of adjusted net income and adjusted pre-tax income to be critical components for determining materiality as we determined these results to be of most importance to the principal external users of the financial statements. We have considered quantitative and qualitative factors such as our understanding of the entity and its environment, history of misstatements, complexity of the Group, and reliability of the internal control environment in our determination of materiality.

We agreed with the Audit Committee that we would report to the Audit Committee any audit differences in excess of $1.5 million or 5.0% of materiality, as well as differences below that threshold that, 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 Group 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 reporting units 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 profit 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 Generics and $21.6 million for Specialty Brands

Other information

The directors are responsible for the other information. The other information comprises the information included in the Directors' Report and Consolidated Financial Statements for the financial period ended 27 December 2019, other than the financial statements and our auditor's report thereon. 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.

In connection with our audit of the financial statements, 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' 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) 2016, 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.

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.

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 the directors' report as specified in our review is consistent with the financial statements and 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 that have been 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 27 December 2019. 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.

/s/ Richard Howard
Richard Howard
For and on behalf of Deloitte Ireland LLP
Chartered Accountants and Statutory Audit Firm
Deloitte & Touche House, Earlsfort Terrace, Dublin 2
Date: 7 April, 2020

MALLINCKRODT PLC
CONSOLIDATED PROFIT AND LOSS ACCOUNT
(in millions, except per share data)

	Note	Fiscal Year					
		2019			2018		
		Ordinary Activities	Discontinued Operations	Total	Ordinary Activities	Discontinued Operations	Total
Turnover	4, 5	$ 3,162.5	$ —	$ 3,162.5	$ 3,215.6	$ —	$ 3,215.6
Cost of sales		1,741.1	—	1,741.1	1,744.4	—	1,744.4
Gross profit		1,421.4	—	1,421.4	1,471.2	—	1,471.2
Distribution and administrative expenses		831.0	—	831.0	834.1	—	834.1
Research and development costs		349.4	—	349.4	361.1	—	361.1
Restructuring charges, net	6	(1.7)	—	(1.7)	103.0	—	103.0
Non-restructuring impairment charges	16	388.0	—	388.0	3,893.1	—	3,893.1
Loss (profit) on disposal of operations	7	33.5	(12.4)	21.1	0.8	(16.3)	(15.5)
Opioid-related litigation settlement charge	30	1,643.4	—	1,643.4	—	—	—
Operating (loss) profit		(1,822.2)	12.4	(1,809.8)	(3,720.9)	16.3	(3,704.6)
Interest payable and similar expenses	9	(309.0)	—	(309.0)	(370.2)	—	(370.2)
Interest receivable and similar income		9.5	—	9.5	8.2	—	8.2
Gains on debt extinguishment, net	23	466.6	—	466.6	8.5	—	8.5
Other income, net		63.6	—	63.6	22.4	—	22.4
(Loss) profit on ordinary activities before taxation		(1,591.5)	12.4	(1,579.1)	(4,052.0)	16.3	(4,035.7)
Taxation (credit) charge	10	(584.3)	1.7	(582.6)	(430.1)	1.4	(428.7)
(Loss) profit after taxation		$ (1,007.2)	$ 10.7	$ (996.5)	$ (3,621.9)	$ 14.9	$ (3,607.0)
Basic/Diluted (loss) earnings per ordinary share:	11	$ (12.00)	$ 0.13	$ (11.88)	$ (43.12)	$ 0.18	$ (42.94)

MALLINCKRODT PLC
CONSOLIDATED STATEMENT OF OTHER COMPREHENSIVE LOSS
(in millions)

	Fiscal Year	
	2019	**2018**
Loss after taxation	$ (996.5)	$ (3,607.0)
Other comprehensive profit (loss), net of taxation		
Currency translation adjustments	18.3	(12.2)
Unrecognized gain on derivatives, net of tax charge	1.8	0.7
Unrecognized (loss) gain on benefit plans, net of tax charge	(4.2)	1.6
Total other comprehensive profit (loss), net of taxation	15.9	(9.9)
Comprehensive loss	$ (980.6)	$ (3,616.9)

MALLINCKRODT PLC
CONSOLIDATED BALANCE SHEET
(in millions)

	Note	December 27, 2019	December 28, 2018
Fixed Assets			
Intangible assets	16	$ 7,018.0	$ 8,282.8
Tangible assets	17	980.0	982.0
Financial assets	18	161.9	130.5
		8,159.9	9,395.3
Current Assets			
Stocks	19	312.1	322.3
Debtors	20	1,076.0	810.8
Cash at bank and in hand		790.9	348.9
		2,179.0	1,482.0
Creditors (amounts falling due within one year)	21	1,258.8	732.4
Net Current Assets		920.2	749.6
Total Assets Less Current Liabilities		9,080.1	10,144.9
Creditors (amounts falling due after one year)	22	5,135.4	6,424.0
Provisions for Liabilities	28	2,004.0	833.6
Net Assets		$ 1,940.7	$ 2,887.3
Capital and Reserves			
Called-up share capital presented as equity	29	$ 18.7	$ 18.5
Share premium account	29	5.7	5.1
Other reserves	29	1,552.0	1,501.9
Profit and loss account	29	364.3	1,361.8
Shareholders' Funds		$ 1,940.7	$ 2,887.3

Approved by the Board of Directors on 7 April 2020 and signed on its behalf by:

/s/ JoAnn A. Reed	/s/ Mark C. Trudeau
JoAnn A. Reed	Mark C. Trudeau
Director	Director

MALLINCKRODT PLC
CONSOLIDATED STATEMENT OF CASH FLOWS
(in millions)

	Fiscal Year	
	2019	**2018**
Cash Flows From Ordinary Operating Activities:		
Loss after taxation	$ (996.5)	$ (3,607.0)
Adjustments to reconcile net cash provided by ordinary operating activities:		
Depreciation and amortization	951.1	852.1
Share-based compensation	33.8	34.6
Deferred taxation	(604.3)	(541.5)
Non-cash impairment charges	388.0	3,893.1
Stocks provisions	18.0	37.9
Losses on divestiture	33.5	0.8
Gain on debt extinguishment, net	(466.6)	(8.5)
Other non-cash items	(65.7)	(42.4)
Changes in assets and liabilities, net of the effects of acquisitions:		
Trade debtors	31.6	(145.8)
Stocks	(23.1)	63.1
Trade creditors	6.7	24.6
Taxation	(2.1)	99.0
Opioid-related litigation settlement liability	1,600.0	—
Other	(161.5)	5.5
Net cash from ordinary operating activities	742.9	665.5
Cash Flows From Ordinary Investing Activities:		
Capital expenditures	(133.0)	(127.0)
Acquisitions, net of cash acquired	—	(699.9)
Proceeds from divestitures, net of cash	95.1	313.0
Other	29.6	33.6
Net cash from ordinary investing activities	(8.3)	(480.3)
Cash Flows From Ordinary Financing Activities:		
Issuance of external debt	695.0	690.3
Repayment of external debt	(945.1)	(1,693.6)
Debt financing costs	(10.1)	(12.1)
Proceeds from exercise of share options	0.6	1.0
Repurchase of shares	(2.6)	(57.5)
Other	(17.9)	(23.1)
Net cash from ordinary financing activities	(280.1)	(1,095.0)
Effect of currency rate changes on cash at bank and in hand	0.6	(1.8)
Net change in cash at bank and in hand and restricted cash	455.1	(911.6)
Cash at bank and in hand and restricted cash at beginning of period	367.5	1,279.1
Cash at bank and in hand and restricted cash at end of period	$ 822.6	$ 367.5
Cash at bank and in hand at end of period	$ 790.9	$ 348.9
Restricted Cash, Noncurrent at end of period	31.7	18.6
Cash at bank and in hand at end of period	$ 822.6	$ 367.5
Supplemental Disclosures of Cash Flow Information:		
Cash paid for interest, net	$ 314.2	$ 309.7
Cash paid for taxation, net	30.7	12.4

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

	Called-up Share Capital			Other Reserves				
	Number	Amount	Share Premium Account (Note 29)	Capital Redemption Reserve	Other (Note 29)	Accumulated Other Comprehensive Loss	Profit and Loss Account	Total
Balance as of December 29, 2017	92.2	$ 18.4	$ 4.1	$ 5.3	$ 1,486.3	$ (12.9)	$ 5,020.8	$ 6,522.0
Impact of accounting standard adoptions	—	—	—	—	—	(1.5)	2.6	1.1
Loss after taxation	—	—	—	—	—	—	(3,607.0)	(3,607.0)
Other comprehensive loss, net of tax	—	—	—	—	—	(9.9)	—	(9.9)
Share options exercised	—	—	1.0	—	—	—	—	1.0
Vesting of restricted shares	0.5	0.1	—	—	—	—	(2.3)	(2.2)
Share-based compensation	—	—	—	—	34.6	—	—	34.6
Repurchase of ordinary shares	—	—	—	—	—	—	(55.2)	(55.2)
Reissued shares	—	—	—	—	—	—	2.9	2.9
Balance as of December 28, 2018	92.7	18.5	5.1	5.3	1,520.9	(24.3)	1,361.8	2,887.3
Impact of accounting standard adoptions	—	—	—	—	—	0.5	(0.5)	—
Loss after taxation	—	—	—	—	—	—	(996.5)	(996.5)
Other comprehensive profit, net of tax	—	—	—	—	—	15.9	—	15.9
Share options exercised	—	—	0.6	—	—	—	—	0.6
Vesting of restricted shares	0.8	0.2	—	—	(0.1)	—	(2.6)	(2.5)
Share-based compensation	—	—	—	—	33.8	—	—	33.8
Reissued shares	—	—	—	—	—	—	2.1	2.1
Balance as of December 27, 2019	93.5	$ 18.7	$ 5.7	$ 5.3	$ 1,554.6	$ (7.9)	$ 364.3	$ 1,940.7

1. Background and Basis of Presentation

Background

Mallinckrodt plc is a public limited company incorporated in the Republic of Ireland with the registration number 522227. The address of its registered office is College Business and Technology Park, Cruiserath, Blanchardstown, Dublin 15, Ireland, and the business address is Three Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG, United Kingdom ("U.K.").

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 and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; analgesics 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 is incorporated in Ireland, with its principal executive offices located in the U.K. The Group continues to be subject to United States ("U.S.") Securities and Exchange Commission ("SEC") reporting requirements and the applicable corporate governance rules of the New York Stock Exchange.

Basis of Presentation

The 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 U.K. and 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 fifty percent of the voting shares, or have the ability to control through similar rights. All intercompany balances and transactions have been eliminated in consolidation and all normal recurring adjustments necessary for a fair presentation have been included in the results reported.

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

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.

During fiscal 2019, the Group experienced a change in its reportable segments, which primarily served to move the results related to Amitiza® (lubiprostone) ("Amitiza") to the Specialty Brands segment from the Specialty Generics segment. All prior

period segment information has been recast to reflect the realignment of the Group's reportable segments on a comparable basis.

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

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 27, 2019. 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 2019 and 2018 each consisted of 52 weeks. Unless otherwise indicated, fiscal 2019 and 2018 refer to the Group's fiscal years ended December 27, 2019 and December 28, 2018, respectively. All references to "fiscal" year are considered to be defined as "financial" year under FRS 102.

2. Summary of Significant Accounting Policies

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 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 inventory 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 to a third party 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 $17.6 million and $12.8 million for fiscal 2019 and 2018, 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 arrangements 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, specific allowances for known troubled accounts 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 for 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. 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 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. The Group used the incremental borrowing rate as of December 29, 2018 for leases that commenced prior to that date. Most leases include one or more options to terminate or renew, with renewal terms that can extend the lease term from one to five years. The exercise of lease renewal options is at the Group's sole discretion. Termination and renewal options are included within the lease assets and liabilities only to the extent they are reasonably certain. Refer to Note 3 for further information regarding the adoption of the lease accounting standard in fiscal 2019.

Acquisitions

Amounts paid for acquisitions that meet the criteria for business combination accounting are allocated to the tangible assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. The 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.

Goodwill and Other Intangible Assets

Irish company law requires indefinite-lived intangible assets and goodwill to be amortized; however, the directors do not believe that this gives a true and fair value because not all goodwill and intangible assets decline in value. In addition, goodwill that does decline in value rarely declines on a straight-line basis, as such straightline amortization of goodwill over an arbitrary

period does not reflect the economic reality. Therefore, to present a true and fair value of the economic reality, under U.S. GAAP, goodwill and certain other intangible assets are considered indefinite-lived and are not amortized.

During fiscal 2018, the Group's annual goodwill impairment analysis resulted in the recognition of a full goodwill impairment of $3,672.8 million related to the Specialty Brands reporting unit. As a result, the Group did not have a goodwill balance during fiscal 2019. Prior to this full impairment, the Group tested goodwill on the first day of the fourth quarter of each year for impairment or whenever events or changes in circumstances indicated that the carrying value may not be recoverable. Goodwill represents the excess of the purchase price of an acquired entity over the amounts assigned to assets and liabilities assumed in a business combination. The impairment test is comprised of comparing the carrying value of a reporting unit to its estimated fair value. The Group estimates the fair value of a reporting unit through internal analyses and valuation, utilizing an income approach (a level three measurement technique) based on the present value of future cash flows. The fair value of the Group's reporting units is reconciled to its share price and market capitalization as a corroborative step. If the carrying value of a reporting unit exceeds its fair value, the Group will recognize the excess of the carrying value over the fair value as a goodwill impairment loss.

Intangible assets acquired in a business combination are recorded at fair value, while intangible assets acquired in other transactions are recorded at cost. Intangible assets 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 27, 2019 were the following:

Completed technology	8	to	25 years
License agreements			30 years
Trademarks	22	to	30 years

Amortization expense related to completed technology and certain other intangible assets is included in cost of sales, while amortization expense related to intangible assets that contribute to the Group's ability to sell, market and distribute products is included in D&A expenses.

When a 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 patent infringement claims, product liability matters, government investigations, environmental matters, employee disputes, contractual disputes and other commercial disputes, and other legal proceedings in the ordinary course of business as further discussed in Note 26. 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 12.

Restructuring

The Group recognizes charges associated with its 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. Deferred tax liabilities are also recorded for deferred tax obligations related to installment sale arrangements. The deferral of tax payments to the U.S. Internal Revenue Service ("IRS") are subject to interest, which is accrued and included within interest expense.

The Group determines whether it is more likely than not that a tax position will be sustained upon examination. The tax credit or benefit of any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the uncertainty. To the extent a full benefit is not expected to be realized on the uncertain tax position, a tax liability 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 tax credits being recognized in the period when it is determined that the liabilities are no longer necessary. Refer to Note 10 for further information regarding the classification of such amounts in the consolidated balance sheets.

3. Recently Issued Accounting Standards

The Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2018-02, "Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income," in February 2018. This ASU allows for a reclassification from accumulated other comprehensive (loss) income ("AOCI") to retained earnings for the stranded tax effects arising from the change in the reduction of the U.S. federal statutory tax rate from 35.0% to 21.0%. The Group adopted this standard as of day 1 of fiscal 2019, which resulted in a reclassification between AOCI and profit and loss account of $0.5 million, and had no impact on the Group's results of operations or financial position.

The FASB issued ASU 2016-02, "Leases," in February 2016. This ASU was issued to increase transparency and comparability among organizations by recognizing all lease transactions (with terms in excess of 12 months) on the balance sheet as a lease liability and a right-of-use asset. The FASB subsequently issued additional ASUs to clarify the guidance of ASU 2016-02 ("Topic 842,") as amended. The Group adopted this standard as of day 1 of fiscal 2019 utilizing the modified transition approach expedient, which allows an entity to elect not to recast its comparative periods in the period of adoption. In addition, the Group elected to use the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed the Group to carry forward the historical lease classification. The Group also elected the hindsight practical expedient to determine the lease term for existing leases. Adoption of the new standard resulted in the recording of additional lease assets and corresponding liabilities of $83.1 million and $99.7 million, respectively, as of December 29, 2018. Refer to Note 17 for further details on the Group's leases.

The FASB issued ASU 2016-01, "Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities," in January 2016. This update addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. Under the new guidance, equity investments, other than equity method investments, are to be measured at fair value with changes in fair value recognized through profit (loss) after taxation. The Group adopted this guidance in fiscal 2018, resulting in a $1.5 million increase to profit and loss account with an offsetting

decrease to other accumulated comprehensive profit relating to the unrealized gain on its investment in Mesoblast Limited ("Mesoblast"). The adoption of this standard did not result in any material changes to the consolidated financial statements.

4. Turnover from Contracts with Customers

Product Turnover

See Note 5 for presentation of the Group's turnover by product family

Reserves for variable consideration

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
Balance as of December 29, 2017	$ 327.4	$ 34.5	$ 14.7	$ 376.6
Provisions	2,281.3	39.3	66.9	2,387.5
Payments or credits	(2,254.4)	(39.8)	(64.5)	(2,358.7)
Balance as of December 28, 2018	354.3	34.0	17.1	405.4
Provisions	2,347.3	22.2	68.2	2,437.7
Payments or credits	(2,405.8)	(27.8)	(72.1)	(2,505.7)
Balance as of December 27, 2019	$ 295.8	$ 28.4	$ 13.2	$ 337.4

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

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

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

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

Costs to fulfill a contract

As of December 27, 2019 and December 28, 2018, the total net book value of the devices used in the Group's portfolio of drug-device combination products, which are used in satisfying future performance obligations, were $26.5 million and $28.4 million, respectively and were classified as tangible assets on the consolidated balance sheets. The associated depreciation expense recognized during fiscal 2019 and 2018 was $6.7 million and $7.4 million, respectively.

Product Royalty Turnover

As part of the Group's acquisition of Sucampo Pharmaceuticals, Inc. ("Sucampo") in fiscal 2018, as discussed in further detail in Note 8, it acquired an arrangement under which the Group licenses certain rights to Amitiza to a third party in exchange for royalties on turnover of the product. The Group recognizes such royalty turnover as the related turnover occurs. The royalty rates consist of several tiers ranging from 18.0% to 26.0% with the royalty rate resetting every year. The associated royalty turnover recognized during both fiscal 2019 and 2018 was $81.3 million.

Contract Liabilities

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

	December 27, 2019	December 28, 2018
Creditors (amounts falling due within one year)	$ 5.6	$ 20.4
Creditors (amounts falling due after one year)	0.6	15.1
Contract liabilities	$ 6.2	$ 35.5

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

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).

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

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 operating profit because management evaluates the operating results of the segments excluding such items. These items include, but are not limited to, intangible asset amortization, net restructuring and related charges, non-restructuring impairments and separation costs. Although these amounts are excluded from segment operating profit, as applicable, they are included in reported consolidated operating (loss) profit and in the following 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 $10,338.9 million and $10,877.3 million as of December 27, 2019 and December 28, 2018, respectively.

Selected information by business segment was as follows:

	Fiscal Year	
	2019	2018
Turnover:		
Specialty Brands	$ 2,423.8	$ 2,496.7
Specialty Generics	738.7	718.9
Turnover	$ 3,162.5	$ 3,215.6
Operating profit (loss):		
Specialty Brands	$ 1,174.5	$ 1,093.1
Specialty Generics	108.1	89.3
Segment operating profit	1,282.6	1,182.4
Unallocated amounts:		
Corporate and allocated expenses [1]	(137.8)	(155.8)
Intangible asset amortization	(853.4)	(740.2)
Restructuring and related charges, net [2]	1.7	(108.2)
Non-restructuring impairment charges	(388.0)	(3,893.1)
Separation costs [3]	(63.9)	(6.0)
R&D upfront payment [4]	(20.0)	—
Opioid-related litigation settlement charge [5]	(1,643.4)	—
Operating loss	$ (1,822.2)	$ (3,720.9)
Depreciation and amortization:		
Specialty Brands	$ 862.4	$ 762.5
Specialty Generics	88.7	89.6
Depreciation and amortization	$ 951.1	$ 852.1

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

(2) Includes restructuring-related accelerated depreciation.

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

(4) Represents R&D expense incurred related to an upfront payment made to Silence Therapeutics plc ("Silence") in connection with the license and collaboration agreement entered into in July 2019. Refer to Note 8 for further details.

(5) Subsequent to December 27, 2019, the Group announced an agreement in principle on the terms of a global settlement of all opioid-related claims against the Group and its subsidiaries. See Note 30 for further information.

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

	Fiscal Year	
	2019	2018
Acthar Gel	$ 952.7	$ 1,110.1
INOmax	571.4	542.7
Ofirmev	384.0	341.9
Therakos	246.9	231.2
Amitiza [1]	208.5	183.8
BioVectra [2]	40.1	53.1
Other	20.2	33.9
Specialty Brands	2,423.8	2,496.7
Hydrocodone (API) and hydrocodone-containing tablets	76.3	65.9
Oxycodone (API) and oxycodone-containing tablets	74.9	66.1
Acetaminophen (API)	189.9	192.7
Other controlled substances	352.5	343.8
Other	45.1	50.4
Specialty Generics	738.7	718.9
Turnover from continuing activities	$ 3,162.5	$ 3,215.6

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

(2) In November 2019, the Group completed the sale of BioVectra Inc. Refer to Note 7 for details.

Selected information by geographic area was as follows:

	Fiscal Year	
	2019	2018
Turnover [1]:		
U.S.	$ 2,765.6	$ 2,834.5
Europe, Middle East and Africa	281.8	256.8
Other	115.1	124.3
	$ 3,162.5	$ 3,215.6

(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.

	December 27, 2019	December 28, 2018
Long-lived assets [1]:		
U.S.	$ 734.3	$ 770.7
Europe, Middle East and Africa [2]	169.9	146.7
Other	4.8	76.8
	$ 909.0	$ 994.2

(1) Long-lived assets are primarily composed of tangible assets.

(2) Includes long-lived assets located in Ireland of $168.4 million and $145.2 million as of December 27, 2019 and December 28, 2018, respectively.

6. Restructuring and Related Charges

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

Net restructuring and related charges by segment were as follows:

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

Net restructuring and related charges were comprised of the following:

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

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

	2018 Program	2016 Program	Acquisition Programs	Total
Balance as of December 29, 2017	$ —	$ 14.7	$ 0.8	$ 15.5
Charges	2.2	76.9	29.9	109.0
Changes in estimate	—	(5.3)	(0.7)	(6.0)
Cash payments	—	(23.4)	(22.2)	(45.6)
Reclassifications	—	(1.9)	—	(1.9)
Balance as of December 28, 2018	2.2	61.0	7.8	71.0
Charges	11.2	4.0	0.1	15.3
Changes in estimate	(1.4)	(14.6)	(1.0)	(17.0)
Cash payments	(9.3)	(13.1)	(2.4)	(24.8)
Reclassifications [1]	—	(5.0)	(4.3)	(9.3)
Currency translation	—	(1.0)	—	(1.0)
Balance as of December 29, 2019	$ 2.7	$ 31.3	$ 0.2	$ 34.2

(1) Represents the reclassification of lease liabilities, net to lease liabilities and lease assets, which are reflected within creditors (amounts falling due within and after one year) and tangible assets on the consolidated balance sheet, due to the adoption of ASU 2016-02.

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

	2018 Program [1]	2016 Program
Specialty Brands	$ 3.0	$ 68.1
Specialty Generics	10.0	14.6
Corporate	2.0	28.9
	$ 15.0	$ 111.6

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

In fiscal 2018, the Group discontinued the marketing of Raplixa after an evaluation of strategic options and incurred restructuring expenses of $51.1 million under the 2016 Program, consisting primarily of contract termination costs related to the production of Raplixa. During fiscal 2019, the Group finalized the settlement of these contract costs.

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. In January 2017, the Group completed the sale of its Nuclear Imaging business to IBA Molecular ("IBAM") for approximately $690.0 million before tax impacts, including up-front considerations of approximately $574.0 million, up to $77.0 million of contingent considerations and the assumption of certain liabilities. The Group received a total of $9.0 million and $15.0 million in contingent consideration related to the sale of the Nuclear Imaging business during fiscal 2019 and 2018, respectively, consisting primarily of the issuance of $9.0 million par value non-voting preferred equity certificates in both fiscal 2019 and 2018, with an additional $6.0 million cash payment in fiscal 2018. The preferred equity certificates accrue interest at a rate of 10.0% per annum and are redeemable on the retirement date of July 27, 2025, or earlier if elected by the issuer, for cash at a price equal to the par value and any accrued but unpaid interest. The receipt of the preferred equity certificates are presented as a non-cash investing activity on the consolidated statements of cash flows for fiscal 2019 and 2018.

Divestitures

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

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

PreveLeak/Recothrom. In March 2018, the Group completed the sale of a portion of its Hemostasis business, inclusive of its PreveLeak™ Surgical Sealant ("PreveLeak") and RECOTHROM® Thrombin topical (Recombinant) ("Recothrom") products to Baxter International Inc. ("Baxter") for approximately $185.0 million, with a base payment of $153.0 million, inclusive of existing inventory and subject to a closing inventory adjustment, with the remainder in potential future milestones. Baxter assumed other expenses, including contingent liabilities associated with PreveLeak. During fiscal 2018, the Group recorded a pre-tax loss on the sale of $0.8 million, which excluded any potential proceeds from future milestones, in the event they are achieved and reflected a post-sale closing inventory adjustment of $13.7 million.

As part of the divestiture and calculation of the loss, the Group wrote off intangible assets of $49.9 million and goodwill of $51.5 million during fiscal 2018, from the Specialty Brands segment, ascribed to the PreveLeak and Recothrom operations. The remaining items included in the calculation of the loss are primarily attributable to inventory transferred, contingent consideration transferred and transaction costs incurred by the Group.

Intrathecal Therapy. In March 2017, the Group completed its sale of its Intrathecal Therapy business to Piramal Enterprises Limited's subsidiary in the U.K., Piramal Critical Care ("Piramal"), for approximately $203.0 million, including fixed consideration of $171.0 million and contingent consideration of up to $32.0 million. The $171.0 million of fixed consideration consisted of $17.0 million received at closing and a $154.0 million note receivable due one year from the transaction closing date. In fiscal 2018, the Group received $154.0 million from Piramal for the settlement of the aforementioned note receivable. The Group is committed to reimburse up to $7.3 million of product development expenses incurred by Piramal, of which $2.1 million and $3.1 million was included in creditors with amounts falling due within one year on the consolidated balance sheet as of December 27, 2019 and December 28, 2018, respectively.

8. Acquisitions and License Agreements

Acquisitions

Sucampo Pharmaceuticals, Inc. In February 2018, the Group acquired Sucampo through the acquisition of all the outstanding common stock of Sucampo. Consideration for the transaction consisted of approximately $1.2 billion, including the assumption of Sucampo's third-party debt ("the Sucampo Acquisition"). The acquisition was funded through the issuance of a $600.0 million aggregate principal amount of senior secured term loan, a $900.0 million borrowing under the Group's revolving credit facility, as discussed further in Note 23, and cash on hand. Sucampo's primary commercialized product was Amitiza, a leading global product in the branded constipation market. Through this acquisition, the Group acquired VTS-270, a Phase 3 development product for Niemann-Pick Type C, a complicated, ultra-rare neurodegenerative disease that typically presents in childhood and is ultimately fatal. Also acquired was an option to exercise a collaborative agreement with Cancer Prevention Pharmaceuticals ("CPP") associated with the development of CPP-1X/sulindac, a Phase 3 development product for Familial Adenomatous Polyposis ("FAP").

Upon completion of the Sucampo Acquisition, Sucampo's 3.25% convertible senior notes due 2021 ("the Sucampo Notes") became eligible to receive increased consideration in conjunction with a make-whole fundamental change, such that each $1,000 principal face amount of Sucampo Notes could be converted into $1,221 cash. The issued convertible debt of $300.0 million had been converted and paid in full by the Group during fiscal 2018.

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

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

(1) During fiscal 2019, the Group recognized a full impairment of the IPR&D asset related to VTS-270 of $274.5 million. Refer to Note 16 for further information.

(2) Refer to Note 16 for further information relating to the full goodwill impairment recorded in fiscal 2018.

The following reconciles the total consideration to net assets acquired:

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

Intangible assets acquired consist of the following:

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

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

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

The fair value of the intangible assets was determined using the income approach. The fair value of the IPR&D, completed technology and trademark was determined using the income approach, which is a valuation technique that provides an estimate of fair value of the assets based on the market participant expectations of cash flows the asset would generate. The discount rates were developed after assigning a probability of success to achieving the projected cash flows based on the current stage of development, inherent uncertainty in the U.S. Food and Drug Administration ("FDA") approval process and risks associated with commercialization of a new product. Based on the Group's preliminary estimate, the excess of purchase price over net tangible and intangible assets acquired resulted in goodwill, which represents future product development, the assembled workforce, and the tax status of the transaction. The goodwill was not deductible for U.S. income tax purposes.

The amount of turnover and operating losses included in the Group's fiscal 2019 consolidated profit and loss account related to the Sucampo Acquisition were $217.2 million and $210.6 million, respectively, as compared to $190.5 million and $369.1 million included in the Group's 2018 consolidated profit and loss account, respectively. Included within Sucampo's operating results was the full impairment of the VTS-270 intangible asset in fiscal 2019 and a charge for the goodwill allocated at the time of acquisition as a result of the full goodwill impairment in fiscal 2018. Also included within the fiscal 2019 and 2018 results was $70.9 million and $62.9 million of amortization associated with intangibles recognized from this acquisition, respectively, and $10.0 million and $118.8 million of expense associated with fair value adjustments of acquired inventory, respectively. During fiscal 2019 and 2018, the Group in total recognized $10.0 million and $120.8 million, respectively, of expense associated with fair value adjustments of acquired inventory. This expense was included within cost of sales. During 2018, the Group incurred $5.2 million of acquisition-related costs related to the Sucampo Acquisition.

License Agreements

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

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

Mesoblast. In January 2017, $21.5 million of consideration was remitted to Mesoblast in exchange for equity shares and rights to a nine month exclusivity period related to any potential commercial and development agreements the Group may have entered into for Mesoblast's therapy products used to treat acute graft versus host disease and/or chronic lower back pain. During fiscal 2018, all of the Group's shares were sold for gross proceeds of $25.5 million resulting in a $3.4 million gain being recognized within other income, net in the consolidated profit and loss account.

Ofirmev. As part of the acquisition of Cadence Pharmaceuticals, Inc. ("Cadence" or "Cadence Acquisition") in March 2014, the Group acquired the exclusive development and commercialization rights to Ofirmev® (acetaminophen) injection ("Ofirmev") in the U.S. and Canada, as well as the rights to the patents and technology, which were originally in-licensed by Cadence from Bristol-Myers Squibb ("BMS") in March 2006. BMS sublicensed these rights to Cadence under a license agreement with SCR Pharmatop S.A. ("Pharmatop"), and the Group has the right to grant sublicenses to third parties. Under this license agreement, the Group made the final milestone payment of $15.0 million in fiscal 2018. In addition, the Group is obligated to pay royalties on turnover of the product. During fiscal 2019 and 2018, the Group paid royalties of $69.8 million and $76.9 million, respectively, which were recorded within cost of sales in the consolidated profit and loss account.

Advanced Accelerator Applications. In 2007, the Group's Nuclear Imaging business entered into a license agreement with BioSynthema, Inc. ("BioSynthema"), which was subsequently amended in 2010 when Advanced Accelerator Applications ("AAA") acquired BioSynthema. Pursuant to the amended agreement, upon the first commercial turnover of Lutathera® ("Lutathera"), AAA is to provide the Group with a royalty based on turnover of the product through January 1, 2020. In early 2018, the FDA approved Lutathera for treatment of gastroenteropancreatic neuroendocrine tumors and commercial turnover commenced. During fiscal 2019 and 2018, in relation to this agreement, the Group recognized royalty income of $39.0 million and $15.5 million, respectively, which was recognized within other income, net in the consolidated profit and loss account.

9. 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:

	Fiscal Year	
	2019	2018
Interest on debt repayable within five years, otherwise than by installment	$ 164.9	$ 184.1
Interest on debt repayable beyond five years, otherwise than by installment	36.4	37.9
Interest on debt repayable within five years, by installment	81.0	—
Interest on debt repayable beyond five years, by installment	23.8	110.7
Amortization of debt issue costs	14.5	16.2
Capitalized interest	(6.3)	(6.8)
Other [1]	(5.3)	28.1
Interest payable and similar expenses	$ 309.0	$ 370.2

(1) Includes other non-cash interest and U.S. Internal Revenue Code ("IRC") Section 453A ("Section 453A") interest. Refer to Note 26 for further information regarding Section 453A interest.

10. Taxation

The U.K. and non-U.K. components of loss on ordinary activities before taxation were as follows:

	Fiscal Year	
	2019	2018
U.K.	$ (64.5)	$ (233.7)
Non-U.K.	(1,514.6)	(3,802.0)
Total	$ (1,579.1)	$ (4,035.7)

Significant components of taxation related to ordinary activities were as follows:

	Fiscal Year	
	2019	2018
Current:		
U.K.	$ 0.1	$ (0.2)
Non-U.K. [1]	21.7	113.0
Current taxation charge	21.8	112.8
Deferred:		
U.K.	(1.1)	1.4
Non-U.K. [1]	(603.3)	(542.9)
Deferred taxation credit	(604.4)	(541.5)
Total	$ (582.6)	$ (428.7)

(1) Total Non-U.K. tax includes $2.2 million and $7.6 million of Irish corporation taxation credits for fiscal 2019 and 2018, respectively.

The fiscal 2019 U.K. current taxation charge reflects a taxation credit of $1.2 million from utilization of net operating loss carryforwards. The fiscal 2019 non-U.K. current taxation charge reflects a taxation credit of $0.9 million from utilization of net operating loss carryforwards.

The fiscal 2018 U.K. current taxation credit reflects a taxation credit of $8.5 million from utilization of net operating loss carryforwards. The fiscal 2018 non-U.K. current taxation charge reflects a taxation credit of $13.7 million from utilization of net operating loss carryforwards.

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

The reconciliation between U.K. taxation at the statutory rate and the Group's taxation on ordinary activities was as follows:

	Fiscal Year	
	2019	2018
Taxation credit at U.K. statutory tax rate [1]	$ (300.0)	$ (767.0)
Adjustments to reconcile to taxation credit:		
Rate difference between U.K. and non-U.K. jurisdictions [2]	(209.1)	(240.9)
Valuation allowances, nonrecurring [3]	61.7	—
Adjustments to accrued taxation liabilities and uncertain tax positions	(12.4)	60.1
Interest and penalties on accrued taxation liabilities and uncertain tax positions	(6.3)	13.1
Credits, principally research and orphan drug [4]	(13.5)	(25.9)
Impairments non deductible	—	788.7
Permanently nondeductible and nontaxable items [3]	100.2	10.7
Divestitures [5]	9.6	(2.7)
U.S. Tax Reform [6]	—	(8.5)
Legal Entity Reorganization [7]	(212.8)	(256.0)
Other	—	(0.3)
Taxation credit	$ (582.6)	$ (428.7)

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

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

(3) For fiscal 2019, the nonrecurring valuation allowances and permanently nondeductible and nontaxable item were primarily driven by the impact from the opioid-related litigation settlement charge. Refer to Note 30 for further discussion.

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

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

(6) For fiscal 2018, the Group completed its analysis of the TCJA and recognized an additional taxation credit. Other line items, to the extent U.S. related, are reflected at the current U.S. statutory income tax rate of 21.0%.

(7) Associated unrecognized taxation credit is netted within this line.

The rate difference between U.K. and non-U.K. jurisdictions changed from $240.9 million of taxation credit to $209.1 million of taxation credit for fiscal 2018 to 2019, respectively. The $31.8 million decrease in the taxation credit included a $101.0 million decrease attributable to the non-restructuring impairment charges, a $48.2 million decrease attributable to changes in operating loss, a $20.2 million decrease attributable to divestitures; partially offset by an increase of $76.7 million attributable to the gain on debt extinguishment, net and $60.9 million attributable to the opioid-related settlement charge.

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

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

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

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

	December 27, 2019	December 28, 2018
Debtors (falling due after one year)	$ 204.7	$ —
Creditors (amounts falling due within one year)	—	1.0
Creditors (amounts falling due after one year)	193.9	189.9
Provision for liabilities	—	96.8
	$ 398.6	$ 287.7

Included within total unrecognized tax benefits as of December 27, 2019 and December 28, 2018 were $395.9 million and $275.8 million, respectively, of unrecognized tax benefits, which if favorably settled would benefit the effective tax rate. The remaining unrecognized tax benefits for each period would be offset by the write-off of related other tax assets, if recognized. During fiscal 2019, the Group recorded $14.4 million of additional interest through taxation and decreased accrued interest and penalties by $18.6 million related to prior period reductions, settlements and lapse of statute of limitations. During fiscal 2018, the Group had a net increase of interest and penalties activity of $30.0 million. The total amount of accrued interest and penalties related to uncertain tax positions was $32.9 million and $37.1 million during fiscal 2019 and 2018, respectively.

It is reasonably possible that within the next twelve months, as a result of the resolution of various U.K. and non-U.K. examinations and appeals and the expiration of various statutes of limitation, that the unrecognized tax benefits could decrease by up to $99.5 million. Interest and penalties could decrease by up to $21.7 million.

Certain of the Group's subsidiaries continue to be subject to examination by the IRS for tax years as early as 2014. In August 2019, the IRS proposed an adjustment to profit on ordinary activities before taxation of Mallinckrodt Hospital Products Inc. (“MHP”) (formerly known as Cadence Pharmaceuticals, Inc.) as a result of its findings in the audit of MHP's tax year ended September 26, 2014. The proposed adjustment to profit on ordinary activities before taxation of $871.0 million, excluding potential associated interest and penalties, is proposed as a multi-year adjustment and may result in a non-cash reduction of the Group's U.S. Federal net operating loss carryforward of $782.0 million. The Group strongly disagrees with the proposed adjustment and intends to contest it through all available administrative and judicial remedies, which may take a number of years to conclude. See Note 26 for further details. In addition, the earliest open years for state tax jurisdictions are 2009 and a number of tax periods from 2013 to present are subject to examination by tax authorities in various jurisdictions, including Ireland, Luxembourg, Switzerland and the U.K.

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

	December 27, 2019	December 28, 2018
Creditors (amounts falling due within one year)	$ 15.0	$ 25.0
Creditors (amounts falling due after one year)	227.1	228.0
	$ 242.1	$ 253.0

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

	December 27, 2019	December 28, 2018
Debtors falling due within one year	$ 8.0	$ 16.2
Debtors falling due after one year	3.1	3.0
	$ 11.1	$ 19.2

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

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

The deferred tax asset valuation allowances of $3,131.5 million and $2,604.9 million as of December 27, 2019 and December 28, 2018, respectively, relate primarily to the uncertainty of the utilization of certain deferred tax assets, driven by U.K. and non-U.K. net operating losses, credits, intangible assets and the opioid-related settlement liability. The Group believes that it will generate sufficient future profit from ordinary activities before tax to realize the tax benefits related to the remaining net deferred tax assets.

Deferred taxation activity for fiscal 2019 was as follows:

As of December 28, 2018	$ (303.8)
Provisions	604.4
Currency translation and other	3.5
As of December 27, 2019	$ 304.1

Deferred taxation was reported in the following consolidated balance sheet captions in the amounts shown:

	December 27, 2019	December 28, 2018
Debtors (falling due after one year)	$ 315.1	$ 20.5
Provision for liabilities	(11.0)	(324.3)
	$ 304.1	$ (303.8)

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

amortization of intangibles and $50.2 million of decreases predominately related to the generation of net operating losses and other operational activity.

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

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

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

As of December 27, 2019, the Group's financial reporting basis in international subsidiaries that may be subject to tax was in excess of its corresponding tax basis by $17.0 million. Such excess amount is considered to be indefinitely reinvested and it is not practicable to determine the cumulative amount of tax liability that would arise if this indefinitely reinvested amount were realized due to a variety of factors including the complexity of the Group's legal entity structure as well as the timing, extent, and nature of any hypothetical realization. The net decrease, as compared to fiscal 2018, was attributable to the divestiture of BioVectra as well as income and losses attributed to current year activity. The Group has recorded a deferred tax liability of $7.6 million for amounts not considered to be indefinitely reinvested.

11. (Loss) Earnings per Ordinary Share

Basic (loss) earnings per ordinary share is computed by dividing (loss) profit after taxation by the number of weighted-average shares outstanding during the period. Diluted (loss) earnings per ordinary share is computed using the weighted-average shares outstanding and, if dilutive, potential ordinary shares outstanding during the period. Potential ordinary shares represent the incremental ordinary shares issuable for restricted share units and share option exercises. The Group calculated the dilutive effect of outstanding restricted share units and share options on (loss) earnings per ordinary share by application of the treasury stock method. Dilutive securities, including participating securities, are not included in the computation of loss per ordinary share when the Group reports a loss on ordinary activities after taxation as the impact would be anti-dilutive. During fiscal 2019 and 2018 the weighted-average number of shares outstanding used in the computations of basic and diluted loss per ordinary share were 83.9 million and 84.0 million, respectively.

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

12. Share Plans

Total share-based compensation cost was $33.8 million and $34.6 million for fiscal 2019 and 2018, respectively. These amounts are generally included within D&A expenses in the consolidated profit and loss account. The Group recognized a related taxation credit associated with this expense of $1.2 million and zero during fiscal 2019 and 2018, respectively.

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:

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

As of December 27, 2019, all equity awards held by the Group's employees were converted from equity awards issued by Questcor Pharmaceuticals, Inc. ("Questcor"), acquired during fiscal 2014, or granted under the aforementioned plans.

Share options. Share options are granted to purchase the 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
Outstanding as of December 29, 2017	4,643,984	$ 57.78		
Granted	3,159,521	13.92		
Exercised	(39,949)	32.00		
Expired/Forfeited	(756,505)	52.63		
Outstanding as of December 28, 2018	7,007,051	38.74		
Granted	1,378,175	22.09		
Exercised	(45,324)	20.67		
Expired/Forfeited	(1,449,202)	34.80		
Outstanding as of December 27, 2019	6,890,700	36.39	1.6	$ —
Vested and unvested expected to vest as of December 27, 2019	6,376,302	37.58	7.1	$ —
Exercisable as of December 27, 2019	3,349,227	49.80	1.2	—

As of December 27, 2019, there was $20.9 million of total unrecognized compensation cost related to nonvested share option awards, which is expected to be recognized over a weighted-average period of 2.4 years.

The grant date fair value of share options has been estimated using the Black-Scholes pricing model. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. The expected volatility assumption is based on the historical and implied volatility of the 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. The weighted-average assumptions used in the Black-Scholes pricing model for shares granted, along with the weighted-average grant-date fair value, were as follows:

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

During fiscal 2019 and 2018, the total intrinsic value of options exercised was $0.3 million and $0.2 million, respectively, and the related taxation credit was $0.1 million in each year, respectively.

Restricted share units. Recipients of restricted share units ("RSUs") have no voting rights and receive dividend equivalent units that vest upon the vesting of the related shares. RSUs generally vest in equal annual installments over a period of four

years. Restrictions on RSUs lapse upon normal retirement, death or disability of the employee. The grant-date fair value of RSUs, adjusted for estimated forfeitures, is recognized as expense on a straight-line basis over the service period. The fair market value of RSUs granted is determined based on the market value of the Group's ordinary shares on the date of grant.

RSU activity was as follows:

	Shares	Weighted-Average Grant-Date Fair Value
Non-vested as of December 29, 2017	1,105,766	$ 60.08
Granted	1,222,568	14.58
Vested	(433,354)	57.93
Forfeited	(209,879)	44.38
Non-vested as of December 28, 2018	1,685,101	29.54
Granted	755,180	20.13
Vested	(713,274)	35.29
Forfeited	(307,987)	24.81
Non-vested as of December 27, 2019	1,419,020	22.68

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

Performance share units. Similar to recipients of RSUs, recipients of performance share units ("PSUs") have no voting rights and receive dividend equivalent units. The grant date fair value of PSUs, adjusted for estimated forfeitures, is generally recognized as expense on a straight-line basis from the grant date through the end of the performance period. The vesting of PSUs and related dividend equivalent units is generally based on various performance metrics and relative total shareholder return (total shareholder return for the 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.

PSU activity was as follows [(1)]:

	Shares	Weighted-Average Grant-Date Fair Value
Non-vested as of December 29, 2017	504,451	$ 64.44
Granted	770,714	13.80
Forfeited	(89,614)	59.18
Vested	(24,022)	98.27
Non-vested as of December 28, 2018	1,161,529	28.61
Granted	448,363	32.46
Forfeited	(414,387)	30.54
Non-vested as of December 27, 2019	1,195,505	23.85

(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. The assumptions used in the Monte Carlo model for PSUs granted during each year were as follows:

	Fiscal Year	
	2019	2018
Expected stock price volatility	55.2%	56.9%
Peer group stock price volatility	41.3%	39.1%
Correlation of returns	47.8%	2.1%

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

Restricted stock awards. Recipients of restricted stock awards ("RSAs") pertained solely to converted awards from Questcor, which were converted at identical terms to their original award. The grant-date fair value of RSAs, adjusted for estimated forfeitures, was recognized as expense on a straight-line basis over the service period. The weighted average grant-date fair value per share is $70.88.

	Shares
Non-vested as of December 29, 2017	4,675
Vested	(3,970)
Forfeited	(705)
Non-vested as of December 28, 2018	—

Employee Stock Purchase Plans

Effective March 16, 2016, upon approval by the shareholders of Mallinckrodt, the 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% 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 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 remained unavailable as of December 27, 2019.

13. Directors' Remuneration

Directors' remuneration is set forth in the table below. Mr. Trudeau, the Group's President and Chief Executive Officer 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 Chief Executive Officer. The amounts below also include compensation for all non-executive directors in their capacities as such (referred to as "Director Services").

	Fiscal Year	
	2019	2018
Director Services		
Fees paid in cash	$ 1.1	$ 1.1
Benefits under long-term incentive schemes [1]	2.7	2.2
Total [2]	$ 3.8	$ 3.3
Managerial Services		
Emoluments	$ 3.9	$ 3.0
Benefits under long-term incentive schemes [1]	8.5	5.4
Group contributions to savings plans and other [3]	0.7	1.0
Total [2]	$ 13.1	$ 9.4

(1) Includes amounts expensed for outstanding equity awards.
(2) The gain on exercise of share options was zero for both fiscal 2019 and 2018 for both directors and managerial services, respectively.
(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 2019 and 2018.

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).

14. Auditor's Remuneration

Auditor's remuneration was as follows:

	Fiscal Year	
	2019 [1]	2018 [1]
Audit of the group accounts [2]	$ 0.2	$ 0.2
Other assurance services [2]	0.3	0.3
	$ 0.5	$ 0.5

(1) No amounts were incurred for tax advisory or non-audit services.

(2) The Group incurred additional fees of $5.2 million and $12.4 million during fiscal 2019 and 2018, 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.

15. Employees

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

	Fiscal Year	
	2019	2018
Manufacturing	1,678	1,601
Turnover, marketing and distribution	778	884
Research and development	381	400
General and administrative	566	632
	3,403	3,517

Employee costs consisted of the following:

	Fiscal Year	
	2019	2018
Wages and salaries	$ 591.4	$ 612.8
Social insurance costs	33.0	35.8
Pension and postretirement costs	31.0	22.1
	$ 655.4	$ 670.7

For information on share based payments not included within the employee costs above, refer to Note 12.

16. Intangible Assets

Intangible asset activity for fiscal 2019 was as follows:

	Completed Technology	Licenses	Trademarks	In-process Research and Development	Customer Relationships	Total Intangible Assets
Cost:						
As of December 28, 2018	$ 10,467.9	$ 120.1	$ 116.9	$ 633.3	$ 27.5	$ 11,365.7
Disposals	(11.0)	—	(4.3)	—	(28.2)	(43.5)
Impairments	—	—	—	(388.0)	—	(388.0)
Currency translation	—	—	0.1	—	0.7	0.8
As of December 27, 2019	$ 10,456.9	$ 120.1	$ 112.7	$ 245.3	$ —	$ 10,935.0
Accumulated Amortization:						
As of December 28, 2018	$ 2,980.6	$ 70.1	$ 18.1	$ —	$ 14.1	$ 3,082.9
Amortization expense	843.9	4.0	3.7	—	1.8	853.4
Disposals	(1.7)	—	(1.7)	—	(16.3)	(19.7)
Currency translation	—	—	—	—	0.4	0.4
As of December 27, 2019	$ 3,822.8	$ 74.1	$ 20.1	$ —	$ —	$ 3,917.0
Net book value:						
As of December 28, 2018	$ 7,487.3	$ 50.0	$ 98.8	$ 633.3	$ 13.4	$ 8,282.8
As of December 27, 2019	6,634.1	46.0	92.6	245.3	—	7,018.0

Goodwill Impairment Analysis

During fiscal 2018, the Group's annual goodwill impairment analysis resulted in the recognition of a full goodwill impairment of $3,672.8 million related to the Specialty Brands reporting unit. The Group performed its annual goodwill impairment analysis for the Specialty Brands reporting unit as of the first day of the fourth quarter. The Group's 2018 annual assessment first considered its internally developed future cash flows, which reflect the Group's overall strategy, future growth and value proposition. At the time of this analysis there continued to be a disparity between the Group's anticipated future performance and present uncertainty reflected in its market capitalization, driven by a sustained decrease in its share price. The Group determined that its share price had been adversely affected primarily by uncertainties regarding patient withdrawal issues impacting turnover of Acthar® Gel (repository corticotropin injection ("Acthar Gel"), ongoing INOmax® (nitric oxide) gas, for inhalation ("INOmax") patent litigation and the perceived value of its various pipeline products. Given the passage of time since first experiencing a substantial decline in its share price during the three months ended December 29, 2017, and the fact that the aforementioned uncertainties were not expected to be resolved in the near-term, the Group determined that its goodwill was fully impaired.

For purposes of the 2018 goodwill impairment assessment for the Specialty Brands reporting unit, the Group made various assumptions regarding estimated future cash flows, discount rate and other factors in determining the respective fair value of the reporting unit using the income approach. The projections of future cash flows were discounted based on a weighted average cost of capital of 12.5% that was determined from relevant market comparisons, adjusted upward for specific reporting unit risks. A terminal value growth rate was applied to the terminal year cash flows, representing the Group's estimate of stable cash flows. The fair value of the Specialty Brands reporting unit represents the sum of the discounted cash flows from the discrete period and the terminal year cash flows.

Long-Lived Asset Impairment Analysis

The Group recorded impairment charges totaling $388.0 million and $220.3 million during fiscal 2019 and 2018, respectively. The valuation method used to approximate fair value in each of these periods was based on the estimated discounted cash flows for the respective asset. During fiscal 2019, the Group recognized a full impairment on its IPR&D asset related to VTS-270 of $274.5 million, primarily driven by continued regulatory challenges. The Group will continue to engage in dialogue with the FDA and assess future opportunities for this development program. Also during fiscal 2019, the Group recognized a full impairment on its IPR&D asset related to stannsoporfin of $113.5 million as the Group is no longer pursuing this development program. The fiscal 2018 impairment charge primarily related to the MNK-1411 intangible asset as a result of lower than previously anticipated pricing assumptions.

Ofirmev

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

Finite-lived intangible asset amortization expense was $853.4 million and $740.2 million during fiscal 2019 and 2018, respectively. The estimated aggregate amortization expense on intangible assets owned by the Group is expected to be as follows:

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

17. Tangible Assets

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

	December 27, 2019	December 28, 2018
Land	$ 43.4	$ 43.9
Buildings	363.6	379.5
Capitalized software	142.2	130.8
Machinery and equipment	1,157.0	1,137.3
Construction in process	193.9	244.7
	1,900.1	1,936.2
Less: accumulated depreciation	(1,003.6)	(954.2)
Total owned tangible assets	896.5	982.0
Lease assets [(1)]	83.5	—
Total tangible assets	$ 980.0	$ 982.0

(1) Represents the capitalization of lease assets due to the adoption of ASU 2016-02. Refer below and to Note 3 for further information.

Owned Tangible Assets

Owned tangible assets activity for fiscal 2019 was as follows:

	Land	Buildings	Capitalized Software	Machinery and Equipment	Construction in Process	Total Owned Tangible Assets
Cost:						
As of December 28, 2018	$ 43.9	$ 379.5	$ 130.8	$ 1,137.3	$ 244.7	$ 1,936.2
Additions	—	1.2	0.1	5.6	117.3	124.2
Disposal of tangible owned assets	(0.5)	(31.5)	(1.6)	(57.1)	(70.5)	(161.2)
Transfers	—	13.7	12.8	70.0	(96.5)	—
Currency translation and other	—	0.7	0.1	1.2	(1.1)	0.9
As of December 27, 2019	$ 43.4	$ 363.6	$ 142.2	$ 1,157.0	$ 193.9	$ 1,900.1
Accumulated Depreciation:						
As of December 28, 2018	$ —	$ 136.7	$ 82.9	$ 734.6	$ —	$ 954.2
Depreciation expense	—	18.1	12.6	67.0	—	97.7
Disposal of tangible owned assets	—	(7.8)	(1.4)	(39.6)	—	(48.8)
Currency translation and other	—	0.1	—	0.4	—	0.5
As of December 27, 2019	$ —	$ 147.1	$ 94.1	$ 762.4	$ —	$ 1,003.6
Net book value:						
As of December 28, 2018	$ 43.9	$ 242.8	$ 47.9	$ 402.7	$ 244.7	$ 982.0
As of December 27, 2019	43.4	216.5	48.1	394.6	193.9	896.5

Depreciation expense was $97.7 million and $111.9 million for fiscal 2019 and 2018, respectively. Gain on disposal of owned tangible assets was $11.7 million and $0.5 million for fiscal 2019 and 2018, 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 27, 2019
Tangible lease assets	$ 83.5
Creditors (amounts falling due within one year)	$ 19.2
Creditors (amounts falling due after one year)	70.2
Total lease liabilities	$ 89.4

Tangible lease assets activity for fiscal 2019 was as follows:

	Lease Assets
Cost:	
As of December 28, 2018	$ —
Day one adoption (Note 3)	83.1
Additions	21.6
Disposal of tangible lease assets	(5.9)
Currency translation and other	1.2
As of December 27, 2019	$ 100.0
Accumulated Amortization:	
As of December 28, 2018	$ —
Amortization expense	17.5
Disposal of tangible lease assets	(0.9)
Currency translation and other	(0.1)
As of December 27, 2019	$ 16.5
Net book value:	
As of December 27, 2019	$ 83.5

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:

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

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

Lease terms and discount rates were as follows:

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

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

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

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

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

18. Financial Assets

The Group's financial asset activity during fiscal 2019 was as follows:

	Assets Held by Rabbi Trusts	Restricted Cash	Other Financial Assets	Total Financial Assets
As of December 28, 2018	$ 91.5	$ 18.6	$ 20.4	$ 130.5
Unrealized gain	6.0	—	20.2	26.2
Additions	—	12.8	9.0	21.8
Cash (received) paid, net	(23.1)	—	4.5	(18.6)
Currency translation and other	—	0.3	1.7	2.0
As of December 27, 2019	$ 74.4	$ 31.7	$ 55.8	$ 161.9

Refer to Note 27 for further discussion of the fair value and the valuation techniques utilized to measure the financial assets at fair value.

19. Stocks

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

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

The estimated replacement costs of stocks does not differ significantly from the figures above.

20. Debtors

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

	December 27, 2019	December 28, 2018
Amounts falling due within one year		
Trade debtors	$ 577.5	$ 623.3
Turnover taxation recoverable	19.0	12.4
Other debtors and prepayments	131.2	120.3
	727.7	756.0
Amounts falling due after one year		
Deferred taxation (Note 10)	315.1	20.5
Other debtors	33.2	34.3
	348.3	54.8
	$ 1,076.0	$ 810.8

21. 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 27, 2019	December 28, 2018
Debt (Note 23)	$ 633.6	$ 22.4
Trade creditors	139.8	147.5
Accrued payroll and employee benefits	105.2	124.0
Other taxes	33.6	28.5
Accrued interest	62.9	77.6
Accrued royalties	40.8	36.8
Lease liabilities (Note 17) [(1)]	19.2	—
Accruals and other creditors	223.7	295.6
	$ 1,258.8	$ 732.4

(1) Represents the capitalization of lease liabilities due to the adoption of ASU 2016-02. Refer to Note 3 for further information.

22. 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 27, 2019	December 28, 2018
Debt (Note 23)	$ 4,741.2	$ 6,069.2
Taxation payable (Note 10)	227.1	228.0
Deferred compensation	39.2	38.5
Section 453A unrecognized benefit	47.4	56.0
Lease liabilities (Note 17) [(1)]	70.2	—
Accruals and other creditors	10.3	32.3
	$ 5,135.4	$ 6,424.0

(1) Represents the capitalization of lease liabilities due to the adoption of ASU 2016-02. Refer to Note 3 for further information.

23. Debt

Debt was comprised of the following at the end of each period (all amounts are fully payable on their maturity date unless otherwise noted):

	December 27, 2019		December 28, 2018	
	Principal	Unamortized Discount and Debt Issuance Costs	Principal	Unamortized Discount and Debt Issuance Costs
Current maturities of long-term debt:				
4.875% senior notes due April 2020 [1]	$ 614.8	$ 0.6	$ —	$ —
Term loan due September 2024 [2]	15.6	0.2	16.4	0.2
Term loan due February 2025 [2]	4.1	0.1	6.0	0.1
Other [1]	—	—	0.3	—
Total current debt	634.5	0.9	22.7	0.3
Long-term debt:				
4.875% senior notes due April 2020 [1]	—	—	700.0	3.2
Variable-rate receivable securitization due July 2020 [1]	—	—	250.0	0.4
9.50% debentures due May 2022 [1]	10.4	—	10.4	—
5.75% senior notes due August 2022 [1]	610.3	3.7	835.2	7.0
8.00% debentures due March 2023 [1]	4.4	—	4.4	—
4.75% senior notes due April 2023 [1]	133.7	0.8	500.2	3.5
5.625% senior notes due October 2023 [1]	514.7	4.4	731.4	8.0
Term loan due September 2024 [2]	1,505.2	15.5	1,597.4	19.8
Term loan due February 2025 [3]	399.5	6.1	591.0	10.7
5.50% senior notes due April 2025 [4]	387.2	3.6	692.1	7.7
10.00% senior notes due April 2025 [4]	322.9	9.9	—	—
Other [3]	—	—	1.9	—
Revolving credit facility [1]	900.0	3.1	220.0	4.5
Total long-term debt	4,788.3	47.1	6,134.0	64.8
Total debt	$ 5,422.8	$ 48.0	$ 6,156.7	$ 65.1

(1) Includes debt repayable within five years, otherwise than by installment, of $2,788.3 million.
(2) Includes debt repayable within five years, by installment, of $1,541.3 million.
(3) Includes debt repayable beyond five years, by installment, of $383.1 million.
(4) Includes debt repayable beyond five years, otherwise than by installment, of $710.1 million.

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 15th and October 15th of each year, which commenced on October 15, 2013.

In August 2014, MIFSA and Mallinckrodt CB LLC ("MCB") ("the Issuers") issued $900.0 million aggregate principal amount of 5.75% senior unsecured notes due August 2022 ("the 2022 Notes"). The 2022 Notes are guaranteed by Mallinckrodt plc and each of its subsidiaries that guarantee the obligations under the 2017 Facilities (as defined below). The 2022 Notes are subject to an indenture that contains certain customary covenants and events of default (subject in certain cases to customary grace and cure periods). The occurrence of an event of default under the indenture could result in the acceleration of the 2022

Notes and could cause a cross-default that could result in the acceleration of other indebtedness of Mallinckrodt plc and its subsidiaries. The Issuers may redeem some or all of the 2022 Notes at specified redemption prices. The Issuers are obligated to offer to repurchase the 2022 Notes at a price of (a) 101% of their principal amount plus accrued and unpaid interest, if any, as a result of certain change of control events and (b) 100% of their principal amount plus accrued and unpaid interest of net proceeds from certain asset sales. These obligations are subject to certain qualifications and exceptions. The Group pays interest on the 2022 Notes semiannually in arrears on February 1st and August 1st of each year, which commenced on February 1, 2015.

In April 2015, in connection with the 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 2017 Facilities (as defined below), which following the acquisition of Ikaria includes Compound Holdings II, Inc. (or its successors) and its U.S. subsidiaries. The Ikaria Notes are subject to an indenture that contains certain customary covenants and events of default (subject in certain cases to customary grace and cure periods). The occurrence of an event of default under the indenture could result in the acceleration of the Ikaria Notes and could cause a cross-default that could result in the acceleration of other indebtedness of the 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 15th and October 15th 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 2017 Facilities (as defined below), which following the acquisition of Therakos, includes TGG Medical Solutions, Inc. (or its successors) and its U.S. subsidiaries. The October 2023 Notes are subject to an indenture that contains certain customary covenants and events of default (subject in certain cases to customary grace and cure periods). The occurrence of an event of default under the indenture could result in the acceleration of the October 2023 Notes and could cause a cross-default that could result in the acceleration of other indebtedness of the 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 15th and October 15th of each year, which commenced on April 15, 2016.

In February 2017, MIFSA and MCB refinanced the March 2014 and August 2014 term loans, both of which were due March 2021. The Group accounted for the term loan refinancing as a debt modification, which resulted in a $10.0 million charge included within the other income (loss) line in the consolidated profit and loss account. The refinanced term loan had an initial aggregate principal amount of $1,865.0 million, is due September 2024 and bears interest at London Interbank Offered Rate ("LIBOR") plus 2.75% ("the 2017 Term Loan"). The 2017 Term Loan requires quarterly principal amortization payments in an amount equal to 0.25% of the original principal balance of the 2017 Term Loan, and may be reduced by making optional prepayments. The quarterly principal amortization is payable on the last day of each calendar quarter, which commenced on June 30, 2017, with the remaining balance due September 2024. In January 2019, the Group made a $25.0 million prepayment on the 2017 Term Loan. In making this payment, the Group satisfied certain obligations included within external debt agreements to reinvest proceeds from the sale of assets and businesses within the year of the respective transaction or use the proceeds to pay down debt.

In conjunction with the term loan refinancing, MIFSA and MCB entered into a $900.0 million revolving credit facility that matures on February 28, 2022 ("the Revolving Credit Facility"). The 2017 Revolving Credit Facility bears interest at LIBOR plus 2.25% and contains a $50.0 million letter of credit provision, of which none had been issued as of December 27, 2019. Unused commitments on the Revolving Credit Facility are subject to an annual commitment fee, which was 0.275% as of December 27, 2019, and the fee applied to outstanding letters of credit is based on the interest rate applied to borrowings. The 2017 Revolving Credit Facility added certain wholly-owned subsidiaries of the Group as borrowers, in addition to MIFSA and MCB.

The 2017 Term Loan and Revolving Credit Facility (collectively "the 2017 Facilities") are fully and unconditionally guaranteed by Mallinckrodt plc, certain of its direct or indirect wholly-owned U.S. subsidiaries and each of its direct or indirect wholly-owned subsidiaries that owns directly or indirectly any wholly-owned U.S. subsidiaries and certain of its other subsidiaries (collectively, "the Guarantors"). The 2017 Facilities are secured by a security interest in certain assets of MIFSA, MCB and the Guarantors. The 2017 Facilities contain customary affirmative and negative covenants, which include, among other things, restrictions on the 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 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 $200.0 million of outstanding obligations. Upon payment in full of such outstanding obligations under the Receivable Securitization, the $250.0 million receivables securitization program was automatically terminated (including (i) the Receivable Securitization, (ii) the Amended and Restated Purchase and Sale Agreement, dated as of July 28, 2017 (as amended, the "Purchase and Sale Agreement"), among certain wholly owned subsidiaries of the 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"). The variable-rate loan bears an interest rate of LIBOR plus 3.00% basis points and was issued with a discount of 0.25%. The incremental term loan requires quarterly principal amortization payments in an amount equal to 0.25% of the original principal balance of the incremental term loan, and may be reduced by making optional prepayments. The quarterly principal amortization is payable on the last day of each calendar quarter, which commenced on June 30, 2018. In February 2019, the Group made a $175.0 million prepayment on the term loan due February 2025. In making this payment, the Group satisfied certain obligations included within external debt agreements to reinvest proceeds from the sale of assets and businesses within the year of the respective transaction or use the proceeds to pay down debt.

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

The 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 New 2025 Notes. The exchanges also resulted in the capitalization of $10.1 million of deferred financing fees related to the New 2025 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.

As of December 27, 2019, the applicable interest rate and outstanding borrowings on the Group's variable-rate debt instruments were as follows:

	Applicable interest rate	Outstanding borrowings
Term loan due September 2024	4.85%	$ 1,520.8
Term loan due February 2025	4.91%	403.6
Revolving credit facility	4.23%	900.0

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

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

24. 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 27, 2019, U.S. plans represented 35.0% 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.

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

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

	Pension Benefits		Postretirement Benefits	
	December 27, 2019	December 28, 2018	December 27, 2019	December 28, 2018
Amounts recognized in accumulated other comprehensive loss consist of:				
Net actuarial (loss) gain	$ (10.1)	$ (8.4)	$ (0.8)	$ 0.9
Prior service (cost) credit	(0.2)	(0.4)	5.9	8.1
Net amount recognized in accumulated other comprehensive loss	$ (10.3)	$ (8.8)	$ 5.1	$ 9.0

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

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

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	
	2019	2018	2019	2018
Discount rate	4.0%	3.3%	2.0%	1.9%
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	
	2019	2018	2019	2018
Discount rate	2.8%	4.0%	1.3%	2.0%
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 or S&P) 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	
	2019	2018
Net periodic benefit credit	4.1%	3.4%
Benefit obligations	3.0%	4.1%

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

	December 27, 2019	December 28, 2018
Healthcare cost trend rate assumed for next fiscal year	5.8%	6.3%
Rate to which the cost trend rate is assumed to decline	4.5%	4.5%
Fiscal year the ultimate trend rate is achieved	2038	2038

Contributions. The 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 2019 and 2018, the Group made $1.9 million and $2.4 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 2020	$ 1.8	$ 3.4
Fiscal 2021	1.7	3.2
Fiscal 2022	1.6	3.0
Fiscal 2023	1.6	2.9
Fiscal 2024	1.6	2.8
Fiscal 2022 - 2025	7.2	12.6

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 three percent 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 six percent of the employee's eligible pay. The deferred compensation plan permits eligible employees to defer a portion of their compensation. Total defined contribution expense was $21.9 million and $25.3 million for fiscal 2019 and fiscal 2018, 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 27 provides additional information regarding the debt and equity securities. During fiscal 2019, a portion of these policies were liquidated. The carrying value of the 62 and 118 life insurance contracts held by these trusts was $43.8 million and $58.4 million as of December 27, 2019 and December 28, 2018, respectively. These contracts had a total death benefit of $94.0 million and $142.9 million as of December 27, 2019 and December 28, 2018, respectively. However, there are outstanding loans against the policies amounting to $23.6 million and $43.8 million as of December 27, 2019 and December 28, 2018, 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 $7.3 million and $8.0 million as of December 27, 2019 and December 28, 2018, respectively. These amounts were also included in financial assets in the consolidated balance sheets.

25. 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 other liabilities on the Group's consolidated balance sheets as of December 27, 2019 and December 28, 2018 was $15.0 million and $14.6 million, respectively, of which $12.3 million and $11.8 million, respectively, related to environmental, health and safety matters. The value of the environmental, health and safety indemnity was measured based on the probability-weighted present value of the costs expected to be incurred to address environmental, health and safety claims made under the indemnity. The aggregate fair value of these indemnification obligations did not differ significantly from their aggregate carrying value as of December 27, 2019 and December 28, 2018. As of December 27, 2019, 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 $18.9 million and $18.6 million remained in financial assets on the consolidated balance sheets as of December 27, 2019 and December 28, 2018, respectively.

The Group has recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 28.

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

26. Commitments and Contingencies

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

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

These amounts include $1.0 million related to contracted capital expenditures. As of December 27, 2019, the Mallinckrodt plc Board of Directors had authorized capital expenditures of $187.0 million, of which $2.5 million had not yet been contracted.

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

Governmental Proceedings

Opioid Related Matters

Since 2017, multiple U.S. states, counties, a territory, other governmental persons or entities and private plaintiffs have filed lawsuits against certain entities of the 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 7, 2020, the cases the Group is aware of include, but are not limited to, approximately 2,528 cases filed by counties, cities, Native American tribes and/or other government-related persons or entities; approximately 259 cases filed by hospitals, health systems, unions, health and welfare funds or other third-party payers; approximately 117 cases filed by individuals; approximately seven 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 7, 2020, the Mallinckrodt defendants in these cases consist of Mallinckrodt plc and the following subsidiaries of Mallinckrodt plc: Mallinckrodt Enterprises LLC, Mallinckrodt LLC, SpecGx LLC, Mallinckrodt Brand Pharmaceuticals Inc., Mallinckrodt Inc., MNK 2011 Inc., and Mallinckrodt Enterprises Holdings, Inc. On November 22, 2019, the Delaware Attorney General filed a motion in the Superior Court of the State of Delaware to amend its complaint to add certain entities of the Group, which the Court granted on December 18, 2019. The Delaware Attorney General has not yet filed its amended complaint. The Hawaii Attorney General filed a complaint against the Group on June 3, 2019. On December 27, 2019, the First Circuit Court entered a written order dismissing the Hawaii Attorney General's claims against all defendants without prejudice, finding that the allegations in the State's complaint failed to give notice of the claims against the defendants. Certain of the lawsuits have been filed as putative class actions.

Most pending federal lawsuits have been coordinated in a federal multi-district litigation (“MDL”) pending in the U.S. District Court for the Northern District of Ohio. The MDL court has issued a series of case management orders permitting motion practice addressing threshold legal issues in certain cases, allowing discovery, setting pre-trial deadlines and setting a trial date on October 21, 2019 for two cases originally filed in the Northern District of Ohio by Summit County and Cuyahoga County against opioid manufacturers, distributors, and pharmacies ("Track 1 Cases"). The counties claimed that opioid manufacturers' marketing activities changed the medical standard of care for treating both chronic and acute pain, which led to increases in the 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 resolves the Track 1 cases against all named Mallinckrodt entities that were scheduled to go to trial in October 2019 in the MDL. Under the agreement, the Group paid $24.0 million in cash on October 1, 2019. In addition, the Group will provide $6.0 million in generic products, including addiction treatment products, and will also provide a $0.5 million payment in two years in recognition of the counties' time and expenses. Further, in the event of a comprehensive resolution of government-related opioid claims, the 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. On October 21, 2019, the MDL court issued a Stipulated Dismissal Order dismissing the claims against the remaining manufacturers and distributors pursuant to a settlement agreement, and severing the claims against the remaining pharmacy defendants to be heard in a subsequent trial, currently scheduled for November 9, 2020. Judge Polster issued Suggestions of Remand for City and County of San Francisco, California and City of Chicago, Illinois. Additionally, all manufacturer defendants, including us, were severed from the “Track Two” MDL cases, City of Huntington and Cabell County Commission, West Virginia. Those cases have subsequently been remanded to the Southern District of West Virginia.

Other lawsuits remain pending in various state courts. In some jurisdictions, such as Arizona, California, Connecticut, Illinois, Massachusetts, New York, Pennsylvania, South Carolina, Texas, Utah and West Virginia, certain of the 241 state lawsuits have been consolidated or coordinated for pre-trial proceedings before a single court within their respective state court systems. State cases are generally at the pleading and/or discovery stage. Trials have been set in certain state cases, including in Alaska (January 4, 2021), Arizona (March 16, 2021), Georgia (January 24, 2022), Louisiana (July 19, 2021), Nevada (January 4, 2021), New Mexico (September 7, 2021), Rhode Island (January 19, 2021), Tennessee (May 18, 2020), and West Virginia (March 22, 2021). There is also a trial in Ohio scheduled to begin on August 10, 2020, but the parties have stipulated to moving the trial to March 2021 and are awaiting the court’s ruling. During a status conference on April 1, 2020, the Texas court stated that it would enter the parties’ joint motion to reschedule the first of two bellwether trials from January 19, 2021 to April 12, 2021, but it has not yet signed the order. We are named in the alternate bellwether candidate. The date and candidates for the second bellwether trial have not been selected yet. On March 26, 2020, the Supreme Court of Tennessee granted defendants’

application for permission to appeal the judgment of the Tennessee Court of Appeals *in Effler et al. v. Purdue Pharma*, LP et al., No. 16596, which reversed the Circuit Court for Campbell County's grant of defendants' motion to dismiss plaintiffs' claims under Tennessee's Drug Dealer Liability Act (DDLA). A successful ruling from the Tennessee Supreme Court in *Effler* would also require dismissal of the DDLA claim brought by the district attorney general plaintiffs in *Staubus et al. v. Purdue Pharma, LP et al.*, No. C-41916. The *Staubus* matter is currently set for trial in the Circuit Court for Sullivan County on May 18, 2020.

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 and negligent misrepresentation, and other common law and statutory claims arising from defendants' manufacturing, distribution, marketing and promotion of opioids and seek restitution, damages, injunctive and other relief and attorneys' fees and costs. The claims generally are based on alleged misrepresentations and/or omissions in connection with the sale and marketing of prescription opioid medications and/or an alleged failure to take adequate steps to prevent diversion.

Subsequent to December 27, 2019, the Group announced an agreement in principle on the terms of a global settlement of all opioid-related claims against the Group and its subsidiaries. See Note 30 for further information.

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 sale, marketing and/or distribution of prescription opioid medications and the Group's suspicious order monitoring programs, including from the U.S. Department of Justice ("DOJ") and the Attorneys General for Missouri, New Hampshire, Kentucky, Washington, Alaska, South Carolina, Puerto Rico, New York, West Virginia, Indiana, the Divisions of Consumer Protection and Occupational and Professional Licensing of the Utah Department of Commerce, and the New York State Department of Financial Services. The 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 sale 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. 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. Since these investigations and/or lawsuits are in early stages, the Group is unable to predict outcomes or estimate a range of reasonably possible losses.

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. The appeal has been fully briefed and argued before the Second Circuit, and the parties are awaiting a decision. In April 2019, the State of New York passed its 2020 budget, which amended the OSA so that if the OSA decision is reversed on appeal, the OSA would apply only to the sale or distribution of certain opioids in New York for 2017 and 2018 and, effective July 1, 2019, imposed an excise tax on certain opioids.

DEA Investigation. In November 2011 and October 2012, the Group received subpoenas from the U.S. Drug Enforcement Administration ("DEA") requesting production of documents relating to its suspicious order monitoring program for controlled substances. The USAO for the Eastern District of Michigan investigated the possibility that the Group failed to report suspicious orders of controlled substances during the period 2006-2011 in violation of the Controlled Substances Act and its related regulations. The USAO for the Northern District of New York and Office of Chief Counsel for the U.S. DEA investigated the possibility that the Group failed to maintain appropriate records and security measures with respect to manufacturing of certain controlled substances at its Hobart facility during the period 2012-2013. In July 2017, the Group entered into a final settlement with the DEA and the USAOs for Eastern District of Michigan and the Northern District of New York to settle these investigations. As part of the agreement, the Group paid $35.0 million to resolve all potential claims and

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

Other Matters

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

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

In March 2020, the Group received an adverse decision from the court, which upheld CMS' decision to reverse its previous determination of the base date AMP used to calculate Acthar Gel rebates. The Group intends to continue to vigorously defend itself in this matter and, on March 16, 2020, filed an Emergency Motion for Reconsideration and Stay of Entry of Judgment Pending Reconsideration Or, Alternatively, Injunction Pending Appeal. In response, the government has agreed that CMS will not require the Group to change the Medicaid rebate calculation for Acthar Gel until at least the end of May 2020, which will allow the court time to decide the Group's motion. In the event the court denies the motion, the Group will immediately appeal the decision to the U.S. Court of Appeals for the D.C. Circuit.

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 is cooperating 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 is cooperating with the Committee's 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 False Claims Act against the Group in which the DOJ has intervened alleging that the Group had failed to pay rebates for its Acthar Gel product. 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 and intends to vigorously defend itself in this matter.

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

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 is cooperating in the investigation.

Texas Pricing Investigation. In November 2014, the Group received a CID from the Civil Medicaid Fraud Division of the Texas Attorney General's Office. According to the CID, the Attorney General's office is investigating the possibility of false reporting of information by the Group regarding the prices of certain of its drugs used by Texas Medicaid to establish reimbursement rates for pharmacies that dispensed the Group's drugs to Texas Medicaid recipients. The Group responded to these requests. In December 2018, the Group entered into a final settlement with the Texas Attorney General's Office to resolve all potential claims in the investigation and recorded a corresponding expense, which is included in SG&A in the consolidated profit and loss account.

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 Subpoena. In March 2014, the USAO for the Eastern District of Pennsylvania requested the production of documents related to an investigation of the U.S. promotion of Therakos® photopheresis ("Therakos")' drug/device system UVADEX/UVAR XTS and UVADEX/CELLEX (collectively, the "Therakos System"), for indications not approved by the FDA, including treatment of patients with graft versus host disease ("GvHD") and solid organ transplant patients, including pediatric patients. The investigation also includes Therakos' efforts to secure FDA approval for additional uses of, and alleged quality issues relating to, UVADEX/UVAR. In August 2015, the USAO for the Eastern District of Pennsylvania sent Therakos a subsequent request for documents related to the investigation and has since made certain related requests. The Group responded to these requests and continues to cooperate in the investigation.

Questcor Subpoena. In September 2012, Questcor received a subpoena from the USAO for the Eastern District of Pennsylvania for information relating to its promotional practices related to Acthar Gel. Questcor subsequently was informed by the USAO for the Eastern District of Pennsylvania that the USAO for the Southern District of New York and the SEC were participating in the investigation to review Questcor's promotional practices and related matters pertaining to Acthar Gel. The investigation also related to Questcor's provision of financial and other support to patients, including through charitable foundations and related matters. On March 9, 2015, the Group received a "No Action" letter from the SEC regarding its review of the Group's promotional practices related to Acthar Gel. On or about March 8, 2019, the U.S. District Court for the Eastern District of Pennsylvania unsealed two *qui tam* actions involving the allegations under investigation by the USAO for the Eastern District of Pennsylvania. The DOJ intervened in both actions, which were later consolidated. In September 2019, the 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 federal False Claim Act 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. 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.

Patent Litigation

Amitiza Patent Litigation: Zydus Pharmaceuticals (USA) Inc. In January 2020, Sucampo GmbH, Sucampo Pharmaceuticals, Inc., Sucampo Pharma Americas LLC and Sucampo Pharma LLC, all subsidiaries of the 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) filed suit in the U.S. District Court for the District of New Jersey against Zydus Pharmaceuticals (USA) Inc. (“Zydus”) alleging that Zydus infringed U.S. Patent Nos. 7,795,312, 8,026,393, 8,338,639, 8,748,481 and 8,779,187 following receipt of a December 2019 notice from Zydus concerning its

submission of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of Amitiza. The Group intends to vigorously enforce its intellectual property rights relating to Amitiza.

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

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

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

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

INOmax Patent Litigation: Praxair Distribution, Inc. and Praxair, Inc. (collectively "Praxair"). In February 2015, INO Therapeutics LLC and Ikaria, Inc., both subsidiaries of the Group, filed suit in the U.S. District Court for the District of Delaware against Praxair following receipt of a January 2015 notice from Praxair concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a nitric oxide drug product delivery system. In July 2016, the Group filed a second suit against Praxair in the U.S. District Court for the District of Delaware following receipt of a Paragraph IV notice concerning three additional patents recently added to the FDA Orange Book that was submitted by Praxair regarding its ANDA for its nitric oxide drug product delivery system. The infringement claims in the second suit were added to the original suit. In September 2016, the Group filed a third suit against Praxair in the U.S. District Court for the District of Delaware following receipt of a Paragraph IV notice concerning a fourth patent added to the FDA Orange Book that was submitted by Praxair regarding its ANDA for its nitric oxide drug product delivery system.

Trial for the suit filed in February 2015 was held in March 2017 and a decision was rendered September 5, 2017 that ruled five patents invalid and six patents not infringed. The Group appealed the decision to the Court of Appeals for the Federal Circuit. The oral arguments in the appeal occurred on February 6, 2019. Praxair received FDA approval of their ANDA for their Noxivent nitric oxide and clearance of their 510(k) for their NOxBOXi device on October 2, 2018. The appeal decision, issued on August 27, 2019, substantively affirmed the District Court decision with respect to the invalidity of the heart failure (HF) patents and the non-infringement of the delivery system infrared (DSIR) patents. The Group filed a petition for en banc review at the Federal Circuit on September 26, 2019, which the Federal Circuit denied on November 19, 2019. The Group filed a petition for a writ of certiorari with the U.S. Supreme Court on March 6, 2020 and the petition was denied on April 6, 2020. There has been limited commercial launch activity by Praxair. The adverse final outcome in the appeal of the Praxair litigation decision could result in the broader-scale launch of a competitive nitric oxide product before the expiration of the last of the listed patents on May 3, 2036 (November 3, 2036 including pediatric exclusivity), which could adversely affect the 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.

INOmax Patents: IPR Proceedings. In February 2015 and March 2015, the U.S. Patent and Trademark Office ("USPTO") issued Notices of Filing Dates Accorded to Petitions for IPR petitions filed by Praxair Distribution, Inc. concerning ten patents covering INOmax (i.e., five patents expiring in 2029 and five patents expiring in 2031).

In July 2015, the USPTO Patent Trial and Appeal Board ("PTAB") issued rulings denying the institution of four of the five IPR petitions challenging the five patents expiring in 2029. The PTAB also issued a ruling in July 2015 that instituted the IPR proceeding in the fifth of this group of patents and the PTAB ruled in July 2016 that one claim of this patent survived review and is valid while the remaining claims were unpatentable. The Group believed the claim held valid by the PTAB describes and encompasses a manner in which INOmax is distributed in conjunction with its approved labeling and that Praxair infringes that claim. Praxair filed an appeal and Mallinckrodt filed a cross-appeal of this decision to the Court of Appeals for the Federal Circuit. Oral argument of that appeal occurred in January 2018. The Federal Circuit decision was issued May 16, 2018 and held all claims unpatentable (invalid).

In September 2015, the USPTO PTAB issued rulings that instituted the IPR proceedings in each of the second set of five patents that expire in 2031. In September 2016, the PTAB ruled that all claims in the five patents expiring in 2031 are patentable.

Ofirmev Patent Litigation: Baxter Healthcare Corporation. In March 2020, Mallinckrodt Hospital Products Inc. and Mallinckrodt Hospital Products IP Limited, both subsidiaries of the Group, and New Pharmatop LP, the current owner of the U.S. patents licensed exclusively by the Group, filed suit in the U.S. District Court for the District of Delaware against Baxter Healthcare Corporation (“BHC”) alleging that BHC infringed U.S. Patent No. 6,992,218 ("the '218 patent"), U.S. Patent No. 9,399,012 ("the '012 patent"), U.S. Patent No. 9,610,265 ("the '265 patent"), U.S. Patent No. 9,987,238 ("the '238 patent") and U.S. Patent No. 10,383,834 following receipt of a February 2020 notice from Baxter concerning its submission of an ANDA, containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev. The Group intends to vigorously enforce its intellectual property rights relating to Ofirmev.

Ofirmev Patent Litigation: Altan Pharma Ltd. In March 2019, Mallinckrodt Hospital Products Inc. and Mallinckrodt Hospital Products IP Limited, both subsidiaries of the Group, and New Pharmatop LP, the current owner of the U.S. patents licensed exclusively by the Group, filed suit in the U.S. District Court for the District of Delaware against Altan Pharma Ltd. (“Altan”) alleging that Altan infringed the '218 patent, the '012 patent, the '265 patent and the '238 patent following receipt of a February 2019 notice from Altan concerning its submission of a new drug application, containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev. On August 29, 2019, the parties entered into a settlement agreement under which Altan was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its New Drug Application ("NDA") on or after December 6, 2020, or earlier under certain circumstances.

Ofirmev Patent Litigation: Aurobindo Pharma U.S.A., Inc. In December 2017, Mallinckrodt Hospital Products Inc. and Mallinckrodt IP Unlimited Company, both subsidiaries of the Group, and New Pharmatop LP, the current owner of the two U.S. patents licensed exclusively by the Group, filed suit in the U.S. District Court for the District of Delaware against Aurobindo Pharma U.S.A., Inc. (“Aurobindo”) alleging that Aurobindo infringed the ‘218 patent, the ‘012 patent) and the ‘265 patent following receipt of a November 2017 notice from Aurobindo concerning its submission of an ANDA, containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev. On May 7, 2018 the parties entered into a settlement agreement under which Aurobindo was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its ANDA on or after December 6, 2020, or earlier under certain circumstances.

Ofirmev Patent Litigation: B. Braun Medical Inc. In April 2017, Mallinckrodt Hospital Products Inc. and Mallinckrodt IP, both subsidiaries of the Group, and Pharmatop, the then owner of the two U.S. patents licensed exclusively by the Group, filed suit in the U.S. District Court for the District of Delaware against B. Braun Medical Inc. ("B. Braun") alleging that B. Braun infringed the '218 patent and the '012 patent following receipt of a February 2017 notice from B. Braun concerning its submission of a NDA, containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev. On October 3, 2018, the parties entered into a settlement agreement under which B. Braun was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its ANDA on or after December 6, 2020, or earlier under certain circumstances.

Ofirmev Patent Litigation: InnoPharma Licensing LLC and InnoPharma, Inc. In September 2014, Cadence and Mallinckrodt IP, both subsidiaries of the Group, and Pharmatop, the then owner of the two U.S. patents licensed exclusively by the Group, filed suit in the U.S. District Court for the District of Delaware against InnoPharma Licensing LLC and InnoPharma, Inc. (both are subsidiaries of Pfizer and collectively "InnoPharma") alleging that InnoPharma infringed U.S. Patent Nos. 6,028,222 ("the '222 patent") and the '218 patent. Separately, on December 1, 2016 Mallinckrodt IP Filed suit in the U.S. District Court for the District of Delaware against InnoPharma alleging that InnoPharma infringed the '012 patent. On May 4, 2017 the parties entered into settlement agreements on both suits under which InnoPharma was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its NDA on or after December 6, 2020, or earlier under certain circumstances.

Ofirmev Patent Litigation: Agila Specialties Private Limited, Inc. (now Mylan Laboratories Ltd.) and Agila Specialties Inc. (a Mylan Inc. Group), (collectively "Agila"). In December 2014, Cadence and Mallinckrodt IP, both subsidiaries of the Group, and Pharmatop filed suit in the U.S. District Court for the District of Delaware against Agila alleging that Agila infringed the '222 and the '218 patents. Separately, on December 1, 2016 Mallinckrodt IP filed suit in the U.S. District Court for the District of Delaware against Agila alleging that Agila infringed the '012 patent. On December 31, 2016, the parties entered into settlement agreements on both suits under which Agila was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its NDA on or after December 6, 2020, or earlier under certain circumstances.

The Group has successfully asserted the '222 and '218 patents and maintained their validity in both litigation and proceedings at the USPTO. The Group will continue to vigorously enforce its intellectual property rights relating to Ofirmev to prevent the marketing of infringing generic or competing products prior to December 6, 2020, which, if unsuccessful, could adversely affect the Group's ability to successfully maximize the value of Ofirmev and have an adverse effect on its financial condition, results of operations and cash flows.

Shire Development LLC, Shire LLC and Shire US, Inc. v. SpecGx LLC. In May 2018, Shire Development LLC, Shire LLC and Shire US, Inc. (collectively "Shire") filed suit in the U.S. District Court for the District of Delaware against the 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.

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

Commercial and Securities Litigation

Health Care Service Corporation Litigation. In February 2020, Health Care Service Corporation ("HCSC") filed a non-class complaint against the Group in California state court alleging improper pricing and distribution of Acthar Gel, in violation of the New Jersey RICO statute and various states' antitrust laws. HCSC also brings claims against the Group 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*, alleges similar facts as those alleged in the *Humana* matter below. The Group intends to vigorously defend itself in this matter.

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.

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 sale and distribution of Acthar Gel. The complaint asserts claims under the New Jersey Consumer Fraud Act, the New Jersey Antitrust Act, the New Jersey RICO statute, negligent misrepresentation, conspiracy/aiding and abetting and unjust enrichment. The proposed class is defined as "All third-party payors 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." The Group intends to vigorously defend itself in this action and, in January 2020, after removing the complaint to federal court in New Jersey, moved to dismiss or stay the case. The Group's motions to dismiss or stay remain pending.

Shareholder Derivative Litigation (Brandhorst). In September 2019, a purported shareholder of the Group's stock filed a shareholder derivative complaint in the U.S. District Court for the District of Columbia against the Group, as nominal

defendant, as well as its Chief Executive Officer ("CEO") Mark Trudeau, its former Chief Financial Officer ("CFO") Matthew K. Harbaugh, its Executive Vice President Hugh O'Neill, and the following members of the Board of Directors: Angus Russell, David Carlucci, J. Martin Carroll, David Norton, JoAnn Reed and Kneeland Youngblood (collectively with Trudeau, Harbaugh and O'Neill, the "Individual Defendants"). The lawsuit is captioned *Lynn Brandhorst, derivatively on behalf of nominal defendant Mallinckrodt PLC v. Mark Trudeau et al.* and relies on the allegations from the putative class action securities litigation that was filed against the 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 Individual Defendants caused the Group to make the allegedly false or misleading statements at issue in the *Shenk* lawsuit. The complaint seeks damages in an unspecified amount and corporate governance reforms. On November 20, 2019, this matter was stayed by agreement of the parties pending resolution of the *Shenk* lawsuit below. The Group and the Individual Defendants intend to vigorously defend themselves in this matter.

Humana Litigation. In August 2019, Humana Inc. ("Humana") filed a lawsuit against the Group in the U.S. District Court for the Central District of California alleging violations of federal and state antitrust laws; RICO violations under 18 U.S.C. § 1962(c); conspiracy to violate RICO under 18 U.S.C. § 1962(d); violations of state unfair competition, consumer fraud and deceptive trade practice laws; state insurance fraud; tortious interference with contract; and unjust enrichment related to the pricing of Acthar Gel. Humana alleges that it paid more than $700.0 million for Acthar Gel and seeks undisclosed damages from 2011 through present. The case alleges similar facts as those alleged in the *MSP* and *Rockford* matters below, and includes references to allegations at issue in a pending *qui tam* action against the Group in the U.S. District Court for the Eastern District of Pennsylvania (see *Questcor Subpoena* above). The case is proceeding as *Humana Inc. v. Mallinckrodt ARD LLC*. In March 2020, the court granted-in-part and denied-in-part the 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. The Group intends to vigorously defend itself in this matter.

Putative Class Action Securities Litigation (Strougo). In July 2019, a putative class action lawsuit was filed against the Group, its CEO Mark Trudeau, its CFO Bryan M. Reasons, its former Interim CFO George A. Kegler and its former CFO Matthew K. Harbaugh, in the U.S. District Court for the Southern District of New York, captioned *Barbara Strougo v. Mallinckrodt plc, et al*. The complaint purports to be brought on behalf of all persons who purchased or otherwise acquired Mallinckrodt's securities between February 28, 2018 and July 16, 2019. The lawsuit generally alleges that the defendants made false and misleading statements in violation of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder related to the 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. 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.

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 Eastern District of Pennsylvania, proceeding as *Steamfitters Local Union No. 420 v. Mallinckrodt ARD, LLC, et al.* The complaint makes similar allegations as those alleged in related state and federal actions that were filed by the same plaintiff's law firm in Illinois, Pennsylvania, Tennessee and Maryland (now dismissed; see *WCBE* below), and includes references to allegations at issue in a pending *qui tam* actions against the Group in the U.S. District Court for the Eastern District of Pennsylvania (see *Questcor Subpoena* 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 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.

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 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 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.

Washington County Board of Education ("WCBE"). In May 2019, WCBE filed a non-class complaint against the Group and other defendants in Maryland state court alleging violations of Maryland Consumer Protection Act, negligent misrepresentation, fraud, unjust enrichment and conspiracy to defraud. The case, which was removed to the U.S. District Court

for the District of Maryland in June 2019, alleges similar facts as those alleged in the *MSP* and *Rockford* matters discussed below. In January 2020, the court dismissed the complaint.

Local 542. In May 2018, the International Union of Operating Engineers Local 542 filed a non-class complaint against the 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 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. Although the court temporarily stayed proceedings in January 2020, the court lifted the stay in February 2020. The Group intends to continue 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.

Grifols. In March 2018, Grifols initiated arbitration against the Group, alleging breach of a Manufacturing and Supply Agreement entered into between the Group's predecessor-in-interest, Cadence Pharmaceuticals Inc., and Grifols. During 2019, the Group entered into a settlement for this matter and appropriate reserves were recorded.

Putative Class Action Litigation (MSP). In October 2017, a putative class action lawsuit was filed against the 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 alleges that the Group unlawfully maintained a monopoly in a purported ACTH product market by acquiring the U.S. rights to Synacthen® Depot ("Synacthen") and reaching anti-competitive agreements with the other defendants by selling Acthar Gel through an exclusive distribution network. The complaint purports to be brought on behalf of all third-party payers, or their assignees, in the U.S. and its territories, who have, as indirect purchasers, in whole or in part, paid for, provided reimbursement for, and/or possess the recovery rights to reimbursement for the indirect purchase of Acthar Gel from August 1, 2007 to present. In March 2020, the court granted the Group's motion to dismiss with leave to amend. The Group intends to continue to vigorously defend itself in this matter.

Employee Stock Purchase Plan (ESPP) Securities Litigation. In July 2017, a purported purchaser of Mallinckrodt stock through Mallinckrodt's ESPPs, filed a derivative lawsuit in the Federal District Court in the Eastern District of Missouri, captioned *Solomon v. Mallinckrodt plc, et al.*, against the Group, its CEO Mark C. Trudeau, its former CFO Matthew K. Harbaugh, its Controller Kathleen A. Schaefer, and current and former directors of the Group. On September 6, 2017, plaintiff voluntarily dismissed its complaint in the Federal District Court for the Eastern District of Missouri and refiled virtually the same complaint in the U.S. District Court for the District of Columbia. The complaint purports to be brought on behalf of all persons who purchased or otherwise acquired Mallinckrodt stock between November 25, 2014, and January 18, 2017, through the ESPPs. In the alternative, the plaintiff alleges a class action for those same purchasers/acquirers of stock in the ESPPs during the same period. The complaint asserts claims under Section 11 of the Securities Act, and for breach of fiduciary duty, misrepresentation, non-disclosure, mismanagement of the ESPPs' assets and breach of contract arising from substantially similar allegations as those contained in the putative class action securities litigation described in the *Shenk* lawsuit below. Stipulated co-lead plaintiffs were approved by the court on March 1, 2018. Co-lead Plaintiffs filed an amended complaint on June 4, 2018 having a class period of July 14, 2014 to November 6, 2017. On July 6, 2018, this matter was stayed by agreement of the parties pending resolution of the *Shenk* lawsuit below.

Putative Class Action Litigation (Rockford). In April 2017, a putative class action lawsuit was filed against the 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 sale 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 Plaintiff's 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 acquiring 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.

Putative Class Action Securities Litigation (Shenk). In January 2017, a putative class action lawsuit was filed against the Group and its CEO in the U.S. District Court for the District of Columbia, captioned *Patricia A. Shenk v. Mallinckrodt plc, et*

al. The complaint purports to be brought on behalf of all persons who purchased Mallinckrodt's publicly traded securities on a domestic exchange between November 25, 2014 and January 18, 2017. The lawsuit generally alleges that the 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 U.S. District Court for the District of Columbia. The *Patel* complaint purports to be brought on behalf of shareholders during the same period of time as that set forth in the *Shenk* lawsuit and asserts claims similar to those set forth in the *Shenk* lawsuit. On March 13, 2017, a third putative class action lawsuit, captioned *Amy T. Schwartz, et al., v. Mallinckrodt plc, et al.,* was filed against the same defendants named in the *Shenk* lawsuit in the U.S. District Court for the District of Columbia. The *Schwartz* complaint purports to be brought on behalf of shareholders who purchased shares of the 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 former CFO in the U.S. District Court for the District of Columbia. The *Fulton County* complaint purports to be brought on behalf of shareholders during the same period of time as that set forth in the *Schwartz* lawsuit and asserts claims similar to those set forth in the *Shenk* lawsuit. On March 27, 2017, four separate plaintiff groups moved to consolidate the pending cases and to be appointed as lead plaintiffs in the consolidated case. Since that time, two of the plaintiff groups have withdrawn their motions. Lead plaintiff was designated by the court on March 9, 2018. Lead plaintiff filed a consolidated complaint on May 18, 2018, alleging a class period from July 14, 2014 to November 6, 2017, the Group, its CEO, its former CFO, and Executive Vice President, Hugh O'Neill, as defendants, and containing similar claims, but further alleging misstatements regarding payer reimbursement restrictions for Acthar Gel. On August 30, 2018, the lead plaintiff voluntarily dismissed the claims against Mr. O'Neill without prejudice. The Group filed a motion to dismiss the complaint which was granted in part, and denied in part by the court on July 30, 2019. The Group intends to vigorously defend itself in this matter.

Generic Price Fixing Litigation

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

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

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

The Kroger Co. Litigation. In February 2020, a proposed amended complaint filed in the U.S. District Court for the Eastern District of Pennsylvania named the 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 purports to be brought by several entities that directly purchased generic drugs from defendants or a co-conspirator. The proposed amended complaint seeks monetary damages and injunctive relief for violations of Section 1 of the Sherman Antitrust Act, and is premised on facts similar to those alleged in the *1199SEIU National Benefit Fund* and *César Castillo* litigations. The motion for leave to file the proposed amended complaint remains pending.

Environmental Remediation and Litigation Proceedings

The 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 27, 2019, it was probable that it would incur remediation costs in the range of $38.2 million to $86.9 million. The Group also concluded that, as of December 27, 2019, the best estimate within this range was $61.9 million, of which $1.9 million was included in accrued and other current liabilities and the remainder was included in provision for liabilities on the consolidated balance sheet as of December 27, 2019. While it is not possible at this time to determine with certainty the ultimate outcome of these matters, the 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.

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

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

Despite the issuance of the revised FFS and ROD by the EPA, the RI/FS by the CPG, and the cash out settlement by the EPA there are many uncertainties associated with the final agreed-upon remediation, potential future liabilities and the 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. The Group retains a share of the liability for this suit related to the Belleville facility. A motion to dismiss several of the claims was denied by the court. While it is not possible at this time to determine with certainty the ultimate outcome of this matter, the 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.

Mallinckrodt Veterinary, Inc., Millsboro, Delaware. The Group previously operated a facility in Millsboro, Delaware ("the Millsboro Site") where various animal healthcare products were manufactured. In 2005, the Delaware Department of Natural Resources and Environmental Control found trichloroethylene ("TCE") in the Millsboro public water supply at levels that exceeded the federal drinking water standards. Further investigation to identify the TCE plume in the ground water indicated that the plume has extended to property owned by a third party near the Millsboro Site. The Group, and another former owner, have assumed responsibility for the Millsboro Site cleanup under the Alternative Superfund Program administered by the EPA. The companies have entered into three AOCs with the EPA to perform investigations to abate, mitigate or eliminate the release or threat of release of hazardous substances at the Millsboro Site and to conduct an Engineering Evaluation/Cost Analysis ("EE/CA") to characterize the nature and extent of the contamination. In January 2017, the EPA issued its Action Memorandum regarding the EE/CA. In March 2020, the EPA approved the Final Action Report documenting the remedial construction activities completed in accordance with Paragraph 8.12 of AOC 3 for Removal Response Action. The report recommended decommissioning the Directed Groundwater Recirculation system and commencing Long Term Monitoring. Upon receipt of

the EPA approved Final Action Report, 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 Department of Justice, the U.S. Department of the Interior and the EPA (together, "the Government Agencies") issued a special notice letter to General Dynamics Ordnance and Tactical Systems, Inc. ("General Dynamics"), one of the other potentially responsible parties ("PRPs") at the CO Site, to compel General Dynamics to perform the RI/FS for the AUS Operable Unit. General Dynamics negotiated an AOC with the Government Agencies to conduct an extensive RI/FS at the CO Site under the direction of the U.S. Fish and Wildlife Service. General Dynamics asserted in August 2004 that the 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. 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 27, 2019, 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 five 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.

Interest-Bearing Deferred Tax Obligation

As part of the integration of Questcor, the Group entered into an internal installment sale transaction related to certain Acthar Gel intangible assets during the three months ended December 26, 2014. The installment sale transaction resulted in a taxable gain. In accordance with Section 453A the gain is considered taxable in the period in which installment payments are received. During the three months ended December 25, 2015, the Group entered into similar transactions with certain intangible assets acquired in the acquisitions of Ikaria and Therakos.

During fiscal 2019, the Group completed its reorganization of its intercompany financing and associated legal entity ownership. As a result, the Group had no remaining interest-bearing U.S. deferred tax liabilities as of December 27, 2019, compared to $227.5 million as of December 28, 2018. See Note 10 for further details regarding this reorganization. The GAAP calculation of interest associated with these deferred tax liabilities was subject to variable interest rates. The Group recognized interest expense associated with these deferred tax liabilities of $23.7 million for fiscal 2018.

The Group has reported Section 453A interest on its tax returns on the basis of its interpretation of the IRC and Regulations. Alternative interpretations of these provisions could result in additional interest payable on the deferred tax liability. Due to the inherent uncertainty in these interpretations, the Group has deferred the recognition of the benefit

associated with the Group's interpretation and maintains a corresponding liability of $47.4 million and $56.0 million as of December 27, 2019 and December 28, 2018, respectively. The decrease of $8.6 million was recognized as a benefit to interest expense during fiscal 2019 due to a lapse of certain statute of limitations. Further favorable resolution of this uncertainty would likely result in a material reversal of this liability and a benefit being recorded to interest expense within the consolidated profit and loss account.

Tax Matters

The Group continues to be subject to examination by the IRS for tax years 2014 to 2018. In August 2019, the IRS proposed an adjustment to the profit on ordinary activities before taxation of MHP as a result of its findings in the audit of MHP's tax year ended September 26, 2014. MHP, formerly known as Cadence, was acquired by the Group as a U.S. subsidiary in March 2014. Following the acquisition of Cadence, the Group transferred certain rights and risks in Ofirmev intellectual property ("Transferred IP") to a wholly owned non-U.S. subsidiary of the Group. The transfer occurred at a price ("Transfer Price") determined in conjunction with the Group's external advisors, in accordance with applicable Treasury Regulations and with reference to the $1,329.0 million taxable consideration paid by the Group to the shareholders of Cadence. The IRS asserts the value of the Transferred IP exceeds the value of the acquired Cadence shares and, further, partially disallows the Group's control premium subtraction. The proposed adjustment to profit on ordinary activities before taxation of $871.0 million, excluding potential associated interest and penalties, is proposed as a multi-year adjustment and may result in a non-cash reduction of the Group's U.S. Federal net operating loss carryforward of $782.0 million. The Group strongly disagrees with the proposed increase to the Transfer Price and intends to contest it through all available administrative and judicial remedies, which may take a number of years to conclude. The final outcome cannot be reasonably quantified at this time, however, the proposed adjustment may be material. The Group believes its reserve for income tax contingencies is adequate. See Note 10 for further information.

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.

27. 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 27, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Debt and equity securities held in rabbi trusts	$ 30.6	$ 21.0	$ 9.6	$ —
Equity securities	26.2	26.2	—	—
	$ 56.8	$ 47.2	$ 9.6	$ —
Liabilities:				
Deferred compensation liabilities	$ 39.2	$ —	$ 39.2	$ —
Contingent consideration and acquired contingent liabilities	69.3	—	—	69.3
	$ 108.5	$ —	$ 39.2	$ 69.3

	December 28, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Debt and equity securities held in rabbi trusts	$ 33.1	$ 22.4	$ 10.7	$ —
	$ 33.1	$ 22.4	$ 10.7	$ —
Liabilities:				
Deferred compensation liabilities	$ 38.5	$ —	$ 38.5	$ —
Contingent consideration and acquired contingent liabilities	151.4	—	—	151.4
	$ 189.9	$ —	$ 38.5	$ 151.4

Debt and equity securities held in rabbi trusts. Debt securities held in rabbi trusts primarily consist of U.S. government and agency securities and corporate bonds. When quoted prices are available in an active market, the investments are classified as level 1. When quoted market prices for a security are not available in an active market, they are classified as level 2. Equity securities held in the rabbi trusts primarily consist of U.S. common stocks, which are valued using quoted market prices reported on nationally recognized securities exchanges.

Equity securities. Equity securities 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 2019, the Group recognized an unrealized gain of $20.2 million 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 and acquired contingent liabilities. As of December 27, 2019, the Group maintains various contingent consideration and acquired contingent liabilities associated with the acquisitions of Questcor, Stratatech Corporation ("Stratatech") and Ocera Therapeutics, Inc. ("Ocera").

In August 2014, the Group recorded acquired contingent liabilities of $195.4 million from the acquisition of Questcor. The contingent liabilities relate to Questcor's contingent obligations associated with their acquisition of an exclusive, perpetual and irrevocable license to develop, market, manufacture, distribute, sell and commercialize MNK-1411 ("Synacthen") from Novartis and their acquisition of BioVectra.

Under the terms of the license agreement with Novartis, the Group made a $25.0 million payment in fiscal 2019, and is obligated to make annual payments of $25.0 million subsequent to fiscal 2019 until such time that the Group obtains FDA approval of Synacthen and makes a $25.0 million payment upon obtaining FDA approval of Synacthen. The terms of the license agreement allow the Group to terminate the license agreement upon the occurrence of certain events following the fiscal 2020 payment. The Group measured the fair value of the contingent payments based on a probability-weighted present value of the consideration expected to be transferred using a discount rate of 4.7%. The fair value of these contingent consideration obligations as of December 27, 2019 and December 28, 2018 were $24.5 million and $76.2 million, respectively.

As part of the acquisition of 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. 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 $29.0 million and $53.7 million as of December 27, 2019 and December 28, 2018, respectively.

As part of the Ocera acquisition, the Group provided contingent consideration to the prior shareholders of Ocera in the form of both patient enrollment clinical study milestones for intravenous and oral formulations of MNK-6105 and MNK-6106, and turnover-based milestones associated with MNK-6105 and MNK-6106. The Group determined the fair value of the contingent consideration based on an option pricing model to be $15.8 million and $21.5 million as of December 27, 2019 and December 29, 2017, respectively.

Of the total fair value of the contingent consideration of $69.3 million, $57.8 million was classified as current and $11.5 million was classified as non-current provisions for liabilities in the consolidated balance sheet as of December 27, 2019.

Financial Instruments Not Measured at Fair Value

- 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 $31.7 million and $18.6 million as of December 27, 2019 and December 28, 2018, respectively (level 1), all of which is included in financial assets on the consolidated balance sheets.
- The Group received a portion of consideration as part of contingent earn-out payments related to the sale of the Nuclear Imaging business in the form of preferred equity certificates during fiscal 2019 and 2018. These securities are classified as held-to-maturity and are carried at amortized cost, which approximates fair value (level 3), of $18.9 million and $9.0 million as of December 27, 2019 and December 28, 2018, respectively. These securities are included in financial assets on the consolidated balance sheet.
- 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 $51.1 million and $66.4 million as of December 27, 2019 and December 28, 2018, 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 4.75%, 4.875%, 5.50%, 5.625%, 5.75% and 10.00% notes are classified as level 1, as quoted prices are available in an active market for these notes. Since the quoted market prices for the Group's term loans and 8.00% and 9.50% debentures are not available in an active market, they are classified as level 2 for purposes of developing an estimate of fair value. The following table presents the carrying values and estimated fair values of the Group's long-term debt, as of the end of each period:

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

Concentration of Credit and Other Risks

Financial instruments that potentially subject the Group to concentrations of credit risk primarily consist of trade debtors. The Group 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 turnover:

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

* Turnover to this distributor were less than 10.0% of total turnover during the respective periods presented above.

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

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

	Fiscal Year	
	2019	2018
Acthar Gel	30.1%	34.5%
INOmax	18.1%	16.9%
Ofirmev	12.1%	10.6%

28. Provisions for Liabilities

As of December 27, 2019 and December 28, 2018, provisions for liabilities was comprised of:

	December 27, 2019	December 28, 2018
Pensions and similar obligations (Note 24)	$ 68.1	$ 66.8
Deferred taxation (Note 10)	11.0	324.3
Opioid-related litigation settlement liability (Note 30)	1,643.4	—
Other provisions	281.5	442.5
	$ 2,004.0	$ 833.6

Other provision activity during fiscal 2019 was as follows:

	Environmental (Note 26)	Restructuring Reserves (Note 6)	Guarantees (Note 25)	Contingent Consideration (Note 27)	Other	Total
As of December 28, 2018	$ 61.8	$ 71.0	$ 25.9	$ 151.4	$ 132.4	$ 442.5
Charged to profit and loss account	2.1	(1.7)	(6.8)	—	154.6	148.2
Accretion	0.5	—	—	3.1	0.1	3.7
Fair market value adjustments	—	—	—	(60.2)	—	(60.2)
Utilization	(2.5)	(24.8)	—	(25.0)	(190.1)	(242.4)
Other, including currency translation	—	(10.3)	—	—	—	(10.3)
As of December 27, 2019	$ 61.9	$ 34.2	$ 19.1	$ 69.3	$ 97.0	$ 281.5

29. Shareholders' Funds

Share Premium Account. During fiscal 2019 and 2018, the share premium account activity resulted from the impact of the exercise of stock options.

Other Reserves. The balance as of December 27, 2019 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 and accumulated share-based compensation.

Profit and Loss Account. During fiscal 2019 and 2018, the profit and loss account activity resulted from accumulated loss after taxation, less share repurchase activity, vesting of restricted shares, and transfer of reserves from the share premium account.

Dividends. The Group currently does not anticipate paying any cash dividends for the foreseeable future, as it intends to retain any earnings to finance R&D, acquisitions and the operation and expansion of its business, while executing disciplined capital allocation.

Other items affecting shareholders' funds, including *Called-up Share Capital Presented as Equity, Preference Shares* and *Acquisition of Own Shares* are described in Note 7 to the Company's Notes to the Company Financial Statements.

30. Post-Balance Sheet Events

Commitments and Contingencies

Certain litigation matters occurred in fiscal 2019 or prior but had subsequent updates through the date of this report. See further discussion below and in Note 26 to the consolidated financial statements.

Opioid-Related Matters

On February 25, 2020, the Group announced an agreement in principle on the terms of a global settlement that would resolve all opioid-related claims against the Group and its subsidiaries (“Litigation Settlement”). The Litigation Settlement would contemplate the filing of voluntary petitions under Chapter 11 of the U.S. Bankruptcy Code (“Chapter 11”) by certain subsidiaries of Mallinckrodt plc operating the Specialty Generics business (the “Specialty Generics Subsidiaries”) and the

establishment of a trust for the benefit of plaintiffs holding opioid-related claims against the Group (the “Opioid Claimant Trust”). Subject to the Settlement Closing (as defined below), the Group would make certain structured payments to the Opioid Claimant Trust. Pursuant to the terms of a channeling injunction and third-party release, which would be subject to court approval, all persons or entities asserting opioid-related claims against the Group would recover solely from the Opioid Claimant Trust on account of such claims. If the Settlement Closing occurs, all other claims against, and equity interests in, the Specialty Generics Subsidiaries would be unimpaired and it is expected that all contracts to which the Specialty Generics Subsidiaries are party would be assumed. The Litigation Settlement would provide for:

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

The terms of the Litigation Settlement included a number of conditions to its consummation (such consummation, the "Settlement Closing") such as, among other things, bankruptcy court approval of the bankruptcy plan effectuating the Litigation Settlement, the emergence of the Specialty Generics Subsidiaries from bankruptcy and:

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

As further described above, on March 16, 2020, the Group received an adverse decision from the federal district court for the District of Columbia with respect to the Medicaid lawsuit, resulting in a failure of the Medicaid Lawsuit Condition. The Group is engaged in constructive dialogue with the plaintiff parties to the Litigation Settlement to address the impact of the

court's decision, but there can be no assurance that such dialogue will result in a modification of or amendment to the Litigation Settlement that will be satisfactory to all parties. In addition, at the time the Group announced the Litigation Settlement, the Group had planned to commence an exchange offer for the 2022 Notes pursuant to the Support and Exchange Agreement, and to refinance the 2020 Notes with the proceeds of new term loans that were then contemplated to be obtained pursuant to the Support Agreement. Both the Support and Exchange Agreement and the Support Agreement have terminated. As further described below, on April 7, 2020, the Group and the Issuers entered into the Exchange Agreement with certain noteholders providing for the exchange of such noteholders' holdings of 2020 Notes for new 10.00% First Lien Senior Secured Notes due 2025 issued by the Issuers.

The Litigation Settlement was reached with a court-appointed plaintiffs' executive committee representing the interests of thousands of plaintiffs in the MDL and supported by a broad-based group of 48 state and U.S. Territory Attorneys General, including the New York State Attorney General. In connection with New York State's support of the Litigation Settlement, on March 9, 2020, the State of New York and Suffolk County, together with Mallinckrodt LLC and SpecGx LLC, jointly filed a motion to sever, or remove, Mallinckrodt LLC and SpecGx LLC from the New York State opioid trial, which, as of March 10, 2020, has been postponed indefinitely due to the coronavirus. Nassau County opposed the motion. The motion to sever Mallinckrodt LLC and SpecGx LLC from the New York State trial is currently pending before the Supreme Court of New York, County of Suffolk.

As a result of the Litigation Settlement, the Group recorded a provision for this contingency of $1,600.0 million related to the structured cash payments and $43.4 million related to the Settlement Warrants in the consolidated balance sheet as of December 27, 2019, with a corresponding non-cash charge to the consolidated profit and loss account as a component of operating loss.

The fair value of the Settlement Warrants to be issued upon the Settlement Closing has been estimated using the Black-Scholes pricing model. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. The expected volatility assumption is based on the historical and implied volatility of the Group's peer group with similar business models. The expected term assumption is based on the contractual term of the Settlement Warrants, including the maximum exercise restriction of 5.0% per calendar quarter, which resulted in the valuation of four separate tranches. The expected annual dividend per share is based on the 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 term assumed. The estimated fair value for the Settlement Warrants will be subject to revaluation at each balance sheet date with any changes in fair value recorded as a non-cash gain or (loss) in the consolidated profit and loss account until the Settlement Warrants are issued, at which point they will be recorded as equity or as a liability based upon the facts and circumstances at the time of issuance.

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

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

Financing Activities

February 25, 2020 Agreements

On February 25, 2020, the Group announced certain financing activities, including entry by the Group and the Issuers into a support agreement (the "Support Agreement") with certain of the Group's existing term lenders, as well as certain of its existing noteholders, as new lenders, relating to a potential amendment to its existing credit agreement and new term loans, and a support and exchange agreement (the "Support and Exchange Agreement") with Aurelius Capital Master, Ltd., Franklin Advisers, Inc. and Capital Research and Management Company contemplating, among other things, a private offer to exchange the 2022 Notes for new second lien secured notes.

Following the execution of the Support Agreement, the Group received informal communications from advisors to certain of its existing term lenders that they did not expect to fund the new term loans. The Support Agreement terminated in accordance with its terms on March 20, 2020. The Support and Exchange Agreement was terminated, effective as of April 7, 2020, under the terms of the Exchange Agreement described below.

Exchange Agreement

On April 7, 2020, the Group and the Issuers entered into an exchange agreement (the "Exchange Agreement") with Aurelius Capital Master, Ltd., Franklin Advisers, Inc., as investment manager to certain funds and accounts, Capital Research and Management Company and private funds managed by Columbus Hill Capital Management, L.P. (collectively, the "Exchanging Holders"). Pursuant to the Exchange Agreement, the Exchanging Holders agreed to exchange with the Issuers, on April 7, 2020, their holdings of 2020 Notes issued by the Issuers (the "Existing Notes") (consisting of approximately $495.0 million aggregate principal amount of the Existing Notes) for new 10.00% First Lien Senior Secured Notes due 2025 issued by the Issuers (the "New Notes"), at a rate of $1,000 of New Notes for every $1,000 of Existing Notes exchanged (such exchange, the "Exchange"). The Issuers and Exchanging Holders consummated the Exchange on April 7, 2020.

The New Notes issued in the Exchange were issued pursuant to an indenture dated as of April 7, 2020 (the "Indenture") among the Issuers, the Note Guarantors (as defined below), Wilmington Savings Fund Society, FSB, as first lien trustee, and Deutsche Bank AG New York Branch, as first lien collateral agent.

Interest on the New Notes is payable semi-annually in cash on April 15 and October 15 of each year, commencing on October 15, 2020.

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

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

The Indenture 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 New Notes and could cause a cross-default that could result in the acceleration of other indebtedness of the Company and its subsidiaries.

The New Notes are jointly and severally guaranteed, subject to certain exceptions, on a secured, unsubordinated basis by the Company and each of its subsidiaries (other than the Issuers) (the "Note Guarantors") that guarantees the obligations under the Issuers' existing senior secured credit facilities.

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

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

31. Subsidiary Undertakings

As of December 27, 2019, 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 Corporation	Finance and Administrative	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 Limited	Holding	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt ARD LLC	Operating	100%	1425 U.S. Route 206 Bedminster, NJ 07921 United States
Mallinckrodt Brand Pharmaceuticals, Inc.	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%	7500 Trans-Canada Highway Pointe-Claire, Quebec H9R 5H8 Canada
Mallinckrodt CB LLC	Finance and Administrative	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Chemical Holdings (UK) Ltd.	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	Holding	100%	3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG United Kingdom
Mallinckrodt Equinox Finance Inc.	Finance and Administrative	100%	ARK Mori Bldg., 30F 1-12-32 Akasaka, Minato-ku Tokyo, Japan
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%	Victor von Bruns-Strasse 19 8212 Neuhausen am Rheinfall, Switzerland
Mallinckrodt Hospital Products Inc.	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Mallinckrodt Hospital Products IP Limited	Holding	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt Inc.	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
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.	Holding	100%	Herikerbergweg 238 Amsterdam 1101CM Netherlands
Mallinckrodt Pharma IP Trading Designated Activity Company	Operating	100%	College Business & Technology Park Cruiserath Road Blanchardstown, Dublin 15 Ireland
Mallinckrodt Pharma K.K.	Operating	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States

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	Holding	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, Inc.	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
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	Holding	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, Inc.	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 Inc.	Holding	100%	675 James S. McDonnell Boulevard Hazelwood, MO 63042 United States
Montjeu Limited	Operating	100%	Arthur Cox Building Earlsfort Terrace Dublin 2 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.	Operating	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 LLC	Other	100%	385 Marshall Ave. Webster Groves, MO 63119 United States
ST Shared Services LLC	Other	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 Acquisitions GmbH	Holding	100%	Baarerstrasse 22 6300 Zug Switzerland
Sucampo GmbH	Operating	100%	Baarerstrasse 22 6300 Zug Switzerland
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
Sucampo, LLC	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	Other	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

As of December 27, 2019, the Group had the following branches and representative offices outside of Ireland:

Branch	Country
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

Company Financial Statements
For the Fiscal Year Ended December 27, 2019

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 parent company financial statements:

- give a true and fair view of the assets, liabilities and financial position of the parent company as at 27 December 2019; 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 parent company financial statements we have audited comprise:

- the Company Balance Sheet;
- the Company Statement of Changes in Equity; and
- the related notes 1 to 12, 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 further described 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.

Conclusions relating to going concern

We have nothing to report in respect of the following matters in relation to which ISAs (Ireland) require us to report to you where:

- the directors' use of the going concern basis of accounting in preparation of the financial statements is not appropriate; or
- the directors have not disclosed in the financial statements any identified material uncertainties that may cast significant doubt about the company's ability to continue to adopt the going concern basis of accounting for a period of at least twelve months from the date when the financial statements are authorised for issue.

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 period 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.

Carrying Value of Financial Assets	
Key audit matter description	There is a risk that an impairment in the company's investments in subsidiary is not appropriately recorded in the financial statements. As at 27 December 2019, the market capitalization of the parent company's investments in subsidiary was lower than the carrying amount of the investment. This was considered an indicator of potential impairment. An impairment test was performed by the company. Refer also to Note 1 (accounting policy for Investments in Subsidiary) and Note 2 Financial Assets.
How the scope of our audit responded to the key audit matter	We considered the appropriateness of the Directors' approach to impairment review which considers the valuation of the parent company's subsidiaries and net assets against other indicators of value, such as the overall market capitalization of the Group adjusted for control premium. An impairment charge of $2,142.5 million was recorded during the year.
Key observations	We have no observations that impact on our audit in respect of the carrying value of financial assets.
Going Concern Basis of Preparation	
Key audit matter description	As set out in the Directors Responsibility Statement on page 47, the Directors are required to prepare the financial statements on a going concern basis of preparation unless it is inappropriate to do so. This requires the Directors to assess the ability of the parent company to continue to meet its liabilities as they fall due for the foreseeable future.
How the scope of our audit responded to the key audit matter	In order to assess this key audit matter, we performed the following specific audit procedures, among others, to assess the appropriateness of the going concern basis of preparation: We reviewed the written assessment of going concern for the Group as prepared by management and evaluated the conclusion reached. We evaluated if the period considered in the assessment covered an appropriate period of time subsequent to the date of approval of the financial statements. We assessed if information obtained subsequent to the balance sheet date has been adequately assessed by management. We evaluated if adequate disclosure has been provided in the financial statements.
Key observations	We have no observations that impact on our audit in respect of the Going Concern Basis of Preparation

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 planning materiality for the company to be $20.0 million which is approximately 3.0% of company's net assets. We have considered net assets to be the critical component for determining materiality because we determined net assets 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 the Audit Committee any audit differences in excess of $1.0 million or 5.0% of materiality, as well as differences below that threshold that, 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 directors are responsible for the other information. The other information comprises the information included in the Directors' Report and Consolidated Financial Statements for the financial year ended 27 December 2019, other than the financial statements and our auditor's report thereon. 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.

In connection with our audit of the financial statements, 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 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.

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.

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 the directors' report as specified in our review is consistent with the financial statements and has been prepared in accordance with the Companies Act 2014.

Other Matters
We have reported separately on the consolidated financial statements of Mallinckrodt plc for the financial year ended 27 December 2019.

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 that have been 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 27 December 2019. 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.

/s/ Richard Howard
Richard Howard
For and on behalf of Deloitte Ireland LLP
Chartered Accountants and Statutory Audit Firm
Deloitte & Touche House
Earlsfort Terrace
Dublin 2
Date: 7 April 2020

MALLINCKRODT PLC
COMPANY BALANCE SHEET
(in millions)

	Note	December 27, 2019	December 28, 2018
Fixed Assets			
Financial assets	2	$ 403.8	$ 2,546.3
Current Assets			
Debtors	3	507.4	575.0
Cash at bank and in hand		0.8	0.4
		508.2	575.4
Creditors (amounts falling due within one year)			
Amounts owed to subsidiaries	4	198.2	233.5
Accruals and other creditors		2.5	0.9
		200.7	234.4
Net Current Assets		307.5	341.0
Total Assets Less Current Liabilities		711.3	2,887.3
Provision for liabilities	12	43.4	—
Net Assets		$ 667.9	$ 2,887.3
Capital and Reserves			
Called-up share capital presented as equity	7	$ 18.7	$ 18.5
Share premium account	7	5.7	5.1
Other reserves	7	418.2	384.5
Capital redemption reserve	7	5.3	5.3
Profit and loss account	7	220.0	2,473.9
Shareholders' Funds		$ 667.9	$ 2,887.3

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 $2,253.4 million and $3,615.8 million for fiscal 2019 and 2018, respectively.

Approved by the Board of Directors on 7 April 2020 and signed on its behalf by:

/s/ JoAnn A. Reed	/s/ Mark C. Trudeau
JoAnn A. Reed	Mark C. Trudeau
Director	Director

MALLINCKRODT PLC
COMPANY STATEMENT OF CHANGES IN EQUITY
(in millions)

	Called-up Share Capital						
	Number	Amount	Share Premium Account	Capital Redemption Reserve	Other Reserves	Profit and Loss Account	Total
Balance as of December 29, 2017	92.2	$ 18.4	$ 4.1	$ 5.3	$ 2,090.5	$ 4,403.7	$ 6,522.0
Loss after taxation	—	—	—	—	—	(3,615.8)	(3,615.8)
Share options exercised	—	—	1.0	—	—	—	1.0
Vesting of restricted shares	0.5	0.1	—	—	—	(2.3)	(2.2)
Share-based compensation	—	—	—	—	34.6	—	34.6
Transfer to profit and loss account	—	—	—	—	(1,740.6)	1,740.6	—
Repurchase of ordinary shares	—	—	—	—	—	(55.2)	(55.2)
Treasury shares reissued under ESPP	—	—	—	—	—	2.9	2.9
Balance as of December 28, 2018	92.7	18.5	5.1	5.3	384.5	2,473.9	2,887.3
Loss after taxation	—	—	—	—	—	(2,253.4)	(2,253.4)
Share options exercised	—	—	0.6	—	—	—	0.6
Vesting of restricted shares	0.8	0.2	—	—	(0.1)	(2.6)	(2.5)
Share-based compensation	—	—	—	—	33.8	—	33.8
Treasury shares reissued under ESPP	—	—	—	—	—	2.1	2.1
Balance as of December 27, 2019	93.5	$ 18.7	$ 5.7	$ 5.3	$ 418.2	$ 220.0	$ 667.9

1. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Preparation

Mallinckrodt plc ("the Company") is a public limited company incorporated in the Republic of Ireland with the registration number 522227. The address of its registered office is College Business and Technology Park, Cruiserath, Blanchardstown, Dublin 15, Ireland, and the business address of the Company is Three Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG, United Kingdom ("U.K.").

The principal activity of the Company and the Group have been set out on page 5 of the Directors' Report for fiscal year ended December 27, 2019.

The fiscal year ended December 27, 2019 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 2019 and 2018 each consisted of 52 weeks. Unless otherwise indicated, fiscal 2019 and 2018 refer to the Company's fiscal years ended December 27, 2019 and December 28, 2018, 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 201 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.

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

Mallinckrodt plc currently does not anticipate paying any cash dividends for the foreseeable future, as it intends to retain any earnings to finance R&D, acquisitions and the operation and expansion of its subsidiaries' business, while executing disciplined capital allocation. The recommendation, declaration and payment of any dividends in the future by Mallinckrodt plc will be subject to the sole discretion of its Board of Directors and will depend upon many factors, including its financial condition, earnings, capital requirements of its operating subsidiaries, covenants associated with certain of its debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by its Board of Directors. Moreover, if Mallinckrodt plc determines to pay any dividends in the future, there can be no assurance that it will continue to pay such dividends.

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. Financial Assets

Investments in subsidiary activity of Mallinckrodt plc during fiscal 2019 was as follows:

As of December 28, 2018	$	2,546.3
Impairment charge		(2,142.5)
As of December 27, 2019	$	403.8

Mallinckrodt plc owns 100% of the share capital of Mallinckrodt UK Limited ("MUK"), a company incorporated in the United Kingdom. The principal activity of MUK during the financial year was that of a holding company.

As of December 27, 2019, the market capitalization of Mallinckrodt plc was substantially below the carrying amount of its equity investments in subsidiary, driven by a sustained decrease in its share price. While the Company identified this as an indication of impairment, it believes that its share price has been adversely affected primarily by uncertainties regarding current litigation matters. These litigation matters include, but are not limited to, the *Medicaid Lawsuit*, which has not yet yielded a liability under U.S. GAAP in the Group's consolidated financial statements, in addition to the *Opioid Related Matters.* These matters are further described in Note 26 and Note 30 to the Group's Notes to the Consolidated Financial Statements. In observance of the market capitalization of the Group adjusted for control premium and working capital on the parent company balance sheet as an indication of fair value, and in accordance with FRS 102, a $2,142.5 million impairment charge was recorded during fiscal 2019.

3. Debtors

Debtors due within one year were comprised of the following at the end of each financial period:

		December 27, 2019		December 28, 2018
Due from subsidiary undertakings	$	498.4	$	571.2
Other debtors and prepayments		9.0		3.8
	$	507.4	$	575.0

Amounts due from subsidiary undertakings of $416.5 million and $497.7 million as of December 27, 2019 and December 28, 2018, respectively, relate to balances due from Mallinckrodt International Finance SA ("MIFSA") as part of a cash management agreement. The balance is repayable on demand and is interest bearing.

Intercompany trade receivables of $72.2 million and $73.5 million as of December 27, 2019 and December 28, 2018, respectively, relate to transactions in the normal course of business and are expected to be repaid in the following three months.

4. Amounts Owed to Subsidiaries

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

		December 27, 2019		December 28, 2018
Due to subsidiary undertakings	$	198.2	$	233.5

In January 2016, MUK issued a promissory note for $300.0 million. In December 2016, MUK assigned $193.6 million of this loan to Mallinckrodt US Pool LLC. The capital balance assigned to Mallinckrodt US Pool LLC of $193.6 million and accrued interest of $8.6 million was settled in full on February 13, 2018. The annual rate of interest on the remaining loan with MUK is 12 month USD LIBOR plus 2.08% and the loan is payable in full on demand. In the absence of an earlier demand for payment or extension by mutual consent, the note shall mature on January 15, 2021. The Company recorded an interest charge of $5.5 million and $4.5 million during fiscal 2019 and 2018, respectively. No interest was paid during the period and at the balance sheet date, the fair value of the loan was $129.4 million and $123.9 million as of December 27, 2019 and December 28, 2018, respectively.

In November 2017, Mallinckrodt Buckingham Unlimited Company issued a promissory note for $24.9 million. The annual rate of interest on the loan balance was 12 month USD LIBOR plus 5.04% and the loan was payable in full on demand. In the absence of an earlier demand for payment or extension by mutual consent, the note would mature on November 17, 2022. The

capital balance of $24.9 million and accrued interest of $2.3 million was settled in full on February 25, 2019. The Company recorded an interest charge of $0.3 million and $1.7 million for fiscal 2019 and 2018, respectively.

Intercompany trade payables of $68.8 million and $82.7 million as of December 27, 2019 and December 28, 2018, respectively, relate to transactions in the normal course of business and are expected to be repaid in the following three months.

5. 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 23 to the Group's Notes to Consolidated Financial Statements. The Company has assessed the fair value of these guarantees and determined them to be insignificant.

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 $35.2 million as of December 27, 2019. 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 litigations described as the *Putative Class Action Securities Litigation (Shenk) and (Strougo),* are described in Note 26 to the Group's Notes to the Consolidated Financial Statements.

6. Financial Instruments

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

	Note	December 27, 2019	December 28, 2018
Financial Assets			
Measured at undiscounted amount receivable			
Amount due from subsidiary undertakings	3	$ 498.4	$ 571.2
Financial liabilities			
Measured at undiscounted amount payable			
Loans due to subsidiary undertakings	4	$ 129.4	$ 150.8
Trade and other payables		2.5	0.9
Amount owed to subsidiary undertakings	4	68.8	82.7
		$ 200.7	$ 234.4

7. Shareholders' Funds

Shareholders' funds activity of Mallinckrodt plc was as follows:

Called-up Share Capital presented as equity. Mallinckrodt plc has authorized 500,000,000 ordinary shares, par value of $0.20 per share, 93,459,206 and 92,705,747 of which were issued as of December 27, 2019 and December 28, 2018, respectively. Changes during fiscal 2019 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 27, 2019 or December 28, 2018. 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, and the Company currently

expects to fully utilize the program. 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 2019, Mallinckrodt plc acquired 160,746 shares at an average market price of $16.12 for $2.6 million, 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 27, 2019, the Company had repurchased a total of 813,935 shares to satisfy minimum statutory tax withholding obligations.

No shares were acquired under the March 2017 Program during fiscal 2019. As of December 27, 2019, 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.

During fiscal 2018, the Company acquired 3,610,968 shares under the March 2017 Program at an average market price of $15.30 for $55.2 million, which were accounted for as treasury shares within shareholders' funds. The remaining 115,692 shares at an average market price of $20.11, or $2.3 million, represent *Vesting of restricted shares.*

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. Mallinckrodt plc reissued 189,196 and 205,220 shares during fiscal 2019 and 2018, respectively. As of December 27, 2019, 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 27, 2019.

Mallinckrodt plc held 9,353,420 and 9,381,870 treasury shares which both had a nominal value of $1.9 million as of December 27, 2019 and December 28, 2018, respectively. Treasury shares represent 7.8% of Company capital as of December 27, 2019, and 6.4% as of December 28, 2018. As of December 27, 2019 and December 28, 2018, the total cost of treasury shares acquired under both the share repurchase program and shares repurchased to cover statutory tax withholding obligations was $1,615.7 million and $1,617.4 million, respectively.

Undistributable Reserves. As of December 27, 2019, 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. During the fiscal 2014, Mallinckrodt plc also recorded an unrealized gain of $1.7 billion on the disposal of MIFSA, a subsidiary company to another group entity. The proceeds from the sale of the MIFSA shares was received in the form of an intercompany note receivable. During fiscal 2015 Mallinckrodt plc contributed this note receivable to MUK in exchange for equity in MUK. Applying principles described in Tech 02/17BL, the $1.7 billion unrealized gain is now represented by the investment in MUK. As a consequence of the prior year impairment of Mallinckrodt plc's investment in MUK of $3,561.2 million, the full $1.7 billion of this unrealized gain was realized (as set out in Tech 02/17) and was used to absorb an equivalent amount of the impairment. This is reflected in the prior year financial statements through the transfer of $1,740.6 million from the other reserve to the profit and loss account reserve. Under Irish law, dividends and distributions cannot be made from undistributable reserves. The undistributable reserves as of December 27, 2019 and December 28, 2018 were $11.0 million and $10.4 million, respectively.

Share Premium. In March 2017, the High Court of Ireland approved the creation of distributable reserves of Mallinckrodt plc through a reduction in the share premium account by $3,996.9 million. During fiscal 2019 and 2018, the share premium account activity resulted from the impact of the exercise of stock options.

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 $33.8 million and $34.6 million for fiscal 2019 and 2018, respectively. The total distributable reserves of the Company as of December 27, 2019 was $638.2 million. The distributable reserves of the Company will facilitate any future repurchase of shares as well as any payment of dividends to shareholders of the Company.

8. Directors' Remuneration and Key Management Personnel Compensation

Note 13 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 2019 and 2018, respectively.

9. Auditors' Remuneration

Auditors' remuneration was less than $0.1 million for the audit of individual accounts and was $0.2 million for other assurance services for both fiscal 2019 and 2018. No amounts were incurred for tax advisory services or other non-audit

services. Note 14 to the Group's Notes to Consolidated Financial Statements provides additional details of fees paid by the Group.

10. 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.

11. Subsidiary Undertakings

Mallinckrodt plc owns MUK. Details of the subsidiaries are included in Note 31 to the Group's Notes to Consolidated Financial Statements.

12. Post-Balance Sheet Events

On February 25, 2020, the Group announced that it has reached an agreement in principle on the terms of a global settlement that would resolve all opioid-related claims against the Group and its subsidiaries ("Litigation Settlement"). As a result of the Litigation Settlement, the Company recorded a provision for this contingency of $43.4 million related to the issuance of warrants in the balance sheet as of December 27, 2019, with a corresponding non-cash charge to the profit and loss account as a component of operating loss. Refer to Note 30 to the Group's Notes to Consolidated Financial Statements for further information.